The People's Terms of Reference

Responses to

Questions on Notice

Senate Legal and Constitutional Affairs Committee

Terms of Reference for a Covid-19 Royal Commission
An inquiry into the appropriate terms of reference for a Covid-19 Royal Commission that would allow all affected stakeholders to be heard

1 March 2024

Index

Terms of Reference

Containing

Responses to Questions on Notice

Written Questions on Notice

Received from Senator Roberts reproduced under each of the following Terms of Reference

Further Questions on Notice

Received during the 1 February 2024 Committee hearing

Senator Antic to Dr Sladden	Re Erosion of Trust
Senator Shoebridge to Dr Madry	Re Lives purportedly saved by Covid vaccines
Senator Scarr to Julian Gillespie	Re Abbreviate The People's Terms of Reference

Annexures

Annexure A: Questions on Notice from Senator Malcolm Roberts

Annexure 1: Mandatory Report of Risk of Significant Harm to Child/ren

Annexure 2: RE: NSW COVID-19 Update 29 July

Annexure 3: RE: COVID-19 NSW | Mask requirements for eight Sydney LGAs

Annexure 4: COVID Calamity

Annexure 5: BIU Rapid Advice to Increase Compliance with COVID Check-In Behaviours

Annexure 6: Presenting COVID-19 vaccination information – behavioural insights

Annexure 7: COVID-19 Flyer Trial

Annexure 8: Opinion Legal Ramifications for Registered Health Practitioners and AHPRA Public Officers

Annexure 9: Altman et al TGA Ivermectin submission 26 September 2022

Annexure 10: FREEDOM OF INFORMATION REQUEST FOI 3643 – Notice of Decision

Annexure 11: FREEDOM OF INFORMATION REQUEST FOI 3604 – Notice of Decision

Annexure 12: RE: Notice to Dr Oosterhuis to produce information

Endnotes: For all answers

Introduction

Ramesh Thakur

Emeritus Professor, Crawford School of Public Policy, The Australian National University, and former United Nations Assistant Secretary General

Pandemics are relatively rare occurrences in history. Looking back at a little over the last one hundred years, the world has experienced only five pandemics: the Spanish flu of 1918–19, the Asian flu of 1957–58, the Hong Kong flu of 1968–69, Swine flu 2009-10, and Covid-19 in 2020–23.

Over that same period, advances in medical knowledge and technology have greatly expanded the toolkits of prevention, treatment, and palliative care, using both pharmaceutical and non-pharmaceutical interventions; and there have been major advances also in medical education, training, and research.

Alongside these developments, countries learnt from one another and cooperated to build national and international public health infrastructure to promote peoples' health around the world. This has been especially relevant and critical for infectious diseases since, by definition, people everywhere are potentially vulnerable to the outbreaks of such diseases anywhere.

Combining the three trends, many countries drew up pandemic preparedness plans that drew on the century's worth of science, data, and experience to map and institutionalise best practice contingency plans for the outbreak of pandemics as low-probability but high-impact 'black swan' events. The World Health Organisation (WHO) published its own report as recently as September 2019 that summarised the 'state of the art' policy advice for governments on health interventions to deal with pandemics.

The world therefore should have been well prepared for Covid-19 in 2020. Instead, some key and influential governments reacted with great panic that itself proved both highly contagious and harmful to health and society. Liberal democratic systems had delivered the greatest combination of gains in freedoms, prosperity, living standards, health and longevity, and education in human history. Good decision-making processes and structures had ensured good policy development and implementation to deliver all-round good outcomes.

The herd panic of early 2020 led to an abandonment of good process, an abandonment of carefully prepared pandemic preparedness plans, and a centralisation of decision-making in a narrow circle of heads of government, ministers, and health experts. Whether it amounted to a worldwide coup against liberal democracy, or represented a hysterical mix of ignorance, incompetence and/or malfeasance, what is beyond dispute is that the 2020–22/23 years were among the most disruptive in many countries, including Australia. The health, mental health,

social, educational, and economic consequences continue to be felt and will continue to impact public life for many years into the future.

Did Australia's Covid-19 policy interventions represent the greatest triumph of public policy, with an unprecedently high number of lives saved as a result of timely, decisive, and appropriate measures instituted by governments acting on the science- and evidence-based advice of experts? Or will they prove to be the biggest public policy disaster of all time?

These are big questions. The answers to them need and demand an independent, impartial, and rigorous inquiry helmed by credible people with the appropriate mix of qualifications, experience, expertise, and integrity, who are not tainted with conflicts of interest.

Eight Sets of Issues to Be Examined

The origins of the virus are beyond the terms of a national Australian inquiry.

Instead, the first set of questions should examine why the existing pandemic preparedness plans and medical decision-making practices were abandoned. The science did not change. In the very brief timeframe between when the WHO and national pandemic preparedness plans were written and adopted, and when the recommended guidelines were thrown out and extreme interventions of society-wide shutdowns were ordered, the data and empirical evidence behind the radical departure from established understandings would have been limited in volume, of low quality and reliability, and derived largely from one city, Wuhan, in one country.

Second, what methodologies were used by Australian experts and authorities to perform key measurements in relation to the pandemic, and how do these compare to other advanced Western democracies? For example, the PCR tests were widely used to check for Covid infection. Yet, the test suffers from two major problems. It can be run continually until it detects a virus. However, the tests are only useful for finding an active virus run up to 28 cycle threshold (CT) counts. Any higher and positive results were known to be fragments of inactive virus. Different jurisdictions used different and much higher thresholds as cut-off points, up to 42 CTs, resulting in millions being deemed actively infected, when in truth this was not the case. In addition, the PCR regime is apparently plagued with false positives and negatives and requires careful analysis to come to reliable conclusions. Were Australian State and Federal testing protocols uniform, and did they prove accurate and reliable?

The methodology used to ascribe Covid as *a* or *the* cause of death also varied enormously between different jurisdictions around the world. These included inconsistencies or irregularities in recording deaths as Covid-caused if people had tested positive either at any time before their death, or within 28 days of dying; recording the deaths of people who were not up to date with the current recommended vaccine dosage, or had received only the first dose, as unvaccinated; categorising all who died within 28 days of a vaccine as unvaccinated; giving financial compensation to hospitals and states for each death recorded as a Covid death, etc. All of these badly distorted the distinctions between dying *with* and *from* Covid and confounded the key

Covid metrics on hospitalisation, ICU admissions, and deaths by vaccination status. So, too, did the under-acknowledgement and under-registration of serious adverse events, including fatalities, related to vaccines. Until these facts, as they apply to Australia, are authoritatively and credibly elucidated by a duly empowered independent inquiry, public trust in health experts and institutions is unlikely to be restored to pre-pandemic levels.

Third, what data was used to estimate the infection and case fatality rates (IFR, CFR) of Covid-19? It rapidly became clear that the risk gradient for severe cases that would require ICU admissions and could cause death of otherwise healthy people, was extremely age-segregated. Why then were the interventions not designed to align with the age-dependent risk profiles? It also became quickly clear that the spread and severity of Covid-19 was highly regionalised around the world and that, unsurprisingly, it was also seasonal. And third, the accumulating evidence from around the world suggested that highly-credentialled experts who questioned the frighteningly high levels of IFR and CFR behind the most alarmist models were closer to the truth than the catastrophists.

Some of these modellers had a track record of predictions of infectious diseases that should have induced extreme caution in adopting their recommended interventions. Even the modelling from the Doherty Institute that triggered Australia's lockdown over-estimated the hospitalisation, ICU and death numbers by several orders of magnitude.

On all these considerations, did Australian experts and authorities undertake urgent seroprevalence surveys to estimate more reliably the numbers who had already been infected, and the Australian IFR and CFR?

A fourth set of questions should probe why long-established guidelines to evaluate competing demands, in particular the quality adjusted life years (QALY) and cost-benefit analyses of the different policy interventions, including the risks of side-effects and collateral harms, were not undertaken. Of course, if the public perception is wrong and they were undertaken, then it would be helpful to establish this.

A fifth set should examine the lack of treatment in the period between being infected, and severe illness requiring in-patient hospital and ICU care. In particular, why did Australian authorities not undertake high quality randomised control trials of repurposed drugs, with well-established safety profiles?

A sixth set should ask for the science, data (including quality and reliability) and decision-making behind mask and vaccine mandates, especially in the context, once again, of the steep age gradient of people at risk of severe and fatal infection among otherwise healthy people. In granting emergency use authorisation, did the Australian regulator(s) require local trials to establish safety and efficacy? If not, why not? Did they undertake their own analyses of the trial results presented by the vaccine manufacturers?

The seventh set of issues that needs authoritative public examination is the relationship between the professional regulatory bodies and clinical practitioners of medicine. The doctor-patient relationship in Western societies has long been governed by four important principles: (i) the sanctity of the doctor-patient relationship; (ii) first, do no harm or, alternatively, avoid doing more harm than good; (iii) informed consent; and (iv) prioritising the health outcomes of the patient over that of any collective group. All four principles would appear to have been gravely compromised when it came to Covid. Moreover, it is counter-intuitive to believe that distant colleges and bureaucrats operating remote controls were in a better position than the doctor to assess the best interests of the patient.

Finally, of course, we need an authoritative answer to the most critically important question of all: on balance, did the totality of Australian pharmaceutical and non-pharmaceutical interventions to manage Covid-19 as a public health challenge do more good than harm? What lessons must be drawn for courses of action that are recommended and not recommended? What principles, procedures, structures, and institutional safeguards must be put in place to ensure optimal health and public policy outcomes in future pandemic outbreaks?

Conclusion

The following comprehensive submission sets out terms of reference for a Royal Commission that could help to answer these big questions on just what was done, by whom, why, and with what consequences. The Australian people deserve these answers. The Parliament of Australia, representing the will of the people, owes it to them to establish a Royal Commission to inquire into and establish the truth of the Covid-19 years. A properly constituted and conducted commission will begin the process of healing and help to restore trust in the major institutions of public life. Anything less will be an abdication of responsibility.

Ramesh Thakur

1 March 2024

Reference: A

Index

A systematic analysis and review of all epidemiological studies undertaken, and expert advices considered in relation to SARS-CoV-2 in 2020, 2021, and 2022 that were accessible to Australian governments for determining the threat posed to Australians by SARS-CoV-2 throughout those years, including but not limited to:

i. epidemiological studies undertaken and published for the Diamond Princess cruise of 2020;
ii. Covid-19 Infection Fatality Rate (IFR) studies undertaken, published, and where published throughout 2020-2022;
iii. a comparison between published IFR studies versus statements and the evidence for statements made, in respect of the risk posed by SARS-CoV-2, by the WHO, foreign country leaders and health authorities and health administrators, and Commonwealth, State and Territory government ministers and health officials.

Explanatory Memorandum

Index

An examination to confirm whether early 2020 epidemiological studies evidenced SARS-CoV-2 represented a threat equivalent to severe influenza.

Question(s) on Notice

Index

In respect of that submission and in particular index **Reference A**, can you please inform the committee whether epidemiological studies were undertaken from early 2020 and afterwards, to support the notion SARS-CoV-2 represented an existential threat to Australians beyond anything we had experienced, sufficient to warrant calling SARS-CoV-2 a global pandemic?

Answer(s)

Index

First Answer

Prof. Ian Brighthope, Co-Author:

A systematic analysis and review of all epidemiological studies undertaken, and expert advice considered in relation to SARS-CoV-2 in 2020, 2021, and 2022 that were accessible to Australian governments for determining the threat posed to Australians by SARS-CoV-2 throughout those years, including but not limited to:

i. Epidemiological studies undertaken and published for the Diamond Princess cruise of 2020;
ii. Covid-19 Infection Fatality Rate (IFR) studies undertaken, published, and were published throughout 2020-2022;
iii. A comparison between published IFR studies versus statements and the evidence for statements made, in respect of the risk posed by SARS-CoV-2, by the WHO, foreign country leaders and health authorities and health administrators, and Commonwealth, State and Territory government ministers and health officials.

Early and later studies by Professor John Ioannidis provided evidence that SARS-CoV-2 had an IFR no worse than a severe influenza season. These facts were not presented by the WHO in early 2020 or subsequently, and they were not presented by the Australian governments. These same studies would have been known by the Australian governments.

Professor John Ioannidis has been a significant figure in the scientific discourse surrounding Covid-19, contributing to a broad spectrum of topics ranging from the infection fatality rate (IFR) to the impact of research citations and public health strategies to the reliability of Covid-19 models and the impact of research citations in the context of the pandemic.

His main findings from studies on Covid-19 include:

Age-stratified infection fatality rate of Covid-19 in the non-elderly population:
Ioannidis and colleagues provided estimates of the IFR for Covid-19, highlighting that the risk of death increases significantly with age. They found that the median IFRs were lower than some previous calculations but emphasised that Covid-19 could still have a substantial impact on the non-elderly population, especially when infection rates are high. The study showed steep progression in the risk of dying from Covid-19 with age, with ratios of median IFRs indicating significantly higher risks for older age groups compared to those 20-29 years old.

Global infection fatality rate estimation: In March 2021, Ioannidis estimated the global IFR from Covid-19 at 0.15%, suggesting that the severity of the disease might be lower than initially feared. This estimation was part of his broader critique of the global response to the pandemic, where he questioned the effectiveness of lockdowns and expressed skepticism about the rapid development and testing of vaccines and treatments.

Impact of indoor and outdoor air quality on Covid-19 spread: Ioannidis co-authored a paper examining the role of environmental health, particularly air quality, in the

prevention of Covid-19. The study concluded that improving indoor and outdoor air quality could be a crucial component in preventing the spread of the virus.

Critique of the response to the Great Barrington Declaration: Ioannidis authored a paper arguing that signatories of the Great Barrington Declaration, which advocated for focused protection of the vulnerable and opposed widespread lockdowns, were unfairly marginalised. He suggested that the declaration raised valid points that deserved consideration in the public health discourse.

Infection fatality rate inferred from seroprevalence data: In a publication in the Bulletin of the World Health Organization, Ioannidis discussed the infection fatality rate of Covid-19 based on seroprevalence data. He highlighted the importance of accurate data to inform public health decisions and guide responses to the pandemic.

Discussion on the bungled response to Covid-19: Ioannidis has been vocal about what he perceives as missteps in the response to the Covid-19 pandemic, including the reliance on flawed models and data. He has emphasised the need for unbiased prevalence and incidence data to guide decision-making and has discussed the unintended consequences of lockdowns, school closures, and travel bans.

These contributions by Professor Ioannidis have sparked significant debate within the scientific community and among policymakers. His work has focused on providing a critical perspective on the data and models guiding the response to the pandemic, the estimation of the infection fatality rate, and the broader implications of public health strategies. The work challenges the Australian authorities' management of the covid pandemic, which as mentioned earlier, was a pandemic of an influenza-like illness and not a killer pandemic for most of the population.

An understanding of the meaning of a pandemic is of utmost importance for future narratives and communications to the public. A pandemic, traditionally defined, is an epidemic that transcends international boundaries, affecting a large number of people worldwide. An expanded conceptualisation of the word pandemic should include not only infectious diseases of varying severity but also non-infectious conditions that have global health implications.

Historically, a pandemic is characterised by the widespread occurrence of disease across countries and continents, impacting a significant portion of the population. The classical definition ***emphasises the scale of spread rather than the disease's severity or the pathogen involved***. This broad definition allows for the inclusion of various infectious diseases that meet these criteria, such as influenza and Covid-19, which have historically been recognised as pandemics due to their extensive global impact. However, a pandemic of the common cold is a cold that has rapidly spread around the world.

In recent times, the term "pandemic" has been closely associated with infectious diseases

that have a significant global impact, such as the Covid-19 pandemic. The World Health Organization (WHO) declared Covid-19 a pandemic in March 2020, highlighting its widespread transmission across the globe. This event underscored the modern interpretation of pandemics, which focuses on infectious diseases capable of rapid and extensive spread, facilitated by increased global mobility.

Infectious disease pandemics can vary widely in their severity, from mild to severe, impacting public health responses and societal consequences. Historical examples include the 1918 H1N1 'influenza pandemic' (which some, and I am inclined to consider, believe to be a bacterial infection), which was highly severe, and the 2009 H1N1 influenza pandemic, which was considered mild. This variability underscores the need for a nuanced understanding of pandemics that considers not only the spread of disease but also its impact on morbidity and mortality.

The concept of a pandemic must be expanded beyond infectious diseases to include global health crises and non-crises caused by non-infectious conditions. For instance, the rising prevalence of obesity and diabetes, often referred to as "diabesity," represents a significant global health challenge with widespread societal and economic implications. Similarly, vitamin D insufficiency has been linked to many health issues, including mental health disorders and cancer, and has garnered attention during the Covid-19 pandemic due to its potential impact on immune function and mental well-being. Mental health crises, exacerbated by factors such as the Covid-19 pandemic, also pose a global challenge, affecting millions worldwide and necessitating coordinated local and national responses.

The definition of a pandemic has evolved from its classical roots to encompass a broader range of infectious diseases characterised by their global spread. However, the impact of non-infectious conditions on global health warrants an expanded conceptualisation of pandemics. This broader perspective recognises the complex interplay between infectious and non-infectious factors in shaping global health outcomes and highlights the need for comprehensive strategies to address the multifaceted challenges of pandemics, whether they arise from infectious diseases or other global health crises.

As Covid-19 was either an asymptomatic or mildly symptomatic illness for the majority of the population, it could at most be regarded as a 'pandemic of low impact' and be treated as a flu-like illness for the majority of the population. The Vitamin D Pandemic is a pandemic of the highest order and sadly ignored by the WHO.

Index

Second Answer

Julian Gillespie LLB, BJuris, Co-Author:

In Summary

An appreciation of the real risk posed by Covid-19 illness begins with knowing the clinical risk, exemplified in the statistical tool known as the Infection Fatality Rate (IFR). The IFR for Covid-19, particularly for how this tool shows Survivability, is shown below.

Infection Fatality Rate: Rates of Death from SARS-CoV-2 Infection

Age Groups	IFR % (Infection Fatality Rate)[i]	Survivability Rate % (100 – IFR)
0-19	0.0003	99.9997
20-29	0.003	99.997
30-39	0.011	99.989
40-49	0.035	99.965
50-59	0.129	99.871
Median 0-59	0.035	99.965
60-69	0.501	99.49
Median 0-69	0.095	99.905
70+ Elderly community-dwelling[ii]	2.9	97.1
70+ Elderly overall[iii]	4.5	95.5

The above table requires little interpretation. Children 0-19 years experience nearly a 0% rate of death when infected by SARS-CoV-2. Children 0-19 years have nearly a 100% chance of surviving Covid-19 infection. This data does not evidence Covid-19 as a statistically significant life-threatening illness in children 0-19 years. Indeed, there is no available evidence to show Covid-19 illness as life-threatening in children 0-19 years, nor is it a substantially life-threatening illness in healthy populations 69 years and younger.

Significantly, the IFR data shown in the table above was gathered during the decidedly more lethal Delta variant of SARS-CoV-2, and even more severe variants pre-dating Delta. Since December 2021 and throughout 2022 the Omicron variant and its sub-linages dominated. The risk of death[iv] from Omicron was established to be 66% lower as compared to Delta. Consequently, the IFR numbers shown above for those aged under 70 years must be further and significantly reduced.

That it is the elderly who face a 2,230 to 3,769 x greater IFR risk than children 0-19 years is confirmed by Australian data[v], where from January 2020 through 31 August 2022 (34 months), SARS-CoV-2 had proven to be a disease mostly affecting the elderly, with the median age of death being 85.3 years. During the same 34-month period 64 deaths were recorded in those aged 0-39 years, compared to 8,248 in those aged 70+ years.

The above data makes clear SARS-CoV-2 and Covid illness simply did not represent an existential threat to the lives and health of Australians. Nonetheless, Australian

government messaging reinforced with exaggerated and misleading media campaigns that SARS-CoV-2 is a clear and present dangers to all Australians, despite the data to the contrary being known to Australian governments. A Covid-19 Royal Commission must ask and examine why Australian governments did this, who was responsible for distorting the true science, and whether overseas organisations participated to fuel the misleading information campaign undertaken by Australian governments.

Endnotes: For all answers
Index

Reference: B

Index

A review and analysis of the planning undertaken, the scientific studies relied upon, and the standing recommendations of Australian governments prior to 2020, for the management of pandemics, including:

i. the WHO report *non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza* (September 2019);
ii. the Australian Health Management Plan for Pandemic Influenza (AHMPPI);
iii. the extent to which the AHMPPI was followed for SARS-CoV-2;
iv. differences between recommendations contained in the AHMPPI and those actions adopted by Australian governments for SARS-CoV-2, and the scientific basis for any departure from AHMPPI recommendations;
v. an examination of Event 201 conducted in October 2019, its participants, sponsors, and associate organisations, including:
    a) all and any involvement by Australian governments, personnel, agencies, or departments;
    b) all and any involvement by Australian citizens;
    c) all Event 201 information materials presented to, received by Australian governments, personnel, agencies, or departments before the event, during the event, and after the event;
    d) all pandemic recommendations compiled by the organisers of Event 201 and their affiliates and associates presented to, or received by Australian governments, personnel, agencies, or departments before the event, during the event, and after the event;
    e) all capacities in which Jane Halton, AO, PSM, FAICD, FIPPA participated in Event 201, including:
        i. any planning for Event 201;
        ii. any promotion of Event 201 to Australian governments, personnel, agencies, or departments before the event, during the event, and after the event;
        iii. any promotion of pandemic recommendations arising from and after conducting the Event 201 tabletop to Australian governments, personnel, agencies, or departments.

Explanatory Memorandum

Index

To review the recommendations contained in the Australian Health Management Plan for Pandemic Influenza (AHMPPI) last updated in 2019, and the adequacy of those recommendations for dealing with SARS-CoV-2, and the extent to which, if any,

recommendations arising from Event 201 influenced Australian governments.

Question(s) on Notice

Index

Question 1

In respect of your joint submission and in particular index **Reference B**, all Australian governments in August 2019 jointly published the Australian Health Management Plan for Pandemic Influenza, within which **Attachment E** details the scientific evidence for masking, Personal Protective Equipment, border controls, stopping international spread, vaccine passports at borders, the use of thermal scanners at borders, isolating asymptomatic inbound passengers, quarantining people in contact with ill people, State border closures, school closures, workplace closures, working from home, cancelling of mass gatherings .. Professor, in nearly every instance our Plan for Pandemic Influenza advised these measures had moderate but mostly minor beneficial effects, that is, less than a 10% possible benefit, and were mostly Not Recommended due to the greater detrimental effects and impacts upon health and the economy.

My question is: did the science change suddenly 6 months later to warrant Australian governments accepting recommendations from the WHO to justify doing the exact opposite to what Australia's own Health Management Plan for Pandemic Influenza when SARS-CoV-2 arrived?

Question 2

In respect of **References B and F**, what was the explanation provided by the AHPPC for completely ignoring the Australian Health Management Plan for Pandemic Influenza which had been reaffirmed by all Australian governments in late 2019?

Question 3

In respect of **Reference B**, please provide any further information concerning Event 201 and any involvement by Australian organisations, agencies, or persons.

Answer(s)

Index

Answer

Julian Gillespie LLB, BJuris, Co-Author:

Lockdown and mandate recommendations that had been explicitly advised ***against*** months before the declaration of pandemic in early 2020, were nonetheless recommended by the Australian Health protection Principal Committee (AHPPC) to the National Cabinet despite a multitude of scientific studies speaking ***against*** those recommendations, as evidenced in the WHO's own 2019 document *Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza*, and Australia's own *Health Management Plan for Pandemic Influenza*.

Australia's Plan for Pandemic Influenza had only just been reconfirmed by all Australian Health Ministers, Chief Health Officers, and (then) CMO Brendan Murphy in August 2019, yet it was completely ignored in early 2020.

Why? A Covid-19 Royal Commission needs to understand why.

A brief summary of the recommendations within Australia's plan that were not followed, include:

IC2: Personal protective equipment (PPE) for healthcare workers, public health officials and other workers in direct contact with infected (symptomatic) individuals

Application
Use should be based on risk of transmission of infectious agents and risk of contamination of clothing or skin. PPE should be used as part of a package of infection control measures, as described in the Australian *guidelines for the prevention and control of infection in healthcare* (2010) (infection control guidelines).[1]
Objective and rationale
To reduce transmission from infected persons to staff members in higher risk settings.
Effectiveness
Moderate. Although work-related influenza infection is well documented (e.g. Kuster et al.)[6], very few studies have been undertaken about the effectiveness of PPE in reducing infection. Many of the studies that have been conducted suffer from poor compliance or lack the power to detect an effect.

IC3: Mask wearing by symptomatic individuals in the community

Application
This measure may be considered by individuals when the disease has a high clinical severity.
Objective and rationale
To reduce transmission within the broader community.
Effectiveness
No evidence. Very few studies have been undertaken about the effectiveness of PPE in reducing infection in the community. Modelling studies of widespread PPE use suggest that mask use could reduce population transmission, although estimates of effectiveness are limited by the quality of data on individual effects. There is evidence from both clinical and modelling studies that earlier initiation of PPE improves its effectiveness.

B6: Passenger locator documents, such as the health declaration cards (HDCs) used during pandemic (H1N1) 2009 or International Civil Aviation Organization (ICAO) Passenger Locator Forms (PLFs)

Application

Recommended only when asymptomatic carriage is unlikely. Not recommended once community transmission is established.

Objective and rationale

To detect infected incoming travellers so that on-going transmission can be prevented; to encourage self-reporting by ill travellers; to raise awareness of the disease and provide information for use in contact tracing.

Effectiveness

For detection of cases: Minor. The measure cannot detect asymptomatic cases, and large numbers of asymptomatic travellers will still bring the disease into Australia. A small-scale pilot study in New Zealand of HDCs reported a voluntary response rate of

B7: Thermal scanners

Application

Not recommended as effectiveness is likely to be low. Experience from SARS and pandemic (H1N1) 2009 shows that there may be a public expectation of entry screening in some form. Decisions not to do so should be supported by information to the public and decision makers.

Objective and Rationale

To detect infected incoming travellers so that on-going transmission can be prevented; to encourage self-reporting.

Effectiveness

Minor. If people are infectious when asymptomatic, the number of people entering without being detected will inevitably make the effectiveness of this measure low. Not all cases of influenza are febrile. Thermal scanners may be useful in identifying cases of

B10: Voluntary isolation of ill travellers not requiring hospitalisation

Application

Ill travellers identified at the border through other measures, such as thermal scanners or HDCs could be encouraged to isolate themselves as part of a broader policy of voluntary isolation of those with influenza-like illness. It should be considered that there may come a time when resources required to initiate this at the border would be better used elsewhere. On its own, it is unlikely to have a high impact on reducing transmission due to limitations in identifying cases. Returning Australians may isolate themselves at home, however other arrangements would be required for other travellers.

Objective and Rationale

To reduce exposure to the disease by managing the entry of ill travellers at the border.

Effectiveness

Minor. In modelling studies, isolation of infectious cases is effective in reducing transmission by reducing cumulative attack rates, even in models assuming high transmissibility.14, 15 However, this assumes the ability to identify cases. Mild or asymptomatic cases are difficult to detect and therefore not usually isolated, reducing the effectiveness of this measure.

B11: Quarantine of contacts of ill travellers at the border

Application
Not recommended. The contact tracing required to identify and contact contacts of ill travellers is difficult to achieve in the necessary rapid timeframes, and requires significant resources. Combined with the limited effectiveness of case identification at the border, it is likely that the benefits will be limited. Returning Australians may quarantine themselves at home, however other arrangements would be required for other travellers.

B12: Exit screening

Application
Not recommended as effectiveness is likely to be low and costs are likely to be high. It could be considered if the virus emerges first in Australia.

B13: Internal travel restrictions (restriction of travel across state or territory borders, or within certain areas of a state or territory, either to protect remote communities or to isolate areas with higher rates of exposure)

Application
Not recommended in general as benefits are likely to be minor.

SD1: Proactive school closure

Application
Not generally recommended, however could be considered when there is evidence of high clinical severity and/or high transmissibility specifically in children. The level of disruption is likely to outweigh benefits.

SD2: Reactive school closure

Application
Not recommended unless the disease has high clinical severity or children are a group at risk of complications.

Note: for Workplace Closures below, as detailed in the answer to Question on Notice for Reference A, the clinical severity of Covid-19 was briefly comparable to severe influenza seasons and was imminently treatable with established protocols.

SD3: Workplace closure

Application
Not generally recommended. Although some specific workplaces may be able to accommodate closure, it is unlikely that a large enough percentage could participate to significantly affect the pandemic's impact. This measure is only relevant if clinical severity is moderate to high.

SD4: Working from home

Application

This measure should be considered for pandemics with a moderate to high clinical severity, and where home working can be reasonably accommodated. Home working may not be practical for many workplaces.

Objective and rationale

To allow employees who may or may not be infectious to work from home and therefore decrease transmission outside domestic settings.

Effectiveness

Minor. This measure is moderately effective in reducing transmission of influenza by about one-fifth. A Japanese trial that assessed the effectiveness of home stay of employees on full payment found that the strategy reduced the overall risk of pandemic (H1N1) 2009 influenza by around 20%.[19]

SD5: Cancellation of mass gatherings

Application

Not generally recommended, however, may be considered if the disease has a high clinical severity rate and moderate to high transmissibility, at certain stages in the progress of the pandemic.

SD6: Voluntary isolation of cases

Application

Voluntary self-isolation of cases is recommended (particularly as the clinical severity of the disease increases), to be used in conjunction with infection control measures to reduce the risk of transmission to household contacts. Most likely to influence the course of the pandemic when clinical severity is high and transmissibility is low.

Objective and rationale

To reduce transmission by reducing contact between infectious cases and uninfected persons.

Effectiveness

Minor. Modelling studies have demonstrated that the action of isolation may delay the peak of an influenza pandemic, especially when combined with other preventive measures.

SD8: Contact tracing

Application

Important part of initial enhanced surveillance activities. If it is aimed at reducing morbidity and mortality, consider if clinical severity is high.

Objective and rationale

To reduce transmission by identifying people who have been in close contact with symptomatic cases and implementing interventions such as voluntary isolation or antivirals. To reduce morbidity or mortality by promoting prompt treatment.

To obtain surveillance data to support modelling of pandemic impact levels.

Effectiveness

Minor. Effectiveness depends on the capacity to identify cases and locate their close contacts, and the effectiveness of the

Antivirals include Ivermectin and Hydroxychloroquine alone or in combination, for example with Azithromycin/ Doxycycline/Zinc. These antivirals have long been known to be extremely safe and effective when prescribed appropriately. Australian health authorities unilaterally and effectively outlawed the use of antivirals in respect of SARS-CoV-2, and never offered any satisfactory studies in support, despite Australia's own Pandemic Plan specifically recognising the benefits in terms of reduction in mortality (deaths) and morbidity. Answers to Question on Notice for References O and P explore possible reasons for this departure from established medicine and science.

Antivirals

Antiviral medications can be used for treatment of infected cases, prophylaxis of exposed contacts, and pre-exposure prophylaxis for healthcare workers at high risk of infection. Treatment with antivirals aims to reduce symptoms in individuals and hence lower morbidity and mortality. Prophylactic use of antivirals aims to reduce the risk of infection and illness in contacts, potentially lowering the spread and hence disease attack rate. A reduction in mortality and morbidity, and transmission, will assist in minimising impact on health care services during a pandemic. The most commonly used antivirals in the community are oseltamivir and zanamivir.

Rapid distribution is key to the effectiveness of antivirals at a population health level. All stakeholders, including jurisdictions, will need to have considered appropriate distribution strategies. Alternate strategies for

Quality of evidence

There is consistent good quality evidence regarding the effectiveness of antivirals to treat cases.

P1: Antivirals for treatment of cases

Application
Recommended for all cases during the Initial Action stage, within available resources and using a syndromic diagnostic strategy.

Effectiveness
Minor. Modelling studies suggest that treatment of cases only will have minimal (<2%) influence on the scale and progress of the pandemic. However, the effectiveness for individuals may be high. There is consistent good evidence for reduced duration of symptoms. For impact on severe outcomes, observational data (including data from pandemic [H1N1] 2009) and some meta-analyses) show reduced complications, hospitalisations and death. Some reduction in infectiousness will also result—for example, household study estimates include a reduction in secondary attack rate from 10.6% to 4.5%, and 16.6% to 2.1%.

P2: Antivirals for post-exposure prophylaxis (PEP) of contacts[4]

Application
Recommended during the Initial Action stage within available resources. In scenarios with low clinical severity, to reduce mortality/

P3: Antivirals for post-exposure prophylaxis for at-risk groups

Application

Recommended during the Initial Action stage, within available resources. In scenarios of lower severity, to reduce mortality/ morbidity, PEP is best directed towards those at greatest risk of severe illness. In scenarios of high severity, PEP for at-risk contacts is important to reduce illness in this group, and therefore reduce morbidity and mortality.

P4: Antivirals for pre-exposure prophylaxis (PrEP) for healthcare workers

Application

Not routinely recommended during the Initial Action stage. The main benefit of PrEP is to maintain the health workforce; however, in low impact pandemics, other types of protection are likely to be adequate. Higher severity pandemics may have significant negative impacts on the healthcare workforce. PrEP may reduce this impact and assist in maintaining an adequate healthcare workforce.

In answer to Questions 1:

> Did the science change suddenly to warrant Australian governments accepting recommendations from the WHO to justify doing the exact opposite to what Australia's own Health Management Plan for Pandemic Influenza when SARS-CoV-2 arrived?

No, the science did not change.

In answer to Question 2:

> What was the explanation provided by the AHPPC for completely ignoring the Australian Health Management Plan for Pandemic Influenza which had been reaffirmed by all Australian governments in late 2019?

No explanation has been provided to the Australian People by the AHPPC.

A Covid Royal Commission will be assisted to know claims by former Prime Minister Scott Morrison that Federal Cabinet privilege also extends to the deliberations of National Cabinet, and to any committees advising the National Cabinet, would appear to be wrong at law.

The case of *Knowles v Commonwealth of Australia* [2022] FCA 741 (27 June 2022) demonstrated a claim of Federal Cabinet *privilege* in respect of certain National Cabinet actions and papers defined in that case, to be unfounded.

In short, all meeting minutes, evidence, and materials considered and relied upon by the AHPPC for the creation of recommendations to the National Cabinet contrary to Australia's Pandemic Preparedness Plans should be readily accessible to a Covid-19 Royal Commission, including all National Cabinet meeting minutes that considered and

ultimately made decisions based upon AHPPC recommendations and evidence in support received by the National Cabinet.

In respect of Question 3:

> Please provide any further information concerning Event 201 and any involvement by Australian organisations, agencies, or persons.

Event 201 took place on 18 October 2019 and was not the first tabletop exercise in pandemic preparedness to be conducted before. However, Event 201 bore striking similarities to what unfolded in early 2020, particularly in the manner media companies were quickly corralled by national governments, forming apparent partnerships which a Covid Royal Commission needs to verify and investigate. The consequence was that national governments and Australian governments very early on in 2020 accomplished Proposal 7 listed in the Event 201 post event publication PUBLIC-PRIVATE COOPERATION FOR PANDEMIC PREPAREDNESS AND RESPONSE: A CALL TO ACTION, which states:

> **Governments and the private sector should assign a greater priority to developing methods to combat mis- and disinformation prior to the next pandemic response.** Governments will need to partner with traditional and social media companies to research and develop nimble approaches to countering misinformation. This will require developing the ability to flood media with fast, accurate, and consistent information. Public health authorities should work with private employers and trusted community leaders such as faith leaders, to promulgate factual information to employees and citizens. Trusted, influential private-sector employers should create the capacity to readily and reliably augment public messaging, manage rumours and misinformation, and amplify credible information to support emergency public communications. National public health agencies should work in close collaboration with WHO to create the capability to rapidly develop and release consistent health messages. **For their part, media companies should commit to ensuring that authoritative messages are prioritized and that false messages are suppressed including though the use of technology**.

The first line and the last line and every other line in between became the new reality and new normal for Australian government Covid messaging. This appears to have been achieved with the help of the Trusted News Initiative discussed further in the answer to the Question on Notice for Reference YY, and Australian government contracts with Australian media, which a Covid Royal Commission has been requested to examine under References X and RR of The People's Terms of Reference.

Questions remain and continue to circulate throughout Australia concerning the

participation of Australians in Event 201, and particularly Jane Halton, previously the Deputy Secretary in the Department of the Prime Minister and Cabinet, then, critically, Secretary of the Department of Health and Aged Care, then the Secretary for the Department of Finance.

Each one of the above roles within the Australian Federal Government has resulted in many doors remaining open to Jane Halton through which to influence Australian policy, and many lines of communication remaining open for her to introduce and advance materials and ideas from organisations lying outside Australian governments.

Event 201 has, since early 2020, been the subject of much global suspicion and speculation aimed at its backers the Johns Hopkins Center for Health Security, the now popularly reviled World Economic Forum, and the now popularly unpopular Bill & Melinda Gates Foundation. Throughout the Covid-19 era Bill Gates generated great distrust and even loathing around the globe due to a litany of statements placing a light on Mr Gates as possibly a Malthusian eugenicist, a participant-planner of the Covid-19 era, and profiteer from the Covid-19 era. This collection of persons and organisations did not come out of the Covid-19 era as trusted entities.

These institutions and the individuals within them were each intimately involved in a variety of Covid-19 responses and activities, some of them extraordinarily profitable, like the multi-billion dollar profits earned by Mr Gates from his well-timed investments in Covid-19 vaccines in 2019, well before the pandemic was declared.

That Jane Halton also Chairs the Coalition for Epidemic Preparedness Innovations (CEPI), with co-founders being again the World Economic Forum and the Bill & Melinda Gates Foundation, and was subsequently appointed a Commissioner of the Australian National Covid-19 Commission, has left many Australians pointing towards too much coincidence in her affairs aligning well with her performance within Event 201. These suspicions are amplified by her fierce pro-vaccine industry commercial affiliations and contacts, and her resultant position of authority for directing the Australian government response to Covid-19, which radically favoured all of her interests and those of her affiliates and associates, especially their financial interests.

Many Australians sense or believe that Covid-19 was a staged event well planned by powerful interests: this very real view is shared widely across Australia, and is not easy to discount or refute.

The coincidence of Event 201 together with the participation of vaccine-industry-invested Australians who possess the ability to greatly influence the Australian government response to Covid-19, demands investigation, so that the appearance of undue and conflicted interests and influences, and possible overseas commercial forces being brought to bear on Australian government Covid-19 decision making can be laid to rest, or confirmed.

Index

Reference: C

Index

A review and analysis of Covid-19 pandemic management decisions, laws, and policies, and particularly Covid-19 vaccine mandates compelling the receipt of Covid-19 vaccines, implemented by State and Territory governments *in addition to* decisions and positions adopted by the National Cabinet throughout 2020, 2021, and 2022, including:

i. the scientific studies advanced in support of any additional pandemic management decisions, laws, policies, and mandates implemented by State and Territory governments;
ii. modelling advanced in support of any pandemic management decisions, laws, policies, and mandates, including:
    a. modelling undertaken by The Peter Doherty Institute for Infection and Immunity;
iii. an assessment of the review and consideration processes and cost-benefit analyses undertaken by State and Territory governments into potential adverse psychological impacts and mental harm from lockdown measures and mandates, with particular focus on children and infants, before lockdown measures were implemented, during lockdown measures, and subsequent to lockdown measures being implemented, including but not limited to the assessed impacts versus actual impacts;
    a) from masking children and infants;
    b) school closures;
    c) from stay-at-home orders for children and infants;
    d) from social distancing children;
    e) on the physical health of children and infants;
    f) on the mental health of children and infants;
    g) on parental relationships with children and infants;
    h) on the impact of parental stress / mental health impairment on children;
    i) on the impact of chronic fear-based messaging on children;
    j) on the impact of chronic mortality-reminders on children;
    k) on the impact of social ostracism on unvaccinated children and young people;
iv. a review of all submissions and reports provided by suitably qualified non-government experts in mental health to State and Territory governments into potential adverse psychological impacts and mental harm from lockdown measures, with particular focus on children and infants, and the review and consideration processes and cost-benefit analyses undertaken by State and Territory governments in respect of any such submissions and reports, before lockdown measures were implemented, during lockdown measures, and subsequent to lockdown measures being implemented, including but not limited to;

a) from masking children and infants;
b) school closures;
c) from stay-at-home orders for children and infants;
d) from social distancing children;
e) on the physical health of children and infants;
f) on the mental health of children and infants;
g) on parental relationships with children and infants;
h) on the impact of parental stress / mental health impairment on children;
i) on the impact of chronic fear-based messaging on children;
j) on the impact of chronic mortality-reminders on children;
k) on the impact of social ostracism on unvaccinated children and young people;

v. an assessment of the review and consideration processes and cost-benefit analyses undertaken by State and Territory governments into potential adverse impacts and from lockdown measures, in response to publicly available expert opinions, including for example:
    a. The Great Barrington Declaration;
vi. the health science evidence upon which State and Territory governments enacted border closures;
vii. the health science evidence upon which State and Territory governments implemented mandates and laws for the compulsory wearing of masks;
viii. the health science evidence upon which State and Territory governments implemented mandates and laws requiring Covid-9 vaccination of healthcare workers;
ix. the health science evidence upon which State and Territory governments implemented mandates and laws and policies for mass testing of asymptomatic populations using a technology (PCR) the inventor of which expressed scepticism when used for the diagnosis of SARS-CoV-2 or Covid-19 infection;
x. health science evidence upon which State and Territory governments implemented mandates and laws for compulsory staying at home when not seeking essential services or performing exercise;
xi. the health science evidence upon which State and Territory governments implemented mandates and laws for social distancing;
xii. the health science evidence upon which State and Territory governments implemented mandates and laws for the isolation of sick persons;
xiii. the health science evidence upon which State and Territory governments implemented contact tracing mandates and laws;
xiv. the health science evidence upon which Australian governments variously enacted vaccine passports;
xv. the health science evidence upon which the Commonwealth government enacted international border closures and travel restrictions;
xvi. the health science evidence upon which State and Territory governments established quarantine camps for those who had not been vaccinated;
xvii. the health science evidence basis upon which State and Territory governments

implemented Covid-19 vaccination mandates when the TGA's own provisional approval decisions (AusPARs) noted Covid-19 vaccines had not been tested to determine whether they prevented transmission;

xviii. the health science evidence basis upon which State and Territory governments implemented mandates controlling travel and access to services based upon vaccination status, when the TGA's own provisional approval decisions (AusPARs) noted Covid-19 vaccines had not been tested to determine whether they prevented transmission;

xix. when State and Territory health authorities first understood Covid-19 vaccines did not prevented infection;

xx. when State and Territory health authorities first understood Covid-19 vaccines did not prevented transmission of SARS-CoV-2;

xxi. the scientific basis upon which State and Territory governments continued to enforce pandemic management decisions, laws, policies, and mandates when possessed of the knowledge Covid-19 vaccines neither prevented infection nor stopped transmission;

xxii. the scientific basis upon which State and Territory governments continued to enforce Covid-19 vaccine passports when possessed of the knowledge Covid-19 vaccines neither prevented infection nor transmission;

xxiii. the legal basis upon which State and Territory governments deemed discriminatory treatment based on vaccination status as legally justified when possessed of the knowledge Covid-19 vaccines neither prevented infection or transmission;

xxiv. the legal basis upon which State and Territory governments deemed as legally justified requirements that Australians had to disclose their medical history in order to physically move or gain access to areas, both before and subsequent to possessing the knowledge Covid-19 vaccines neither prevented infection or transmission;

xxv. the legal and scientific basis upon which State and Territory governments chose to not observe The Australian Immunisation Handbook;

xxvi. the extent to which State and Territory governments and their expert public health advisors understood the difference between *absolute risk reduction* versus *relative risk reduction* in respect of Covid-19 vaccines, and the extent to which this understanding was conveyed by State and Territory governments and their expert public health advisors to Australian citizens;

xxvii. an examination of potential or perceived conflicts of interests in members constituting any bodies responsible for advocating or advising on or promoting the uptake and receipt of Covid-19 vaccines by Australians, including such bodies as:

a. the Australian Technical Advisory Group on Immunisation (ATAGI);
b. the National Centre for Immunisation Research and Surveillance (NCIRS);
c. the National Health and Medical Research Council (NHMRC);
d. the Australian Academy of Science (AAS);
e. the Australian Academy of Health and Medical Sciences (AAHMS);
f. the TGA Advisory Committee on Vaccines (ACV);
g. The Peter Doherty Institute for Infection and Immunity; and

xxviii. an examination of any Commonwealth government or Commonwealth agency informal correspondence, informal communications, informal agreements, informal understandings, or informal undertakings with any foreign nations, foreign agencies, foreign security services, or foreign defence organisations to collectively or in unison adhere to some or all of the lockdown measures described above, particularly (iv) and (vi) through (xiv).

Explanatory Memorandum

Index

An examination to confirm whether Covid-19 mandates imposed by Australian State and Territory governments throughout 2020, 2021, 2022, and 2023 were reasonable and proportionate and consistent with real-time Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known by and shared between Australian governments.

An examination to confirm whether Covid-19 mandates imposed by Australian State and Territory governments throughout 2020, 2021, 2022, and 2023 were reasonable and proportionate and considered all available scientific evidence and submissions for completing all reasonable cost-benefit analysis in respect of each mandate item or policy or rule implemented and required of Australian citizens.

In a review of Covid-19 decisions and mandates implemented by Australian governments, each measure analysed should be approached in terms of whether the action taken involved costs and benefits in relation to overall human health and wellbeing during and following the Covid era, rather than with reference to particular phenomena such as disease spread or cause-specific morbidity or mortality within a prescribed timespan.

In respect of Ref C (iii) and (iv) and impacts on Australian children.

In 1990 Australia ratified the *Convention on the Rights of the Child (CRC)* within which Article 3 states:

> In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

In the Australian Human Rights Commission report *Impacts of Covid-19 on children and young people who contact Kids Helpline* the AHRC noted:

> Children and young people, especially teenagers, frequently expressed the view that their friends provide them with their main mental health support in times of crisis and were worried about being unable to connect with these friends because

> of social distancing measures. Some spoke of loneliness, feelings of abandonment, introspection, and insecurities about their friendships especially those with pre-existing mental health conditions.

Further:

> Teenagers raised the adverse impacts of social distancing measures on their romantic relationships, in some cases causing them significant anxiety and distress.

The Australian Government Department of Education noted in its report *Improving Outcomes for All*:

> The Panel heard that students with strong social and emotional wellbeing are more engaged with learning and tend to have higher levels of academic achievement and attainment. However, students with poor wellbeing may have challenges with their ability to engage and learn, their academic achievement, and their relationships and social interactions at school.

Schools play an essential role in childhood development where UNESCO noted in 2020:

> School closures carry high social and economic costs for people across communities. Their impact however is particularly severe for the most vulnerable and marginalized boys and girls and their families. The resulting disruptions exacerbate already existing disparities within the education system but also in other aspects of their lives.

Any policy or action contemplating the disruption of schooling during Covid-19 was required to conduct a careful analysis of harms to children and their emotional and psychological development against purported benefits.

SARS-CoV-2 was widely acknowledged to represent virtually no threat to children of schooling age, however Australian governments enforced widespread and prolonged school closures, and whether in school or not, enforced prolonged social distancing measures which impacted childhood activities which develop social skills, despite the abundance of evidence-based scientific literature speaking against these measures. As the Norfolk Group noted in *Questions for a Covid-19 Commission*:

> There were no data indicating differences in transmission rates between social distancing of 6 feet or 3 feet (or fewer).

Again, in the 2020 study titled Child behaviour during the social distancing in the Covid-19 pandemic the authors placed the evidence forward:

> Maintaining the routine helps the children to keep their stability and balance. To all of them, playing is their favorite activity, regardless of their environment.

> Through playing, the child acquires knowledge and increases interaction with people, thus improving ways of dealing with their expectations and frustrations, learning to live together in a group, and to expose their feelings.
> Although 84% of the children in this study were having some online class or video lesson, in children and adolescents, the stress of the pandemic generated by the interruption of pedagogical activities, the disorganization of family and social coexistence, the interruption of team sports and, often, the difficulty of those responsible for meeting emotional needs can contribute to the emergence of psychological suffering, such as insomnia, anorexia, anxiety crises or depression.
> Anxiety is the expectation of an imagined or potential threat at any level; it is usually vague and unfocused and can affect emotions, thinking processes, body sensations, and behaviours. In this study, those responsible for children reported that 52% presented anxiety, with no statistical difference between ages. The Brazilian Society of Paediatrics (BSP) points out that severe psychological traumas appear when situations out of the order of ordinary life experiences overcome the individual's mental elaboration capacity, leaving marks on mind and body.
> This study shows that children who did not practice physical activities have 1.37 times more chance to develop anxiety than those who performed physical activity.

In March 2021 UNICEF remarked in the article titled *Covid-19 and School Closures: One year of education disruption*:

> We are facing a Covid-19 education crisis. As this report finds, schools for more than 168 million children globally have been closed for almost a full year. With every day that goes by, these children will fall further behind and the most vulnerable will pay the heaviest price.

A NSW Department of Education document *Term 2 2020 Guidelines for Schools* noted a significant decrease in schooling hours during school closures to 3.5 hours for Years 7-10 (ages approximately 13 – 16 years). The average school day is approximately 6.5 hours. NSW school closures caused a 46% reduction in learning time. Remote learning was not able to deliver the same quantity of learning hours. Further impacting children, and no mitigation or remediation strategy was articulated by the NSW Department of Education at the time of writing.

A recent literature review and editorial, *The Impact of School Closures on Learning and Mental Health of Children: Lessons From the Covid-19 Pandemic*, in a prominent psychology journal reported:

> .. the unprecedented scale and length of school closures resulted in a substantial deficit in children's learning and a deterioration in children's mental health.

The negative consequences of school closures and other lockdown measures

disproportionately affected children of families from low socioeconomic backgrounds.

Under the *Universal Declaration of Human Rights* the Australian Human Rights Commission acknowledges:

> .. the United Nations has proclaimed that childhood is entitled to special care and assistance.

Despite this statement there is no clear evidence Australian governments turned their minds to the special care and assistance to be afforded Australian children when considering school closures.

Instead, evidence suggests school closures were used by some Australian governments for messaging purposes unrelated to the special care and assistance to be afforded Australian children.

For example, the Brisbane Times reported CHO Dr Jeannette Young in April 2020:

> .. while evidence showed schools were not a high-risk environment for the spread of the virus, closing them down would help people understand the gravity of the situation. "If you go out to the community and say, 'this is so bad, we can't even have schools, all schools have got to be closed', you are really getting to people," Dr Young says. "**So sometimes it's more than just the science and the health, it's about the messaging**."

In the US the National Bureau of Economic Research released an assessment in November 2021 titled *Pandemic Schooling Mode and Student Test Scores: Evidence from US States*, and noted:

> there were considerable declines in test scores overall during the 2020-21 school year, and these declines were larger in school districts with less in-person instruction. There are consequences for inequality in outcomes in these results. Students in districts with larger populations of Black and Hispanic students, for example, were less likely to have access to in-person learning… our analyses demonstrate that that virtual or distanced schooling modes cannot support student learning in the same way as in-person schooling. As such, educational impacts of schooling mode on students' learning outcomes should be a critical factor in policy responses to future pandemics or other large-scale schooling disruptions.

The Australian situation appears to have fared no better and only to the detriment of Australian children.

According to Professor Gigi Foster and Sanjeev Sabhlok PhD in their book *Do lockdowns*

and border closures serve the "greater good"? A cost-benefit analysis of Australia's reaction to Covid-19:

> Lost future productivity of children of school age during lockdowns equates to $465 million in lost lifetime earnings of schoolchildren.

However, school closures and social distancing measures, compounded by closures to community playgrounds and after school activity groups, did not only impact negatively on the physical and emotional development of Australian children, but also the mental health of Australian families as a whole.

Infancy, childhood, and adolescence are critical stages in the development of future generations becoming well-functioning and productive members of society.

This development is crucially rooted in a nurturing, happy, and well supported family environment.

In Australia, the government's sweeping mandates and restrictions during the pandemic directly impacted the biopsychosocial development of all children and adolescents. Measures such as masking, social distancing, and stay-at-home orders exacerbated social isolation, negatively impacting neurodevelopment, behaviour, learning, and psychological well-being, particularly in children.

The loss of essential support services, both in homes and schools, along with diminished religious and social support and the absence of extended family, created a dangerous situation resulting in severe effects on our society's youngest, exacerbated by isolated parents forced to cope and manage and implement Australian government mandates aimed at their children, but with no support or guidance from Australian governments for circumstances never before experienced in Australian history.

The adage *'It takes a village to raise a child'* became painfully relevant: during the pandemic children effectively lost their 'village'.

The consequences of these unique pressures brought to bear upon Australian families and children in child maltreatment terms has yet to be fully studied, and was a critical issue of concern absent in the mandating and lockdown measures enforced by Australian governments on Australian children and their parents.

Child maltreatment has long been a problem in society with particularly deleterious effects potentially impacting the child for the rest of their lives.

Child maltreatment includes physical, emotional, and sexual abuse as well as physical and emotional neglect. The WHO outlines several risk factors that make children particularly vulnerable to childhood maltreatment. Listed below are those exacerbated by Australian

government pandemic measures:

Family isolation in the community or lacking a support network and support in child rearing from the extended family:

Parental difficulties bonding with a new-born;
Parents not adequately nurturing children;
Parents lacking awareness of child development or having unrealistic expectations.

High levels of unemployment or poverty:

Potential impacts on the mental health of parents;
A lack of services to support families and institutions;
Easy availability of alcohol and drugs;
Parents misusing alcohol or drugs, including during pregnancy;
Family breakdown or violence between other family members.

Further stresses on Carer(s) with pre-existing mental or neurological disorders.

Further analysis is required into the immediate and long-term impacts on the psychological and practical development of Australian children as a consequence of their being subjected to Covid-19 lockdown measures.

The national consequences require examination by a Covid-19 Royal Commission.

Question(s) on Notice

Index

In respect of **Reference C**, please provide any further information concerning the Covid-19 pandemic management decisions, laws, policies, and the review and consideration processes and cost-benefit analyses undertaken by State and Territory governments into potential adverse impacts and mental harm from lockdown measures and mandates, with particular focus on children and infants.

Answer(s)

Index

First Answer

Prof. Paul Frijters, Co-Author:

I am the inventor of the WELLBY method for estimating cost-effectiveness, having written the Handbook on how to apply it in 2019, though it came out in 2021 (Frijters and Krekel, 2021, Oxford Uni Press), and saw its main components adopted by the UK Treasury in 2021. This method is particularly suited to quick calculations of the cost and benefits of major policies with many effects across different sectors and groups.

At the outbreak of the Covid panic, on March 18th 2020, I applied basic cost-benefit analysis to suggest that the panic was going to cost us at least 10 million lives in the world via the impacts of the economic devastation on health services. Three days later I could calculate the maximum possible benefits of lockdowns using data from the Diamond Princess, a ship whose passengers were forced to remain on board in Yokohama (Japan) whilst the disease ran its course. Out of some 3700 elderly, some 8 to 11 died from Covid (depending on whether one counts those who later died off the ship as well as those on it). This allowed one to say that the disease would maximally claim about 0.2-0.3% of the population, and even then, only among the most elderly.

Given that those dying from Covid were on average over 80 and normally had one to three years of life left, I had a maximum number for what any intervention could possibly have as a benefit. Considering that lockdowns would cost entire populations months of their lives in terms of lost health care, social interaction, education, festivities, and much else that is the point of life and for which the wellbeing literature had reasonable estimates of importance, I could say on March 21st, 2020, that the costs were at least 70 times the benefits. At best, for every person who had 1-3 years 'saved', there would be 300-500 people losing the equivalent of months of their life. Of course, it was already then highly dubious that there was any intervention that would have any effect on the spread of this disease. Before 2020 the idea that keeping people indoors, idle, and sharing air with the rest of the people in their buildings and supermarkets was going to do anything but increase obesity, alcoholism, abuse, and susceptibility to airborne diseases was considered anathema to the WHO and others.

My estimates were published on a blog website (clubtroppo.com.au) but these numbers then made the New York Times, and the second piece (a blog piece called "The Corona Dilemma") has since been cited in 7 peer-reviewed articles. Not bad for a blog, but of course a drop in the ocean compared to the pro-lockdown waterfalls of that time. My early ballpark number has since been replicated wherever teams used to looking at cost-benefit calculations have made the effort (see Foster and Frijters 2024 for a review, with the working paper freely available since 2022). I have published such cost-benefit analyses in peer-reviewed articles and books for the Netherlands (Frijters, 2020), the world (Frijters, Foster, and Baker 2021), and Australia (Foster and Frijters 2022, 2024), whilst I supported international scholars doing similar calculations for Canada, Ireland, the UK, and elsewhere (see Foster and Frijters 2024). The only pro-lockdown cost-benefit analyses I know of (and there are many) were conducted after the fact, by academics who were not previously involved in cost-benefit analyses for governments and invariably neglected the mental health cost and lost schooling effects, often believing in the idea that a few weeks

of lockdowns would keep out Covid forever (see for example Kompas et al. 2021 for such magical reasoning by Australian academics published in mainstream journals).

Index

Second Answer

Prof. Gigi Foster, Co-Author:

From March 2020 until the present day, I have been one of Australia's loudest and more consistent critics of Covid lockdown policy, and my engagements have included both public, structured and private, informal conversations with people in and advising government about decisions to lock down and issue mandates. These experiences have shown me the approach and mindset adopted by public servants in multiple Australian governments as they took Covid policy decisions.

The first such experience I had was on ABC's Q&A program, in April and then July 2020, where I was joined by people representing bodies that were advising government on the Covid policy response. In both of those appearances I stressed the enormous costs of lockdowns and found my co-panellists (and the moderator) essentially unable to apprehend what I was saying. Then, in August 2020, at the invitation of David Limbrick MP I addressed the Victorian state's Public Accounts and Estimates Committee and once again opined on the enormous costs of lockdowns compared to their plausible benefits. Yet again, I encountered perplexity and a "deer in the headlights" reaction from the MPs interviewing me, as well as clear attempts to discredit me as someone without professional training in health care or immunology and therefore whose views on Covid policy were not valid or valuable. During this period, I am told I was defamed on Twitter for my allegedly "heartless" views as a "granny-killer" and "neoliberal Trumpkinaut death cult warrior" even though I have no account on that platform. These reactions collectively informed me that a scientific, cool-headed, sniff-test-passing analysis of lockdown policy was not taking place either within government or in the public square.

Some examples of these exchanges are available at the links below:

> A news report about my comments and the reaction to them on the ABC Q&A panel in mid-April 2020, together with, as the report notes, "Professor Jodie McVernon from the Doherty Institute, which has been advising the government on its steps with modelling throughout the Covid-19 outbreak": https://au.news.yahoo.com/coronavirus-economist-slammed-horrible-lockdown-idea-013505468.html
>
> A radio discussion between myself and Adjunct Professor Bill Bowtell from the Kirby Institute for Infection and Immunity, who takes the "zero Covid" position so prevalent at the time, from 5 May 2020:

https://www.abc.net.au/listen/programs/melbourne-drive/the-cost-of-saving-lives-coronavirus-debate/12217614

A news report of my interaction again with Bill Bowtell, other panellists, and ABC Q&A host Hamish McDonald about the costs of lockdowns, from 28 July 2020: https://www.news.com.au/entertainment/tv/current-affairs/qa-economist-gigi-foster-advocates-swedish-model-for-australian-lockdown/news-story/53de1ed88f3e5e427b8a11c7e7c8d9e2

The video recording of my testimony to and interaction with MPs about the costs and benefits of lockdowns at the Victorian PAEC in August 2020: https://www.youtube.com/watch?v=mpyYwQFtF-U

Further, I have written one of three thorough cost-benefit analyses (CBAs) I know of to date of Australia's Covid lockdowns, and as such I am intimately familiar with the costs and benefits of these policies in terms of human health, dollars, wellbeing, or any other currency in which one might like to quantify and compare costs and benefits, as estimated by multiple independent scholars. In all three of these published studies of the costs and benefits of Australia's lockdowns (mine, Martin T Lally's, and the Institute for Public Affairs'), the costs of lockdowns are found to significantly outweigh their benefits.

Worth mentioning is also at least one contribution of which I am aware wherein Australian economists attempting to produce a cost-benefit-based argument in favour of the lockdowns made elementary errors in their calculations which were not picked up by the site hosting their effort, which when corrected lead to a conclusion that lockdowns are bad policy (these economists are Richard Holden and Bruce Preston, and their analysis – in which the lives of a newborn child and of a 90-year-old man one second from death are valued equally – is available here: https://theconversation.com/the-costs-of-the-shutdown-are-overestimated-theyre-outweighed-by-its-1-trillion-benefit-138303). I also know from reliable sources that the "scientific modelling" being relied upon by many government decision-makers to determine the alleged benefits of lockdowns (such as that produced by the Doherty Institute) that predicted huge numbers of deaths without lockdowns was highly stylised, dangerously based on simulations rather than real data, and limited to epidemiological factors, with no consideration of the obvious broader effects of lockdowns on individuals and society. To my knowledge, the same can be said of much of the supposed "evidence" underpinning mask mandates.

In my CBA, I use the currency of the wellbeing year, or WELLBY, to capture both costs and benefits. This is a currency built from people's self-evaluations of life satisfaction, and hence captures in broad form all inputs that make life more or less satisfying, including physical health state, mental health state, quality of relationships, social status, financial wellbeing, and whatever else people consider when evaluating their satisfaction with their life. I also use actual data, rather than computer simulations, in generating my estimates of both the costs and the benefits of lockdowns. The Executive Summary of my

cost-benefit analysis, published in full as *Do Lockdowns and Border Closures Serve the 'Greater Good'?* with Sanjeev Sabhlok in September 2022, is available for free download here: https://www.thegreatCovidpanic.com/_files/ugd/23eb94_33b4f30ef8fa4e6eaf1a7e62d571a9a7.pdf

Quoting from this Executive Summary:

> Choosing conservatively to exclude or under-estimate many costs, and to make generous estimates of benefits, I estimate the maximum benefits from Australia's lockdown policies to be 343,800 WELLBYs, and the minimum costs from lockdowns to be 23.41 million WELLBYs. This indicates that the costs of Australia's Covid lockdowns have been at least 68 times greater than the benefits they delivered. Because I make assumptions in this CBA that are extremely favourable to the government's choice to pursue a lockdown strategy, the true ratio of costs to benefits of the Australian Covid lockdowns is likely to be greater than this.

To my knowledge, no level of Australian government has produced for public consumption a cost-benefit analysis in any currency to defend Covid lockdowns and mandates – and this is four years after the initial policy decisions were made. Normal government procedure is for policies to be evaluated in such a manner, as a means of assessing whether policies selected by government are indeed meeting the needs of the people the government serves. This convention – and its abandonment during Covid times by the Victorian government – is explained in *The Great Hysteria and the Broken State*, a book by ex-Victorian Treasury economist Sanjeev Sabhlok, published in late 2020 after he resigned from his post due to being asked to remove social media posts critical of the government's approach to Covid. His is the first book I know of to comprehensively and convincingly critique Australian governments' response to Covid on economic, moral, and scientific grounds.

What can be gleaned from a careful review of broadcasts at the time is that at least some Australian governments were looking at some of the more obvious costs of lockdowns in 2020. For example, in the ABC radio link above from 5 May 2020, the host mentions that 1 million jobs had been lost since the inception of the lockdowns 5 weeks prior, and that the federal Treasury had estimated that the lockdowns were costing $4 billion each week. We can put this number together with an estimate of lockdowns' benefits to construct a back-of-the-envelope CBA, which allows me to sketch the magnitude of the error made by our governments during this time. In April 2022, Scott Morrison claimed that 40,000 lives had been saved by lockdowns in Australia, providing us with that required estimate of the benefits of lockdowns – offered by the government itself.

As I explain in my CBA, an average Covid death represents, generously, the loss of 5 quality-adjusted life years (QALYs), a typical currency used to measure the time in health

enjoyed by people. The social willingness to pay for a QALY in Australia has been estimated to be a maximum of $100,000, meaning that "we" Australians would normally be willing to pay up to $500,000 to save one person from death by Covid. This means that each week in which we "paid" $4 billion (according to the federal Treasury), we would have to have been expecting a savings of at least ($4 billion/$500,000) = 8,000 people from death by Covid, in order for the lockdown to be considered worthwhile from a social standpoint. Were our lockdowns really saving 8,000 people per week? Scott Morrison's own estimate in April 2022 of 40,000 lives saved across the whole Covid period to that point is very far from 8,000 lives saved per week, and even the most alarmist modelling never suggested that extreme an estimate of benefits from lockdowns.

Recall that this back-of-the-envelope calculation is using a likely politically driven estimate of benefits, and considering only one category of costs of lockdowns – i.e., the Treasury's estimate of their financial cost per week, in May 2020 – when in reality, as I discuss in detail in my published CBA, lockdowns carry an enormous array of other costs including direct mental health damage, disruption in human capital accumulation, the development of bad habits, a loss of trust in authority and between people, an increase in inequality, a reduction in market competition and a loss of belief in a positive future. My confidence in representing the view that the costs of Covid lockdowns would exceed their benefits many times over was formed early in the Covid era based on a back-of-the-envelope assessment similar to what I have sketched above but using real data, including Sweden's experience, to gauge potential benefits (an assessment represented in my August 2020 submissions to the Victorian PAEC here and here), while recognising the other inevitable losses of lockdowns, of which many are difficult to quantify.

What we see today in government reports, such as the recent 2023/24 budget report published by the Victorian Treasury, is not a careful cost-benefit analysis of Australia's Covid policy response, but rather deft side-stepping of the underlying cause of the economic stress of lockdowns (i.e., lockdown edicts issued by that government itself), coupled with robust self-congratulations about the laudable effects of the subsequent stimulus programs, such as JobKeeper, created to staunch the self-inflicted wounds of lockdowns. It may be that some type of cost-benefit-based evaluation of Covid lockdowns was conducted in the back rooms of governments early in 2020, but if that happened, those analyses and their conclusions have been brushed out of public sight. This is despite the fact that Australia's pre-Covid pandemic management plans, including those of the state of Victoria, which represented the distillation of generations of health science, categorised lockdowns of healthy people as unacceptable as a means of fighting infectious disease because they were known to be so costly, and their benefits had not been proven. "Science," as represented by such plans, and whatever analyses might have accorded with it, were completely disregarded at the onset of the Covid era.

As my co-authors and I opine in our September 2021 book, *The Great Covid Panic: What happened, why, and what to do next*, it was not good health care or "science" that stopped ideas other than the government's lockdown-based approach to Covid from being aired or

taken seriously. What perpetuated the harmful policy trajectory in our country was a combination of crowd thinking, power hunger, profiteering, incompetence, and path dependence. Colossal human destruction was the result.

Index

Third Answer

Dr Sanjeev Sabhlok, Proposed Witness:

On 10 September 2020, I resigned my job as a senior economist in the Victorian Department of Treasury and Finance, a job I had held for nearly 15 years, to protest against disproportionate public health measures by Premier Daniel Andrews that had led to a police state.

Soon thereafter I published a book entitled *The Great Hysteria and the Broken State*, which tells the story of my experience working in government in these early months of the Covid crisis, demonstrating the climate of the time. Some excerpts from this book appear below:

> In the normal course of policy making, a government intervenes in the market to try to resolve its failures. To assist decision making, we use cost-benefit analysis (CBA) which is the practical implementation of Bentham's utilitarianism – the greatest good for the greatest number.
>
> Accordingly, the Victorian Government needed, in February 2020, to commission a detailed analysis of alternative policy options that took into account scenarios…After that, the Government should have chosen the best option, cognisant of the uncertainty and considering also the need to intrude in the least invasive way possible into human freedoms.
>
> But the lockdown screw got tighter and tighter. Just as comprehensive data started coming in from mid-April that this virus is *far* less lethal than originally thought, the Victorian government started tightening the screw and has continued to do so, till now it has become truly intolerable to live in Melbourne. Not just home imprisonment: one cannot even breathe fresh oxygen. This is a comprehensive attack on one's existence.
>
> I kept raising concerns within the Treasury but after not being taken seriously, I gave up.
>
> The core of public service is citizenship. The public servant's job, as the role clearly states, is to serve the public – in my case, the people of Victoria. He does "serve" the elected government of the day, but in doing so he provides it with

independent advice.

As mentioned earlier, had the Victorian government exercised the due diligence required by its own policy-making processes, published all information about the options available to it for dealing with the pandemic, and in doing so demonstrated that its heavy-handed lockdowns, curfews and mandatory mask requirements outdoors were essential, then I would have supported these measures. But they did not.

Instead, the Andrews Government has operated like a Star Chamber with no disclosure about the logic and reasons that underpin these lockdowns – which self-evidently violate Victoria's own pandemic plan.

I asked the Chief Health Officer via Twitter for his evidence for requiring masks outdoors. He has never responded.

In my opinion, most pandemic directions issued by the Chief Health Officer to date violate Victoria's laws except perhaps those in which he may thoroughly have justified the intervention – but I'm not aware of any.

The mandatory mask decree in open spaces was the direct cause of events that led to widespread police brutalities in Victoria. These brutalities distressed me enormously. Even more distressing was that Daniel Andrews did not raise his voice against them. Instead, he blamed the people of Victoria. His Assistant Police Commissioner called the protestors against lockdowns a "tinfoil hat-wearing brigade".

At that point, I ceased being largely neutral in my comments about the Victorian administration in my social media commentary – and I started to escalate my commentary. I think I probably called Victoria a Police State.

How could this happen?

And how can I watch this and keep quiet?

…On 9 September 2020, the Treasury asked me to remove any direct *and indirect* social media criticisms of the Victorian government's pandemic policies. I was not provided with any specific post to delete. Until then, I had made very few direct criticisms of Victoria's policies but for many months I had vigorously challenged lockdown policies across the world. Were such attacks on lockdowns an "indirect" criticism of the Victorian Government's policy?

The VPS Code of Conduct moderates the free speech rights of Victorian Public Service employees, but these rights are not eliminated. Social media posts on

topics that are unrelated to the policy area in which I provide professional advice do not violate the Code. I had also made it clear on my social media profiles that my views are personal and do not in any way represent the views of my employer.

I continue to believe a public servant in a non-executive role has the right to publicly question the actions of a government that violate the laws and sound principles, and especially when the foundations of civil society are being attacked – particularly in an area unrelated to his or her professional role. Nevertheless, it became clear to me that a broken government cannot be fixed from within.

I had intended to work at the Treasury till age 65, if not 67. But that day I chose to resign within minutes of the meeting in which I was directed (that is the word used) to remove my posts.

My resignation process was completed on 10 September 2020.

I published an op-ed on 16 September 2020 entitled, "Why I quit rather than be silenced: Vic Treasury insider" in the *Australian Financial Review*. Key extracts of this op-ed that address this Question on Notice are reproduced below:

The pandemic policies being pursued in Australia – particularly in Victoria – are the most heavy-handed possible, a sledgehammer to kill a swarm of flies. These policies are having hugely adverse economic, social and health effects, with the poorer sections of the community that don't have the ability to work from home suffering the most.

Australia is signalling to the world that it is closed for business and doesn't care for human freedoms. This will dampen business investment but also impact future skilled migration, the education industry and tourism.

The whole thing hinges on the scare created by politicians and health professionals. For instance, Victoria's Chief Health Officer Brett Sutton claims this is the 'greatest public health challenge since the Spanish flu'.

But this is no Spanish flu – we can verify that easily.

The Spanish flu killed at least 50 million people worldwide in 1918 when the global population was 1.8 billion. Proportionately, to be as lethal as Spanish flu, a virus would have to kill at least 210 million people today. Instead, only around 0.9 million have died so far (compare this also with the 60 million who ordinarily die each year).

The need for good policy process does not disappear just because we face a public health crisis. In fact, it gets even more urgent.

> The Victorian Guide to Regulation notes that 'It is not possible for governments to provide a completely "risk free" society, or to prevent every possible event that might cause harm'. Further: 'The direct and indirect costs imposed by regulatory approaches may not be ... immediately obvious. Risk regulation that is poorly targeted or costly will divert resources from other priorities.'
>
> Governments back in February needed to commission a cost-benefit analysis of alternative policy options that took into account different scenarios (such as with and without a vaccine). Thereafter, the best option had to be picked given the uncertainty, but consistent also with the need to intrude minimally into human freedoms. This cost-benefit analysis and policies needed then to be updated as new information emerged (such as the fact that epidemiological models have badly exaggerated the risk).

In due course as more data came in, it became even more abundantly clear that Covid was not once-in-a-100 year pandemic. I published a piece two months later, on 30 December 2020, entitled, "Swedish Covid-19 data exposes our fatal lockdown hysteria" in *The Australian*. Key extracts are reproduced below:

> In May, modellers had said Sweden would experience more than 100,000 additional deaths from Covid this year, with 96,000 additional deaths by July if lockdowns were not imposed. … I estimate Sweden will end up with about 97,000 deaths this year. Long-term trends suggest Sweden would have had about 92,500 deaths this year, so there will be about 4500 additional deaths this year, a far cry from the models.
>
> Sweden's Public Health Agency noted in October that 'the 2019-2020 influenza season was mild'. As a result, 3419 fewer people died in Sweden last year than in 2018. Many of the frail among these 3419 survivors last year would have died this year anyway. Of its own accord, therefore, Covid has caused a much smaller number of deaths than these 4500 additional deaths. Sweden's average two-year death rate in 2020 will be around 0.92 per cent, the second lowest in the past 10 years.
>
> One struggles from this analysis to identify a serious pandemic in Sweden: just a bad flu, milder than the Hong Kong flu.

In 2023, when the official mortality rate statistics for Sweden for previous years emerged, I found that the combined two-year average mortality rates per 10,000 (using the year rate adjusts for the dry tinder effect of 2019), were the following since 2010: 2011-12: 95.9; 2013-14: 93; 2015-16: 92.25; 2017-18: 91; 2019-20: 90.6; 2021-22: 89.3. This series re-confirms two things: (a) There was absolutely no "pandemic" in Sweden in 2020. Further, (b) contrary to claims made by some "experts", there is no evidence that vaccines

administered in Sweden starting in late 2021 caused any noticeable excess deaths in 2021-22. Plenty of other corroborative proofs by eminent experts like John Ioannidis confirm my analysis above.

In relation to Covid vaccines, I conducted econometric research in 2021 (jointly with Jason Gavrilis) using global data that showed that lockdowns increased even non-Covid deaths, while Covid vaccines did reduce Covid deaths.

I have further examined the empirical evidence regarding quarantine policies (lockdowns) and found extensive evidence that the men who arguably founded the discipline of public health in the 1800s, Dr. Southwood Smith and lawyer Edwin Chadwick, repeatedly demanded the abolition of quarantine which conclusively caused more harms than any good. They offered modern sanitation as a substitute for quarantine. Unfortunately, modern "public health" has abandoned their recommendations and insists on the medieval and dangerous policy of quarantine despite conclusive proofs of the harms it cause. These harms have, of course, been proven yet again via a 2022 cost-benefit analysis led by Prof. Gigi Foster to which I also contributed. It is time to abolish all forms of human quarantine.

On how the disaster of lockdowns could have happened in Australia and continued for so long, many factors played a role, including the folding of peer nations overseas (like the UK), the involvement of behavioural scientists in fuelling populations' fear, and extreme model projections which were hyped up further by the media. As I state in *The Great Hysteria and the Broken State*:

> It also appears that similar over-estimates were being churned within Victoria by a few well-known institutes. Any future Royal Commission must investigate whether the models used by the Victorian Government were scientifically valid. More importantly, whether Treasury officials (many of whom have significant mathematical skills) were involved in cross-checking these models, or did groupthink prevail.
>
> Not once did the Victorian Government's messaging reflect the age-based risk profile of the pandemic or even provide any balanced presentation of the facts.
>
> So, everything that could have stopped the Great Hysteria fell by the wayside. There was no hope after that.
>
> The questions arise: Are our politicians evil? Was there a conspiracy?
>
> I believe that the much simpler explanation outlined above might work better. Governments are hierarchical and dramatically prone to groupthink. They are also prone to unbelievable stupidity (the public choice literature has explored this at length). And on top of all this, the road to hell is paved with good intentions.

> We cannot let governments use public health as an excuse to brutalise citizens and destroy their right to occupation (shutting down shops and businesses) – effectively confiscating their property rights; as well as brutalising people by restricting their right to movement, to cross borders or even to breathe.

I recommend a full-fledged review of public health by the government, since the "science" and methods of this discipline are fundamentally flawed at many levels.

Index

Fourth Answer

Ros Nealon-Cook BPsychSc, Co-Author:

In my answer below I have also included correspondence with professional colleagues, which is duly identified.

In August 2021, I took a public stand as a Registered Psychologist to voice my alarm over the dire collateral consequences faced by Australian children as a direct result of the government's pandemic policies. I lodged a formal report under the Mandatory Reporting Guidelines, firmly stating that all eight categories of significant harm recognised in New South Wales (NSW) were unfolding at a population level among Australian children. This not only included detrimental effects on unborn children but also highlighted the alarming surge in postnatal depression – the predominant precursor to psychopathology later in life.

Regrettably, my license to practice was promptly suspended, and it is with deep frustration and disappointment that I write nearly three years later, forced to say, "I told you so." It is crucial to confront the reality that some may attempt to shirk responsibility by claiming ignorance. The unfolding tragedy within our community is heart-wrenching, and it demands an urgent, substantial response to rectify these harms. Moreover, I staunchly believe an apology to the Australian public is not just warranted but necessary, to begin mending the profound breaches of trust and care we have witnessed.

Assessment and Review of Processes: Was an analysis of potential harms conducted?

I focus first on the question of whether any due diligence was conducted regarding the potential impacts on children prior to the implementation of government pandemic measures, such as lockdowns, school closures, and masking mandates. As a professional in psychology, I am compelled to categorically state that the answer is an emphatic 'no'.

The rationale is simple: even a marginally competent first-year psychology undergraduate would have immediately recognised that the impacts of such measures on children would

be devastating. To comprehensively explain and provide evidence for the extensive systemic impacts our children have endured would require thousands of pages and an exhaustive literature review. A close reading of an introductory textbook on child development, with Berk being a foremost authority in this area, might provide a basic understanding.

In this section, I will illuminate a few critical issues, specifically concentrating on the infancy stage – arguably the most valuable asset within our communities. I firmly maintain that government pandemic policies have inflicted profound damage on the psychosocial and neurological development of infants and children by overlooking the paramount importance of early-life social and emotional interactions. The imposition of social distancing and mask-wearing mandates has disrupted vital neurobiological processes indispensable for healthy development, leading to a marked increase in stress-induced neurobiological reactions, such as cortisol spikes, which undermine immune response and emotional well-being.

For infants, the consequences are particularly severe. At a juncture where neurodevelopmental plasticity reaches its zenith, the absence of nurturing interactions and supportive environments has paved the way for enduring developmental impairments. Mothers, isolated during pregnancy and childbirth, have encountered unparalleled stress levels without the customary support of the community, severely impeding the establishment of secure attachments between parent and child – attachments that are crucial for a child's future emotional regulation and social competencies.

This situation is alarmingly setting the stage for an impending mental health crisis among the youngest members of our society. Government policies during the Covid era, by overlooking the communal necessities for emotional and social development, are poised to inflict lasting damage on an entire generation at the very least. The disruption of essential interactions during a pivotal period of child development represents a grave error in public health policy, demanding immediate re-evaluation and action to ameliorate the long-term effects on children's well-being.

I wish to raise a final critical point on behalf of children, namely the widespread addiction among huge numbers of Australian children (and no doubt millions globally) to YouTube Shorts. This is a direct consequence of the pandemic-induced shift to remote learning and shift to Google classroom which is concretely coupled with YouTube. With a background in computer science, I assert that the technical means to separate educational content from addictive digital platforms is not only feasible but straightforward. However, this action has been conspicuously avoided, suggesting a prioritisation of Google’s financial gains over the mental and educational welfare of our children – a stance that has provoked widespread concern among parents worldwide, including myself.

The failure to address this problem, despite its clear solution and the global outcry from parents, signals an unsettling preference for profits at the detriment of our children's well-

being. It is crucial that the Australian Government intervenes, mandating technology providers to implement a strict demarcation between educational resources and addictive content such as YouTube Shorts. This intervention is essential not only for safeguarding the developmental integrity of millions of children but also for establishing a precedent in digital ethics and child protection on a global scale.

Some starting references on perinatal development:

Paper: Tronick, E., Als, H., Adamson, L., Wise, S., & Brazelton, T.B. (1978). The infant's response to entrapment between contradictory messages in face-to-face interaction. Journal of the American Academy of Child Psychiatry, 17(1), 1-13.	*Summary*: The Still Face Experiment, led by Edward Tronick, offers profound insights into the critical nature of responsive caregiver-infant interactions for emotional and social development. This experiment's findings are particularly relevant when considering the effects of postnatal depression. Infants' pronounced distress in response to unresponsive caregivers mirrors the potential impact of postnatal depression, where a parent's emotional unavailability or inconsistency due to depression can disrupt the essential interactive cues needed for healthy infant development. It underscores the urgency of addressing postnatal depression not just as a maternal health issue but as a pivotal factor in the emotional and social trajectory of the developing child, highlighting the need for early intervention and support for affected families to mitigate these adverse effects.
Paper: Murray, L., & Cooper, P. J. (1997). Effects of postnatal depression on infant development. Archives of Disease in Childhood, 77(2), 99-101.	*Summary*: This paper by Lynne Murray and Peter J. Cooper is foundational in highlighting the adverse effects of postnatal depression on infant development, particularly focusing on the mother-infant interaction and the child's cognitive and emotional development. They have conducted extensive research on the topic, and their work underscores the importance of early identification and treatment of postnatal depression to mitigate its impact on children.
Paper: Meltzer-Brody, S., & Stuebe, A. (2014). The long-term psychiatric and medical prognosis of perinatal mental illness. Best Practice & Research Clinical Obstetrics &	*Summary*: This review focuses on the long-term outcomes of perinatal mental health disorders, including postnatal depression. It emphasises the significance of recognising and treating perinatal mental health issues to prevent long-lasting impacts on the child's mental, emotional, and physical

Gynaecology, 28(1), 49-60.	health.

Did anyone try to warn the government, and if so, did they listen?

As previously mentioned, in August 2021, I made a public statement in my role as a Registered Psychologist, highlighting the significant collateral consequences faced by Australian children due to the government's pandemic policies. By that time, I had become disheartened by the widespread censorship of health professionals attempting to sound the alarm. In an effort to ensure that my report would be officially documented and reviewed by the relevant government personnel, I brought these issues forward, fulfilling my legal mandatory reporting duties – a responsibility enshrined in law to safeguard the children of our nation. It is important to note that mandatory reporting, as dictated by law, holds precedence over any Australian government 'gag orders'.

My report was made as a video and distributed widely to the following groups of individuals:

27th August 2021: all Australian Attorneys General (a copy of the email I sent, similar to the one I sent to all subsequent groups listed here, is attached as Annexure 1)
30th August 2021: all Members of the Australian government (Federal & State)
30th August 2021: all Australian government Senators
30th August 2021: all members of the Australian government opposition
30th August 2021: senior executive of AHPRA

30th August 2021: all Australian government Science and Health Officers
30th August 2021: all Australian government Science and Health Officers
Early Sept 2021: 1014 journalists and senior staff members of the ABC

Despite my widespread distribution of this crucial information, the single response I received was from Senator Gerard Rennick. Otherwise, there was not a peep in response.

Refusing to comply with government 'gag orders' was not a decision I made lightly, considering the potential risks to my career, livelihood, and both my professional and personal reputation. However, there are moments – such as this one – when the stakes are so high that silence is not an option.

Before deciding to voice my concerns, in July 2021, I had reached out to three of Australia's leading professional associations within the fields of psychology (AAPI & APS: Annexure 2 and Annexure 3) and childhood trauma (ACF: Annexure 4). I sent them similar versions of the same email, all included here as annexures, expressing my profound frustration that psychologists and child mental health professionals were remaining silent.

The AAPI responded explaining that they agreed with my points and had heard similar things from other concerned psychologists, but they warned me about speaking out when Government Health Directives in place – i.e., the aforementioned 'gag orders'. Of note in their response was the following text (which I have not corrected for grammatical errors):

> Many members have written to us about this issue as well. We have addressed this with government through media interviews, policy consultation and press releases. We are aware of the high levels of distress that people are experiencing, this is being reported across Australia ... I agree that there will be intergenerational trauma and impacts from this for many years and that we do need the Government to address the mental health needs of the community. The difficulty for psychologists is the requirement to abide by public health directives …

The APS replied saying they too had been making consistent submissions to the government:

> The APS is very aware of the mental health impacts of lockdowns due to Covid-19 outbreaks and has been constantly and consistently advocating for recognition of this in our submissions and correspondence with Government – including the long-term effects that are potentially going to be experienced for many years to come. … The issues you raise in your email are incredibly important. I hear your concern about the impact of lockdowns ... and most especially on children especially.

Disappointingly, the ACF did not reply at all.

Supplemental Answer

Correspondence received in support of my answer, which I fully adopt and advance to the Committee, from Sandra Scott BEdSec; MACounsPsych, GDpsych, PGDNutMedMH, (MAPS):

> I am a registered psychologist and Full Member of the Australian Psychological Society College of Educational & Developmental Psychologists. My concerns relate primarily to the psychologically harmful messaging which primed population level compliance at the commencement of lockdowns, and the resulting incalculable deleterious mental health and developmental impacts on children and young people.
>
> Daytime television images of mass graves, daily infection and death counts, extreme lockdown and school closures, vaccine mandates and the responsibility levelled at children to protect grandma are each serious examples of psychological abuse. Each was likely to cause extreme harm to a child's psyche, but in combination they became a diabolical and systematic form of torture.

Four years out from the beginnings of the pandemic I cannot fathom what happened. Did the Australian government set out to torture children, or did they just do so inadvertently? Gross incompetence? A lack of expertise or resourcing to take account of the predictable consequences? Did AHPRA or the Australian Psychological Society sanction this ill-informed behaviour, and if so, what has happened to my profession? These questions remain unanswered and are deeply disturbing to me as a health professional and Australian citizen. I participate in the People's Terms of Reference in the hope of some acceptable answers.

During the first pandemic lockdowns in March 2020, I was working in a promotional position as a senior psychologist within the NSW Department of Education. By the second lockdown period in July 2021, I had resumed my regular role as a school counsellor at a selective high school. I witnessed irrevocable damage from government Covid policy before taking leave under the strain of increased workload involving constant responsibility and vigilance in the face of student suicidal ideation. Ultimately, I realised that despite my around-the-clock efforts, I could not keep the students safe. There was a marked absence of reliable integrated mental health cooperation between Department of Education and Health. Ironically, whilst the mature minor doctrine gives students access to vaccination, they could not self-refer to outside-of-school mental health support. One student suicide in 2020 and two more in 2021 was the worst tragedy my school has ever seen and the only suicide deaths under my watch during my 20-plus year career.

The priming, modelling and exploitation of fear during the pandemic has left an indelible mark on the developing child, powerfully precipitating an explosion in children's anxiety disorders, separation anxiety, social phobia and school refusal. In the context of selective schooling where many of the brightest students start competing for their academic career in infancy, the interference to study ambitions was devastating. I spoke to students who were self-harming because they could not go to their local library, who were subject to 24/7 parental control of their study effort and for whom suicide seemed the only escape.

Whilst the convergence of factors playing into an individual's mental health disposition and suicidal ideation may be complex, what isn't complex was the predictable consequence of isolating young people from protective factors such as routines, social, emotional and recreational supports and simultaneously intensifying a plethora of risk factors. This is exactly what the pandemic measures did. Trauma is hard to undo. It weaves itself into the brain, and in children it can manifest in developmental delay and predispose the sufferer toward lifelong social and emotional disability.

Significantly, education staff working under the dark cloud of Covid messaging were also among the most intensely traumatised, feeling they had been sacrificed

without PPE to the frontline. I witnessed the common sense and mental health of colleagues slide into an abyss. Some demanded to know the vaccination status of every student, some wore face shields over masks, some spent their evenings washing every item they'd taken to school, some stopped working in settings where they could not rely on children to wear masks; many took excess sick leave. At one of my schools there were arrows in the corridors to show everybody they could only walk in one direction, presumably designed to somehow reduce the risk of contagion. There was an atmosphere of overt and constant policing, and needless to say, teachers modelled anxiety to their students.

In the name of safety, our government inflicted untold damage which has left a permanent scar. No amount of data collection or research will capture the full impacts. No amount of funds thrown towards the aftermath, or apology if that ever happens, will do justice to the individual lives that have been shattered. And to make matters worse, where normally if one sustains an injury during a natural disaster or traumatic event, they might receive assistance and empathy from those around them, in the context of the pandemic measures we've seen the opposite.
For all my effort, over 20 years of service to public education and the valuable expertise I have acquired to support the mental health of children, the NSW Department sought to end my career for misconduct. My misconduct was to submit a valid Covid-19 vaccination exemption which met the government's stated criteria at the time. I cannot understand or accept that the Australian government rejected the terms of their own exemption criteria. I cannot accept their careless misconduct, chasing me down with an ultimatum to place my life at risk with an experimental injection or lose the career I love.

As an employee still committed to the Public Service, my submission to the People's Terms of Reference is made in good faith, relying on of the validity and integrity of witness protection.

Conclusion

Beyond my personal observations and the concerns echoed by the APS and AAPI, I am directly connected to a significant number of psychologists who took the initiative to write to MPs, AHPRA, the psychology board, and various other 'grey suits' who, inexplicably, seemed to believe they possessed greater insight than the professionals actively engaged in the field.

I am utterly confounded by the rationale driving these devastatingly misguided responses to a virus, which we were initially assured posed a substantial threat only to the elderly and those with pre-existing conditions. Was this sheer incompetence? Deliberate malfeasance? Or perhaps an alarming amalgamation of both? Irrespective of the underlying motive, the children of Australia – and, by extension, our wider community – have been subjected to irreparable and wholly unnecessary harm. The moment has arrived

for us to rectify this calamity and take unwavering measures to guarantee that such a debacle is never repeated. The outrage this situation warrants cannot be overstated; it is a clarion call for accountability and reform.

Index

Fifth Answer

Dr Monique O'Connor MBBS FRANZCP, Proposed Witness:

Australian is in the aftermath of a seismic societal event that represented an unprecedented, highly complex, traumatising and transformative life event for many Australians. As I document below, the deterioration in mental health of Australians is undeniable since the onset of the pandemic, and an issue of pressing national importance. A Royal Commission is required to examine in detail the mental health harms arising from the pandemic measures.

Man-made disasters pose greater mental health risk than natural disasters. Covid-19 virus was an infectious illness but the pandemic response, which deviated from pre-pandemic public health plans, was man-made and hence more harmful to mental health. The utilisation of threat and fear as a tool for enforce community wide compliance with public health measures was notability detrimental to mental health of Australians, and a chronic stressor during the pandemic. Mental well-being is dependent on a sense of safety, security, trust and predictability regarding daily life, society and the anticipated future. This was upended by the pandemic response, with resultant mental health harms that will have intergenerational negative consequences. The mental health, health and economic harms of the pandemic continue to emerge in the context of a failing mental health system because demand for mental health services outstrips supply.

Mental well-being

Good mental health is associated with well-being. It promotes physical health, enables a person to navigate life stresses, fulfill daily responsibilities and contribute fully to the well-being of society. Mental well-being thrives when stressors are minimised, or when the person has sufficient resilience, resources and ability to manage greater stress. There is considerable variance across individuals in vulnerability to mental illness and ability to manage stress. At a societal level, access to promoters of health, social supports, and quality health and mental health services are critical to health and mental well-being.

Pandemic measures and known mental health risks

Many pandemic response measures exposed Australians to multiple risks known to be contributory to poor mental health and risks known to contribute to suicidality. The mental health harms caused by lockdowns, travel restrictions, school closures, restrictions

on funerals, religious worship and important cultural rituals, and vaccine mandates (and many more) were for many a 'major life stressor'. Others experienced isolated highly traumatising events, such as escaping from riot police firing rubber bullets whilst protesting unarmed and peacefully. Major life events are well recognised to be causally related to the onset or relapse of mental illness. Mental health injury can be caused by either 'isolated traumatic events' or the 'cumulative exposure to mental health stressors' that cause either abrupt or chronic destabilisation of previously healthy emotional, cognitive, biological, developmental, physiological, social, cultural, economic or spiritual systems.

Pandemic measures introduced were known to cause predictable psychological distress and social harms, thereby posing a direct risk to mental health. Known risks to mental health operative during the pandemic included adverse life events, social isolation, loneliness, difficulty accessing health or mental health services, discrimination, bullying, lack social support, job insecurity, job loss, unemployment, financial difficulty, homelessness, educational risk, aversive childhood experience, poor parental care, exposure to violence and substance abuse. Many people were unable to fulfill their biologically motivated 'roles' (such as parenting, caregiving, teaching, etc.) normally integral to sense of self-identity, leading to stress, loss of identity, shame and sense of failure. Further, many suffered 'moral injury', a form of severe mental distress that arises when a person witnesses or participates in events that transgress their values, conscience or moral code. This can include harming, betraying, or failing to help others; or being subjected to such events, e.g., being betrayed by leaders.

At an individual level, there is a continuum running from good mental health, through the experience of mental stress, to mental illness (which is clinically impairing and requires professional care).

Mental Health: Post-pandemic Australia 2024

A marked deterioration in mental well-being has occurred in Australia.

The National Study of Mental Health and Wellbeing, published by the Australian Bureau of Statistics in October 2023, covering 2020-2022, indicated that 21.5% of Australians met the diagnostic criteria for having a mental disorder within 12 months of completing the survey. This figure was as high as 38.8% for those aged 16 to 24.

The Australian Institute for Health and Welfare (AIHW) has reported a range of information that demonstrates worsening mental health, evidenced by increased demand for mental health services, crisis and support organisation usage, psychological distress, loneliness, suicide, and ambulance attendances for suicidal ideation. This report utilises much work done at the Centre for Social Research and Methods at the Australian National University by Professor Biddle and colleagues (see AIHW reference list for details). Biddle et al. report that measures of severe psychological distress were significantly

higher during the pandemic. Rates of severe psychological distress (i.e., those with 'probable serious mental illness') peaked between August and October 2021, when an increase from 10.1% to 12.5% was observed. A change of 1 percentage point in this statistic represents approximately 200,000 people.

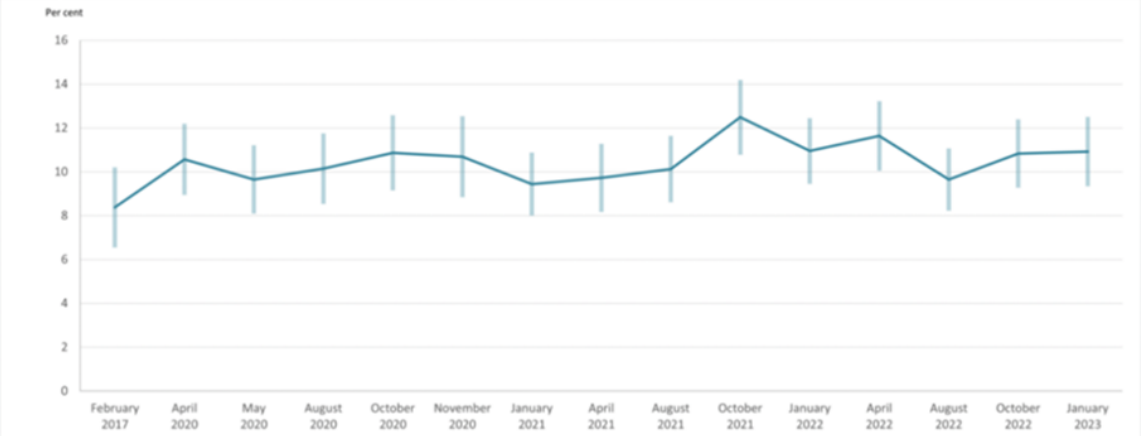
Another gauge of mental health is suicidality. NSW and Victoria both recorded a higher number of completed suicide deaths in 2022 compared to 2021, 2020 or 2019 (AIHW). The impact of suicide on bereaved family and loved ones is significant and enduring. The suicide bereaved are themselves at risk of suicide. Prolonged Grief Disorder, a serious mental disorder, occurs in approximately 25-30% of those closely bereaved by suicide.

Covid-19 pandemic as risk for completed suicide

The Covid pandemic and responses to it contributed to suicidal behaviour and outcomes. The Covid pandemic as a cause or contributor to suicide was reported in 81 (2.6%) of 3144 suicides in Australia in 2021 (ABS), including 21 (2.7%) of 783 suicides in Queensland. By contrast, Griffith University reported the pandemic as cause or contributor in 86 (5.6%) of 1539 suicides in Queensland in the two years, 2020-2021. It is unclear why there is a two-fold difference across these reports of Covid and/or Covid response measures as causative of or contributing to suicide, but these data suggest an under-reporting of Covid and/or Covid response as being an aetiologic factor: in 2022, the ABS reported 84 people died by suicide with the Covid-19 pandemic identified as a risk factor, with 47.6% having an employment-related co-occurring suicide risk factor. Notably, 'employment or unemployment' as a 'risk factor' was the most mentioned risk factor in deaths by suicide for Australians aged 45-64 years in 2022.

The graph below taken from AIHW shows a peak of severe psychological distress in October 2021. This correlates with the announcement of vaccine mandates. Interestingly, no official reporting or discussion of mental health issues (such as by ABS, AIHW or ANU) mentions vaccine mandates, coercive government public health levers, or the experience of discrimination by those unvaccinated against Covid-19 as a factor in suicide or severe mental distress.

Figure 1: Proportion of Australians aged 18 years and over experiencing severe psychological distress, by survey month from February 2017 to January 2023



A recent Australian study found responders to a survey of Queensland public health employees impacted by non-compliance with mandated Covid-19 vaccination for employment reported:

> " .. a reduction in income (reported by 94.4%). The majority (94.9%) believed psychosocial harm was caused as a direct result of state government policy. Anxiety and depression were experienced by 92.1% while 34.1% had had thoughts of suicide."

Specific populations with pandemic mental injury

Many specific populations were particularly sensitive to harm from the pandemic measures. These populations include (but are not limited to) children, the elderly, pregnant women, new mothers, families with young children, minority groups, the bereaved, the Covid-19 unvaccinated, those with mental illness, prisoners, victims of torture, indigenous Australians, minority groups and victims of domestic violence.

The bereaved

The pandemic was a particularly difficult time for those either grieving a pre-pandemic death or bereaved during the pandemic. A multitude of pandemic measures were predictably harmful to healthy, normal grieving. In addition to a higher number of deaths recorded, the following factors all contributed to poor mental health outcomes for the bereaved: 1) the extreme media spotlight on death, hospitals and sickness (all often triggering of difficult memories and emotional pain for the bereaved); 2) the prevention of normal grief rituals, funerals and religious/cultural rituals; 3) difficulty in accessing family support, social connections or professional care; and 4) the unusual types and circumstances of deaths during the pandemic. Bereavement is a known risk for suicide, onset of mental illness and substance abuse. Unfortunately, rates of Prolonged Grief Disorder have substantially increased since the pandemic, from a background rate of

approximately 10% of close bereavements, to over 30%; however, services specialising in care of the bereaved are woefully inadequate.

The Unvaccinated

Those who declined Covid-19 vaccination can be considered a new 'demographic of special interest'. This group was exposed to a range of severely injurious mental health harms and psychosocial punishments without historical precedent. This minority group are unstudied in terms of mental health injury, with harms experienced by this group yet to be adequately documented and continuing to evolve. Many were exposed to multiple major life stressors that potentially align with mental health injury often associated with victims of torture, including human rights infringement, social ostracisation, stigmatisation, differential treatment by society, mandated job loss, and banishment from many normal promoters of good health and mental health.

Mental Health Care for those with pandemic mental health injury

Many of those tasked with providing care to those suffering pandemic-related mental health harms were both complicit in the causation of the harms (either by commission or omission) or blind to the harms. Notably, 'mental illness' was specifically denied as grounds for exemption from Covid-19 vaccination, which of itself is discriminatory against those with mental illness, stigmatising, and medically unethical. Peak bodies not only failed to condemn discrimination against the unvaccinated, but actively were involved in or promoted coercive and discriminatory vaccination policies. The consequence of this is loss of trust in the medical profession. This loss of trust disproportionately impacts those most in need of mental health care due to 'pandemic mental health injury'.

Access to quality, non-discriminatory health and mental health care was markedly hindered by the professional and societal endorsement of harmful discrimination against the unvaccinated. Most unvaccinated health care providers and doctors were mandated out of work or silenced by threat of regulatory sanction, leaving a mental healthcare workforce that largely acquiesced to coercive pandemic harms.

Summary

This response provides evidence of mental health harm originating from the Australian government's Covid response. It serves as an introduction to the extent and types of mental health harm and the needs of those injured. It demonstrates that an independent Royal Commission is required to examine the mental health harms attributable to the Australian Government's public health response to the pandemic.

Index

Sixth Answer

Jason Strecker BCompSc, DipEd, Co-Author:

There were no considerations provided publicly by State and Territory governments on the potential adverse impacts and mental harm caused by the lockdown measures and mandates on children. There was an acknowledgement that education would be impacted as outlined in Reference C in the *Term 2 2020 Guidelines for Schools*. This noted a 46% reduction in learning time. There were no mitigation strategies listed or plan on how this time and learning were to be recovered.

There was no cost-benefit analysis provided which compared the benefit to children against the cost of any measure. Schools were provided with guidelines which were communicated and implemented through implied legal mandates enforceable by the threat of fines, police coercion or implied removal of school registration or funding for failure to comply to all orders including social distancing, masking, vaccine mandates, testing and isolation. No attempt to quantify physical, emotional or developmental harm was provided to aid teachers in assessing the risk to themselves and the children in their care.

The response quoted from CHO Jeannette Young in the Explanatory Memorandum to Reference C gives a strong indication that some governments were willing to use schools, and hence children, as collateral to provide a wider societal acceptance of compliance measures. There was no mention of costs to children or consideration of potential harms in her statement.

Index

Seventh Answer

A/Prof Peter Parry, Co-Author:

Due to time constraints this is a very brief and impressionistic answer. Most of my career as a psychiatrist has been in child & adolescent psychiatry and during the 2021 school lockdown in Qld, I was on call for part of the time. I cannot recall the exact period of the school closures, but they were for several weeks.

What our child & youth mental health services observed and anecdotally discussed was a wide divergence of effects of the lockdowns. Families with good income security and likely home garden spaces, for example in public servant jobs, and parents able to work from home, who also had good warm family dynamics – actually appeared to fare better than normal from a mental health perspective.

This contrasted markedly with families of low income or uncertain income such as small

businesses under lockdowns, and particularly if there were problematic family dynamics. Mental health problems led to new referrals, or children and young people we saw were more adversely affected by the school closures. There appears to have been an increase in school refusal (social anxiety leading to avoiding school attendance) which persisted post-school closures.

Of particular concern was a correlation of a suicide cluster of what I recall as five high school aged adolescents tragically losing their lives across South-East Qld in the final two weeks before the government announcement that the schools were going to reopen. I was on call over the middle weekend and aware that in perhaps three of these cases statements of suicidal ideation because they couldn't see their friends were made. That was the largest cluster of adolescent suicide within a two-week period that I am aware of since coming to work in SE Qld in 2011.

In attending the World Congress of the International Association of Child and Adolescent Psychiatry and Allied Professions in Dubai in December 2022, one of the major topics of presentations at the conference was the effects of lockdowns and school closures and general anxiety provoking media messaging about the Covid-19 pandemic on paediatric mental health. The overall findings were that it was deleterious.

By the time a Royal Commission investigates this issue there is likely to be a significant body of peer-reviewed literature quantifying these potential harms. A 2023 literature review titled "The impact of COVID-19 lockdown on child and adolescent mental health: systematic review" in *European Child & Adolescent Psychiatry* (a prominent journal in the field), reports in its abstract:

> Anxiety symptoms and depression symptoms were common in the included studies and ranged 1.8–49.5% and 2.2–63.8%, respectively. Irritability (range=16.7–73.2%) and anger (range=30.0–51.3%), were also frequently reported by children and adolescents. Special needs and the presence of mental disorders before the lockdown, alongside excessive media exposure, were significant risk factors for anxiety. Parent–child communication was protective for anxiety and depression. The Covid-19 lockdown has resulted in psychological distress and highlighted vulnerable groups such as those with previous or current mental health difficulties. Supporting the mental health needs of children and adolescents at risk is key. Clinical guidelines to alleviate the negative effects of Covid-19 lockdown and public health strategies to support this population need to be developed.

Which corroborates the clinical impressions I expressed above.

Index

Reference: D

Index

A review and analysis of all relevant national and international Human Rights laws, conventions, and treaties, including the Nuremberg Code and the Constitution and other rights protection mechanisms such as the separation of powers and the Principal of Legality, to assess whether any Australian citizens suffered any violations of Human Rights in the context of:

i. Covid-19 vaccines;
ii. mandates created by Australian governments requiring Australian citizens to receive one or more Covid-19 vaccine in order to participate in any activity;
iii. Covid-19 pandemic management decisions, laws, and policies implemented by Australian governments;
iv. the Nuremberg Code and whether any aspects of the receipt of Covid-19 vaccines by Australians involved:
    a) any elements of human experimentation;
        i. if so found, whether any instances of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion were experienced by a recipient of a Covid-19 vaccine deemed to have been involved in human experimentation;
        ii. if so found, any instances where all inconveniences and hazards reasonably to be expected and the effects upon health which may possibly have come from receipt of a Covid-19 vaccine, were not shared with those recipients identified as having undergone human experimentation;
    b) de facto clinical trials on humans;
        i. if so found, whether any instances of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion were experienced by a recipient of a Covid-19 vaccine deemed to have been involved in a de facto clinical trial on humans;
        ii. if so found, any instances where all inconveniences and hazards reasonably to be expected and the effects upon health which may have possibly come from receipt of a Covid-19 vaccine, were not shared with those recipients identified as having been involved in de facto clinical trials on humans;
    c) de facto clinical trials on humans conducted without appropriate regulations;
        i. if so found, whether any instances of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of

constraint or coercion were experienced by a recipient of a Covid-19 vaccine deemed to have been involved in a de facto clinical trial on humans conducted without appropriate regulations;

ii. if so found, any instances where all inconveniences and hazards reasonably to be expected and the effects upon health which may have possibly come from receipt of a Covid-19 vaccine, were not shared with those recipients identified as having been involved in de facto clinical trials on humans without appropriate regulations;

d) the administration of Covid-19 vaccines to sub-populations of Australians for which insufficient clinical trial data or studies existed, or no satisfactory clinical trial data or studies existed, or for which no clinical trial data or studies existed in respect of the safety or efficacy;

i. if so found, whether any instances of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion were experienced by the sub-population to receive a Covid-19 vaccine;

ii. if so found, any instances where all inconveniences and hazards reasonably to be expected and the effects upon health which may have possibly come from receipt of a Covid-19 vaccine, were not shared with sub-populations of Australians who received Covid-19 vaccines for which insufficient clinical trial data or studies existed, or no satisfactory clinical trial data or studies existed, or for which no clinical trial data or studies existed in respect of the safety or efficacy; and

e) in the event of a positive determination or finding for one or more of (a) through (d) above, a thorough examination of all elements of the Nuremberg Code to identify any other failures to observe the Code in Australia, and where appropriate, the identification of those responsible for any observed failures to observe the Code.

This review and analysis should include an investigation into the following questions, expanded upon in the Explanatory Memorandum:

1. Did Australia fulfill its obligations under the international human rights treaties and covenants it is a signatory to during Covid-19? If not, why not?
2. Did the Australian Human Rights Commission perform its statutory function during Covid-19? If not, why?
3. Did the Principle of Legality fail as an effective barricade to human rights breaches in Australia during Covid-19?
4. Has the law on informed consent in Australia been ignored?

5. Is the Separation of Powers functioning appropriately in Australia?
6. Are Australia's discrimination and privacy laws adequate to protect people against discrimination on the basis of their medical status, and to protect people's private medical information?
7. Were provisional approval laws utilised for Covid-19 vaccines used to enable the supply and administration of drugs that would have historically been subject to much more rigorous animal and human clinical trials, with the consequence being, the early deployment and administration of Covid-19 drugs saw Australian citizens partake in the assessment of the efficacy and safety of those drugs?

Explanatory Memorandum

Index

Australia as a nation is founded on the rule of law and has a strong common law and jurisprudential tradition of protecting the rights and freedoms of individuals. Fundamental elements of our Governance structure and laws serve to protect these rights and freedoms, including the separation of powers between the judiciary and the executive and the Principle of Legality, which ensures that legislation should not infringe fundamental rights and freedoms unless the legislation expresses a clear intention to do so, and the infringement is reasonable.

Domestically, Australia has comprehensive statutory frameworks in place intended to protect the right of Australian citizens to privacy, as well as the right to equal treatment and freedom from discrimination. The High Court has found that the Constitution contains an implied freedom of political communication, and there remains some open questions as to whether other rights, such as freedom of movement, are protected as well (via prohibitions on restrictions of trade between States, for example).

On the international stage, Australia has asserted itself as among the leaders in becoming a party to and advocating for the core international treaties and covenants. Australia was one of only eight nations involved in drafting the Universal Declaration of Human Rights. In addition, Australia as a nation is a party to the seven core international human rights treaties. These are:

1. the International Covenant on Civil and Political Rights (**ICCPR**)
2. the International Covenant on Economic, Social and Cultural Rights (**ICESCR**)
3. the International Convention on the Elimination of All Forms of Racial Discrimination (**CERD**)
4. the Convention on the Elimination of All Forms of Discrimination against Women (**CEDAW**)

5. the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (**CAT**)
6. the Convention on the Rights of the Child (**CRC**)
7. the Convention on the Rights of Persons with Disabilities (**CRPD**).

(collectively, the **Core Treaties**)

In addition, Australia is also a party to the UN Declaration on Bioethics and Human Rights.

Australia also took the additional step of signing the optional protocols to the above Treaties, emphasising Australia's responsibility to uphold them, and increasing Australia's obligations under them.

The Australian Human Rights Commission

The Australian Human Rights Commission is a statutory body established by the *Australian Human Rights Commission Act 1986* (**the AHRC Act**). In general, the Core Treaties render it incumbent on party states to ensure there is a domestic mechanism in place for the protection of the human rights protected under those Treaties. The Australian Human Rights Commission is intended to fulfill that function for Australian citizens.

The AHRC Act makes clear the "duties" (Section 10A) and "Functions" (Section 11) of the Commission. First, with **emphasis added**;

> **10A Duties of Commission**
>
> (b) It is the duty of the Commission to ensure that **the functions of the Commission under this or any other Act are performed:**
>
> **(a) with regard for:**
>
> (b) **the indivisibility and universality of human rights**; and
>
> (ii) the principle that every person is free and equal in dignity and rights; and
>
> (b) efficiently and with the greatest possible benefit to the people of Australia.

So, any expression of the functions of the Commission must be maintained with regard for the indivisibility and universality of human rights. Importantly, the Act defines 'human rights' as follows;

> **Human rights means the rights and freedoms recognised in the Covenant, declared by the Declarations or recognised or declared by any relevant international instrument.**

Section 11 of the Act lists the various functions of the AHRC. Relevantly, these include (emphasis added);

11 Functions of Commission

(b) The functions of the Commission are:

…

(d) the functions conferred on the Commission by section 31; and

I to examine enactments, and (when requested to do so by the Minister) proposed enactments, **for the purpose of ascertaining whether the enactments or proposed enactments, as the case may be, are, or would be, inconsistent with or contrary to any human right,** and to report to the Minister the results of any such examination; and

(f) to:

(b) **inquire into any act or practice that may be inconsistent with or contrary to any human right; and**

(ii) if the Commission considers it appropriate to do so—endeavour, by conciliation, to effect a settlement of the matters that gave rise to the inquiry; and

(g) to promote an understanding and acceptance, and the public discussion, of human rights in Australia; and

…

(j) on its own initiative or when requested by the Minister, to report to the Minister as to the laws that should be made by the Parliament, or action that should be taken by the Commonwealth, on matters relating to human rights; and

(k) on its own initiative or when requested by the Minister, to report to the Minister as to the action (if any) that, in the opinion of the Commission, needs to be taken by Australia in order to comply with the provisions of the Covenant, of the Declarations or of any relevant international instrument; and

…

(n) to prepare, and to publish in such manner as the Commission considers appropriate, guidelines for the avoidance of acts or practices of a kind in respect of which the Commission has a function under paragraph (f); and

…

(p) to do anything incidental or conducive to the performance of any of the preceding functions.

So, it is the very statutory function of the AHRC to:

1. "inquire into any act or practice that may be inconsistent with or contrary to any human right" (and in particular, with any covenant or

declaration specifically included in the Act), and, "effect a settlement of the matters that gave rise to the inquiry"; and

2. to perform the functions conferred on the AHRC by section 31 which have to do with equal opportunity in employment and occupation; and

3. to examine enactments (i.e.; laws) for the purpose of ascertaining whether those laws are, or would be, inconsistent with or contrary to any human right; and to report to the Minister the results of same.

Human Rights Breaches During Covid-19

The Australian Federal, State and Territory Governments' responses to Covid-19 saw unprecedented impositions on the rights enshrined in the Core Treaties as well as domestic law. A citizen's status as either 'vaccinated' or 'unvaccinated' against Covid-19, along with their ability to wear a face covering or otherwise, have, among other examples, determined their ability to;

- Work in most industries, and for most employers;
- Enter shopping centres, bars, live entertainment venues or other public places;
- Enter or exit each State and Territory;
- Enter and exit the country;
- Enter places of worship;
- Enter aged care homes and hospitals;
- Complete tertiary education; and
- Receive treatment and critical care.

There has been a persistent campaign, encouraged predominantly by State and Territory Governments as well as in the media, to demonise citizens who chose not to undergo vaccination for Covid-19. The clear messaging from both Government and media has been that everybody should be vaccinated, and any choice otherwise, for whatever reason, is irresponsible, reprehensible, and to be admonished.

For those who chose not to be vaccinated, they have undergone huge personal sacrifice in order to maintain this choice. Careers have been abandoned, relationships damaged, and debt accrued. This gives rise to several areas of inquiry:

1. Did Australia fulfill its obligations under the Core Treaties? If not, why?

There are a long list of Treaty articles and parts that were breached during Covid-19. In most cases, the rationale provided was one of the following:

a) The Core Treaties allow derogations from obligations under them in certain circumstances, including generally in times of public emergency; and

b) The Core Treaties have (in most cases) not been formally enshrined in Australian domestic law, leading to a lack of enforceability.

Both of the above rationales are oversimplifications of the true position at law. With regards to the former, the Core Treaties are very particular about the circumstances in which these derogations can occur (see Part II, Article 4 of the ICCPR, for example), and several treaty provisions are themselves non-derogable, meaning the aforementioned exceptions do not apply (see Part III, Article 7 of the ICCPR for example). With regards to the latter, several rights protections *have been* enshrined into Australian domestic law (see inquiry number 6 below), and the Australian Human Rights Commission, itself enacted by statute, is tasked with defending the rights obligations of Australian citizens whether or not those rights are enshrined in domestic statute. It is worth noting that the AHRC Act itself actually includes several of the international human rights conventions which Australia is party to, and which the Act's definition of 'human rights' refers to, within it.

A full and comprehensive assessment of the rights enshrined under the Core Treaties (and in the ICCPR in particular) must occur, vis a vie the measures implemented by Federal State and Territory Governments, for the purpose of assessing whether rights derogations were compliant with Australia's obligations under international human rights law, and for the purpose of informing Australia's approach to such a pandemic in future. To date, no such detailed analysis has occurred, and such analysis is owed to the many Australians whose fundamental rights and liberties were severely curtailed by the Federal and State Government responses to Covid-19.

2. Did the Australian Human Rights Commission perform its statutory function during Covid-19? If not, why?

The statutory functions of the Australian Human Rights Commission are clear and are featured above.

In summary, they are to:

1. "inquire into any act or practice that may be inconsistent with or contrary to any human right" (and in particular, with any covenant or declaration specifically included in the Act), and, "effect a settlement of the matters that gave rise to the inquiry" (**First Function**); and

2. to perform the functions conferred on the AHRC by section 31 which have to do with equal opportunity in employment and occupation (**Second Function**); and

3. to examine enactments (i.e.; laws) for the purpose of ascertaining whether those laws are, or would be, inconsistent with or contrary to any human right; and to report to the Minister the results of same (**Third Function**).

During Covid-19, the Commission received an unprecedented number of complaints, and requests for help, from the Australian public, noting in their responses to those requests that due to their inundation, complainants had to wait up to six months for a response. Clearly, the Australian public had a perception that the AHRC would assist them, and sought that assistance, desperately.

With respect to their First Function, the AHRC did not make any inquiry into any act or practice that was inconsistent with or contrary to any human right. Part of their stated reasoning for this was an interpretation of the words "act" and "practice" in the AHRC Act which encompassed measures taken by Federal Government, but not State or Territory Governments. Even if this interpretation of the AHRC Act is correct (which is questionable), it is not clear why the AHRC did not make any inquiry into the actions of Federal Government during the most significant human rights impositions in Australia's history. Further, even if the AHRC's interpretation is correct, should not then the discussion turn to amending the AHRC Act so that it may properly operate to require all States and Territories to observe and give effect to the Core Treaties, in circumstances where the Commonwealth Government entered into those Treaties on behalf of all Australians, States and Territories?

With respect to their Second Function, Section 31 of the AHRC Act states that the AHRC is obligated:

(a) to examine enactments, and (when requested to do so by the Minister) proposed enactments, for the purpose of ascertaining whether the enactments or proposed enactments, as the case may be, have, or would have, the effect of nullifying or impairing equality of opportunity or treatment in employment or occupation, and to report to the Minister the results of any such examination;
(b) to:
    (i) inquire into any act or practice (including any systemic practice) that may constitute discrimination

The definition of "discrimination" which applies to Section 31 of the AHRC Act includes discrimination on the basis of medical record. It is unclear why the AHRC did not inquire into the widespread practice of employers in Australia restricting their employees from working on the basis of their medical record (vaccination

status).

With respect to their Third Function, Covid-19 saw the widespread use of public health orders and public health directives to severely limit the human rights of Australian citizens in an unprecedented way. The AHRC is the body in Australia with the power and duty to examine these controversial enactments and did not do so. If Covid-19 was not reason enough to enact this function, what is?

3. Did the Principle of Legality fail as an effective barricade to human rights breaches in Australia during Covid-19?

The Principle of Legality (**the Principle**) is a rule of statutory construction which states that, in the absence of clear indication to the contrary, it is to be presumed when interpreting a statute that the statute was not intended to modify or abrogate fundamental rights (see *Coco v The Queen* (1994) 179 CLR 427; [1994] HCA 15 at 437; "Coco"). Australia does not have a bill of rights, so the principle has often been said to be a fundamental protection in Australian law.

However, in *Kassam v Hazzard; Henry v Hazzard [2021]* NSWSC 1320, the plaintiffs sought to rely on the Principle to challenge the public health orders made under the auspices of Section 7 of the *Public Health Act 2010 (NSW)*, only to find his Honour's conclusion that, because the Public Health Act is an Act that deals with "public safety…curtailing the free movement of persons including their movement to and at work are the very type of restrictions that the PHA clearly authorises. Hence, the principle of legality does not justify the reading down of s 7(2) of the PHA to preclude limitations on that freedom" [at 9]. This precedent suggests that the Principle will be powerless to dilute any Act of Parliament which allows for particular human rights limitations or derogations, which in turn calls into question the utility of the Principle. In particular, this NSW departure from the *Coco v R* precedent demonstrated a State judicial effort to dilute the Principle, rendering it powerless to dilute the Act of Parliament under review. This then allowed for particular human rights limitations and derogations to essentially be sanctioned by the Court, in turn calling into question whether Australia observed a failure of the Principle itself during Covid-19.

4. Has the law on informed consent in Australia been ignored?

Australia has a long legal history of upholding the central medical tenet of fully informed and free consent.

Various domestic statutes, such as the *Guardianship Act 1987 (NSW)*, the *Mental Health Act 2007 No 8 (NSW)* and the *Victorian Charter of Human Rights and Responsibilities Act 2006 (VIC)* contain definitions of the concept that are generally analogous. The latter, for example, has the following definition: "A person must not

be…subjected to medical or scientific experimentation without his or her full, free or informed consent".

This is, again, an example of a human right which Australia has covenanted into via an international treaty (Part III, Article 7 of the ICCPR) which has been enshrined into our domestic law.

The principle is also reflected in the many regulations that inform both the medical and legal professions in this country. For example, the Code of Conduct for doctors states unequivocally that "informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved". The Australian Law Reform Commission states that "Informed consent refers to consent to medical treatment and the requirement to warn of material risk prior to treatment. As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment. Failure to do so may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent". There are many other examples.

In the common law, there is a well-known positive duty for Doctors to warn patients of material risks inherent to any treatment proposed (see *Rogers v Whittaker (1992)).* A 'failure to warn' patients of material risk, and the subsequent breach of duty of care at common law, is the foundation of most medical negligence cases in Australia, of which there are thousands per annum.

In *Wallace v Kam [2013] HCA 19*, the High Court was clear:

> *The common law duty of a medical practitioner to a patient is a single comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment […] The component of the duty of a medical practitioner that ordinarily requires the medical practitioner to inform the patient of material risks of physical injury inherent in a proposed treatment is founded on the underlying common law right of the patient to choose whether or not to undergo a proposed treatment.*

Given the above, which must be described as a comprehensive and consistent approach in Australian law, it is remarkable that so many Australian citizens underwent vaccination against Covid19, a provisionally approved medical treatment, in circumstances where they:

a) Did not fully understand the material risks associated with that treatment; and
b) Were subjected to significant social and economic pressures to undergo that treatment.

It is not unreasonable to argue that **nobody in Australia** was capable of providing fully informed and free consent to vaccination against Covid-19, given the pressure being exerted daily by employers, media and politicians, and the inaccurate and incomplete information being made available to them.

This poses the question of whether the law on informed consent in Australia has been bypassed or ignored, and if so, how and why this was allowed to occur.

5. Is the Separation of Powers functioning appropriately in Australia?

The Australian Constitution distributes power to govern among the Parliament, Executive and the Judiciary. With respect to the judiciary, this is an important separation, because the judiciary is often tasked with assessing the legality and correctness of Government laws and decisions. Indeed, this is one of the primary functions of the judiciary.

On 27 September 2021**,** a decision in the matter of *Jennifer Kimber v Sapphire Coast Community Aged Care Ltd (C2021/2676)* was handed down by a full bench of the Fair Work Commission.

That decision featured a dissenting judgment by Deputy President Lyndall Dean, which was highly critical of the approach taken by Governments in Australia to Covid-19. It is, to date, the only decision by a member of any Tribunal or Court in Australia that has been critical of the measures taken by Government in response to Covid-19.

This may be partly due to the way the Deputy President was punished for her judgment. President Justice Iain Ross immediately barred the Deputy President from appeal cases. The President told the Deputy President that her conduct constituted "misuse of her statutory office" and that she had breached "basic principles of quasi-judicial decision-making including criticising government policy and doing so in highly inflammatory terms". She was forced to undergo professional conduct training.

Of course, members of the Fair Work Commission, as well as other Tribunals and Courts in Australia, are appointed by the Government. The removal of an appointee from the Fair Work Commission can only be done through a vote by Parliament.

By contrast, the Judge who heard perhaps the most famous case involving the assessment of Government measures against Covid-19 (*Kassam v Hazzard*), and who essentially endorsed the actions of Government as lawful and reasonable, has recently been elevated to the High Court.

It is not unreasonable to wonder whether such elevation would have occurred if that

Judge was to have made a different decision in that case, and whether that kind of potential detriment might have influenced, consciously or subconsciously, his decision. High Court judges, of course, are appointed by the Governor-General, who is part of the Parliament and the Executive.

The question thus must be asked: Is it appropriate that judicial officers be appointed and promoted by members of Parliament and the Executive given they are often tasked with critiquing the decisions of those members?

6. Are our discrimination and privacy laws adequate to protect people against discrimination on the basis of their medical status, and to protect people's private medical information?

Federal and State discrimination statutes focus on 'protected attributes', including race, sex, pregnancy, marital status, family responsibilities, breastfeeding, age, disability, sexual orientation, gender identity or intersex status. These protected attributes do not include medical status or record, despite the AHRC Act including 'medical record' within its definition of 'discrimination' (but not 'unlawful discrimination', which has a different definition).

This means that, in brief, somebody who has been discriminated against in Australia on the basis of their medical record or status cannot proceed to the Federal Court accordingly. The only means of action available to that person is, if the discrimination occurred in the context of their employment, to complain to the AHRC pursuant to Section 31 of the AHRC Act, and to hope that the AHRC chooses to inquire into and conciliate the issue. This is not very effective protection. Do we need a more explicit protection against this form of discrimination?

With respect to Privacy, Covid-19 saw employers intrude violently into the private medical histories and records of their employees, often with no regard for the Australian Privacy Principles, enshrined in the *Privacy Act 1988 (Cth)* which provide stringent restrictions and conditions on the collection and storage of this information. In almost all cases, employers said that the collection of records of employees' vaccination status was lawful and reasonable to ensure that the employee could safely perform the inherent requirements of their job – but this is an oversimplification of a law which is supposed to be applied in exceptional circumstances only, based on the individual circumstances of each employee. Did employers generally breach Federal and State privacy laws in Australia during Covid-19, and if so, how and why was this allowed to happen, and how can it be avoided in future?

7. Constitutionality of Mandates

In an issue related to the vitiation of informed consent, attention must be given to the way that Section 51 (xxiiiA) of the Constitution was interpreted in the context of vaccine mandates. The Section, which allows for the provision of various services by the federal government, but not to the extent of authorising any form of civil conscription, means that medical practitioners must not be compelled by the Federal government to provide mandatory services, such as vaccinations. The argument oft made (and accepted by the NSW Supreme Court in *Kassam*) is that the section only bars the Federal Government from forcing doctors to do something; it doesn't stop or deem unlawful a vaccine mandate created by a State. The problem is that doctors were still forced to vaccinate their patients, unless they wanted to face regulatory punishment and fines from their regulators, and the *intent* of this important section of our Constitution was nonetheless flouted, even if it wasn't technically breached. The question that must be asked is whether we are satisfied with an approach to our Constitution involving pedantic interpretation applied with an intention to get around the intention and spirit of the document. In contract law, intention of the drafters is a key element of construction. Shouldn't that same reasoning apply to our most important national contract, the Constitution?

8. **The External Affairs Power**

Section 51 (xxix) of the Constitution gives the Parliament power to make laws for the peace, order and good government of the Commonwealth with respect to external affairs. This is a power that has increased over time as the Courts broaden the scope of what "external affairs" may involve, particularly in a world that is becoming more open and global, and particularly with the rise of customary international law. In *R v Burgess; Ex parte Henry* (1936), the High Court ruled that the power to regulate external affairs is not limited to the subjects listed in section 51.

The *Tasmanian Dam Case 1983* saw the High Court explicitly say that this power can be used by the Federal Government to implement obligations that have been assumed by the federal government under international treaties and conventions, even in areas formerly under State control. This raises several questions:

a) Were statements made by the Federal Government that they did not agree with or encourage State and Territory government vaccine mandates disingenuous in circumstances where they could have used the external affairs power to enact a law which prohibited such mandates?
b) Given Australia's vehement support of the international treaties and covenants, and the now established manner in which the Federal Government can meaningfully and practically implement them, why didn't the Federal Government move to protect the rights they have covenanted into protecting?
c) Is the external affairs power an appropriate power for the Federal Government if it is only going to be implemented in such a selective way?

Question(s) on Notice

Index

In respect of that submission and in particular index **Reference D**, can you please inform the committee whether in your view Australian governments need to answer for any Human Rights violation during 2020 into 2023, and whether Australian governments failed to observe the Nuremberg Code during the same period?

Answer(s)

Index

Answer

Peter Fam, Co-Author:

Australia as a nation is founded on the rule of law and has a strong common law and jurisprudential tradition of protecting the rights and freedoms of individuals. Fundamental elements of our Governance structure and laws serve to protect these rights and freedoms, including the separation of powers between the judiciary and the executive and the Principle of Legality, which ensures that legislation should not infringe fundamental rights and freedoms unless the legislation expresses a clear intention to do so, and the infringement is reasonable.

Domestically, Australia has comprehensive statutory frameworks in place intended to protect the right of Australian citizens to privacy, as well as the right to equal treatment and freedom from discrimination. The High Court has found that the Constitution contains an implied freedom of political communication, and there remains some open questions as to whether other rights, such as freedom of movement, are protected as well (via prohibitions on restrictions of trade between States, for example).

On the international stage, Australia has asserted itself as among the leaders in becoming a party to and advocating for the core international treaties and covenants. Australia was one of only eight nations involved in drafting the Universal Declaration of Human Rights. In addition, Australia as a nation is a party to the seven core international human rights treaties. These are:

I. the International Covenant on Civil and Political Rights (**ICCPR**)
II. the International Covenant on Economic, Social and Cultural

Rights (**ICESCR**)

III. the International Convention on the Elimination of All Forms of Racial Discrimination (**CERD**)

IV. the Convention on the Elimination of All Forms of Discrimination against Women (**CEDAW**)

V. the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (**CAT**)

VI. the Convention on the Rights of the Child (**CRC**)

VII. the Convention on the Rights of Persons with Disabilities (**CRPD**).

(collectively, the **Core Treaties**)

In addition, Australia is also a party to the UN Declaration on Bioethics and Human Rights.

Australia also took the additional step of signing the optional protocols to the above Treaties, emphasising Australia's responsibility to uphold them, and increasing Australia's obligations under them.

The Australian Human Rights Commission

The Australian Human Rights Commission is a statutory body established by the *Australian Human Rights Commission Act 1986* (**the AHRC Act**). In general, the Core Treaties render it incumbent on party states to ensure there is a domestic mechanism in place for the protection of the human rights protected under those Treaties. The Australian Human Rights Commission is intended to fulfill that function for Australian citizens.

The AHRC Act makes clear the "duties" (Section 10A) and "Functions" (Section 11) of the Commission. First, with **emphasis added**:

> **10A Duties of Commission**
>
> (c) It is the duty of the Commission to ensure that **the functions of the Commission under this or any other Act are performed:**
>
> **(a) with regard for:**
>
> (c) **the indivisibility and universality of human rights**; and
>
> (ii) the principle that every person is free and equal in dignity and rights; and
>
> (b) efficiently and with the greatest possible benefit to the people of Australia.

So, any expression of the functions of the Commission must be maintained with regard for the indivisibility and universality of human rights. Importantly, the Act

defines ‘human rights’ as follows:

> **Human rights means the rights and freedoms recognised in the Covenant, declared by the Declarations or recognised or declared by any relevant international instrument.**

Section 11 of the Act lists the various functions of the AHRC. Relevantly, these include (emphasis added):

11 Functions of Commission

(c) The functions of the Commission are:

…

(d) the functions conferred on the Commission by section 31; and

I to examine enactments, and (when requested to do so by the Minister) proposed enactments, **for the purpose of ascertaining whether the enactments or proposed enactments, as the case may be, are, or would be, inconsistent with or contrary to any human right,** and to report to the Minister the results of any such examination; and

(f) to:

(c) **inquire into any act or practice that may be inconsistent with or contrary to any human right; and**

(ii) if the Commission considers it appropriate to do so—endeavour, by conciliation, to effect a settlement of the matters that gave rise to the inquiry; and

(g) to promote an understanding and acceptance, and the public discussion, of human rights in Australia; and

…

(j) on its own initiative or when requested by the Minister, to report to the Minister as to the laws that should be made by the Parliament, or action that should be taken by the Commonwealth, on matters relating to human rights; and

(k) on its own initiative or when requested by the Minister, to report to the Minister as to the action (if any) that, in the opinion of the Commission, needs to be taken by Australia in order to comply with the provisions of the Covenant, of the Declarations or of any relevant international instrument; and

…

(n) to prepare, and to publish in such manner as the Commission considers appropriate, guidelines for the avoidance of acts or practices of a kind in respect of which the Commission has a function under paragraph (f); and

…

(p) to do anything incidental or conducive to the performance of any of the preceding functions.

So, it is the very statutory function of the AHRC to:

i) "inquire into any act or practice that may be inconsistent with or contrary to any human right" (and in particular, with any covenant or declaration specifically included in the Act), and, "effect a settlement of the matters that gave rise to the inquiry"; and

ii) to perform the functions conferred on the AHRC by section 31 which have to do with equal opportunity in employment and occupation; and

iii) to examine enactments (i.e.; laws) for the purpose of ascertaining whether those laws are, or would be, inconsistent with or contrary to any human right; and to report to the Minister the results of same.

Human Rights Breaches During Covid-19

The Australian Federal, State and Territory Governments' responses to Covid-19 saw unprecedented impositions on the rights enshrined in the Core Treaties as well as domestic law. A citizen's status as either 'vaccinated' or 'unvaccinated' against Covid-19, along with their ability to wear a face covering or otherwise, have, among other examples, determined their ability to;

- Work in most industries, and for most employers;
- Enter shopping centres, bars, live entertainment venues or other public places;
- Enter or exit each State and Territory;
- Enter and exit the country;
- Enter places of worship;
- Enter aged care homes and hospitals;
- Complete tertiary education; and
- Receive treatment and critical care.

We saw thousands upon thousands of individual rights violations during the Government's response to Covid-19. Many were caught on video, including the battery and pepper spray of a 70+ year old woman by Victorian police, the firing of rubber bullets at protestors, and the issue of thousands of invalid fines.

There has been a persistent campaign, encouraged predominantly by State and Territory Governments as well as in the media, to demonise citizens who chose not to undergo vaccination for Covid-19. The clear messaging from both Government and media has been that everybody should be vaccinated, and any choice otherwise, for whatever reason, is irresponsible, reprehensible, and to be admonished.

For those who chose not to be vaccinated, they have undergone huge personal

sacrifice in order to maintain this choice. Careers have been abandoned, relationships damaged, and debt accrued. This gives rise to several areas of inquiry:

1. **Did Australia fulfill its obligations under the Core Treaties? If not, why?**

There are a long list of Treaty articles and parts that were breached during Covid-19. In most cases, the rationale provided was one of the following:

a. The Core Treaties allow derogations from obligations under them in certain circumstances, including generally in times of public emergency; and

b. The Core Treaties have (in most cases) not been formally enshrined in Australian domestic law, leading to a lack of enforceability.

Both of the above rationales are oversimplifications of the true position at law. With regards to the former, the Core Treaties are very particular about the circumstances in which these derogations can occur (see Part II, Article 4 of the ICCPR, for example), and several treaty provisions are themselves non-derogable, meaning the aforementioned exceptions do not apply (see Part III, Article 7 of the ICCPR for example). With regards to the latter, several rights protections *have been* enshrined into Australian domestic law (see inquiry number 6 below), and the Australian Human Rights Commission, itself enacted by statute, is tasked with defending the rights obligations of Australian citizens whether or not those rights are enshrined in domestic statute. It is worth noting that the AHRC Act itself actually includes several of the international human rights conventions which Australia is party to, and which the Act's definition of 'human rights' refers to, within it.

A full and comprehensive assessment of the rights enshrined under the Core Treaties (and in the ICCPR in particular) must occur, vis a vie the measures implemented by Federal State and Territory Governments, for the purpose of assessing whether rights derogations were compliant with Australia's obligations under international human rights law, and for the purpose of informing Australia's approach to such a pandemic in future. To date, no such detailed analysis has occurred, and such analysis is owed to the many Australians whose fundamental rights and liberties were severely curtailed by the Federal and State Government responses to Covid-19.

2. **Did the Australian Human Rights Commission perform its statutory function during Covid-19? If not, why?**

The statutory functions of the Australian Human Rights Commission are clear and are featured above.

In summary, they are to:

i) "inquire into any act or practice that may be inconsistent with or contrary to any human right" (and in particular, with any covenant or declaration specifically included in the Act), and, "effect a settlement of the matters that gave rise to the inquiry" (**First Function**); and

ii) to perform the functions conferred on the AHRC by section 31 which have to do with equal opportunity in employment and occupation (**Second Function**); and

iii) to examine enactments (i.e.; laws) for the purpose of ascertaining whether those laws are, or would be, inconsistent with or contrary to any human right; and to report to the Minister the results of same (**Third Function**).

During Covid-19, the Commission received an unprecedented number of complaints, and requests for help, from the Australian public, noting in their responses to those requests that due to their inundation, complainants had to wait up to six months for a response. Clearly, the Australian public had a perception that the AHRC would assist them, and sought that assistance, desperately.

With respect to their First Function, the AHRC did not make any inquiry into any act or practice that was inconsistent with or contrary to any human right. Part of their stated reasoning for this was an interpretation of the words "act" and "practice" in the AHRC Act which encompassed measures taken by Federal Government, but not State or Territory Governments. Even if this interpretation of the AHRC Act is correct (which is questionable), it is not clear why the AHRC did not make any inquiry into the actions of Federal Government during the most significant human rights impositions in Australia's history. Further, even if the AHRC's interpretation is correct, should not then the discussion turn to amending the AHRC Act so that it may properly operate to require all States and Territories to observe and give effect to the Core Treaties, in circumstances where the Commonwealth Government entered into those Treaties on behalf of all Australians, States and Territories?

With respect to their Second Function, Section 31 of the AHRC Act states that the AHRC is obligated:

a) to examine enactments, and (when requested to do so by the Minister) proposed enactments, for the purpose of ascertaining whether the enactments or proposed enactments, as the case may be, have, or would have, the effect of nullifying or impairing equality of opportunity or treatment in employment or occupation, and to report to the Minister the results of any such examination;
b) to:

i) inquire into any act or practice (including any systemic practice) that may constitute discrimination

The definition of "discrimination" which applies to Section 31 of the AHRC Act includes discrimination on the basis of medical record. It is unclear why the AHRC did not inquire into the widespread practice of employers in Australia restricting their employees from working on the basis of their medical record (vaccination status).

With respect to their Third Function, Covid-19 saw the widespread use of public health orders and public health directives to severely limit the human rights of Australian citizens in an unprecedented way. The AHRC is the body in Australia with the power and duty to examine these controversial enactments and did not do so. If Covid-19 was not reason enough to enact this function, what is?

3. Did the Principle of Legality fail as an effective barricade to human rights breaches in Australia during Covid-19?

The Principle of Legality (**the Principle**) is a rule of statutory construction which states that, in the absence of clear indication to the contrary, it is to be presumed when interpreting a statute that the statute was not intended to modify or abrogate fundamental rights (see *Coco v The Queen* (1994) 179 CLR 427; [1994] HCA 15 at 437; "Coco"). Australia does not have a bill of rights, so the principle has often been said to be a fundamental protection in Australian law.

However, in *Kassam v Hazzard; Henry v Hazzard [2021]* NSWSC 1320, the plaintiffs sought to rely on the Principle to challenge the public health orders made under the auspices of Section 7 of the *Public Health Act 2010 (NSW)*, only to find his Honour's conclusion that, because the Public Health Act is an Act that deals with:

> "public safety…curtailing the free movement of persons including their movement to and at work are the very type of restrictions that the PHA clearly authorises. Hence, the principle of legality does not justify the reading down of s 7(2) of the PHA to preclude limitations on that freedom" [at 9].

This precedent suggests that the Principle will be powerless to dilute any Act of Parliament which allows for particular human rights limitations or derogations, which in turn calls into question the utility of the Principle. In particular, this NSW departure from the *Coco v R* precedent demonstrated a State judicial effort to dilute the Principle, rendering it powerless to dilute the Act of Parliament under review. This then allowed for particular human rights limitations and derogations to essentially be sanctioned by the Court, in turn calling into question whether

Australia observed a failure of the Principle itself during Covid-19.

4. Has the law on Informed Consent in Australia been ignored?

Australia has a long legal history of upholding the central medical tenet of fully informed and free consent.

Various domestic statutes, such as the *Guardianship Act 1987 (NSW)*, the *Mental Health Act 2007 No 8 (NSW)* and the *Victorian Charter of Human Rights and Responsibilities Act 2006 (VIC)* contain definitions of the concept that are generally analogous. The latter, for example, has the following definition: "A person must not be…subjected to medical or scientific experimentation without his or her full, free or informed consent".

This is, again, an example of a human right which Australia has covenanted into via an international treaty (Part III, Article 7 of the ICCPR) which has been enshrined into our domestic law.

The principle is also reflected in the many regulations that inform both the medical and legal professions in this country. For example, the Code of Conduct for doctors states unequivocally that:

> "informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved".

The Australian Law Reform Commission states that:

> "Informed consent refers to consent to medical treatment and the requirement to warn of material risk prior to treatment. As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment. Failure to do so may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent".

There are many other examples.

In the common law, there is a well-known positive duty for Doctors to warn patients of material risks inherent to any treatment proposed (see *Rogers v Whittaker (1992)).* A 'failure to warn' patients of material risk, and the subsequent breach of duty of care at common law, is the foundation of most medical negligence cases in Australia, of which there are thousands per annum.

In *Wallace v Kam [2013] HCA 19*, the High Court was clear:

> *The common law duty of a medical practitioner to a patient is a single comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment [...] The component of the duty of a medical practitioner that ordinarily requires the medical practitioner to inform the patient of material risks of physical injury inherent in a proposed treatment is founded on the underlying common law right of the patient to choose whether or not to undergo a proposed treatment.*

Given the above, which must be described as a comprehensive and consistent approach in Australian law, it is remarkable that so many Australian citizens underwent vaccination against Covid-19, a provisionally approved medical treatment, in circumstances where they:

a) Did not fully understand the material risks associated with that treatment; and
b) Were subjected to significant social and economic pressures to undergo that treatment.

It is not unreasonable to argue that **nobody in Australia** was capable of providing fully informed and free consent to vaccination against Covid-19, given the pressure being exerted daily by employers, media and politicians, and the inaccurate and incomplete information being made available to them.

This poses the question of whether the law on informed consent in Australia has been bypassed or ignored, and if so, how and why this was allowed to occur.

5. Is the Separation of Powers functioning appropriately in Australia?

The Australian Constitution distributes power to govern among the Parliament, Executive and the Judiciary. With respect to the judiciary, this is an important separation, because the judiciary is often tasked with assessing the legality and correctness of Government laws and decisions. Indeed, this is one of the primary functions of the judiciary.

On 27 September 2021**,** a decision in the matter of *Jennifer Kimber v Sapphire Coast Community Aged Care Ltd (C2021/2676)* was handed down by a full bench of the Fair Work Commission.

That decision featured a dissenting judgment by Deputy President Lyndall Dean, which was highly critical of the approach taken by Governments in Australia to Covid-19. It is, to date, the only decision by a member of any Tribunal or Court in Australia that has been critical of the measures taken by Government in response to Covid-19.

This may be partly due to the way the Deputy President was punished for her judgment. President Justice Iain Ross immediately barred the Deputy President from appeal cases. The President told the Deputy President that her conduct constituted "misuse of her statutory office" and that she had breached:

> "basic principles of quasi-judicial decision-making including criticising government policy and doing so in highly inflammatory terms".

She was forced to undergo professional conduct training.

Of course, members of the Fair Work Commission, as well as other Tribunals and Courts in Australia, are appointed by the Government. The removal of an appointee from the Fair Work Commission can only be done through a vote by Parliament.

By contrast, the Judge who heard perhaps the most famous case involving the assessment of Government measures against Covid-19 (*Kassam v Hazzard*), and who essentially endorsed the actions of Government as lawful and reasonable, has recently been elevated to the High Court.

It is not unreasonable to wonder whether such elevation would have occurred if that Judge was to have made a different decision in that case, and whether that kind of potential detriment might have influenced, consciously or subconsciously, his decision. High Court judges, of course, are appointed by the Governor-General, who is part of the Parliament and the Executive.

The question thus must be asked: Is it appropriate that judicial officers be appointed and promoted by members of Parliament and the Executive given they are often tasked with critiquing the decisions of those members?

6. Are our discrimination and privacy laws adequate to protect people against discrimination on the basis of their medical status, and to protect people's private medical information?

Federal and State discrimination statutes focus on 'protected attributes', including race, sex, pregnancy, marital status, family responsibilities, breastfeeding, age, disability, sexual orientation, gender identity or intersex status. These protected attributes do not include medical status or record, despite the AHRC Act including 'medical record' within its definition of 'discrimination' (but not 'unlawful discrimination', which has a different definition).

This means that, in brief, somebody who has been discriminated against in Australia on the basis of their medical record or status cannot proceed to the Federal Court accordingly. The only means of action available to that person is, if

the discrimination occurred in the context of their employment, to complain to the AHRC pursuant to Section 31 of the AHRC Act, and to hope that the AHRC chooses to inquire into and conciliate the issue. This is not very effective protection. Do we need a more explicit protection against this form of discrimination?

With respect to Privacy, Covid-19 saw employers intrude violently into the private medical histories and records of their employees, often with no regard for the Australian Privacy Principles, enshrined in the *Privacy Act 1988 (Cth)* which provide stringent restrictions and conditions on the collection and storage of this information. In almost all cases, employers said that the collection of records of employees' vaccination status was lawful and reasonable to ensure that the employee could safely perform the inherent requirements of their job – but this is an oversimplification of a law which is supposed to be applied in exceptional circumstances only, based on the individual circumstances of each employee. Did employers generally breach Federal and State privacy laws in Australia during Covid-19, and if so, how and why was this allowed to happen, and how can it be avoided in future?

7. Constitutionality of Mandates

In an issue related to the vitiation of informed consent, attention must be given to the way that Section 51 (xxiiiA) of the Constitution was interpreted in the context of vaccine mandates. The Section, which allows for the provision of various services by the federal government, but not to the extent of authorising any form of civil conscription, means that medical practitioners must not be compelled by the Federal government to provide mandatory services, such as vaccinations. The argument oft made (and accepted by the NSW Supreme Court in *Kassam*) is that the section only bars the Federal Government from forcing doctors to do something; it doesn't stop or deem unlawful a vaccine mandate created by a State. The problem is that doctors were still forced to vaccinate their patients, unless they wanted to face regulatory punishment and fines from their regulators, and the *intent* of this important section of our Constitution was nonetheless flouted, even if it wasn't technically breached. The question that must be asked is whether we are satisfied with an approach to our Constitution involving pedantic interpretation applied with an intention to get around the intention and spirit of the document. In contract law, intention of the drafters is a key element of construction. Shouldn't that same reasoning apply to our most important national contract, the Constitution?

8. The External Affairs Power

Section 51 (xxix) of the Constitution gives the Parliament power to make laws for the peace, order and good government of the Commonwealth with respect to external affairs. This is a power that has increased over time as the Courts broaden

the scope of what "external affairs" may involve, particularly in a world that is becoming more open and global, and particularly with the rise of customary international law. In *R v Burgess; Ex parte Henry* (1936), the High Court ruled that the power to regulate external affairs is not limited to the subjects listed in section 51.

The *Tasmanian Dam Case 1983* saw the High Court explicitly say that this power can be used by the Federal Government to implement obligations that have been assumed by the federal government under international treaties and conventions, even in areas formerly under State control. This raises several questions:

a) Were statements made by the Federal Government that they did not agree with or encourage State and Territory government vaccine mandates disingenuous in circumstances where they could have used the external affairs power to enact a law which prohibited such mandates?
b) Given Australia's vehement support of the international treaties and covenants, and the now established manner in which the Federal Government can meaningfully and practically implement them, why didn't the Federal Government move to protect the rights they have covenanted into protecting?
c) Is the external affairs power an appropriate power for the Federal Government if it is only going to be implemented in such a selective way?

Index

Reference: E

Index

An examination of the Department of Home Affairs (DHA) throughout 2020 to 2023, including the Social Cohesion Division and Extremism Insights and Communications division, and the Emergency Management Australia (EMA) division, including:

i. the decision to appoint DHA/EMA to lead the Whole of Government response to Covid-19 through the activation of the National Coordination Mechanism (NCM) by the National Security Committee of Cabinet on 5 March 2020:
   a) in circumstances where DHA is a national security ministry lacking any public health expertise;
   b) why in his 5 March 2020 press release the Prime Minister did not disclose the DHA/EMA were delegated responsibility for the NCM;
   c) whether the delegation of the NCM powers to DHA/EMA required DHA/EMA to observe the '*Australian Health Sector Emergency Response Plan for Novel Coronavirus*' published on 18 February 2020;
   d) whether the delegation of the NCM powers to DHA/EMA empowered DHA/EMA to pursue any other plans not disclosed to the Australian public or public health experts;
   e) why Australia's national security ministry (DHA) was delegated the NCM powers 6 days before the WHO declaration of a pandemic on 11 March 2020;
   f) why Australia's national security ministry (DHA) was delegated the NCM powers 13 days before the announcement of a biosecurity emergency by the Governor General on 18 March 2020; and
   g) an examination of the process of consultation and due diligence undertaken to assess the costs and benefits of placing Australia's public health response under the leadership of a national security ministry, particularly at such an early stage, when medical and scientific understanding of SARS-CoV-2, and therefore the appropriate public health response, were nascent and only just beginning to form; and
   h) an examination of the process by which DHA/EMA formulated its Whole of Government strategies and its advices to entities throughout the Whole of Government response, including due diligence with respect to the medical, scientific, legal and human rights aspects of its advice, requests and instructions;

ii. any national plans, strategies, policies, or relationship involving the NHEMRN working with the DHA in the coordination of State and/or Territory and/or Commonwealth Government Covid-19 messaging amongst Australian governments;

iii. any national plans or strategies or relationship involving the NHEMRN working with the DHA in the coordination of State and/or Territory and/or Commonwealth Government Covid-19 messaging using Australian media outlets

and companies;

iv. any relationship between the DHA and NHEMRN involving Covid-19 messaging;

v. any relationship between the DHA and Covid-19 vaccine suppliers and manufacturers involving Covid-19 messaging;

vi. any plans or strategies or directives or policies or initiatives involving the DHA in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning the safety or efficacy of Covid-19 vaccines;

vii. any plans or strategies or directives or policies or initiatives involving the DHA in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning State or Territory or Commonwealth Government mandate measures in response to Covid-19;

viii. any plans or strategies or directives or policies or initiatives or relationships involving the DHA and State and Territory governments and their departments in respect of (iv), (v), (vi), and (vii) above;

ix. any plans or strategies or directives or policies or initiatives or relationships involving the DHA and social media and media companies in respect of (vi) and (vii) above, including 'fact checker' organisations;

x. any plans or strategies or directives or policies or initiatives or relationships involving the DHA and the Trusted News Initiative;

xi. any plans, strategies, policies, or relationship involving foreign government agencies, security services, or defence organisations working with the DHA in the coordination of State and/or Territory and/or Commonwealth Government Covid-19 messaging amongst Australian governments;

xii. any plans, strategies, policies, or relationship involving foreign government agencies, security services, or defence organisations working with the DHA for the deployment of Covid-19 vaccines in Australia, including medical counter-measure programs.

Explanatory Memorandum

Index

An examination to confirm whether the activities of the DHA in respect of Covid-19 public messaging, including any actions undertaken to censor non-government public messaging throughout 2020, 2021, 2022, and 2023 was reasonable and proportionate and consistent with real-time Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known and shared amongst Australian governments.

An examination to ensure appropriate, reasonable, and proper due diligence was understood and undertaken by the DHA, as a national security ministry, for upholding the core principles of the scientific method in its Whole of Government Response.

In other words: (a) a hypothesis-testing approach, whereby scientific positions are held as hypotheses, which remain fluid and under perpetual review as new evidence comes to light; (b) peer review, by which hypotheses are held up to collective critique and scrutiny, to ensure that only the most reliable and valid positions survive, and; (c) persistent scrutiny of the quality of evidence entertained, with an emphasis on reliability (replicability) and validity (in other words that constructs, such as PCR test results, represent what they claim to represent), along with reliance on sources that are independent (absent conflicts of interest), primary rather than secondary, and possess the relevant subject matter expertise.

An examination of whether these pillars of the scientific method were flouted during the Covid-19 response (such as the use of censorship and the rigid enforcement of a singular narrative) as a result of a national security ministry, rather than a scientific body, co-ordinating Australia's Whole of Government response.

Lastly, seeking to understand why the Australian public and science and medical communities were not informed that public health strategies for Covid-19 were being coordinated by our national security ministry, and the consequences of this failure of transparency.

Question(s) on Notice

Index

In respect of **Reference E**, what details were made public about the involvement of the Department of Home Affairs (DHA) throughout 2020 to 2023, and what if any possible shortcomings may have arisen and should be investigated and examined when a department of national security was made responsible for directing Australia's whole-of-government public health response to Covid-19?

Answer(s)

Index

Answer

Dr Lissa Johnson, Co-Author:

Answer 1: In respect of Question on Notice E, what details were made public about

the involvement of the Department of Home Affairs (DHA) throughout 2020 to 2023?

To the best of my knowledge, no standalone information was made public that enabled Australian citizens to understand the involvement of the Department of Home Affairs (DHA) in the Government's Covid response. To gain an overview of the DHA's role, it has been necessary to piece together disparate pieces of information, in some cases from obscure sources, including the former DHA Secretary's testimony on pp. 2717-2741 of a 2,986-page archived transcript of the Royal Commission into Natural Disaster Arrangements ('Bushfire') hearings.

As far as I am aware, key publicly available information regarding the DHA's involvement in Australia's whole-of-government response throughout 2020 to 2023 is as follows:

A) 5 March 2020 - A joint media release on the Parliament of Australia website titled '*Update on novel coronavirus (Covid-19) in Australia*',[vi] issued by then Prime Minister Scott Morrison, Minister for Foreign Affairs and Minister for Women Marise Payne, Minister for Health Greg Hunt, and Minister Assisting the Prime Minister for the Public Service and Cabinet. The media release focussed primarily on travel restrictions, with one sentence noting, 'As part of the Australian Government's preparedness response beyond the health system, today we have also activated the National Coordination Mechanism. The mechanism will coordinate activities across the Commonwealth, state and territory governments as well as industry to ensure a consistent national approach is taken to provide essential services across a range of critical sectors and supply chains."
The fact that DHA would assume authority for coordinating the Government's response outside the health sector via activation of the National Coordination Mechanism (NCM) (see section C below) was not explained. Nor was that fact that the NCM had been newly created in response to Covid-19, bringing pandemics under a more generic emergency management rather than specifically public health management organisational structure (See section H 'Bushfire' Royal Commission Transcripts).

B) 1 April 2020 – A media release on the Defence Ministers website titled, '*Expansion of ADF Support to Covid-19 Assist.*' The media release explained that Emergency Management Australia (EMA), which is a division within the DHA, would be leading Australia's whole-of-government response. It announced the establishment of the Australian Defence Force's (ADF's) Operation Covid-19 Assist, noting that, "Assistance from the ADF is being co-ordinated through the Emergency Management Australia-led whole-of-government response to Covid-19." However, like the media release of 5 March, the ADF release did not name DHA directly.

C) 28 April 2020 - An 11-page document on the Parliament of Australia website titled '*Australian Covid-19 response management arrangements: a quick guide*'. On

pages 9-10 the 'Quick Guide' document explains that the NCM, "will operate through the department of Home Affairs and, together with the states and territories, will coordinate the whole-of-government responses to issues outside the direct health management of Covid-19. The NCM has already brought together crisis planners from Australian Government agencies, including Home Affairs and the Australian Defence Force."

The document notes that as part of coordinating Australia's whole-of-government response under the NCM, DHA would be responsible for keeping the Australian government abreast of developments and informing government decision making. Via its EMA division, the DHA ran the Crisis Coordination Centre (CCC, now the National Situation Room), which the Quick Guide describes as, "the key national operational level, whole-of-government coordination body…a 24/7 centre providing whole-of-government situational awareness to inform national decision making."

The Quick Guide adds that to in order to keep the whole-of-government informed, the DHA's CCC "monitors open source as well as social media to gain an appreciation of rapidly developing events." (In response to Question 2 I will expand upon the implications of a body tasked with informing government decision-making, particularly in a scientifically complex arena such as Covid-19, relying upon social media - which it was simultaneously actively censoring - for its understanding of events.)

D) Date unknown, last updated May 2023 - A page on the DHA website titled '*About Emergency Management*'. Under the sub-heading '*National Coordination Mechanism*' the web page states, "As announced by the Prime Minister on 5 March, the Australian Government has activated the National Coordination Mechanism (NCM) in response to the spread of Covid-19. The NCM within Emergency Management Australia operates through the Department of Home Affairs and together with the states and territories co-ordinates the whole-of-government responses to issues outside the direct health management of Covid-19."

It should be noted here that that the appointment of DHA to coordinate the whole-of-government response on 5 March constituted a significant departure from previous publicly disclosed arrangements. On 27 February 2020 the 'Australian Health Sector Emergency Response Plan for Novel Coronavirus (Covid-19)' (Covid-19 Plan) had been instituted, and was announced by the then Prime Minister, Health Minister and Deputy Chief Medical Officer in a media release the same day. According to the Covid-19 Plan, the whole-of-government response was to follow the 2017 'Emergency Response Plan for Communicable Diseases Incidents of National Significance: National Arrangements' (National CD Plan). Specifically, under the heading '*Whole of government planning to support the novel coronavirus response'*, the February 2020 Covid-19 plan stated: "The National CD Plan outlines how non-health sector agencies will support the health sector response and how agencies across Australian, state, territory and local governments will work together to protect Australia" (p.7). The aforementioned non-health sector National CD Plan, in turn, stipulated that the government's response would fall under the oversight of the Minister for Health (not the Minister for Home Affairs). It explained

that, 'the Australian Government Minister for Health will lead the Australian Government response to a domestic health crisis" (p.11).

As far as I can ascertain, no public statement was made regarding the sudden change on 5 March from Minister for Health oversight of the whole-of-government response to Minister for Home Affairs oversight, leaving the Australian Public with the misapprehension that their government's Covid response came under the Department of Health rather than the Department of Home Affairs.

This change of coordinating authority was significant, in that it constituted a shift from a specifically public health oriented response framework and leadership structure to a generic emergency management / natural disaster mechanism, which takes a broad and "elastic" (p.2725) interpretation of what can be deemed to constitute a "natural disaster". This had the effect of expanding EMA's ambit to bring public health matters such as pandemics under DHA's "emergency management" architecture (see section H for further details).

The timing of the decision to change course to a DHA emergency management mechanism (5 March), six days before the World Health Organisation (WHO) declaration of a pandemic on 11 March, and 13 days before the Governor General's announcement of a biosecurity emergency in Australia, on 18 March, appears to have gone equally publicly unexplained.

E) Date unknown, last updated May 2023 - A page on the DHA website titled '*National Coordination Mechanism*': The web page provides an overview of the NCM, noting that Covid-19, "saw Emergency Management Australia (EMA), through the Department of Home Affairs, drive the implementation of the National Coordination Mechanism (NCM)." It stresses that the NCM's main purpose, and therefore by extension a key element of DHA's role in Covid-19, was to promote cooperation between government and industry in times of crisis. The web page states that the NCM brings together government and private stakeholders "in a way that has never been done before". Without elaborating on what was new about the arrangement, it notes that the primary purpose of embedding the NCM (and therefore DHA) into the Australian Government Crisis Management Framework going forward is to link government with industry and the private sector in emergency management.

F) Date Unknown, last update May 2023 – A page on the Department of Home Affairs website titled, 'Improve trade efficiency'. Although the whole-of-government Covid response coordinated by DHA is defined as falling outside the direct health management of Covid-19, the DHA lists as one of its main achievements for 2021 intercepting 397,000 tablets of Ivermectin and 120,000 tablets of Hydroxychloroquine, which it erroneously categorised together with fake, counterfeit or illegitimate test kits. (see Reference O for information on Ivermectin and Hydroxychloroquine). Arguably, blocking medicines falls within the direct health management, or mismanagement, of

Covid-19.

G) 2020-2022 - Various posts on the ADF Website regarding DHA's EMA-led ADF activities with respect to Covid-19. The earlier April 1 ADF media release had made clear that the ADF's Covid-19 activities were being co-ordinated through the DHA's EMA-led whole-of-government response. Despite that whole-of -government response purportedly focussing only on aspects outside the direct health management of Covid-19, most posts described ADF personnel providing direct health management in addition to their other duties. Examples include:

i) *April, 2020* **- *Medical duties***: The post announces training programs "designed to quickly prepare ADF personnel, who do not have a medical background, to conduct medical support tasks and other duties as part of Operation Covid-19 Assist." Those medical support tasks included working in health facilities as orderlies, while other duties included quarantine compliance measures. The ADF medical training was being provided to over 52,000 Defence personnel and had been offered to Australia's international military partners.

ii) *April 2021* – ***police checkpoints, compliance measures, testing and contact tracing, supplying medicines and PPE, staffing a hospital emergency department and administering vaccines*:** In a review of one year of Operation Covid-19 Assist, the post notes that ADF activities over the previous year had included: supporting police vehicle control points, quarantine compliance, making over 35,000 'contact visits', production of medical supplies, designing and producing personal protective equipment, Covid testing, contact tracing, operating a hospital emergency department, and administering Covid vaccines in nursing homes (also reported in a *Guardian* article here). The post describes Operation Covid-19 Assist as the ADF's largest ever domestic operation.

iii) *July 2021* **– *Assisting with compliance measures and policing***: The post reads, "This afternoon Defence received a request from [DHA's] Emergency Management Australia on behalf of the NSW State Emergency Operations Centre to provide Australian Defence Force personnel to support the NSW Police with their response to the Covid-19 situation in Greater Sydney...Up to 300 Defence personnel will deploy in the coming days to assist NSW authorities with Covid-19 restriction compliance measures." The post adds that, over 13,000 ADF personnel had been deployed around Australia as part of Operation Covid-19 Assist to date.

iv) *August 2021* – ***Vaccine administration in rural, remote and indigenous communities.*** The post describes sending Vaccination Outreach Teams to remote locations and establishing a mass vaccination centre in Dubbo, NSW.

v) August 2021 – ***Compliance measures, food distribution, vaccination and testing***. Compliance measures included ensuring stay-at-home orders were observed and assisting police with compliance checks. The post also describes ADF attendance at Covid testing centres, vaccination stations and welfare checks.

v) *February 2022* – ***Ambulance and paramedic assistance, policing and hotel quarantine:*** The post reads, "Responding to an Emergency Management Australia request, the ADF is providing 20 ambulance drivers to Ambulance Victoria and six planners to Emergency Management Victoria from January, 20. The ADF personnel working as ambulance drivers will partner with paramedics on non-urgent tasks after being trained at the Ambulance Victoria Training Centre." It adds that the ADF had also previously "supported the Victorian Department of Health, Victoria Police and hotel quarantine", noting that over 7,000 ADF personnel had been deployed to Victoria since 2020.

H) 12 October 2020 - Consolidated Transcript of All Hearings, Royal Commission into Natural Disaster ('Bushfire') Arrangements[vii], available on the National Library of Australia Web Archive. As a major part of his oral evidence to the 'Bushfire' Royal Commission, then Secretary of the Department of Home Affairs, Mike Pezzullo, explained the creation and operation of the NCM in response to Covid-19, providing what appears to be the most detailed publicly available explanation regarding the nature of DHA's involvement in Australia's Covid response. Pezzullo remained Secretary, overseeing DHA's Covid involvement, from the invocation the NCM on 5 March 2020 to his departure in September 2023. In his oral evidence given on 6 August 2020[viii] the DHA Secretary explained that the advent of Covid-19 saw the establishment of the NCM, and "the fusing of the NCM and EMA functions" (p.2727). Counsel Assisting the Bushfire Royal Commission summarised Pezzullo's submission as indicating that the EMA and NCM "enable the Department [of Home Affairs] to work hand-in-glove with our Commonwealth colleagues as well as the State and Territories and industry" (p.2718).

Secretary Pezzullo's evidence conveyed the following about DHA's role in coordinating the Australian government's Covid response.

i) ***DHA adopts a templated, top-down, command and control approach to emergency management, which is transferrable across different types of emergency "vectors", whether pandemics, bushfires or cyber attacks, and implements population-wide interventions.*** The DHA secretary described a recent expansion of his department's EMA purview to an "all hazard" focus, such that DHA's emergency management architecture could apply across different emergency types, from bushfires to pandemics. He said that the ambit of the EMA, which "led" the whole-of-government Covid response according to the ADF website, had historically been "fire, flood, storm, etcetera." Pezzullo noted, however, that, "The thing that we've bolted on since over the last two and a half years, is an ability to truly operate across all hazards." He traced this development to a pandemic preparedness exercise two and a half years earlier, adding, "So what EMA has evolved over the last two years is into very much a node that that can lock into, whether it's a fire, storm or a flood vector, if you think of these threats as vectors, [and] pandemic[s]" (p.2718). The DHA Secretary later added, regarding the

breadth of DHA's new emergency management ambit, "To us, again short of a war involving military conflict - and even the term 'natural hazards' for us is not ambiguous but we have soft edges around it… So 'natural' [as in natural disaster] for us is a sort of elastic concept" (p.2725).

In addition to a broad and elastic new emergency management purview, Secretary Pezzullo relayed a process whereby once an emergency situation had been assessed to have occurred, a pre-determined emergency response set, and organisational architecture were set in train. He described, "having pre-set plans - you're not going to slavishly follow them exactly because on the day you will need to adjust – but having present plans, set preparedness standards, pre-set doctrine and preset communications protocols, driven from the top down." He also advocated in his submission to the Royal Commission for "greater centralisation of decision-making in relation to preparedness, response, resilience and recovery from all hazards" (p.2727).

Under this top-down, pre-set, centralised control doctrine, Pezzullo described no mechanism for reviewing, as the scientific and medical understanding of Covid-19 and its countermeasures evolved, the legitimacy or appropriateness of DHA's original emergency assessment, and therefore the legitimacy of its ongoing emergency response. In other words, the same set of assumptions applicable to a clear and unambiguous single incident emergency such as a bushfire or cyber attack, whose instigating event requires no ongoing re-appraisal, were applied to the vastly different case of a purportedly novel infectious disease, whose true nature and dangerousness was initially unclear, and was subsequently the object of ongoing and highly specialised scientific debate. This failure to differentiate between vastly different kinds of instigating events (scientifically complex versus not) represents a foundational, fundamental flaw in the DHA-led whole-of-government architecture, which, in my submission, negates any claim that the whole-of-government response has its basis in science (see Question 2 for elaboration on this issue).

In an equally counter-scientific vein, contrary to a later DHA web page claiming that the NCM "exerts no command and control", Pezzullo explicitly described DHA Covid activities in terms of command and control frameworks. When asked how the DHA approach taken for Covid could be transferred to other crises he said, "you would have a fixed core group whose day job was command, control, coordination, crisis management irrespective of vector" (p.2725). Similarly, in summarising the DHA's activities during Covid he described using "surge teams" "to assist with command, control, communications [and] triaging" (p.2724). In making a separate point later in his testimony Pezzullo again referred to the DHA's "EM [emergency management] function in the way that I've been describing it - which is really about command, control, communication, [and] situational awareness" (p.2737).

Within that command-and-control ethos, the DHA Secretary described no process to ensure due diligence in consulting appropriate vector-specific experts (i.e. in specialised

scientific and medical sub-disciplines relevant to novel diseases and novel pharmaceuticals), with appropriate levels of expertise (e.g. senior researchers in their fields), across an appropriate range of specialisations (e.g. immunologists and pharmacovigilance experts as well as medical practitioners and epidemiologists). Rather, he described relying on internal staff who are "generalist public servants first and then they are specialists in their realm second" (p.2723). He added that as part of their secondary specialisation, DHA staff are, "professionally and deeply trained in those disciplines that I mentioned… be it a fire, a terrorist vector, cyber, pandemic" (p.2725). Which is based on the false premise that pandemics represent a discrete "discipline" in which singular specialisation can be attained. To specialise in pandemics and their countermeasures would require specialisations in immunology, microbiology, infectious disease, pharmacology, epidemiology, nanoscience, emergency medicine, respiratory and cardiovascular medicine, clinical trials, and so-on.

By grouping pandemics together with unrelated "disciplines" such as fires and floods, under the disingenuously broad category of crisis vector, with generalist public servants doubling as pandemic experts, the DHA director's evidence reveals how woefully disconnected the DHA emergency management leadership is from genuine subject matter expertise. This, in my submission, as I will discuss further respect to Question 2, constitutes a catastrophic failure of competence and care with respect to complex biomedical agents and their countermeasures, such as in the case of Covid-19.

In terms of adopting a population-wide response, Pezzullo said, "All of the contingencies that I've been describing from the most existential to the catastrophic… they all fit within - and perhaps this is my defence planning background showing - they will fit in the realm of contingencies. And a contingency is a risk materialised… How you deal with those contingencies, flood, fire, agricultural risk, pandemic, cyber, is the contingency framework and obviously my - in my submission I contend that that framework is best managed on a national basis" (p.2728). Which, as also discussed in response to Question 2, flies in the face of evidence-based medical care.

ii) ***Consistent with the explanation of the NCM on the DHA website, the focus of DHA liaison in crafting and coordinating the whole-of-government response appeared to be primarily industry and the private sector, rather than citizens, science or medicine.*** The DHA Secretary said, "And so one of the ways in which we think about EMA now, you are the node that brings those disciplines together [fire, flood, storm, cyber attack, pandemic, agricultural catastrophe] and then depending on the vector you partner on to different parts of both government and industry" (p.2719). Partnering with scientific and medical experts in the case of pandemics was not described.

When asked why Covid-19 saw the creation of the NCM to replace the former National Crisis Committee, Pezzullo replied, "because Covid was going to be such a wide societal and economic impact..." (Which begs the question - how did the DHA know this? By early March 2020, when the NCM was created, the public mantra was still 'two weeks to

flatten the curve'). Secretary Pezzullo continued, "…we have to build in deeper connections to industry, supply chains, supermarkets, providers of essential supply such as hand sanitisers" (p.2721). Deeper connections to scientific research centres or subject matter experts were not mentioned. Similarly, the Bushfire Royal Commission Report itself refers to 30 different private sectors that the Australian Government had engaged under the NCM (p.80).

When asked about the taskforces that were coordinated by the NCM in the case of Covid-19 Pezzullo cited only industry-related taskforces under the rubric of "non-health" measures (e.g. focussed on supermarkets, freight, and telecommunications), to ensure that industry continued to operate during lockdowns and school closures. The answer, however, like the question to which it applied, failed to acknowledge the reality that lockdowns and school closures were themselves presumably whole-of-government measures, nor how, or by which whole-of-government mechanism or authority, based on what scientific evidence or information, those measures were instituted in the first place. Rather, the whole-of-government emergency response imposed upon populations (in this case lockdowns and school closures) was taken as a fixed and given necessity, with industry consequences as the DHA's prime concern.

The DHA secretary said of his role on the National Covid Coordination Commission, which focussed on "how do we build a stronger economy coming out of Covid", that he and the other commissioners "agreed from the outset to the extent that the commissioners could use their personal contacts, their networks, their deep insight into retail, wholesale, trucking, telecommunications, to the extent that they could assist the NCM with troubleshooting and immediate response" (p.2723). In other words, senior government officials assisting industry (via the NCM) to navigate the whole of government response drew on their own personal networks and contacts.

iii) ***In addition to the private sector and government officials, the EMA's expertise is in connecting and coordinating police and the military***. Pezzullo said, "EMA's connectivity [is] to the commissioners and Chief Officers and their command centres, EMA also plugs in if it's a police or CT incident through the Federal Police, and also directly into the incident response centres; very well connected with the ADF interstate crisis emergency centres as well. So I would contend to this Commission, vector by vector these connections are very, very good" (p.2720).

iv) ***Despite the whole-of-government response being publicly described as pertaining to non-health aspects of Covid-19, the DHA secretary described DHA involvement in health matters.*** These included triage, staffing nursing homes, and facilitating distribution of medicines.

v) ***The DHA's role in emergency management included crafting messaging and communication via the CCC*** (Crisis Coordination Centre, which the 'Quick Guide' on the Parliament of Australia website notes is operated by the DHA's EMA). Pezzullo

explained that the CCC is used for purposes such as to "amplify an urgent message" (p.2719) directed at "stakeholders" to enable them to act accordingly. It is worth reiterating here that, according the Quick Guide, the CCC draws on "open source" platforms including social media for its understanding of events. Which, once again, as revisited in Question 2, underscores the chasm between DHA's information base and that of science.

vi) ***DHA provides the Australian government with information to guide government decision making in times of crisis.*** When asked by the Royal Commission whether part of DHA's emergency management responsibility is, "to create a better sense of national situational awareness for the purposes of decision-making at a national level?" the DHA secretary answered in the affirmative (p.2731). Which, when applied to a complex biomedical subject such as Covid-19 is a sobering reality.

To discover the former DHA Secretary's evidence, and therefore gain some understanding of the DHA's role in Australia's Covid response, is a painstaking endeavour. To do so, a member of the public must first happen upon reference to relevant information in the 594-page Bushfire Royal Commission Report and subsequently navigate to footnote 38 of Chapter 3, which reads, 'HAF.507.001.0001'. Having surmised that the footnoted code likely pertains to the Report's Appendices, the reader must then navigate to a separate 387-page appendices document, and search for the code 'HAF.507.001.0001'. That search will reveal, on p.166, that HAF.507.001.0001 refers to Exhibit 33.1.2, which is listed as 'Supplementary evidence related to Secretary Pezzullo's evidence'. However, neither Exhibit 33.1.2 nor the supplementary evidence are to be found within the Appendices. Accordingly, the reader must search the name "Pezzullo" in the Appendices to find on p.115 a 'transcript reference' for his Royal Commission evidence, which is listed as P-2717. To then locate the appropriate transcript, the reader must search the archived version of the Bushfire Royal Commission on the National Library of Australia Website, as the transcripts are no longer available on the Royal Commission Website itself. The reader then must browse the archived web site to locate a link titled 'Hearings', which hosts the relevant transcripts. Surmising that P-2717 refers to page 2717 of the full transcript, the reader must navigate to page 2717 and read 27 pages of Pezzullo's testimony. In other words, the information is deeply buried, where few if any members of the Australian public would ever find it.

I) 2020 – The Department of Home Affairs 2019-2020 Annual Report. The 2019-2020 Annual Report provides additional information regarding DHA's 2020 role in Covid-19, which is broadly consistent with Secretary Pezzullo's Royal Commission testimony. It states that, "The Home Affairs Portfolio has played a vital role in responding to the 2019–20 bushfires and the Covid-19 pandemic." The report continues, "With the Covid-19 pandemic closely following the 2019–20 bushfires, we adopted an all-hazards approach to emergency management and crisis coordination and response… On 5 March 2020, drawing on and complementing existing capabilities within the Department and across the Portfolio, the Australian Government established the National

Coordination Mechanism (NCM), with the primary focus being to coordinate and facilitate nationally consistent approaches to non-health-related planning and responses to Covid-19… The NCM demonstrated effective collaboration and sharing of information across the Commonwealth, states and territories and the private sector which enabled timely and comprehensive advice to be provided to national leaders on both practical solutions and emerging risks" (pp.13-14).

The report explains that the Deputy Secretary, National Coordination Mechanism Taskforce, Paul Grigson, was responsible for supporting operations of Government, including the Australian Cabinet, National Cabinet, National Security Committee, Secretaries' Committee on National Security, National Coordination Mechanism, Emergency Management Australia, and liaison with the Australian Health Protection Principal Committee" (p.9).

It also lists a Deputy, National Coordination Mechanism Communication and Information Operations, Richard Johnson, who was responsible for, "driving communications to inform the Australian public about actions the Government is taking to slow the spread of Covid-19, save lives and maintain public safety" (p.11).

The DHA activities related to Covid-19 covered in the report include:

- Rapidly ("within hours") implementing border control measures (including based on one 'case'), noting that the Australian Border Force "has been at the forefront of the Australian Government's response to the Covid-19 pandemic" (p.14)
- Establishment of quarantine facilities
- Information sharing across government and private sectors
- Providing advice to national leaders
- Ensuring domestic supply of face masks, gloves and sanitiser products
- Ensuring continuity of supply chains and critical infrastructure
- Establishing a call centre to support stay-at-home orders by connecting housebound citizens with goods and services
- Operationalising police powers under the 2015 Biosecurity Act (e.g. at mass gatherings and in supermarkets)
- Working with the geospatial intelligence division to plot demographic data, for the NCM's supermarket taskforce
- Facilitating industry participation in weekly Crisis Coordination Centre (CCC) briefings
- Providing daily to twice daily "intelligence briefings" (based on "public online narratives")
- "Misinformation" operations
- Running information operations directed at the Australian public

The report stated that the DHA would "continue to monitor and adjust its Covid-19

response arrangements to the advice provided by health officials" (p.26). However, given that the DHA assumed responsibility for informing stakeholders and national decision makers (presumably such as health officials) via the CCC (now the National Situation Room), it is unclear the extent to which "advice from health officials" involved a recirculation of DHA advice, sent out via the CCC and daily briefings. No mechanism (such as external consultation) for avoiding such a circular echo-chamber scenario, with its attendant groupthink implications, is described.

Rather, a DHA take-away from 2020 was to double down on a centralised organisational framework. The report opined that the work of EMA and the NCM had "highlighted the importance and efficacy of central coordinating systems" (p.18).

In terms of the DHA's "misinformation" operations, the report describes an "intelligence response to countering Covid-19 misinformation and disinformation", including establishing an All Source Fusion Cell (ASFC), which drew on information provided by departments and agencies across government, and "works closely with domestic and international partners" (p.67). It states that, "Since March 2020, the ASFC has produced over 60 reports, and made over 180 referrals to digital industry and law enforcement for further prevention, disruption and strategic communications" related to Covid-19.

The report notes that from 1 July 2020, "the NCM has been embedded as a permanent function of the Department, with work currently being scoped on scaling the NCM to respond to other crisis situations in the future" (p.18). In other words, DHA has been positioned as the default coordinating body for any whole-of-government response across "all hazards", including public health hazards, going forward.

J) 2021 – The Department of Home Affairs 2020-2021 Annual Report. The 2020-2021 Annual Report once again makes clear that the NCM is a DHA mechanism, referring to the NCM as "the Department's National Coordination Mechanism" (pp. 69 and 75), and stating in its definition of terms that the NCM: "Operates through the Department of Home Affairs to coordinate the whole-of-government response with states and territories to issues outside of the direct health management of Covid-19" (p. 354).

New DHA activities listed for the 2020-2021 period with respect to Covid-19 include:

- Facilitating expedited passage of Covid-19 vaccines across Australia's border under Operation HANGFIRE (Bravo)
- A focus on digital identity in the aftermath of Covid-19, including providing "expertise in new emerging identity technology, specialist training, complex identity analysis, and quality assurance of identity" (p.39), along with DHA support for a proposed Digital Passenger Declaration, which would digitise incoming passenger cards, "to provide biometrically-anchored and digital-verified travel, health and vaccine status information" (p.14)
- Facilitating Covid-19 disaster payments

- Continued "misinformation" operations, primarily focussed on social distancing measures and the vaccination roll-out. This included identifying and referring "Covid-19 related malign misinformation online to the AFP and digital industry for further action, including removal" (p.105)
- Progressing work "to capture Covid-19 testing and vaccination within health processing systems" (p.84)

The report entails the same focus on the private sector as other DHA material, and notes that the NCM "maintains an extensive list of contacts and stakeholders" (p.69). (That list of NCM stakeholders, however, is not publicly available as far as I can ascertain.) The report also notes that, "the Department had hosted and attended 129 National Coordination Mechanism (NCM) cross-jurisdictional fora relating to emergency management and Covid-19 responses", both in 2020 and 2021 (p.74).

K) 2022 – The Department of Home Affairs 2021-2022 Annual Report.

New DHA Covid-related activities in the 2021-2022 Annual Report included:

- Initial implementation of the Digital Passenger Declaration (DPD) for incoming passengers, which collected health screening and vaccine information
- Crafting messages in different languages to counter "vaccine hesitancy" in local communities, in conjunction with Community Liaison Officers and Community Leaders
- Reopening borders contingent on vaccination status
- 163 cross-jurisdictional NCM meetings compared to 129 per year in 2020 and 2021

L) 2023 – The Department of Home Affairs 2022-2023 Annual Report

For the first time since 2020 the DHA Annual report contained no mention of the NCM, nor misinformation operations nor reference to vaccines or vaccination.

M) Date unknown (Sep 2022-2023) - A Page on the National Emergency Management Australia (NEMA) website titled, '*Emergency Management*'. (NEMA replaced EMA as the DHA's emergency management division in September 2022.) Under the sub-heading 'National Coordination Mechanism' the web page states, "Following its successful management of the non-health consequence of the Covid-19 pandemic, the National Coordination Mechanism (NCM) has been embedded into the Australian Government's crisis management architecture and is at the centre of the Australian Government Crisis Management Framework" (AGCMF). The post notes that in order to be part of the NCM, organisations are invited for a seat. The page makes statements that contradict information from other DHA sources, however, including that the NCM "Is not a decision-making mechanism" and "exerts no command and control".

Note: It appears that since EMA became NEMA in 2022, explanations of the NCM include the statement that the NCM "is not a mechanism for command and control" - e.g.

here, p.43 - despite the DHA Secretary clearly stating on three occasions during the Bushfire Royal Commission that the DHA emergency management process involves command and control.

N) For further information on EMA's (now NEMA's) role, see the annual Australian Government Crisis Management Framework (AGCMF) reports for 2020, 2021, 2022 and 2023. Interestingly, none of the whole-of-government scenarios in the 2020 report appear to match the arrangements instituted for Covid-19 as described in other DHA materials and testimony. The "natural disaster" whole-of-government framework listed in the 2020 AGCMF report appears to most closely accord with that described elsewhere for Covid-19. However, pandemics are not included under the "natural disaster" heading in the AGCMF report. Rather, pandemics are listed as falling under the "public health" whole-of-government framework (with Minister for Health oversight).

In addition to information summarised thus far, the 2022 AGCMF report notes that one of the NCM's critical objectives is to, "coordinate information and messaging and maintain community confidence in government(s), their agencies and processes" (p.43).

Unsurprisingly, given the difficulty piecing together these disparate sources of information, no media outlets of which I am aware reported on the appointment of DHA, via the NCM, to coordinate Australia's whole-of-government response. Indeed, in a July 2020 interview on the DHA's response to Covid-19, the then Home Affairs Secretary declined to mention his department's coordinating role. Similarly, a 2021 *Guardian* article wrote, "Despite not having direct responsibility over social media companies like Facebook and Twitter, *or being responsible for the government's response to the pandemic*, [emphasis added] Peter Dutton's mega agency has sent more than 500 takedown requests for misinformation and scams related to Covid-19."

In short, the Australian public were not kept apprised of the Government's decision on 5 March 2020 to appoint DHA as coordinating authority over its whole-of-government response, under the newly created NCM. With DHA having been created in 2017 to assume "responsibility for all national security" as part of sweeping intelligence agency reforms, amid criticism for enabling "an undue aggregation of authority and power" and "securitising a space that is about more than security," it seems likely that bringing Australia's Government Covid response under the oversight of a such a controversial national security body might have been an unpopular decision with many Australians. Accordingly, whether DHA's new powers under the NCM represent the securitisation of a space that is about more than security (i.e. science, medicine, and public health), and a further undue aggregation of authority and power, seem pertinent questions for a Covid Royal Commission.

Specific potential questions for a Royal Commission arising from the information above include:

A. Why was the Australian public not kept informed of DHA's role in the Australian government's Covid response?
B. Why did the Media Release of 5 March neglect to explain the implications of invoking the NCM for DHA's involvement?
C. Does embedding the DHA's NCM into Australia's emergency management framework going forward exacerbate pre-existing concerns about DHA "securitising a space that is about more than security," and fostering "an undue aggregation of authority and power"?
D. Why was the public announcement on 27 February, that Australia was following the Covid-19 Plan, which placed the whole-of-government response under the Department of Health rather than the Department of Home Affairs, allowed to stand, without publicly explaining that this arrangement had been superseded on 5 March, replacing the Department of Health with the Department of Home Affairs as the coordinating body?
E. Was there a case of deception by omission at work here? It is untenable that the Australian Government did not understand the importance of public messaging, nor how to implement such messaging, particularly in the context of the shock-and-awe information operations undertaken to drive compliance with government Covid measures.
F. Given that the then Secretary for Home Affairs had a great deal to say to the 'Bushfire' Royal Commission about the DHA's involvement in Australia's Covid response, why was that information not publicly shared?
G. What are the implications of this omission in terms of manipulating citizens into compliance with government measures such as stay-at-home orders, restrictions on gatherings, travel restrictions and vaccine mandates? If the social contract underpinning compliance was founded on a public perception that Australia's whole-of-government response was being coordinated by the Health Department rather than a national security department, was the public misled into following government orders?
H. What was the decision-making process behind creating and invoking the NCM on 5 March? What communication was undertaken, between whom and/or which bodies? Including any outside Australia.
I. What role if any did the DHA play in government decision-making regarding measures such as stay at home orders, restrictions on gatherings, travel restrictions, quarantine measures, lockouts, mask mandates, vaccine mandates and vaccine certificates? (Including via any of its mechanisms and divisions such as EMA, CCC or NCM, and/or mechanisms involving the DHA secretary and/or other DHA personnel, such as the NCCC; and including via informing, communicating or collaborating with health management mechanisms or authorities such as CMOs, health ministers or the AHPPC).
J. What communications took place between DHA and its industry partners with respect to measures such as stay at home orders, restrictions on gatherings, travel restrictions, quarantine measures, lockouts, mask mandates, vaccine mandates and

vaccine certificates? What communications took place between the DHA and scientific or medical experts with respect to the above?

K. Did the DHA and its whole-of-government framework deem non-pharmaceutical interventions such as stay at home orders, restrictions on gatherings, travel restrictions, quarantine measures, lockouts, mask mandates, vaccine mandates and vaccine certificates to be part of, or outside of, the health management of Covid-19?

L. How does the claim that the DHA coordinated only activities outside the direct health management of Covid-19 accord with the reality that, under EMA leadership, the ADF clearly engaged in a wide range of direct health management practices? (Such as administering vaccines, staffing a hospital emergency department, and working with paramedics.)

M. Why was extensive external consultation undertaken with industry stakeholders across a wide range of sectors (over 30), while no comparable external consultation appears to have taken place with scientific and medical experts, for instance across a comparable range of specialties?

N. To what extent did DHA's role providing daily (and for much of 2020 twice-daily) intelligence briefings, and disseminating information to stakeholders and informing decision-making via the CCC, influence in a circular fashion the guidance coming back to DHA from said stakeholders, including government colleagues, health officials and health bodies such as the AHPPC?

O. What safeguards were in place to avoid such a circular recycling of information and advice?

P. To what extent did direct health coordination mechanisms such as the AHPPC utilise information disseminated by DHA, via any of DHA's mechanisms such as the CCC / NSR, meetings, personal communications, or daily briefings?

Q. Which organisations and/or stakeholders have been invited to a seat at the NCM since its creation on 5 March 2020?

R. Who was on the board of the National Coordination Mechanism from 2020-2023?

S. Who were/are the NCM's industry partners mentioned on the DHA website, and what is the extensive list of NCM stakeholders cited in the DHA 2020-2021 Annual Report?

T. What was discussed at the hundreds of NCM Cross Jurisdictional Fora held between 2020 and 2022? What do the minutes of those meetings contain?

U. What representatives from which industries attended weekly Crisis Coordination Centre briefings?

V. What are details of the DHA's "information operations" cited in its 2019-2020 Annual Report? Was there any coordination with international bodies, whether public or private, including Five Eyes partners, over information operations and strategic communication efforts? If so, what are the details of those communications and collaborations?

W. Which domestic and international partners, and which departments and agencies, worked with the DHA's All Source Fusion Cell (ASFC) information operations group? What are the details of the 60 or more ASFC reports and 180 or more referrals to digital industry and law enforcement for further "prevention, disruption"

(i.e. censorship) and "strategic communications" related to Covid-19?

X. What process of scientific and medical due diligence, other than consulting government colleagues, was undertaken to inform these information operations and "misinformation" activities?

Y. What training and/or briefings did the DHA (including any of its divisions or response mechanisms or staff) provide to ADF agencies and/or personnel?

Z. What was the pandemic preparedness exercise undertaken two and half years prior to the DHA director's Bushfire Royal Commission testimony of 2020? What external and/or international, private and/or governmental entities, if any, were involved? What were the details of the exercise? How did it relate to DHA's activities in 2020?

AA. What messaging or information was distributed by DHA via CCC, to whom or what stakeholders or bodies, with respect to Covid-19? What was the source of that information besides online narratives and social media? What due diligence was undertaken with respect to its quality and veracity?

Answer 2: In respect of Reference E, what if any possible shortcomings may have arisen and should be investigated and examined when a department of national security was made responsible for directing Australia's whole-of-government public health response to Covid-19?

Building upon points raised in answer to Question 1, I submit that two primary shortcomings that arise and should be investigated when a department of national security is made responsible for coordinating Australia's whole-of-government public health response to Covid-19 is that its approach is fundamentally incompatible with: A) the principles of science, and B) the tenets of evidence-based medical care. Which makes the national security emergency management paradigm wholly inappropriate for a public health matter such as Covid-19.

A) Incompatibility with the Tenets of Science

The scientific paradigm is based in a set of core principles and practices, whose object is accurate and reliable knowledge. Throughout Covid-19 citizens were entreated to follow science, as their health and safety depended upon it. An accurate understanding of the risk / benefit calculus they faced, spanning Covid-19 and its countermeasures (whether lockdowns, masks, or vaccines), was critical for citizens' health, for their wellbeing, and for society at large. In this way, perhaps as never before, science and survival – physical, emotional and social – became intertwined. Faced with the uncertainty of a purportedly novel virus, which was met with novel nonpharmaceutical measures such as lockdowns, followed by novel gene-based and nanoparticle-based vaccines, many citizens turned to their governments and their government authorities for guidance. Those governments and their authorities, therefore, acquired a solemn responsibility to anchor their guidance, and their actions, in science. Which involves:

(i) A hypothesis-testing approach, whereby scientific positions are held as hypotheses,

which remain fluid and under perpetual review as new evidence comes to light.
(ii) Peer review, by which hypotheses are held up to collective critique and scrutiny, to ensure that only the most reliable and valid positions survive, and:
(iii) Persistent scrutiny of the quality of evidence entertained, with an emphasis on reliability (replicability) and validity (in other words that constructs, such as PCR test results, represent what they claim to represent), along with reliance on sources that are independent (absent conflicts of interest), primary rather than secondary, and possess the relevant subject matter expertise.

None of these tenets were to be found in the DHA's approach to coordinating the whole-of-government response from 2020-2023. Based on the DHA's involvement described in response to Question 1, I will address each of the three principles in turn.

(i) A hypothesis-testing approach, whereby scientific positions are held as hypotheses, which remain fluid and under perpetual review as new evidence comes to light.

As discussed in my answer to Question 1, the essential structure of the DHA's emergency response mechanism was the antithesis of a hypothesis-testing approach. With respect to hypothesis-testing in the Covid era I wrote in 2020 (unpublished, see Appendix):

> Contrary to some widely publicised claims, there is no 'scientific consensus' on Covid-19. This is particularly true of government measures such as lockdowns and social restrictions. In reality, scientific theories are not typically readily or easily 'proven', and scientific 'facts' are not readily or easily obtained, let alone readily widely agreed upon.
> Science involves a process of **hypothesis-testing**, whereby hypotheses (i.e. educated guesses) are proposed, and the wider scientific community tests, critiques, evaluates and re-evaluates those hypotheses, based on evidence and informed analysis by experts in relevant fields.
> To arrive at a valid scientific position, a '**convergence of evidence**' is sought, whereby hypotheses gain stronger or weaker support over time, depending on how the underlying hypotheses hold up to data collection, replication and peer review… Crucially, ***science only progresses through debate and discussion of competing hypotheses***. Disagreement is the essence of science.
> In the case of Covid-19, however, the opposite process has taken place. Rather than adopting a scientific stance of openness, in which hypotheses and data are held up to scrutiny, a deeply **anti-scientific rush to premature judgement** has occurred. Due largely to the surrounding political context, the usual scientific hypothesis-testing

> processes have been curtailed, an environment of peer review and collective critique has been shut down, and the public has been misled into a false sense of scientific certainty, before a realistic, evidence-based understanding of Covid-19 could emerge.

In Australia's case, the DHA's whole-of-government response was a prime example. From the outset, DHA's involvement was predicated on precisely the anti-scientific rush to premature judgement described above, both regarding the threat posed by Covid-19 and the necessity, efficacy and safety of its countermeasures. Locking into place a pre-set emergency response template on 5 March 2020, as described in answer to Question 1, flew in the face of science. Once activated, there was no room under the DHA's emergency response template to review the initial emergency assessment as new evidence and understanding came to light, which a hypothesis-testing approach demands. By sweeping pandemics under the DHA's "elastic", "all hazards" purview, the same set of assumptions applicable to a clear and unambiguous single incident emergency such as a bushfire or cyber attack, whose instigating event requires no ongoing re-appraisal, were applied to the vastly different case of a purportedly novel infectious disease.

This was particularly inapplicable in the case of Covid-19 whose true nature and dangerousness was initially unclear, and the object of early and ongoing scientific debate (see Appendix). A science-based emergency response would have engaged in not only regular and ongoing reappraisal of the nature of the threat posed by Covid-19, but also that posed by proposed countermeasures. Those reappraisals would have involved risk-benefit analyses that were calibrated in line with a representative sample of evidence from quality sources (as opposed to a narrow selection of evidence from favoured sources, in line with confirmation bias). As it was, however, once activated the DHA's emergency response mechanism rolled forward without looking back. The attendant failure to differentiate between vastly different kinds of instigating events (scientifically complex versus not), with a response template that was deemed transferrable across substantively different 'vectors', rendered the entire DHA emergency mechanism not only inapplicable to Covid-19 but inherently unscientific.

Indeed, as early as March 17th, just 12 days after the DHA's NCM had been instigated, while government measures were being proposed and decided upon, John Ioannidis (professor of medicine, epidemiology, population health, biomedical data science and statistics at Stanford University), wrote, "the data collected so far on how many people are infected and how the epidemic is evolving are utterly unreliable". He warned that while Covid-19 was being framed as a once-in-a-century pandemic, the science was shaping up to be a "once-in-a-century evidence fiasco".

Similarly, while lockdowns, quarantine and social distancing were predicated upon the notion of asymptomatic transmission, such that the healthy were deemed to be infectious, a large study of nearly 10 million people published in November 2020 dealt a heavy blow to that claim, with not one case of asymptomatic transmission detected. Moreover,

a Lancet study of 50 countries published in August 2020 concluded that "government actions such as border closures, full lockdowns, and a high rate of Covid-19 testing were not associated with statistically significant reductions in the number of critical cases or overall mortality." In addition, several studies in 2020 indicated that a substantial proportion of the population already possessed cellular immunity to SARS-CoV-2 based on previous coronavirus exposure, conferring immunity that appeared to be robust and lasting (over 17 years - see Appendix, pp.20-24). This undermined the claim that SARS-CoV-2 was immunologically novel, leaving populations immunologically unprotected, and requiring lockdowns and vaccines as a result. Nevertheless, the DHA's emergency response mechanism was immune to such evidence. Once in train, like a military operation, the emergency campaign rolled on.

(ii) Peer review, by which hypotheses are held up to collective critique and scrutiny, to ensure that only the most reliable and valid positions survive.

I wrote in 2020 (see Appendix):

> Professor Michael Levitt, biophysicist from the Department of Structural Biology in the School of Medicine at Stanford University, and recipient of the Nobel Prize for Chemistry in 2013, remarked in June 2020.
> "We let economics and politics dedicate the science… And the fact is that almost all the science we were hearing - for example, from organisations like the World Health Organisation - was wrong. We had Facebook censoring [views contrary to] the World Health Organisation. This has been a disgraceful situation for science… For political reasons, we as scientists let our views be corrupted. The data had very clear things to say. Nobody said to me: 'Let me check your numbers'. They all just said: 'Stop talking like that'."
>
> The net result has been an arrested development of the public understanding of Covid-19, whereby knowledge about the virus was frozen at a very early moment in time, when empirical information was just emerging, and scientific knowledge was tentative to non-existent.
> Now, efforts to engage in the usual scientific practices of peer review, collective critique and critical discussion are being branded "dangerous". Much information in the public domain regarding Covid-19 is therefore highly censored, highly politicised, poorly scrutinised and out of step with the existing evidence-base.
>
> In other words, it is the embodiment of science to challenge pretensions to a 'scientific consensus' on Covid-19

In the DHA's case, with its information operations branding online content as 'dangerous', and its command-and-control frameworks, its approach was incompatible

with the critical enquiry that lies at the heart of science. The DHA Secretary described to the Bushfire Royal Commission a top-down organisational structure with centralised decision-making, which enabled rapid roll-out of pre-templated, if partially flexible, response plans. Which is no doubt effective in national security contexts where a high level of mass coordination is key, or for natural disasters where rapid responses are critical. However, in the case of Covid-19 what was required was evidence-based responsivity to a scientifically complex and evolving biomedical landscape. Which requires infinitely more flexibility and a critical interrogation of evidence and assumptions than the DHA doctrine allowed. Similarly, the DHA's approach to information control, policing of speech, and online censorship may well align with the ethos of a national security environment, in which compliance with superiors' orders is demanded. It embodies, however, an intolerance of disagreement and dissent that is fatal to science.

An additional shortcoming of a command-and-control approach to Covid-19 and its countermeasures, where a range of different and legitimate scientific positions apply, is the risk of groupthink. Groupthink is a potentially catastrophic failure of group decision making. It is prone to occur within forceful top-down command structures, when decisions are taken under stress and time pressure (the DHA prided itself on the rapidity of its responses), with little contradictory outside influence, little tolerance of disagreement, and castigation or punishment of dissenters. This psychological formula, in my opinion, provides an apt description of the DHA's approach to Covid-19, as summarised in response to Question 1.

(iii) Persistent scrutiny of the quality of evidence entertained, with an emphasis on reliability (replicability) and validity (in other words that constructs, such as PCR test results, represent what they claim to represent), along with reliance on sources that are independent (absent conflicts of interest), primary rather than secondary, and possess the relevant subject matter expertise

Once again, the DHA showed no appreciation of these tenets of science. The pace of DHA's actions, which is no doubt an asset in national security or natural disaster contexts, left issues of scientific reliability for dead. Verifying the reliability of scientific findings requires efforts by different investigators to replicate and extend each other's findings, using different methods, measures and samples, while seeking to rule out alternative explanations. It is a process that takes time, which no amount of emergency management experience or pandemic preparedness can overcome.

Lest it be countered that 2020 afforded no time for science as lives were at stake, this position is misguided (see Appendix, pp.12-16). In fact, the rush to premature judgement obscured the reality that the countermeasures themselves carried their own risk / benefit calculus, requiring an equally reliable scientific response. Casting scientific considerations aside to run from one unreliable position to the next may have ticked boxes on the emergency management schedule, but it created very serious dangers all its

own. It risked an out-of-the-frying-pan-into-the-fire scenario, which, by many measures appears to be what occurred (see the Appendix and others' submissions regarding other Terms of Reference for details).

In terms of scientific validity (the principle that constructs should represent what they claim to represent) the DHA's Border Force began implementing border controls in response to the first PCR-defined Covid 'case' on 25 January, 2020. However, the reliance on PCR tests, particularly at the high amplification cycles routinely applied to Covid-19, were known not to be diagnostic of infection, nor to constitute evidence of an active Covid 'case'. In other words, as performed and interpreted with respect to Covid-19 they were scientifically invalid (see Appendix, pp.17-20). Being a national security body rather than a scientific body, the DHA appears not to have assessed the validity or otherwise of its central metric – a PCR-defined Covid 'case'. Had the department's core area of expertise been science rather than national security, this may have been a different matter.

As regards seeking sources that are independent and absent conflicts of interest, two features of the DHA's standard operating procedures worked against such an outcome. One involves following set lines of command, including relying narrowly on fellow government officials such as Chief Medical Officers, at the expense of a representative sample of independent and appropriately specialised outside sources. The second is the industry-focussed, corporate-centric nature of the DHA's NCM.

In the case of a complex and contested realm of science such as Covid-19 and Covid-19 countermeasures, the former bias risks drawing too heavily on the same pool of institutionally recycled opinion and information, with colleagues who are subject to shared pressures and influences (whether groupthink or the influence of 'stakeholders'), limiting the range of perspectives and understandings involved. It also underestimates the difference in levels of specialist expertise between a career government official or bureaucrat and active researchers and practitioners in their fields.

The second issue, i.e. a heavy focus on industry partnerships under the NCM, risks not only bias and groupthink but outright conflicts of interest, where scientific interests take a back seat to commercial ones. This risk is particularly salient in a culture where senior officials "use their personal contacts, their networks, their deep insight" (p.2723) into the private sector to augment their government activities. The fact that the former DHA Secretary, who sat at the DHA helm of Australia's whole-of-government response from March 2020 to September 2023, described such an ethos among fellow Commissioners was a case in point. His later dismissal over failing to disclose conflicts of interest and using his power for personal benefit only brings the point to life.

Under the circumstances, it seems pertinent to ask whether powerful stakeholders with profits to be made from Covid measures exerted any influence over whole-of-

government actions between 2020 and 2023, via the DHA or its NCM. Regardless, the fact that this question hangs in the aftermath of DHA's stewardship of Australia's whole-of-government response is an indictment of the corporate-focus, rather than science-focus, of the DHA emergency response mechanisms. Given that the NCM has been embedded into Australia's emergency response architecture going forward, whether a DHA-led emergency response should be applied to public health crises in the future, risking once again elevating industry over science, is, in my view, a critical question for a Covid-19 Royal Commission.

With respect to relying on primary rather than secondary sources (primary sources being clinical trials, empirical research, data, original documents and so-on), the DHA showed no cognisance of this distinction in its approach to information-gathering. The fact that DHA drew upon online platforms and social media to issue information to stakeholders and national decision-makers via the CCC, and to provide daily intelligence briefings, is staggering. The fact that DHA actively censored the same platforms upon which it relied is more staggering still.

In terms of relying on sources with appropriate subject matter expertise, the DHA's readiness to lump pandemics together with fires and floods, while viewing generalist public servants as possessing sufficient specialist subject matter expertise, reveals how ill-equipped a national security body is to consult appropriately on matters of science. Even appreciating which disciplines were pertinent to understanding Covid-19 and its countermeasures appeared to be lacking (i.e. immunology, microbiology, infectious disease, pharmacology, epidemiology, emergency medicine, respiratory and cardiovascular medicine, clinical trials and so-on). Rather, the DHA Secretary deemed "pandemics" to be a "discipline" in its own right.

Put differently, should the tables be turned, appointing a scientific body to coordinate a national military campaign would be equally nonsensical and reckless. Knowing whether to consult signals intelligence, navy, army, cyber, submarine and so on, which rank, in what order, and how to evaluate conflicting advice would be beyond a team of scientists. Likewise, national security bodies should not be expected to know with whom and how to consult on matters of science. In my submission, both scenarios are equally dangerous.

B) Incompatibility with the Tenets of Evidence-Based Medical Care

Finally, despite the DHA purportedly limiting its whole-of-government activities to those outside the direct health management of Covid-19, it nevertheless involved itself in the nationwide vaccination campaign. This occurred both via ABF facilitation of vaccine imports across borders and the direct administration of vaccines by ADF personnel. While the nationwide mass administration of vaccines was consistent with the DHA director's doctrine that emergency responses are "best managed on a national basis" (p.2728), it was incompatible with medicine and science. Evidence-based medicine revolves around the doctor-patient relationship, whereby medical interventions are

tailored to each individual person, their medical needs, and their particular risk profile, based on a doctor's patient-specific knowledge combined with relevant available science. What is safe and effective for one person may be dangerous or counterproductive for the next. Mass deployment of medical interventions on a nationwide scale, however, precludes this process from taking place. As a result, it violates the principle of non-maleficence (do no harm) by taking medical care out of the doctor's consulting room and placing it on a political, whole-of-government stage. It is a trans-vector, all-hazards approach that may align nicely with the DHA's emergency management doctrine, but it is devastating for evidence-based medical care, and public health.

Potential questions for a Covid Royal Commission arising from the above include:

A. What process of review, if any, did DHA undertake in 2020 and 2021 to assess the legitimacy and necessity of its emergency response, as the understanding of Covid-19 evolved?
B. What does DHA mean when it says its staff, who are generalist public servants first and foremost, specialise in the "discipline" of pandemics? What due diligence did senior DHA staff undertake to ensure that they grasped the wide range of subject matter expertise necessary to genuinely understand pandemics and their countermeasures, and therefore to consult adequately and appropriately, in the interests of crafting an appropriate and proportionate whole-of-government response?
C. What is the full list of scientific experts, bodies, research papers and literature consulted by DHA (including its divisions, mechanisms and personnel) to inform its activities, its messaging, and its guidance?
D. What due diligence was undertaken to ensure that DHA's misinformation activities, including removal of content it deemed "harmful", accorded with rigorous, evidence-based science? What is the full list of scientific experts, bodies, research papers, and literature consulted by DHA (including its divisions, mechanisms and personnel) to guide its censorship activities?
E. What process did DHA undertake to scrutinise its sources of information for conflicts of interest? Given that it relied on social media and online platforms for its understanding of events, was it aware that Reuters, for instance, which "fact checked" online content, had ties to Pfizer?
F. What scientific due diligence was undertaken to inform and guide DHA's activities intercepting Ivermectin and Hydroxychloroquine? From whence did the decision to intercept these medicines originate?
G. What communications took place between DHA (and/or its divisions or personnel) and its industry partners with respect to the above?
H. Was there groupthink at work in the DHA's understanding of, and response to, Covid-19? Given the number of risk factors for groupthink present in DHA's processes and practices, what safeguards were in place to mitigate against it? Are they adequate?

The NCM is described by DHA as bringing together government and private

stakeholders "in a way that has never been done before", and by the Bushfire Royal Commission as, "enable[ing] the Department [of Home Affairs] to work hand-in-glove with our Commonwealth colleagues as well as the State and Territories and industry". Thus, in the wrong hands or under the wrong confluence of circumstances, the NCM is ideally placed to serve as a vehicle for conflicts of interest and corporate capture.

Accordingly:

- In light of the magnitude of pharmaceutical profits to be made from pandemics and other public health emergencies, with Pfizer earning $36 billion from its Covid vaccine in 2021 alone, is the NCM, with its heavy industry focus, an appropriate mechanism for coordinating whole-of-government responses to public health crises?
- Given that the government official with authority over the DHA and NCM from 2020 - 2023, and therefore the whole-of-government response, was found to have held conflicts of interest and abused his power, what steps if any are being taken to protect Australian citizens from similar abuses of power infecting whole-of-government responses to public health crises going forward?
- What contact and/or communication did the DHA (or its divisions, mechanisms or personnel) have with the pharmaceutical sector, including the manufacturers of Covid vaccines deployed in Australia? (e.g. Pfizer, BioNTech, AstraZeneca, Moderna, and Novavax)
- What role if any did DHA play in federal and state governments' vaccine mandates? Did any parties to mandating vaccines (e.g. National Cabinet, National Security Committee, CMOs, Health Ministers, AHPPC or other involved parties) derive any of their information via the DHA or its mechanisms (e.g. CCC, NCM, daily intelligence briefings, and so-on)
- How can the Australian public be assured that government public health advice, such as vaccine mandates, have been issued in citizens' best interest rather than those of corporate stakeholders? Particularly in the case of profitable pharmaceuticals whose necessity, efficacy and safety were scientifically questioned from the start? What mechanisms and safeguards if any are in place to protect against such risks moving forward? Are those safeguards adequate?
- If conflicts of interest and abuses of power in applying the NCM cannot be ruled out, should it be disbanded?

Should DHA be allowed to coordinate whole-of-government responses to public health emergencies again?

Appendix: Unpublished Fact Sheet, 2020

Covid – State of the Data

Since a pandemic was declared by the World Health Organization (WHO) on

March 11th 2019, discussion of medical and scientific information regarding Covid-19[ix] has been subject to a level of government and media control that is unprecedented in recent history. The resulting environment of censorship and smear has served to curtail open discussion on a range of important medical and scientific issues surrounding Covid-19.
Several myths and misconceptions support this climate of censorship. They are addressed in turn below.

It is anti-scientific to question the scientific consensus on Covid-19

Contrary to some widely publicised claims[x], there is no 'scientific consensus' on Covid-19. This is particularly true of government measures such as lockdowns and social restrictions. In reality, scientific theories are not typically readily or easily 'proven', and scientific 'facts' are not readily or easily obtained, let alone readily widely agreed upon.
Science involves a process of **hypothesis-testing**, whereby hypotheses (i.e. educated guesses) are proposed, and the wider scientific community tests, critiques, evaluates and re-evaluates those hypotheses, based on evidence and informed analysis by experts in relevant fields.

To arrive at a valid scientific position, a '**convergence of evidence**' is sought, whereby hypotheses gain stronger or weaker support over time, depending on how the underlying hypotheses hold up to data collection, replication and peer review. In fact, so central is critique and collective endeavour to science that scientific papers typically end on a critique of their own methodology and conclusions, along with suggestions for further research and review.

Crucially, ***science only progresses through debate and discussion of competing hypotheses***. Disagreement is the essence of science.

In the case of Covid-19, however, the opposite process has taken place. Rather than adopting a scientific stance of openness, in which hypotheses and data are held up to scrutiny, a deeply **anti-scientific rush to premature judgement** has occurred. Due largely to the surrounding political context, the usual scientific hypothesis-testing processes have been curtailed, an environment of peer review and collective critique has been shut down, and the **public has been misled into a false sense of scientific certainty**, before a realistic, evidence-based understanding of Covid-19 could emerge.
As early as March 17th, when government measures were being proposed and decided upon, John Ioannidis (professor of medicine, epidemiology, population health, biomedical data science and statistics at Stanford University), wrote, "the data collected so far on how many people are infected and how the epidemic is evolving are utterly unreliable". He warned that while Covid-19 was being framed as a once-in-a-century pandemic, the science was shaping up to be a

"**once-in-a-century evidence fiasco**".
Similarly, Professor Michael Levitt, biophysicist from the Department of Structural Biology in the School of Medicine at Stanford University, and recipient of the Nobel Prize for Chemistry in 2013, remarked in June 2020.

> "**We let economics and politics dedicate the science**… And the fact is that almost all the science we were hearing - for example, from organisations like the World Health Organisation - was wrong. We had Facebook censoring [views contrary to] the World Health Organisation. This has been a disgraceful situation for science… For political reasons, we as scientists let our views be corrupted. The data had very clear things to say. Nobody said to me: 'Let me check your numbers'. They all just said: 'Stop talking like that'."

The net result has been an **arrested development of the public understanding** of Covid-19, whereby knowledge about the virus was frozen at a very early moment in time, when empirical information was just emerging, and scientific knowledge was tentative to non-existent.

Now, efforts to engage in the usual scientific practices of peer review, collective critique and critical discussion are being branded "dangerous". Much information in the public domain regarding Covid-19 is therefore highly censored, highly politicised, poorly scrutinised and out of step with the existing evidence-base.
In other words, ***it is the embodiment of science to challenge pretensions to a 'scientific consensus' on Covid-19***

1) But Covid-19 is deadly and unprecedented. We don't have time for a normal hypothesis-testing, collective scientific endeavour. It's dangerous to give people a platform to undermine Covid-19 policy, and risk spreading the disease

In reality, the reverse is the case. Accurate information regarding the lethality and prevalence of Covid-19 has been one of the key casualties of the unscientific approach to this virus.

What has been dangerous is the rush to impose deadly containment measures such as lockdown, which are set to cause millions of deaths worldwide (See Section 9), based on poorly scientifically defined, evaluated and validated population data.

Early over-estimates of lethality

At the outset of the announcement of a pandemic in March 2020, when governments and health bodies were formulating a response, an influential yet

scientifically controversial model of anticipated deaths from Covid-19 was proposed by the Imperial College of London, on March 16th, 5 days after a pandemic was declared, on March 11th. The model predicted up to 510,000 deaths in the UK, and 2.2 million in the US, unless population-wide suppression measures were undertaken. The report recommended mass social distancing, quarantine of Covid-19 cases and their families, and school and university closures, describing such measures as "the only viable option" until a vaccine becomes available, "potentially 18 months or more".

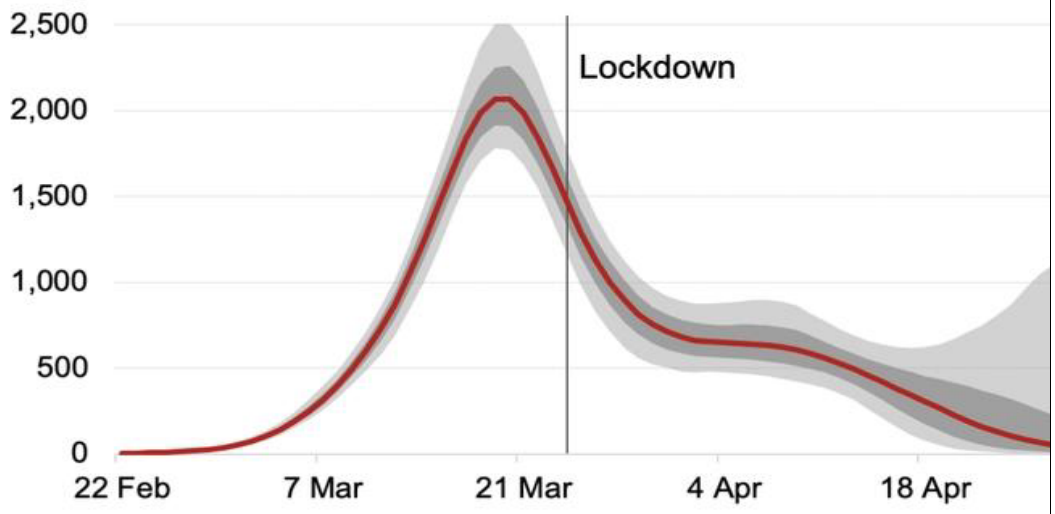
The paper's lead author was a prominent member of the UK Government's Scientific Advisory Group for Emergencies (SAGE) until he resigned from SAGE for violating Covid-19 lockdown rules himself, in late March and early April 2020.

Although (still) highly influential in both the UK and the US, the Imperial College paper was not peer reviewed. One of the world's leading infectious diseases epidemiologists, Professor Senetra Gupta, who was part of a team at Oxford University which produced a different model[xi] on March 26th, noted that she was "surprised that there has been such unqualified acceptance of the Imperial model."

In contrast to the Imperial model, the Oxford model accurately predicted that the "vast majority" of people who contracted Covid-19 would have "mild cases" or be "free of symptoms"; that deaths would "occur only in a vulnerable fraction of the population"; and that the epidemic, left to its own devices, would have "an approximate duration of 2-3 months".

This is indeed what occurred, irrespective of lockdowns and other population-wide measures, around the world. The pattern in England and Wales, for example, followed the trajectory illustrated below.

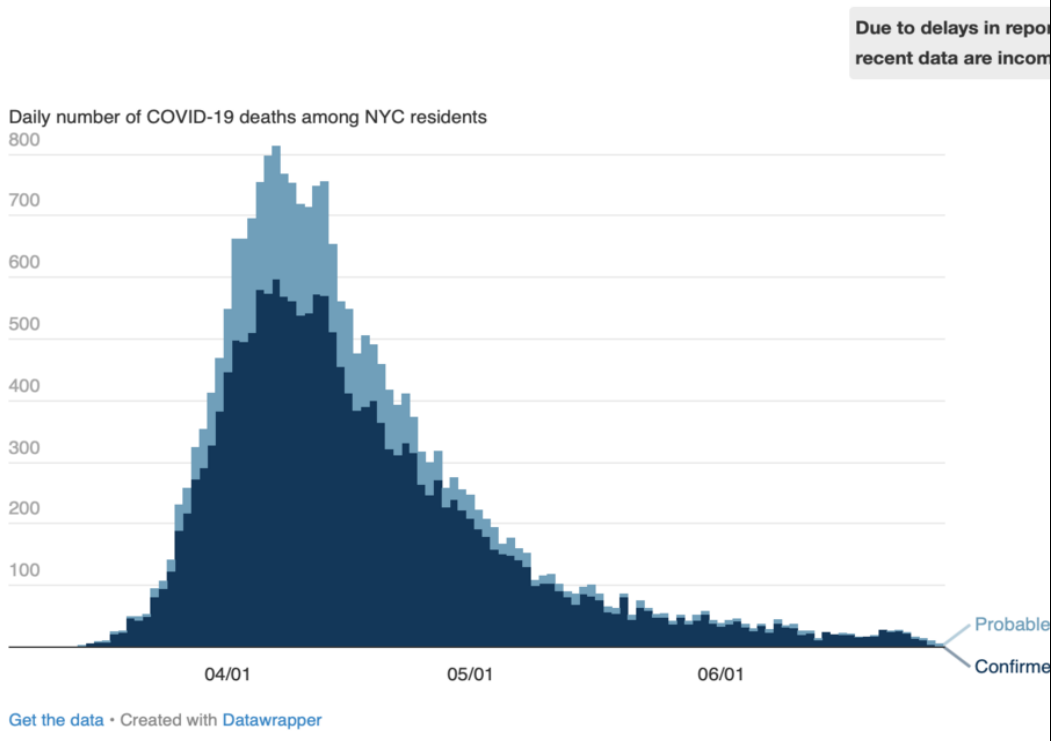
Inferred daily fatal infection rate for Covid in England and Wales

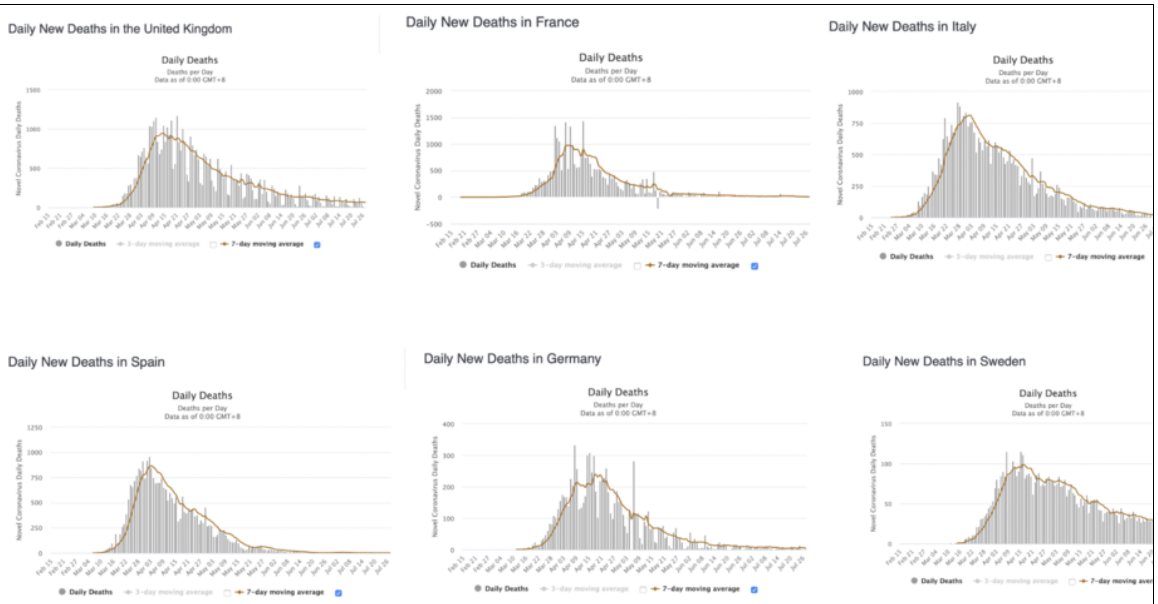


Light grey and dark grey regions show 95% and 68% confidence regions, respectively.
Source: Simon Wood.

Daily Reported Death Totals

New York City's first confirmed COVID-19 death was reported on March 11.

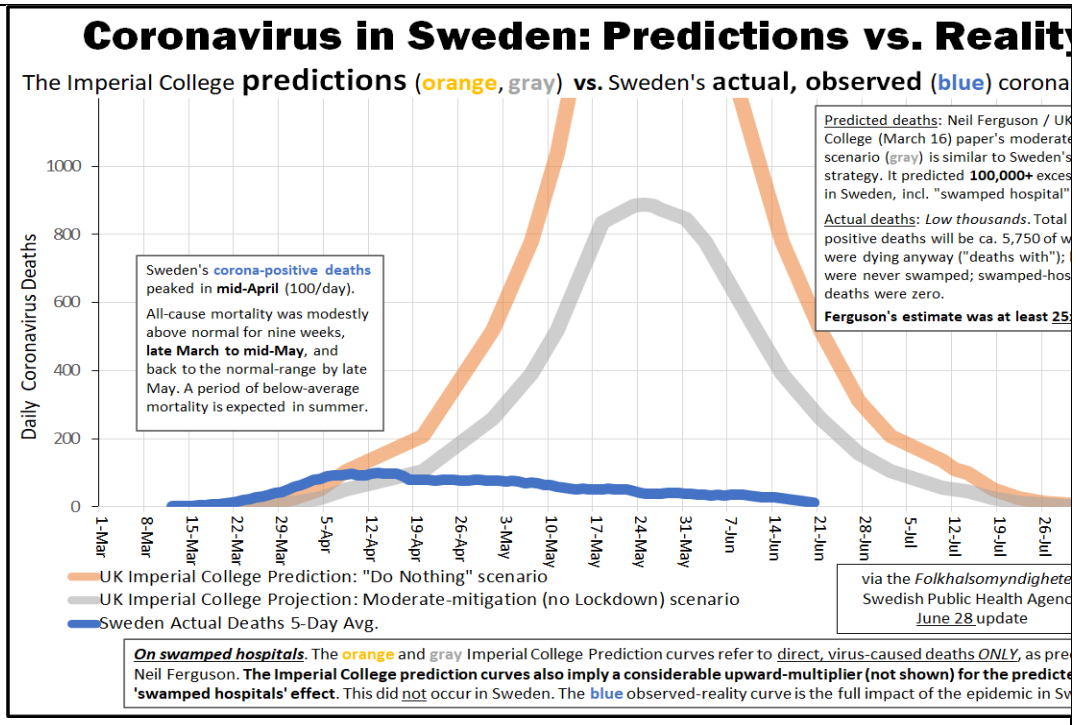




See also here, here, here, here, here, and here.
A Lancet study of 50 countries concluded that "government actions", including "border closures, full lockdowns, and wide-spread testing were not associated with Covid-19 mortality".

In reality, consistent with the Oxford model, irrespective of lockdown and other restrictions, deaths, hospitalisations and severe cases peaked and subsided within a few months, falling far short of the Imperial model's predictions.

According to the Imperial model, for instance, Sweden, which did not implement full suppression measures, should have experienced over 100,000 deaths. Instead it experienced deaths in the low thousands, as the graph below illustrates. In reality, "all cause mortality was modestly above normal for nine weeks, late March to mid-May, and back to the normal range for late May".



As of mid-November, Sweden has a lower per capita and case fatality rate than many countries that locked down, and continue to lock down, such as the UK.

As part of the initial over-estimates of lethality, the **WHO had declared a fatality rate of 3.4%** in March, based on early reports from Wuhan China. By October 7th 2020, however, using global Covid-19 data, a paper in the European Journal of Clinical Investigation (EJCI) by John Ioannidis (of the Departments of Medicine, Epidemiology and Population Health, and Biomedical Data Science, and the Statistics, and Meta-Research Innovation Center at Stanford University), reported a global infection **fatality rate of 0.15-0.20%,** and **0.03-0.04%** for those under 70 years of age.

By way of comparison, the infection fatality rate for influenza is around 0.1%.

The EJCI paper noted that the early inflated fatality estimates were "probably extremely flawed", yet were "irresponsibly circulated widely in media and social media."

In short, government policies involving population-wide suppression measures, including lockdown, are consistent with models that do not fit the data, and inconsistent with models that do.

2) But how could government scientists get things so wrong? It's just not plausible

Dr Michael Yeadon, former Vice President & Chief Scientist for Allergy & Respiratory at Pfizer, with over 30 years experience leading new medicines research, and degrees in biochemistry and toxicology and a PhD in respiratory pharmacology, has said of the UK Government's SAGE membership:

> "There were no clinical immunologists. No one who had a biology degree and a post-doctoral qualification in immunology. A few medics, sure. Several people from the humanities including sociologists, economists, psychologists and political theorists. What there were in profusion – seven in total – were mathematicians. This comprised the modelling group."

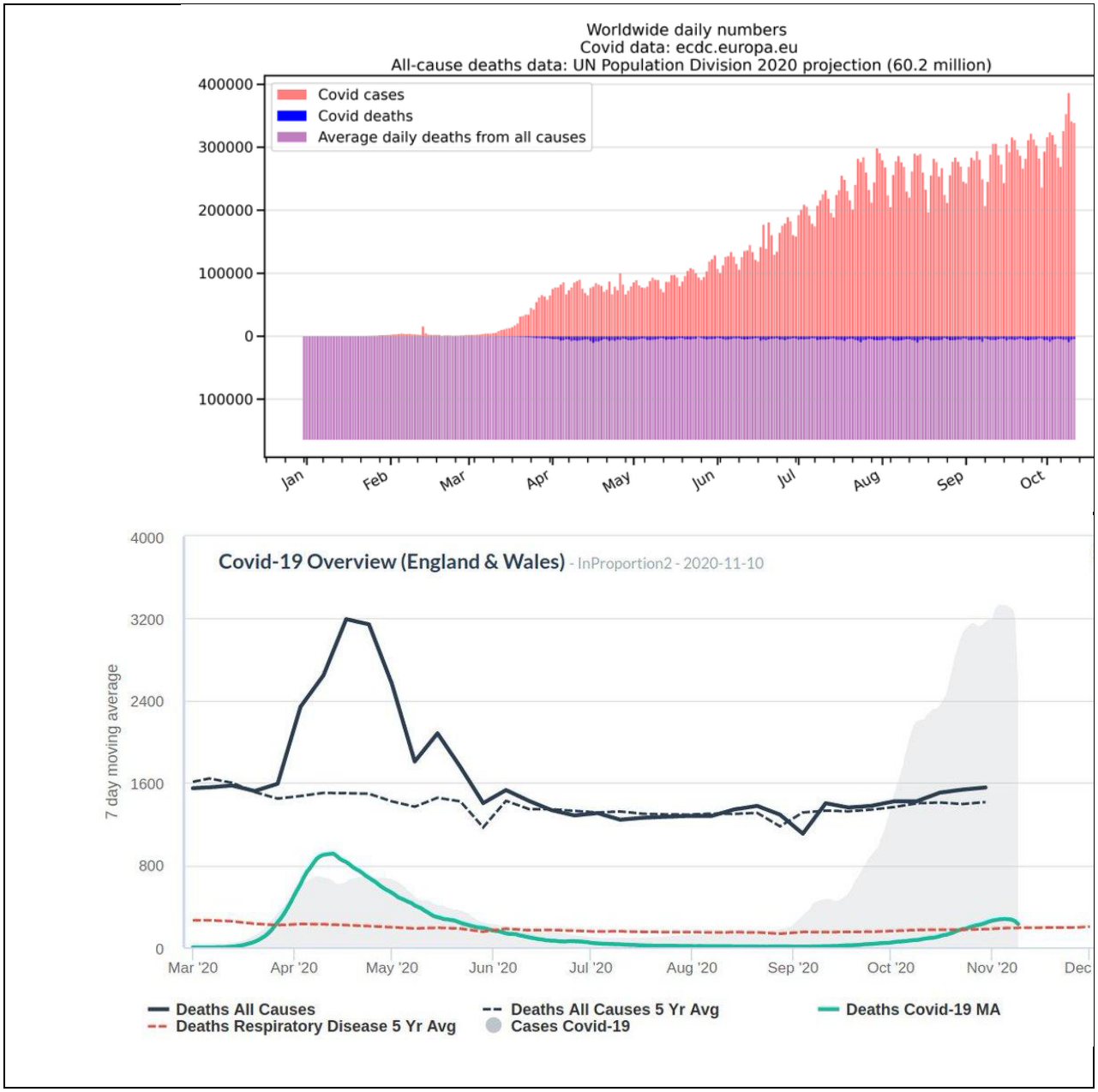
Nobel Prize winner for Chemistry, Professor Levitt of Stanford University, said, "The epidemiologists made their normal error. Epidemiologists see their job not as getting things correct, but preventing an epidemic. So, therefore, if they say it's a hundred times worse than it's going to be, it's okay... They said the same thing for Ebola; they said the same thing for Bird Flu. No-one shut down for them. We should never have listened to the epidemiologists."

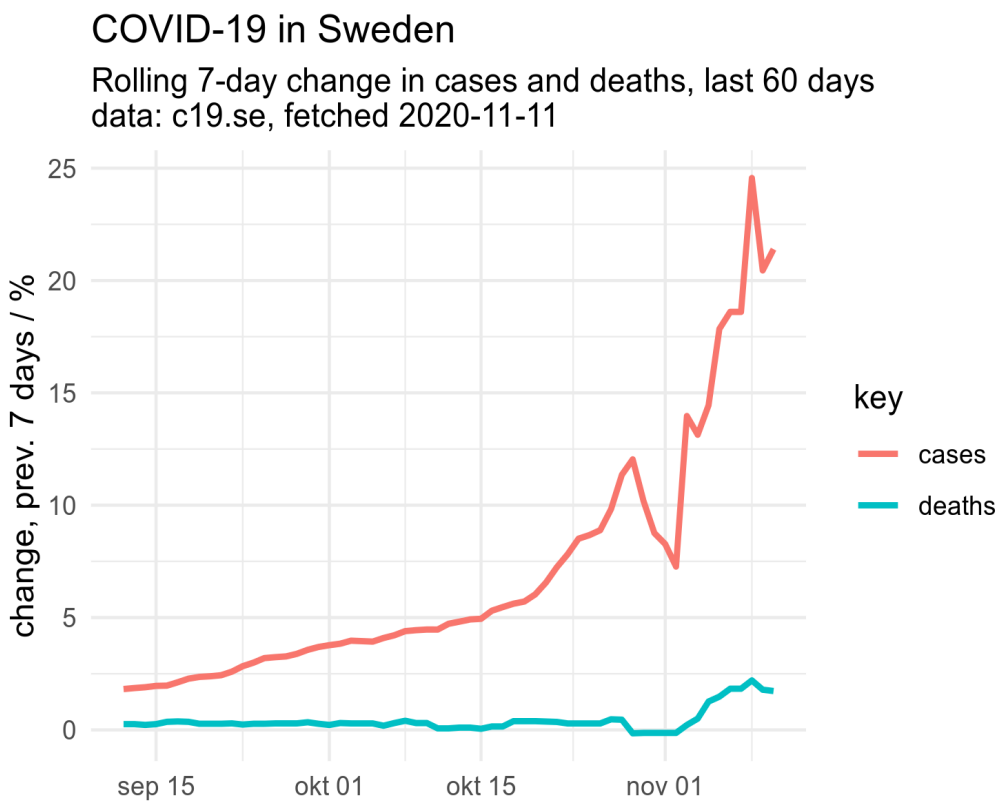
In terms of why the Imperial College epidemiological model received such "unqualified acceptance" as opposed to other models, a New York Times article in March 2020 noted that the Imperial College London historically holds significant sway with governments. The article quoted the director of the Global Health Governance program at Edinburgh University as to why governments tend to heed certain pieces of advice over others. He explained that "a lot of it is not what they say, but who says it."

Dr Yeadon noted, "It's my view that SAGE has been appallingly negligent and should be dissolved and reconstituted properly."

3) That's all well and good, but cases are spiralling out of control now that societies have opened back up. Second waves are happening all around the world. Deaths will follow if we don't clamp down again

Not exactly. There is an **increase in positive PCR test results**, which is **not the same thing as 'cases'**. Mortality is also not following the same trajectory as PCR-defined cases, as the graphs below illustrate, including in Sweden.


Worldwide daily numbers
Covid data: ecdc.europa.eu
All-cause deaths data: UN Population Division 2020 projection (60.2 million)
Covid cases
Covid deaths
Average daily deaths from all causes
400000
300000
200000
100000
0
100000
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Covid-19 Overview (England & Wales) - InProportion2 - 2020-11-10
7 day moving average
4000
3200
2400
1600
800
0
Mar '20
Apr '20
May '20
Jun '20
Jul '20
Aug '20
Sep '20
Oct '20
Nov '20
Dec
Deaths All Causes
Deaths Respiratory Disease 5 Yr Avg
Deaths All Causes 5 Yr Avg
Cases Covid-19
Deaths Covid-19 MA



There are two main potential reasons for the increasing dissociation between cases and deaths. The issue of PCR test results vs cases, and the issue of cellular immunity.

3a) PCR tests and 'cases'

The apparent increase in cases may well be an artefact of testing practices, rather than a true trajectory of Covid-19 infections.

Importantly, PCR tests such as those used to identify Covid-19 **detect fragments of viral genetic material** (RNA). Those fragments must be amplified in the laboratory in order to be detectable. **A positive PCR result may indicate a currently active virus, or leftovers of a previous viral infection that is no longer active**.

As this paper in the Journal of Clinical Epidemiology explains, the PCR test "does not distinguish between the presence of live virus and non-infectious viral debris." The more amplifications of genetic material that are performed in a PCR test, the greater the likelihood that the test will detect remnants of spent viruses, as opposed to active infections.

In the case of Covid-19, the causal virus (SARS-Cov-2), can continue to shed detectable RNA for up to 3 months, according to the Centres for Disease Control and Prevention (CDC).

Given the number of amplifications being performed in Covid-19 PCR tests, a New York Times article reported that **as many as 90% of positive results** in the United States may result from **fragments of viral RNA so small and/or old that the person is carrying "barely any virus"**, and is neither infected nor contagious. In other words, up to 90% of Covid 'cases' may not be active cases at all.

Indeed, the Journal of Clinical Epidemiology explains that testing for **the *virus*** (SARS Cov-2), whether past or present, is distinct from testing for **the *disease*** *(Covid-19)*. Testing for the disease is based not merely on "viral detection" (i.e. PCR tests) but also "on clinical characteristics, epidemiological history, [and] chest imaging,"

Accordingly, the Centre for Diseases Control and Prevention (CDC) wrote in July 2020 that, "detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms."

The Covid 'case' data, then, do not accurately represent the prevalence of Covid-19 illness, or infectiousness, in the population. To portray positive PCR tests as indices of Covid-19 disease prevalence is medically misleading.

Moreover, to use trajectories of PCR results as the basis for emergency powers, repressive legislation, curfews, quarantine, lockdown and other population-wide measures is legally and democratically unprecedented.

Even so, we have no immunity to Covid-19. We need to be protected by things like lockdowns and social distancing until a vaccine arrives.

3b) Population cellular immunity

It is often claimed that there is no natural immunity to Covid-19, because it is a "new" virus, which our immune systems do not recognise, and/or because antibodies to SARS-Cov-2 fade rapidly, or are not produced at all.

However, while it is true that population levels of antibodies for SARS-Cov-2 are low (around 7% according to UK Government estimates), it is untrue that we are therefore necessarily 93% immunologically unprotected against Covid-19.

First, we do not necessarily need antibodies to fight Covid-19; second, antibody resistance is not reliably reflected in blood antibody levels; and, **third**, there is a convergence of evidence **that Covid-19 is not 'new' to our immune systems.** Empirical findings indicate that we can - and do - fight the virus with T-Cells, including based on previous encounters with related coronavirus.

One of the body's primary lines of defence against respiratory viruses such as Covid-19 is cellular immunity. **Cellular immunity** involves **T-cells** rather than antibodies. T-cells go to war against invading pathogens such as SARS-Cov-2, by targeting and killing infected cells, and they 'remember' previous battles, so that they when they encounter the same or similar pathogens again, they can head them off at the pass.
People with a healthy T-cell response may not produce antibodies to mount a resistance. They can fight off a respiratory virus such as Covid-19 with cellular immunity alone. Population antibody levels are therefore a poor indicator of population immunity to Covid-19.

Moreover, circulating antibodies in the blood are not necessarily a good indicator of our level of antibody resistance to a disease, including Covid-19. Once they are no longer needed, antibody 'memory' can be stored in B-cells, which remain ready to produce antibodies again when needed, **without those antibodies showing up in blood tests**.
Furthermore, evidence indicates that rather than being "new" to our immune systems, **Covid-19's immunological cousins, common cold coronavirus**, as well as other more lethal SARS diseases, have **paved the immunological way for Covid-19**.

SAGE, however, is assuming no previous resistance to Covid-19, and relying solely on blood antibody data to estimate population immunity to SARS-Cov-2, and therefore to guide government policies. Dr Yeadon calls the reliance on circulating antibody levels "a truly dreadful error, one that could not have been made but for the inadequate skillsets of the members of SAGE."

Importantly, contrary to government antibody-based assumptions, there are various lines of evidence that **populations have indeed developed cellular immunity to Covid-19,** and that that immunity is likely to be widespread and lasting. The upshot is that neither recurrent lockdowns, nor mass vaccinations, are necessary.

What lines of evidence?

First, there are findings of **SARS-CoV-2 reactive T-cells in people who have never been exposed to the virus**, most likely as a result of previous exposure to common cold coronaviruses. An October 2020 study in *Science*, for instance, found "pre-existing reactivity against SARS-CoV-2" from "memory T cells", indicating that "cross-reactive T cells can specifically recognize a SARS-CoV-2… from a common cold coronavirus."
Such cross-over reactivity is a normal feature of immune function. Dr Yeadon explains:

> "While SARS-CoV-2 is indeed novel, coronaviruses are not. There's no such thing as an 'ancestor-less virus'… It's well understood by clinicians and scientists who've spent any time reading the scientific literature that at least four coronaviruses circulate freely in UK and elsewhere where they've been studied. They have names: OC43, HKU1, 229E and NL63… It is my belief and that of multiple, top quality research groups around the world, that many individuals who've been infected by one or more of these endemics, common-cold producing coronaviruses in the past, have a long-lived and robust immunity, not only to those viruses, but to closely related viruses. SARS-CoV-2 is one such closely-related virus."

Consistent with that hypothesis, this study in the journal *Cell* indicates that ***40-60% of people*** **who have never been exposed SARS-Cov-2 already possess cellular immunity**, due to previous coronavirus exposure. Scientists at the la Jolla Institute for Immunology, which hosts a multi-lab Coronavirus taskforce, explain that the research provides "direct molecular evidence" that "unexposed individuals can produce a range of memory T cells that are **equally reactive against SARS-CoV-2 and four types of common cold** coronaviruses."

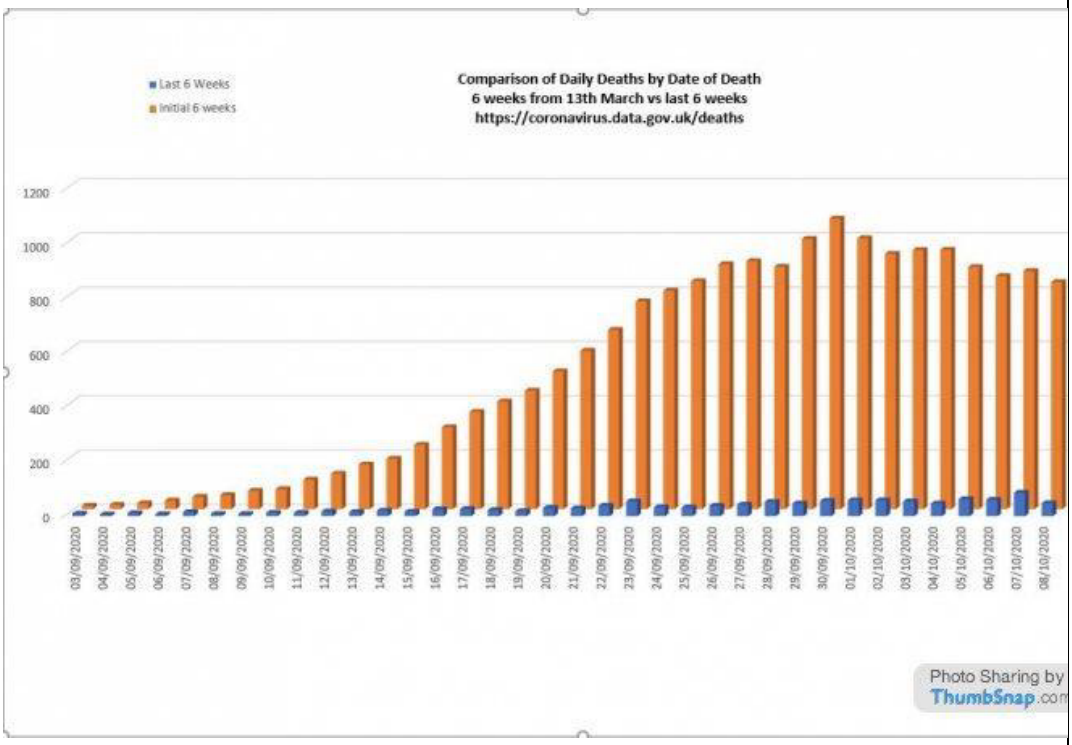
Similarly, a Singapore study published in the journal *Nature* found SARS-CoV-2-specific T cell immunity in both recovered **Covid**-19 and SARS patients. As this report in *Science Daily* explains, "Importantly, the team showed that patients who recovered from SARS 17 years ago after the 2003 outbreak, still possess virus-specific memory T cells and displayed cross-immunity to SARS-CoV-2". The *Nature* paper noted that the cross-reactivity from SARS to SARS-Cov-2, 17 years later, was "robust".

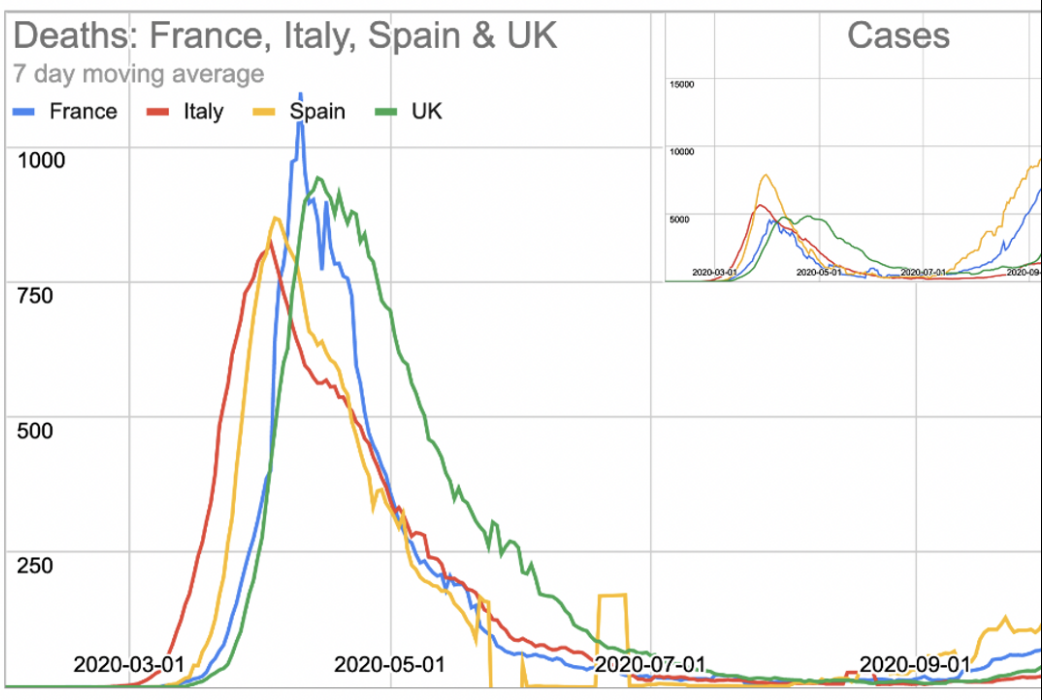
A Second line of evidence comes from other molecular research showing that individuals exposed to SARS-Cov-2 can develop specific SARS-Cov-2 cellular (T-cell) immunity without producing antibodies, such as this study in *Nature Reviews Immunology*, and this one in *Cell*.[xii]

Third, an August 2020 study found that the increase in hospitalisation rates for Covid-19 with advancing age almost exactly "mirrors the exponential decline of thymus volume and T-cell production" across age groups.

Fourth, epidemiological models that account for cellular and pre-existing immunity, as well as individual variation in immunity, hold that since the Covid-19 outbreak, levels of population immunity have developed such that many exposed populations are currently at, or close to, a level of immunological resistance that will no longer support expanding disease.

In accordance with the molecular data, population data indicate substantially decreased lethality of SARS-Cov-2 compared the first few months of the outbreak, as illustrated by the graphs below.





With respect to the antibody-informed models behind government lockdowns, which ignore the existence of cellular immunity, Michael Yeadon has said that

they "run entirely counter to known science regarding viruses". He stressed that "If the model is constructed by people who are not subject-matter experts about the thing being modelled [in this case immunology], then if they've constructed it in error, they will not know."
Indeed so reduced is the lethality and severity of SARS-Cov-2, as molecular T-cell studies would predict, that on 16 October 2020, Dr Yeadon said of the UK, "The pandemic is effectively over, with small, self-limiting outbreaks which will soon subside."

Two weeks later, the UK locked down.

4) Well if all this is true, why would the UK Government use misleading antibody data to guide lockdown, while ignoring valid evidence on cellular immunity?

Apart from the fact that there are "no clinical immunologists" on the SAGE advisory committee, Professor Daniela Weiskopf of the la Jolla institute for immunology told Reuters that "it is a lot easier to collect antibody data" than to test for T-cell responses.

5) Regardless of whether we have cellular immunity, Covid-19 is unusually deadly. Death is death. We can't take any chances

The outbreak of Covid-19 has caused deaths, particularly in the first few months. Of that there is no question. But how many? And how often is Covid-19 the true cause?
Like the data on 'cases' and immunity, the data on 'Covid-19 deaths' have been poorly scientifically defined, assessed and validated, leaving mortality statistics wide open for challenge and misinterpretation.

In the UK, for instance, a 'Covid-19 death' can mean that the person who died "had had a positive [PCR] test result for Covid-19 [as opposed to an active infection] and **died within 28 days of the first positive test**", regardless of whether they suffered from Covid-19 symptoms at the time of death. Even according to the UK Government website, as of late September, in cases listed as Covid-19 deaths, "**the actual cause of death may not be Covid-19**". Earlier in the outbreak, if a person had *ever* tested positive for Covid-19, no matter how long previously, their death was listed as a Covid-19 death, regardless of other more proximal causes.

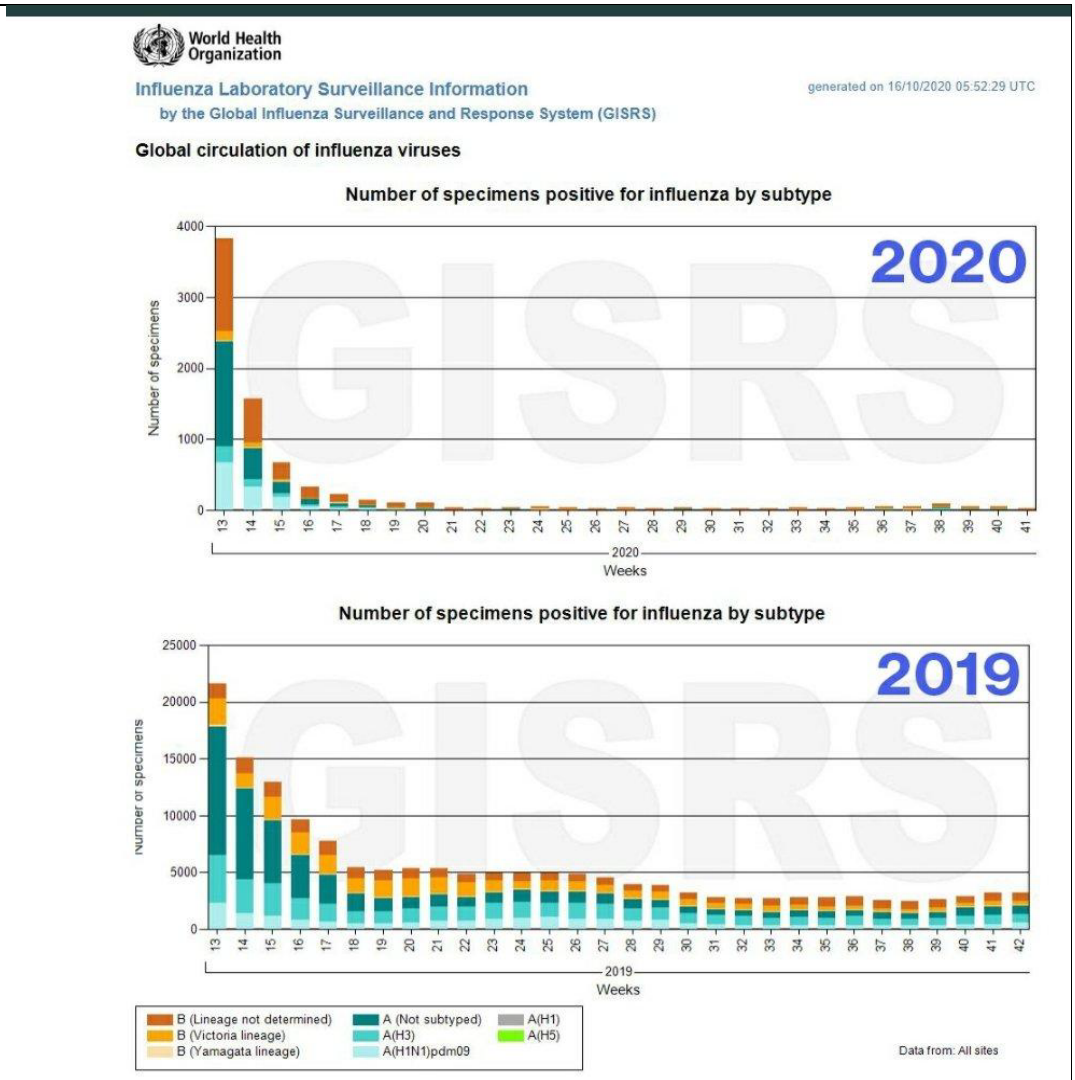
According to Dr Michael Yeadon, in these ways, the gathering of Covid-19 mortality data has entailed "**numerous questionable practices, all designed to artificially increase the number of apparent Covid-19 deaths**."
The resulting ambiguity around the actual cause of death in many cases reflects

the difference between dying **'*of* Covid-19'** versus dying **'*with* Covid-19'**. An Australian doctor, for example, expresses anger here on air that a patient who died of a blood clot in the leg was recorded as a Covid-19 death, despite suffering no Covid-19 or respiratory symptoms at the time of death.

To make matters even more opaque, the definition of 'Covid-19 death' varies from country to country, and across time within countries. Australia**,** for instance, **altered its definition** of a 'Covid-19 case', and therefore a 'Covid-19 death',12 times from January 23rd to August 3rd 2020.

In the United States, the Centre for Diseases Control (CDC) uses death certificate data to determine Covid-19 mortality. Medical personnel completing death certificates exercise individual judgement in listing Covid-19 as the cause of death, whether or not the patient was ever tested for Covid-19. The CDC website itself notes that as "Covid-19 symptoms can be similar to influenza-like illness", **deaths may be misclassified**, particularly "in the absence of positive test results."

The two graphs below suggest that this may indeed be occurring, in that influenza diagnoses are down in 2020 compared to 2019. (Note that the graphs under-represent the potential effect by a factor of 5 approximately, given the different values on the Y axes).



The director of the CDC has also admitted during a Department of Health and Human Services hearing that US medical staff received higher financial reimbursements for patients diagnosed with Covid-19, which may have created **financial incentives** to over-diagnose Covid-19. Concern was expressed at the hearing that any potential over-diagnosis of Covid-19 may have spilled over into death certificate data.

To further muddy the waters around causes of death, the European Journal of Clinical Immunology reported in that, globally, "**some/many of the first 1 million recorded [Covid-19] deaths were potentially due to errors and mismanagement**", as opposed to the inherent lethality of Covid-19, including "suboptimal mechanical ventilation management [and] strategic choices, for example, sending Covid-19 infected patients to nursing homes."

All in all, around the world, deaths counted in the Covid-19 statistics may or may not have been caused by the Covid-19 illness.

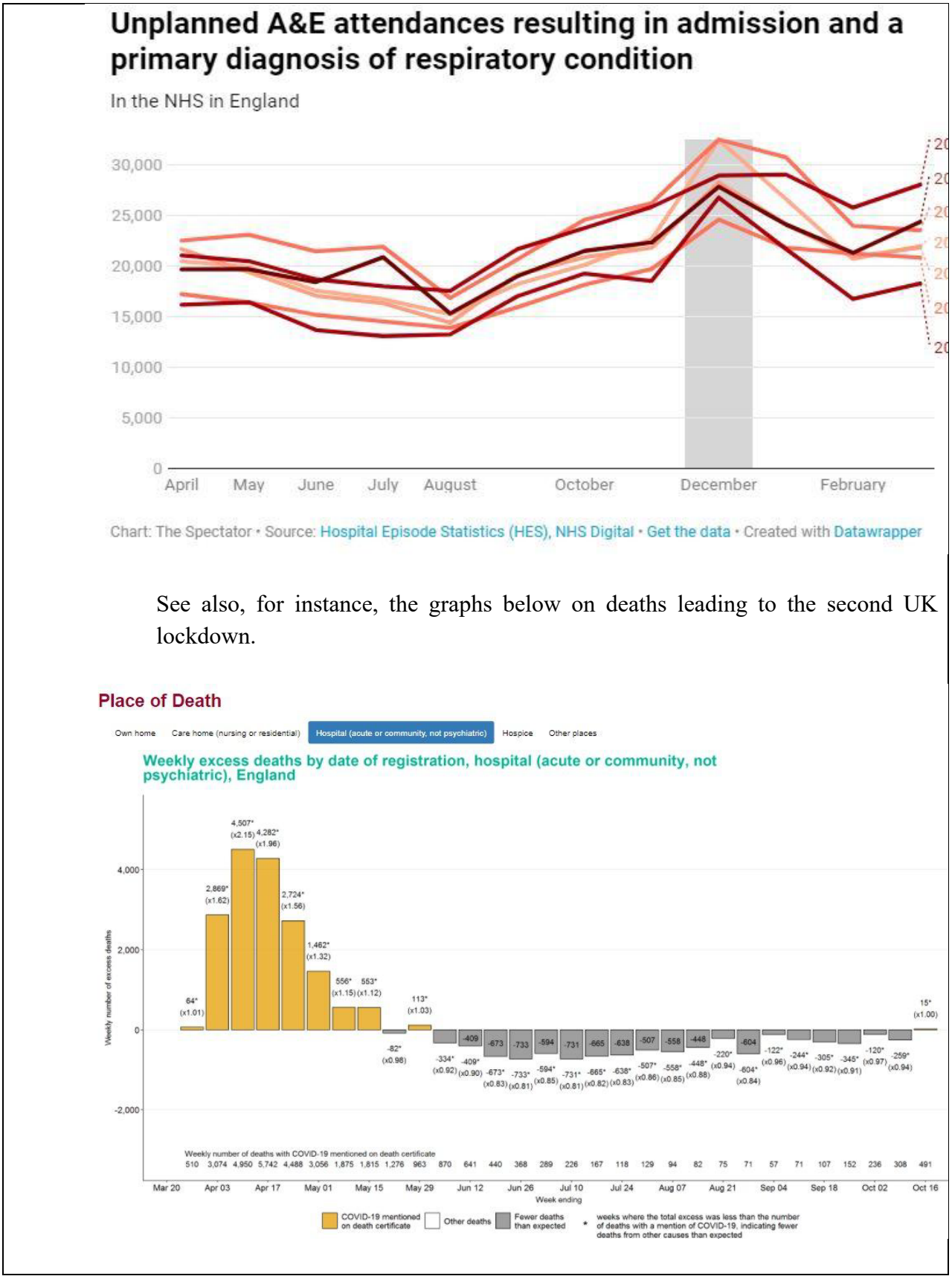
On August 23rd, having scrutinised the data closely, Carl Heneghan, Professor of the Centre for Evidence-Based Medicine at Oxford University said, "We now have more data which shows the disease is not as deadly as we first thought… we need to de-terrorise the population."

Given that **measures such as lockdown themselves cause millions of deaths**, such approximate, unstandardised, unreliable and inconsistent methods of determining Covid-19 mortality carry very serious consequences.

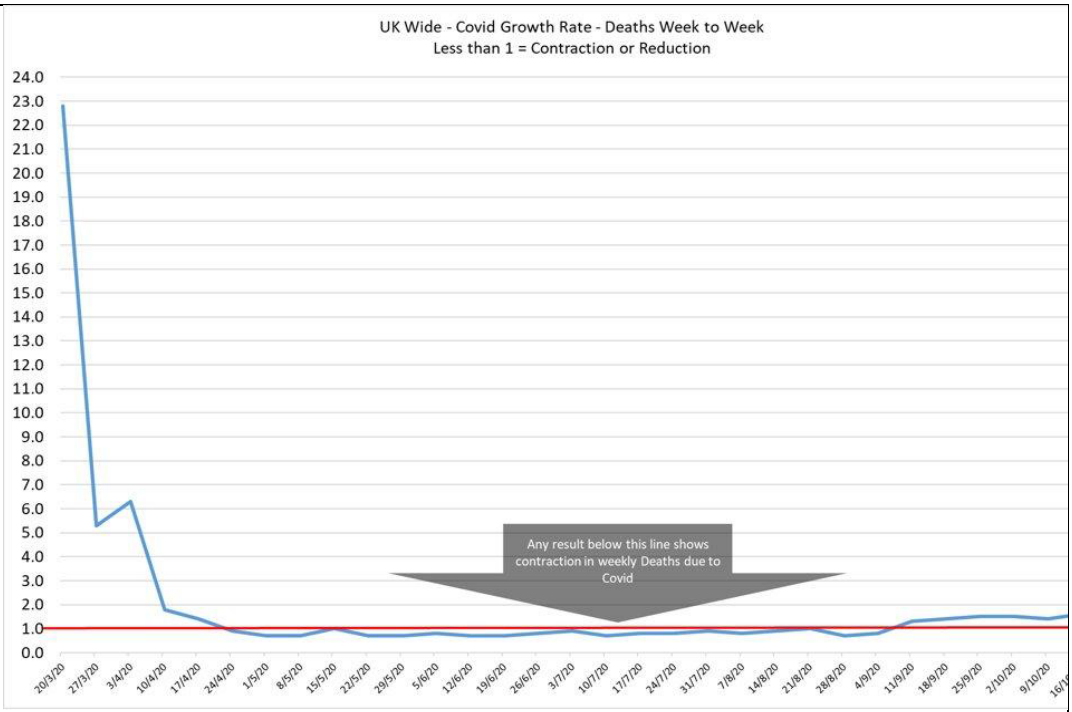
6) Well, how do you explain the second waves of deaths happening around the world now, if Covid-19 isn't the cause?

The fact that the Covid-19 death toll contains such a grab-bag of various potential causes means that the true drivers of mortality trajectories are difficult to determine. Covid-19 cannot be reliably disentangled from other causes of death based on the mortality data.
The UK rise in deaths that led to the November 2020 lockdown, for instance, were reportedly not abnormal for that time of year, and may well have reflected seasonal variation in respiratory illness rather than a Covid-19 'second wave'.
In fact, according to Dr Mike Yeadon, the number of respiratory deaths prior to the November lockdown was low for late October.

The rise in UK hospital admissions over the two months prior were also unremarkable for the season, running at levels that were around average compared to the previous 10 years. Professor Carl Heneghan, director of the Centre for Evidence Based Medicine at the University of Oxford, and Tom Jefferson, Honorary Oxford Research Fellow, explain that a rise in respiratory admissions typically "starts in September and peaks in December-January" as the graph below illustrates.



See also, for instance, the graphs below on deaths leading to the second UK lockdown.



More broadly, "mortality in the UK in 2020 to date, adjusted for population, lies in 8th place out of the last 27 years. It's not been that exceptional a year from a mortality point of view" Dr Yeadon said. He added that 42,000 deaths, the number that had died of or with Covid as of September 20, "is about ~24 days worth of normal mortality" in the UK.

Dr John Lee, former professor of pathology and NHS consultant pathologist has said that:

> "The whole Covid drama has really been a crisis of awareness of what viruses normally do, rather than a crisis caused by an abnormally lethal new bug.
>
> "An early maintained but exaggerated belief in the lethality of the virus reinforced by modelling that was almost data-free, then amplified by further modelling with no proven predictive value. All summed up by recommendations from a committee based on qualitative data that hasn't even been peer-reviewed."

7) You sound like one of those conspiracy theorists who says that Covid-19 is just like the flu

'More akin to a severe seasonal influenza'?

Dr Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases since 1984 and advisor to every U.S. president since Ronald Reagan, has written with co-authors in the New England Journal of Medicine:

> The "overall clinical consequences" of Covid-19 are "more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively."

8) You sound like an anti-vaxxer

With respect to mass vaccination for Covid-19, Michael Yeadon, former chief scientist at Pfizer said, based on three decades of experience leading new drug discovery in the pharmaceutical industry:

> "There is absolutely no need for vaccines to extinguish the pandemic. I've never heard such nonsense talked about vaccines. You do not vaccinate people who aren't at risk from a disease. You also don't set about planning to vaccinate millions of fit and healthy people with a vaccine that hasn't been extensively tested on human subjects. This much I know after 30 years in the pharmaceutical industry… Any such proposals are not only completely unnecessary but if done using any kind of coercion at all, illegal."

It is not anti-vax to raise legitimate questions about the safety and efficacy of vaccines that have been rushed to market in record time, without the usual testing processes and safety measures. It is not anti-vax to question the need for mass or forced vaccination when molecular and epidemiological evidence of population immunity exists (see section 3). It is not anti-vax to consider all available information and expert opinion before adopting a position on mass vaccination, rather than rushing to a pro-vaccination stance.

Science is not about being pro- or anti- anything. It is about gathering evidence and information with an open mind, engaging in critical thinking and evaluation, and genuinely seeking to understand the data and its implications.

9) But aren't you are being callous to the vulnerable? Covid-19 disproportionately affects the elderly, racial minorities and people with pre-existing medical conditions.

There is no doubt that Covid-19 disproportionately affects specific vulnerable

groups, who are at increased risk of severe illness and death from the virus.
While Covid-19 is **non-fatal for 99.96 – 99.97% of those under 70 years old** according to global population data, and is often mild or asymptomatic, survival rates fall to around 90% in those aged 70-79, and 85% in those over 80, possibly due partly to declining cellular immunity with age. Older adults with co-morbid health conditions are particularly vulnerable.

In those over 65, hospitalisation rates and deaths from or with Covid-19 are also significantly higher among Hispanic, Black and Indigenous Americans than white Americans, likely due to the health impact of structural inequalities including poverty and discrimination.

All of these vulnerable groups, and those with pre-existing illnesses that render them susceptible to severe infection, absolutely need and deserve protection from Covid-19.
Other vulnerable groups that also need and deserve protection include children and young people, the world's poorest and most oppressed, and the critically and chronically ill.

Children and young people

While children and young people are not at risk from Covid-19, they are at risk from lockdown. Between 6 million and 20 million children in developing countries are expected to **die from the economic impact of lockdown measures** in the coming decade, depending on how much longer lockdowns and economic downturns persist.
As Professors Battacharya and Packalen, from Stanford Medical School and the University of Waterloo Ontario explain, "**policies that depress the global economy** - no matter how well-intentioned - **put millions of the world's most vulnerable young people at risk**. The decision to lift our lockdowns thus involves **weighing lives to lives** rather than lives to money."

Young people are also at elevated risk of lockdown-related harms to mental and emotional health. In the United States, **25% of young people aged 18-24 said that they had** seriously considered suicide during the month of June in the context of lockdown. 25% also said that they had increased their substance use to cope with the pandemic.
The Wellbeing Trust anticipates around 75,000 'deaths of despair' in the US in the wake of coronavirus measures from alcohol and **drug use and suicide**, in response to "unprecedented economic failure paired with massive unemployment, mandated social isolation for months and possible residual isolation."

Lockdown and the world's poorest and most oppressed

Lockdown is hitting the world's **poorest and most disadvantaged hardest**. The World Bank estimates that the global depression caused by coronavirus measures will force 115 million people into extreme poverty **this year alone**, and up to 150 million by 2021. This will represent the first increase in extreme poverty for 20 years. By the end of the year, the number of people facing **acute hunger will double to** 265 million according to the UN World Food Programme.

Moreover, Scott Atlas, Senior Fellow of the Hoover Institution of Stanford University and Member of the Working Group on Health Care Policy points out that in developed countries, affluent classes are less affected by lockdown, as they are more likely to be able to work from home. Those in **disadvantaged socioeconomic classes and oppressed demographic groups,** in contrast**, are more likely to lose their jobs and livelihoods** as a result of both lockdown and economic depression, driving up suicides, ill-health, drug use and death.

A paper in *QJM, An International Journal of Medicine* notes, "millions of people around the world lost their jobs. Measures required to contain the virus, including self-isolation by workers and consumers, shutting of plants and stores and prohibitions on sports and entertainment events are detrimental for economy. Historically, economic downturns were associated with mental health disorders and suicides. Studies observed that increases in the unemployment rate were associated with higher prevalence of depression, alcohol and other substance use disorders and suicide deaths."

Lockdown and untreated illness

Also vulnerable to lockdown are those suffering from illnesses and diseases that have been de-prioritised in light of Covid-19. A report from the Department of Health, the Office for National Statistics and the Home Office in the UK, for instance, estimated that 75,000 will die in the UK **as a result of lockdown, through factors such as cancelled operations, missed cancer diagnoses, and lack of treatment**.

A leaked document from the German Ministry of the Interior, written on April 15th, warned that up to **125,000 patients could die in Germany as a result of postponed surgery**. It added that "the **forced reduction of care in nursing homes** in March and April 2020", which affected 3.5 million nursing home residents, "will have caused premature deaths".

Similarly, a study out of Virginia Commonwealth University School of Medicine and the Yale School of Public Health, published in the *Journal of the Medical Association of America,* found that around one third **of the excess deaths** in the United States from March 1 to August 1 2020 were **due to lockdown-related health-care disruption** and emotional crises, not Covid-19. Affected groups

included those suffering from heart conditions, Alzheimer's Disease and diabetes.

The study's lead author predicted that preventable early deaths are also likely to increase in coming years due to interruptions in chemotherapy for cancer, and delays in routine mammogram screening. In addition, he said that "**many people who survive this pandemic will live with lifelong chronic disease complications" from missed treatment** and compromised disease management.

The purpose of public health policy is not to prioritise one patient group, and one disease, over all others. Nor to jettison the Hippocratic Oath to do no harm. It is to promote population health, in **the interests of all medically vulnerable groups**, rather than throwing the world's most vulnerable, by the million, under a bus.

In light of the millions of deaths, untreated illness, extreme poverty, and hundreds of millions facing acute hunger as a result of scientifically unfounded lockdown measures, Dr. Reiner Fuellmich has called coronavirus policy "probably the greatest crime against humanity ever committed".

10) So what are we supposed to do?

A group of the world's leading infectious diseases experts and epidemiologists, from Harvard, Oxford and Stanford Universities[xiii], have proposed adopting a focussed protection strategy to deal with Covid-19. Focussed protection allows "those who are at minimal risk of death to live their lives normally to build up immunity to Covid-19 through natural infection, while better protecting those who are at highest risk."
The approach acknowledges that:

> "Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden… Keeping these measures in place until a vaccine is available will cause irreparable damage, with the underprivileged disproportionately harmed."

A focussed protection strategy, in contrast, proposes that, "adopting measures to protect the vulnerable should be the central aim of public health responses to Covid-19."

How?

> "By way of example, nursing homes should use staff with acquired immunity and perform frequent PCR testing of other staff and all visitors. Staff rotation should be minimized. Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside. A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals."

Under the Great Barrington Declaration, issued on October 5th, over 11,000 medical and public health scientists and 23,000 medical practitioners joined Drs Bhattacharya, Gupta and Kulldorff in calling for a focussed protection approach to Covid-19.

11) You mean herd immunity? Just let the virus rip through the population and leave older people and vulnerable people to die?

No.

The term 'herd immunity' gained a bad reputation when it was first proposed and then retracted by governments, as deaths from Covid-19 around the world were spiralling. The phrase has since understandably come to be associated with widespread death and fear, and regarded as a ruthless, reckless strategy, which treats human beings as cattle, willing to sacrifice the vulnerable for the strong, in the interests of a healthy 'herd'.
This, however, is not the case. Terminology aside, the concept simply means that human beings, like other social species, develop population or collective immunity to disease. If such a thing did not exist, viruses and other pathogens would have killed us all long ago. Population immunity is as old, and as vital, as life itself.

It is only upon exposure to pathogens that individual and collective immunity can emerge (see section 3b), such that those who acquire immunity act as fire-breaks to disease, ultimately preventing an outbreak from spreading throughout the entire population. In this way, a "self-limiting" capacity is exerted upon the spread of infection, including epidemics, causing them to settle and reach equilibrium, as Infectious Diseases Epidemiologist Senetra Gupta explains here.

Paul McKeigue, Professor of Genetic Epidemiology and Statistical Genetics at the University of Edinburgh adds that, "Herd immunity is the goal of most vaccination programs." Equally importantly, he explains, "natural infection

generally confers better protection than vaccines."

In other words, rather than posing infectious dangers to one another, as the prevailing approach to Covid-19 has led us to believe, in reality we protect one another by exposing ourselves to pathogens (as opposed to shielding ourselves), thereby cultivating our immunity, so that those of us who are immunologically healthy can act as barriers against disease for those who are immunologically weak.

It is how we – collectively and naturally – have always fought and survived infection.
Denying the existence of population immunity, or branding it "reckless" and "dangerous", is simply to misunderstand immunology and biology. Nothing more, nothing less. (Except, of course, if you happen to have a vested financial interest in selling artificial population immunity via mass vaccination, in which case you may wish to misconstrue natural immunity, your natural competitor, as unnatural, and unhinged).
These basic immunological facts are why over 45,000 medical and public health scientists and medical practitioners have signed the Great Barrington Declaration. Not because they are deranged or homicidal, but because they are medical and scientific experts, who understand immunology and infectious disease.

Endnotes: For all answers
Index

Reference: F

Index

A review and analysis of the operations, deliberations, and recommendations of the Australian Health Protection Principal Committee (AHPPC) in respect of Covid-19 pandemic management measures in 2020, 2021, and 2022, including:

i. Covid-19 pandemic management recommendations received pursuant to the International Health Regulations (IHR) from the World Health Organisation (WHO), including the scientific studies advanced in support of any Covid-19 IHR recommendations;
ii. Covid-19 pandemic management recommendations received from any sovereign nations including the scientific studies advanced in support of any such recommendations;
iii. Covid-19 pandemic management recommendations created by the AHPPC, including the scientific studies advanced in support of any AHPPC created recommendations;
iv. any orders, directions, requests, instructions, or recommendations received from the Chair of the National Cabinet, or from the National Cabinet relating to Covid-19 pandemic management;
v. where relevant, all minutes of meetings of the AHPPC;
vi. all documents tabled during AHPPC meetings; all documents shared between AHPPC members and their staff prior to and subsequent to all AHPPC meetings, including all correspondence between members of the AHPPC (including their support staff) as it may relate to Covid-19 pandemic management measures or recommendations.

Explanatory Memorandum

Index

An examination to confirm that any departure from recommendations contained in the AHMPPI by the AHPPC, and the adoption and recommending of any WHO/IHR SARS-CoV-2 recommendations, or the development of new and unique to Australia recommendations, advanced to the National Cabinet, were reasonable and appropriately backed by the best available scientific evidence.

An examination to confirm whether the recommendations and advice provided by the AHPPC to National Cabinet were reasonable, based on the best available scientific evidence, including continually updated Australian epidemiological and pathology/serum data throughout 2020, 2021, 2022, and 2023.

Question(s) on Notice

Index

First Question

In respect of **References B and F**, what was the explanation provided by the AHPPC for completely ignoring the Australian Health Management Plan for Pandemic Influenza which had been reaffirmed by all Australian governments in late 2019?

Second Question

In respect of **References F**, what was the scientific evidenced provided by the WHO when issuing Covid-19 recommendations pursuant to the International Health Regulations, which the AHPPC considered as sufficiently good to abandon the Australian Health Management Plan for Pandemic Influenza? Did the AHPPC share this scientific evidence with Australians or Australian scientists?

Answer(s)

Index

Answer

Julian Gillespie LLB, BJuris, Co-Author:

Please also see my answer provided for the Question on Notice for Reference B.

From early 2020 the WHO began issuing a series of 'guidance' documents to member nations on a variety of subjects 'in the context of Covid-19'.

These guidance documents were ***not*** couched as Recommendations issued under the International Health Regulations but were received by member nations as though they were.

This WHO guidance related to Public Health and Social Measures, or PHSMs, and addressed those measures Australia had previously documented in Attachment E of the ***Australian Health Management Plan for Pandemic Influenza*** (**AHMPPI**).

However, most of the WHO PHSM guidance received by the AHPPC recommended actions that were ***the opposite*** to those recommended in Attachment E of the AHMPPI.

An example is the 18 May 2020 Interim Guidance document *Overview of public health and social measures in the context of COVID-19*, where the following can be seen:

Background

The overarching goal for all countries is to control COVID-19 by slowing down transmission of the virus and preventing associated illness and death. In response to COVID-19, every country should be implementing a comprehensive set of measures, calibrated to the local context and epidemiology of the disease.[1] Central to this comprehensive strategy are time-tested, core public health measures that break chains of person-to-person transmission, including (i) identification, isolation, testing, and clinical care for all cases, and (ii) tracing and quarantine of all contacts,[2-6] which should be a part of all national COVID-19 responses.

Immediately apparent is the WHO assertion of 'time-tested' PHSM measures which were anything but 'core public health measures' – this statement was false – nonetheless documents like this proceeded to recommend as 'guidance' an invasive range of restrictive social measures as having been known to work ~~and~~ based on science. When one looks to the science references contained in these guidance documents, one finds a series of only months old and premature 2020 studies on various aspects of Covid-19, which are under-powered, speculative, and in many instances inconclusive. Yet the WHO has raised these to the level of *established* science to serve as the evidence basis for recommending severe lockdown measures cloaked as PHSMs, the euphemistically phrased Public Health and Social Measures. The WHO adopted a narrative style of impending doom that required urgent, immediate, and strict adoption of its guidance, lest member nations perish from SARS-CoV-2. Another passage of note follows:

Public health and social measures contribute to stopping individual chains of transmission and preventing outbreaks, and are therefore critical in limiting further spread of COVID-19, particularly while vaccines and therapeutics are not yet available. These measures include the following:

- **Personal measures** aim to limit person-to-person spread, protect individuals and their contacts, and reduce contamination of frequently touched surfaces.[6,7] Personal measures include frequent hand hygiene, physical distancing, respiratory etiquette, use of masks if ill or attending to someone who is ill, and environmental cleaning and disinfection at home.
- **Physical and social distancing measures** in public spaces prevent transmission between infected individuals and those who are not infected, and shield those at risk of developing serious illness. These measures include physical distancing, reduction or cancellation of mass gatherings,[8] and avoiding crowded spaces in different settings (e.g. public transport, restaurants, bars, theatres), working from home, staying at home, and supporting adaptations for workplaces[9] and educational institutions.[10] For physical distancing, WHO recommends a minimum distance of at least one metre[a] between people to limit the risk of interpersonal transmission.
- **Movement measures** aim to prevent introduction and limit movement of the virus from one area to another. Measures include limiting movement of persons locally or nationally, offering guidance regarding travel, arranging orderly travel in advance to

In just 14 lines the above excerpt from the 18 May 2020 document effectively overturned the Attachment E recommendations contained within Australia's AHMPPI. When the *implied* science in support of the above statements is reviewed at references 6, 7, 8, 9, and 10, readers can confirm that the WHO is referencing earlier WHO documents from 2020, some being earlier versions of the same 18 May 2020 document, with another reference being to the WHO's own 2019 document *Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza.* In that document on page 37, readers can see a variety of social distancing or PHSM measures which the WHO advised the world ***against*** only a few short months prior. These very bad references were also very sloppy.

In brief, the WHO guidance calling for the implementation of strict and severe and invasive PHSMs was ***not*** based on new and ground-breaking scientific studies warranting a complete departure from the pre-existing scientific understanding as reconfirmed in late 2019, but was guidance hurriedly made-up by the WHO *on the run*,

filled with language of imminent doom, facilitated by a concerted global media campaign designed to create a false belief in the existential danger posed by SARS-CoV-2. In short, member nations were sold a lie.

Much more could be written here exposing the series of WHO Covid-19 guidance documents calculated to have member nations turn their backs on all their prior pandemic planning, but time constraints require the example provided above as representative of the *modus operandi* adopted by the WHO throughout 2020 and 2021, deserving and requiring thorough examination by a Covid-19 Royal Commission.

Throughout all of these WHO materials can be seen a constant theme and messaging justifying strict PHSMs as necessary and only temporary – *until vaccines are available*.

Public health and social measures contribute to stopping individual chains of transmission and preventing outbreaks, and are therefore critical in limiting further spread of COVID-19, particularly while vaccines and therapeutics are not yet available. These

In the background of 2020, the WHO was expending enormous energies and resources ensuring member nations were ready to receive and distribute Covid-19 vaccines.

Absolutely no consideration was given to the possibility that non-effective and/or unsafe Covid-19 drugs would result from the many Phase 1 or 2 or 3 clinical trials that had been recklessly created in the first half of 2020. The WHO otherwise spent no time or energy properly examining or investigating the use of safe and inexpensive repurposed drugs - the WHO was adamant that no other therapeutics were available. That was another lie by the WHO, and is further discussed in the answers to Questions on Notice for Terms of Reference O, P, and Q.

Instead, and as has been observed by countless commentators, WHO guidance throughout 2020 was designed to instil fear, masquerade as guidance when it was coercion, using the sheer force of its media barrage to obtain compliance and agreement from member nations to imp the WHO was ahead of all this messaging were its unseen public efforts at keeping member nations preoccupied with only one possible solution for escaping severe PHSMs – readiness for the deployment of Covid-19 vaccines.

A document exemplifying this strategic aim and single-minded objective is the WHO's *COVID-19 vaccine introduction readiness assessment tool*, version 21 September 2020 (the 'WHO Assessment Tool").
Recall that as of September 2020 not one single Covid-19 vaccine had been approved, with all the clinical trials that had been hurriedly created and compressed from a typical 8 years into less than 8 months, still to conclude.

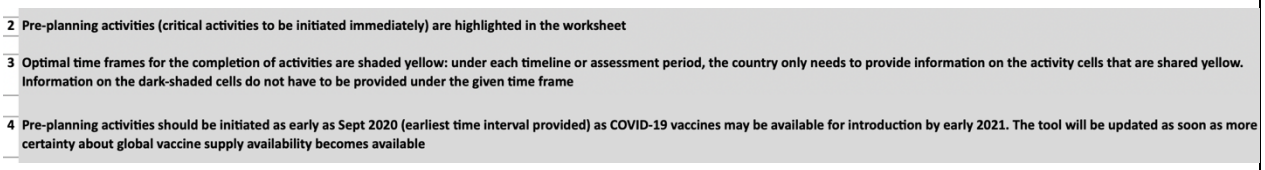
Nonetheless, and without ever countenancing the possibility that ***no*** truly safe and effective drugs might come from any of the many clinical trials, and despite all previous attempts at creating Coronavirus vaccines having failed prior to 2020, the WHO was

requiring all member nations to implement *pre-planning* by September of 2020 for the introduction of Covid-19 vaccines: somehow the WHO was possessed of foreknowledge that all global drugs regulators would be approving the previously unattainable, Coronavirus vaccines for Covid-19 very soon afterwards.

When one steps back, this was not science being conducted by the WHO, but a global drug distribution operation that had global drugs regulators organised in pre-planning to effectively pre-authorise never before achieved drugs, because of the – WHO *declaration of emergency*.

The WHO Assessment Tool clearly provides the details for a most efficient rollout of new drugs never before created anywhere, and yet to be authorised anywhere.

The Assessment Tool cover page is populated with urgency and orders:



⇓

> **Pre-planning activities (critical activities to be initiated immediately) are highlighted in the worksheet**
>
> **Pre-planning activities should be initiated as early as Sept 2020 (earliest time interval provided) as COVID-19 vaccines may be available for introduction by early 2021. The tool will be updated as soon as more certainty about global vaccine supply availability becomes available**

The reader can then see in the tabs following the cover page WHO orders that appear to pay no respect to national laws, with the imperative presumption being enforced by the WHO that the Covid-19 emergency overrode all other legal considerations.

What can be seen are directives for the optimal marketing of Covid-19 drugs with the least amount of regulatory interference, where member nations are exhorted to at all costs, cut away any and every time consuming regulation that could impede the swift receipt and uptake of the new drugs – the implication being, *because people are dying in droves from SARS-CoV-2!*. (Yes, people were dying in a small number of areas globally, notably and strangely, *only in some* regions of Italy and *only in some* US States, but mostly not dying from Covid-19 as the media was then asserting, but from iatrogenesis, a subject for examination and understanding by a Covid-19 Royal Commission). In other words, any national laws for protecting the safety and health of national populations from

new and unknown drugs, were being subtly and effectively suggested by the WHO to be suspended wherever possible, upon the basis once again of the WHO declaration of a pandemic emergency. Under the tab ***Pre-Planning Check List*** we see:

B. REGULATORY	**B.1 Confirm the regulatory pathway for licensing and market authorization of COVID-19 vaccines (i.e. expedited NRA processes, exceptional approval/waiver mechanism, etc) to WHO**
F. SAFETY SURVEILLANCE	**F.1 Ensure that minimal capacity for vaccine safety surveillance is in place (refer to the attached document that defines minimum capacity)**
G. ADVOCACY, SOCIAL MOBILIZATION & COMMUNICATION	**G.1 Design a communications, social mobilization, and community engagement strategy to generate support for vaccine confidence, trust, and demand for COVID-19 vaccines.**

The above three cells contain wording best described as giving any Covid-19 drug manufacturer unfettered entry into national markets for their drugs. In marketing speak this was setting up to be *a bonanza*, one where national governments were performing the marketing duties and providing the sales pitches. The situation had become unprecedented in history, very quickly, fuelled by a surreal media campaign of fear everywhere, all coordinated out of the WHO, with its lieutenants based in nearly every country of the world by virtue of WHO's own pre-planning and assisted through the *International Health Regulations*, which designated in every country a Focal Point to receive and follow WHO recommendations and guidance. In Australia our Focal Point for Covid was the WHO's man Dr Brendan Murphy.

Until understood otherwise, this WHO Assessment Tool must be viewed as the operational blueprint adopted by the AHPPC and recommended to the National Cabinet, because all conduct by Australian governments towards the end of 2020 moving into 2021 with the first deployment of Covid-19 drugs appears to have drawn directly from this WHO 'guidance', and without any questions from Australian health authorities.

Under tab three titled ***National Readiness***, once again we see WHO instructions written as orders, written as *fait accompli*:

A.6 Develop the National Deployment and Vaccination Plan (NDVP) with input from relevant bodies (National COVID-19 Response Coordinating Committee, CNCC, CTWG, NITAG, National Immunization Programme, National Regulatory Authority, AEFI committee and other relevant groups such as private sector). The NDVP should be in line with WHO guidance and SAGE recommendations (plan can be developed by adapting the Pandemic Influenza NDVP, if existing)

A.8 Review and prepare Government signature for legal agreement to receive Covid-19 vaccine (Additional information to follow)

C.1 Confirm to WHO the existence of any expedited regulatory pathway for approval of COVID-19 vaccines (i.e. emergency use authorization, exceptional approval/waiver mechanism based on reliance/recognition, abbreviated procedure, fast track, etc.). Time lines and maximum number of days should be mentioned. (expected timeline: maximum 15 working days)

C.4 Confirm to WHO the existence of an expedited import approval/waiver from appropriate authorities. Time lines and maximum number of days should be mentioned. (expected timeline: maximum 5 working days)

In the following section can be seen WHO instructions effectively demanding that national drugs regulators dispense with testing the safety of imported Covid-19 vaccine lots. This is unprecedented and amounts to instructing drugs regulators to not observe national legislation whose objective is to safeguard the health of citizens. The non-observance of such legislation at the request of a foreign organisation very quickly moves the needle of legal liability into criminal negligence.

C.5 Ensure a system to waive local lot release testing based on review of summary protocols is in place. Identify the requirements and documents needed for NRA lot release or waiver of lot release for COVID-19 vaccines. Time lines and maximum number of days for lot release/waiver process should be mentioned. (expected timeline: maximum 2 days)

As the following cells detail, national governments were already planning communications strategies from mid 2020 for promoting Covid-19 vaccine confidence at all costs, irrespective of adverse events including deaths caused by the new drugs – the only objective was 'to *generate confidence*'.

J.1 Design a demand plan (includes advocacy, communications, social mobilization, risk and safety comms, community engagement, and training) to generate confidence, acceptance and demand for COVID-19 vaccines. Must include a crisis communications preparedness planning

J.2 Establish data collection systems, including 1) social media listening and rumor management, and 2) assessing behavioral and social data

The WHO Assessment Tool evidences a *very* high degree of forward planning in anticipation of Covid-19 vaccines. The document shown above must have been first drafted much earlier than September 2020, and must have involved a great deal of collaboration and input from a significant number of persons, and quite possibly Australian input.

Assessment Tool version 21 September 2020 provides further evidence that Australian authorities and especially the AHPPC recommended and implemented severe lockdown measures across Australia, while possessed of full knowledge and already involved in detailed planning for the late 2020/early 2021 release of Covid-19 vaccines.

Should a Covid-19 Royal Commission establish this to be the case, then we can speculate that bodies like the AHPPC were not concerned with the science the WHO repeatedly upturned in its guidance documents – no, those guidance documents directing member nations to lockdown their populations were simple precursors, pre-planning, and guides for the psychological conditioning of populations in readiness of a greater plan – receiving and deploying on national scales Covid-19 vaccines to populations desperate to regain their freedoms.

As the evidence increasingly reveals, it appears that this was not about a mistaken appreciation of the true and limited threat posed by SARS-CoV-2, but rather a global drugs rollout using the false pretext of a dangerous pathogen, assisted and promulgated by the WHO, who told naïve global citizens told to 'trust the science'.

The exact role played by the Australian Health Protection Principle Committee, the AHPPC, steered as it was mostly by Brendan Murphy in 2020, must be established by a Covid-19 Royal Commission by a thorough examination of all AHPPC members, materials, correspondence, and appointments attended by AHPPC members throughout 2020 and 2021.

Index

Reference: G

Index

A review and analysis of the Covid-19 pandemic management recommendations issued by the AHPPC to the National Cabinet, and the Covid-19 pandemic management decisions and positions adopted by the National Cabinet throughout 2020, 2021, and 2022, including:

i. AHPPC meeting Minutes discussing and formulating recommendations for the National Cabinet; and
ii. Corresponding National Cabinet meeting Minutes discussing recommendations received from the AHPPC, and National Cabinet resolutions on recommendations received from the AHPPC.

Explanatory Memorandum

Index

An examination to confirm that any departure from recommendations contained in the AHMPPI by the AHPPC, and the adoption and recommending of any WHO/IHR SARS-CoV-2 recommendations, or the development of new and unique to Australia recommendations by the AHPPC, and advanced to the National Cabinet, were reasonable and appropriately backed by the best available scientific evidence.

Question(s) on Notice

Index

First Question

In respect of **References G**, what was the explanation provided by the National Cabinet for completely ignoring the Australian Health Management Plan for Pandemic Influenza which had been reaffirmed by all Australian governments in late 2019?

Second Question

In respect of **References G**, what was the scientific evidenced relied upon by the National Cabinet when announcing Covid-19 lockdown and mitigation measures as advised by the AHPPC?

Answer

Julian Gillespie LLB, BJuris, Co-Author:

Time constraints prevent a full and complete response to the above questions which with further time would have seen an extensive response.

However, the Committee has the answers to Questions on Notice for References B and F strongly suggesting and providing evidence of a globally coordinated plan prioritising the receipt of Covid-19 vaccines at all costs, using lockdown measures to coerce uptake of Covid-19 vaccines, with virtually no scientific rigour or attention devoted to alternate, cheap, and known to be safe treatments and protocols – the WHO had one objective which through propaganda and false information it coerced, urged upon and sold to all WHO member nations – *lockdown your populations and wait for **our** recommended vaccines*.

What information packages and presentations were received by National Cabinet from the AHPPC advancing and recommending WHO *guidance* calling for the draconian and invasive lockdown of the Australian People, *against the science? What* information was received by National Cabinet from the AHPPC for strongly advising National Cabinet to devote enormous resources to pre-planning for receiving millions of doses of Covid-19 vaccines? What resources and presentations were made available to facilitate selling those doses to the Australian People and ensuring a *blind confidence* in Covid-19 vaccines, and to maintaining a whole-of-government medical propaganda campaign? This is evidence a Covid-19 Royal Commission must call for.

As mentioned in the answer to the Question on Notice for Reference B, the case of *Knowles v Commonwealth of Australia* [2022] FCA 741 (27 June 2022) appears to open the way to all National Cabinet meeting minutes and by extension, all materials delivered to the National Cabinet by the AHPPC.

Only once those materials are made public via the Royal Commission mechanism can a faithful assessment be undertaken as to the state of the scientific evidence presented to the National Cabinet by the AHPPC, and any other evidence relied upon by the National Cabinet for arriving at the eventual decisions it did, with respect to lockdown measures and pre-planning and planning in anticipation of Covid-19 vaccines.

Since National Cabinet and the AHPPC advising it purported to be serving the

Australian People and the best interests of the Australian People, by ensuring the health and safety of the Australian People during Australia's first ever Biosecurity Act Declaration of Emergency, where the Australian People were told repeatedly that the National Cabinet was relying upon the best available science to inform its every decision, then there should be no basis or reason for the AHPPC nor National Cabinet to frustrate an open examination of all sessions of both bodies during 2020 and 2021 and 2022, by a properly empowered Covid-19 Royal Commission.

Index

Reference: H

Index

A review and analysis of the functioning of the National Health Emergency Media Response Network (NHEMRN) during 2020, 2021, and 2022, including:

i. any plans or strategies or relationships involving the NHEMRN in the coordination of Covid-19 messaging amongst Australian governments;
ii. any plans or strategies or relationships involving the NHEMRN in the coordination of Covid-19 messaging amongst Australian media;
iii. any plans or strategies or relationships involving the NHEMRN in the coordination of Covid-19 messaging amongst Covid-19 vaccine suppliers and manufacturers;
iv. any plans or strategies or relationships involving the NHEMRN in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning the safety or efficacy of Covid-19 vaccines;
v. any plans or strategies or relationships involving the NHEMRN in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning State or Territory or Commonwealth Government mandate measures in response to Covid-19;
vi. any plans or strategies or relationships involving the NHEMRN and social media and media companies in respect of (iii) and (iv) above, including 'fact checker' organisations;
vii. any plans or strategies or relationships involving the NHEMRN and the Trusted News Initiative.

Explanatory Memorandum

Index

An examination to confirm whether the activities of the NHEMRN in respect of Covid-19 public messaging and information campaigns throughout 2020, 2021, 2022, and 2023 was reasonable and proportionate and consistent with real-time Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known and shared amongst Australian governments.

Question(s) on Notice

Index

In respect of **Reference H**, please provide any further information concerning the role and function of the National Health Emergency Media Response Network during Covid-19.

Answer(s)

Index

Answer

Julian Gillespie LLB, BJuris, Co-Author:

Time constraints prevented a full and complete response to the above question which would have seen an extensive response.

However, in light of answers detailing the 'guidance' and messaging received from the WHO by the Australian government, and particularly the AHPPC, a Royal Commission examination of policies promulgated and directives received by the National Health Emergency Media Response Network (NHEMRN) during the Covid years, and the national implementation of those policies and directives, *it can be speculated there will* evidence that the NHEMRN was utilised to broadcast information packages and media messaging originating mostly out of media units of the WHO, with initial focus on lockdown measures and appeasing civilian populations, followed by Covid-19 vaccination messaging to civilian populations.

Further evidence will *likely* reveal instructions to Australian government media units (sent by the NHEMRN) to de-platform or delete or censure any discussion of the use of repurposed drugs for treating or protecting against Covid-19. The Department of Home Affairs (DHA) is already on record in Senate Committee hearings admitting to censorship activity of this nature. As the DHA was tasked to be an integral coordinator of the Covid-19 response, inter-department coordination of censorship procedures and activities should be expected.

The NHEMRN is contained within the Department of Health and Aged Care, created to the assist Australia's designated National IHR Focal Point under the International Health Regulations, and appears to work within or alongside the National Incident Centre (NIC) within the same department.

The testimony of Dr Lissa Johnson in answer to the Question on Notice for

Reference N provides further details.

The NIC is activated by the Chief Medical Officer (CMO) when a significant threat arises. For the most part of 2020 when WHO guidance was being recommended by the AHPPC to National Cabinet, Dr Brendan Murphy was the CMO, before the end of 2020 becoming the Secretary of Health, responsible for the TGA, and fast-tracking the provisional approval of Covid-19 vaccines.

As further testimony from Co-Authors and Proposed Witnesses to these Questions on Notice detail, the TGA performed virtually no independent safety assessments of Covid-19 vaccines, nor required Covid-19 vaccine sponsors to provide a range of safety studies for first proving the safety of their products, before they were made available to the Australian People.

Instead, Brendan Murphy enabled Covid-19 drugs to arrive in Australia and be supplied to millions of Australians with virtually no independent safety oversight, a departure from international standard practices for ascertaining the safety of new drugs, that *had been* rigorously performed for decades prior by the TGA, but dispensed with for the Covid-19 drugs.

Why when all the epidemiological data available from as early as 2020 evidenced a threat on par with severe Influenza that was quickly diminishing with every evolution of subsequent strains of the virus?

That the man responsible for recommending to National Cabinet the WHO guidance to lockdown Australians should then assume the post and position able to create and command the pathway for receiving into Australia and ultimately the Australian People, new and largely untested drugs also recommended by the WHO, demands an inquiry by a Covid-19 Royal Commission into possible conflicts within Brendan Murphy; such conflicts appear to have resulted in the extraordinary passage of Covid-19 drugs via new *provisional approval* pathways never before seen, let alone used at such scale, for drugs known to be rushed through questionable clinical trials.

The TGA's conduct under Brendan Murphy involved a dangerous lack or indeed absence of any safety profiling or the receipt of long-established safety studies from other sources.

In short, the TGA appears to have been taken over and designated a shipping agent for Big Pharma's Covid-19 drugs, with the theatre of the WHO dressing the activities of the TGA with a false legitimacy and the never-ending WHO orchestra maintaining the sense of urgency created by the international declaration of pandemic emergency made by who else, but the WHO.

Index

Reference: I

Index

A systematic review of the involvement of Australian government departments in the creation or recruitment and use of "nudge" units and social media "disinformation" units, including:

i. the tools and techniques used by any such units in the management of public views and opinions providing information and criticisms not in keeping with Covid-19 messaging from Australian governments and agencies;
ii. an examination of whether Covid-19 government units established to 'nudge' Australian citizens towards Covid-19 vaccination, and compliance with other mandates and directives, employed tactics of psychological manipulation, and/or exploitation of vulnerabilities in human information-processing;
iii. an examination of due diligence undertaken to ensure that strategic messaging and censorship did not violate:
    a) the human rights of message recipients (i.e. to freedom of thought without political interference);
    b) psychological codes of ethics regarding evidence-based practice and non-maleficence; and
    c) the rights of democratic electorates to be freely informed.

Explanatory Memorandum

Index

An examination to confirm whether Covid-19 government units established to 'nudge' Australian citizens towards Covid-19 vaccination and compliance with Covid-19 mandates operated reasonably and proportionately when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

An examination to confirm whether Covid-19 government units tasked with challenging or possibly censoring Australian citizens with differing public views towards Covid-19 vaccines and mandates operated reasonably and proportionately when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 adverse event reports;

iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference I**, please provide any further information concerning Australian government "nudge" units and social media "disinformation" units.

Answer(s)

Index

First Answer

Prof. Gigi Foster, Co-Author:

Documented behaviour of the NSW Behavioural Insights Unit

On 21 September 2022, a journalist who knew of my opposition to the government's draconian response to Covid-19 sent me products of a Freedom of Information Act request that she had lodged with the New South Wales Behavioural Insights Unit – namely, several internal documents (short internal reports and PowerPoint slide decks) dated April 2021 and August 2022 that show what was being discussed within the New South Wales government's "nudge unit" in considering how to craft policy measures and public messaging about Covid-related actions that the government wanted people to take. These documents contain many references to academic work in behavioural science, making it clear that the government was openly generating means of manipulating people based on knowledge that has been discovered in the disciplines of behavioural economics and psychology. I sketch below some of the exploitative uses of behavioural insights evidenced in these documents, which themselves are attached as Annexures, categorised by desired Covid response behaviour.

Check-Ins at Businesses based on Covid Status

Annexure 5: The suggestion to run lotteries to encourage people to check in (rewarding individuals who engage in the desired behaviour); the suggestion to increase the salience of the check-in procedure via manipulation of environmental cues; the suggestion for businesses to "harness the surveillance effect" and "harness social norms" to increase check-in rates; the use of social comparisons via framing such as "Your Covid-19 check-ins are lower than similar businesses in

your area"; framing the use of QR codes not as a burden but positively, as a means of businesses "avoiding paperwork".

Vaccinations

Annexure 6: Attempting to manipulate downwards people's perception of the risk of accepting the vaccine – e.g., the suggestion to "When discussing risks, use the absolute percentage (i.e. 0.000004%) rather than 1 in 250,000. We find it easier to imagine ourselves as the '1' so perceive the risk expressed this way as greater."; framing vaccination as the norm or status quo, and the choice not to be vaccinated as an international choice away from that status quo – e.g., "When are you getting vaccinated? Pick a date today.", "if you choose to not be vaccinated…", "changing the default to having the vaccine can help reframe being vaccinated as the norm"; underscoring the loss or risks associated with not complying with the desired behaviour (e.g., "loss of freedom" for the unvaccinated; and the suggestion to pose questions like "how would you cope with weeks of feeling unwell due to Covid-19, unable to go to work or care for your family?"), thereby exploiting loss aversion and risk aversion; associating the desired behaviour with personal ownership, rights, or special status (e.g., "you have a vaccine reserved for you"); exploiting people's vulnerability to social norms – e.g., the suggestion to encourage the vaccinated to share their vaccination status on social media, to "use the messenger effect", and of "building a social norm that vaccination uptake is widespread and accepted by the majority of Australians/New South Welshmen can help increase the intentions to get vaccinated", despite the fact that this "norm" had not developed organically in the population, based on the survey data quoted at the start of the document ("Based on the current state-wise sentiment on vaccinations, 48% of people report they would get vaccinated as soon as eligible, 36% report they might get vaccinated, while 16% report they would 'probably' or 'definitely not' get vaccinated.").

Testing

Annexure 7: Express references to exploiting the power of salience, temporal discounting, and the scarcity mindset in order to encourage testing; sentences were added that further encouraged desired behaviour, such as "if you feel unwell again with even the mildest of symptoms – don't go out, don't see family and friends – get re-tested."

Conclusion

What is revealed in the documents released in accordance with this FOI request is the manipulation of a population by its government, using tactics that have been found in the behavioural economics and psychology literatures to be particularly effective at changing behaviour. It is an example of what those trained in

behavioural economics are capable of when they become merely the servants of power.

I teach a Masters course at UNSW entitled Policy Applications of Behavioural Economics, and have used these materials as an example to my students of the dangers of applying their skills and knowledge to a cause whose end purpose they have not vetted morally, or even economically. The restrictions placed on rights and freedoms by the Australian government during the Covid era were an economic catastrophe as well as an affront to such moral principles as care and compassion for our fellow man, and so on both fronts, assisting the government in manipulating people into complying with them is wrong. Similarly, coercing people into accepting an experimental medical procedure has not been morally acceptable at least since the penning of the Nuremberg Code. The tactics used to convince people to get vaccinated against Covid were more like shoves than nudges, and unethical shoves at that.

When "nudge unit" workers or other behavioural scientists who see themselves as being in the business of "helping" people do "what is best for them" lose their perspective on the morality of the activities to which they are contributing, and with it lose their humility and their self-doubt, they cease to become pro-social scientists and instead risk becoming unthinking bullies who catalyse the destruction of human welfare.

Index

Second Answer

Ros Nealon-Cook BPsychSc, Co-Author:

In my answer below I have also included correspondence from a professional colleague, which is duly identified.

In March 2022, I together with more than 30 legal professionals and mental health care specialists drafted a position statement about governmental abuses of psychological techniques to manipulate the Australian population during the Covid era. I reproduce this statement below, with minimal alterations.

> **An Open Letter to highlight the use of coercive psychological tactics to influence the Australian public throughout the Covid-19 pandemic**
>
> We write as a group of Australian psychology and mental health specialists to express our grave concerns about the inappropriate and unethical use of 'behaviour modification' techniques, employed by the Australian government and related health authorities, throughout the Covid pandemic.

As these behavioural science techniques directly target the primal, subcortical areas of the brain (beyond an individual's conscious awareness), they are designed to subconsciously coerce the populace into complying to government health directives, without question.

In particular, we highlight the adoption of 'Nudge Theory' (commonly known as 'nudges'), which targets cognitive processes relating to reward and punishment, in order to manipulate behaviour. Used without transparency (and therefore, without consent), and combined with constant reinforcement through repetition, these techniques are used as tools of mind control.

These techniques have been implemented in lockstep with other countries – and we stand in solidarity with other health professionals and groups, such as our international colleagues in the HART Group, who have expressed similar concerns. There is clear evidence that the same behaviour modification strategies devised to generate psychological distress and trigger compliance in the British people have also been used in Australia since at least 2010.

Although most people believe they are not susceptible to being psychologically manipulated in ways that influence their behaviours, research strongly suggests otherwise. Higher levels of education have not been found to be protective, as these influences are operating at a subcortical (subconscious) level. These subconscious influences are amplified further when 'information' is disseminated through those presenting as 'trusted' experts, leaders, and media personalities. These authority figures are used to reassure the public that they are in safe hands – and that they have no need to ask questions.

Alarmingly, thousands of international health experts who have raised serious concerns about the pandemic response (many of whom are collaborating with us) have been targeted by an internationally coordinated campaign of censorship, professional disciplinary action and ad hominem attacks designed to discredit and deny them the opportunity to debate. We are told that all of the pandemic measures have been justified for our protection and safety in the face of a global health crisis that required invoking 'emergency powers'. Given the absence of transparency and open debate, we consider this deliberate use of nudge tactics to push the unilateral government narrative to be a form of psychological warfare.

We echo the HART Group's call for a comprehensive inquiry into the ethics of using nudge strategies (in this case, on the Australian people) as a means of promoting compliance with public health directives. We also call

for transparency around the source of the directives given to the Australian Government that were used to justify the use of covert psychological techniques to intentionally target and modify behaviours in the Australian population.

Background

The British Government established a 'Behavioural Insights Team' (BIT) in 2010 (commonly referred to as 'The Nudge Unit'), which was the world's first government institution 'dedicated to the application of behavioural science to policy.' Following their example, the Australian Government added BETA (Behavioural Economics Team Australia) to the Department of the Prime Minister and Cabinet in 2016, stating that, 'Behavioural economics is a field of economic research that recognises that people do not always make decisions on a purely rational basis.'

Although the field associated with nudges is labelled 'behavioural insights' (BI), it is evident from public statements made by groups that use BI, and the ways in which BI research is applied, that a more appropriate label would be 'behavioural modification' (BM).

In a media release from the Department of the Prime Minister and Cabinet about the BETA Exchange Conference: BX2018 (with the tagline, 'From nudges big things grow,') it was stated that:

> Attendees discussed the various applications for behavioural insights and drew from past lessons and future opportunities.
>
> A broad range of topics were covered including neuroscience, diversity, big data and machine learning, health, morality, and violence and crime. The conference concluded with a discussion on new frontiers in behavioural insights.

The conference included talks by Professor David Halpern, Chief Executive of the BIT and member of the Scientific Pandemic Insights Group on Behaviours (SPI-B), and Dr Julie Leask, who has authored many papers in this field, including one entitled, *Want to Change Minds About Vaccines? A 'Nudge' May Be Better Than Facts*.

Whilst many may be aware that these 'psychological warfare' strategies are commonly deployed in advertising, marketing and in the digital space, people do not expect their elected government representatives to adopt such strategies against innocent law-abiding citizens. Those who understand psychology are abundantly aware of the role such techniques

play in manipulating behaviour and contributing to addictions (such as gambling, alcoholism, pornography, online gaming and shopping), as well as the associated financial and emotional cost to individuals and their families.

This use of nudges and behavioural science to influence, manipulate and mould the minds and behaviour of the Australian public (through intentionally bypassing mechanisms of conscious thought) is compounded by the strict control of the dissemination of information and the heavy censorship of any information that is not in complete agreement with the official narrative.

The majority of people still believe that they live in a free, democratic society that respects the rights and preferences of its individuals. People expect that their elected representatives and those presented as 'experts' can be trusted to be honest and transparent and have their best interests at heart. They expect that any process of change involves engaging the public in dialogue and open debate, i.e., treating adults as thinking, discerning and autonomous individuals.

Any covert psychological manipulation of the Australian public is a gross betrayal of this public trust. Similarly, heavy censorship and tight information control must be considered to be propaganda. Psychological nudges have become a weaponised version of behavioural science deployed against the Australian public to produce a desired government policy outcome. These techniques are not only unethical – they are antithetical to democracy and represent a radical and unprecedented shift in our social contract with our government.

The Nudges of Concern

In psychology and neuroscience, it is well understood that the majority of our behaviour is unconscious and reflexive. That is, it arises from the more primal, sub-cortical areas of the brain that humans share with animals. The neo-cortex, the front part of the brain that differentiates humans from animals, is responsible for our cognitive executive functioning. These higher brain functions are easily disoriented or shut down by fear, trauma, and ongoing stress.

We echo our British colleagues in identifying three main nudge categories of particular concern amongst the behavioural science techniques deployed against the Australian people. These are nudges that change behaviour via the utilisation of:

1. Fear (grossly inflating the level of threat posed by Covid-19)
2. Shame (designating those who do not comply as a reprehensible minority)
3. Peer pressure (ostracising and marginalising those who do not comply)

Examples of these nudges of concern, used in Australian government communications (and in particular, used by state governments) as part of their Covid response with the intent of influencing behaviours, are outlined below.

1: Fear

Fear is an innate physiological and psychological survival response that mobilises the primitive brain to hijack attention and keep the nervous system on high alert. It has been used throughout history to manipulate and control people through the application of psychological pain. Depending on the individual, fear can trigger defensive or compliant reactions that are well documented in research on abuse and coercive control. Fear overrides the rational part of the brain and may also manifest in physical symptoms including anxiety and panic. Applied over time, an individual's autonomic nervous system will attempt to regain homeostasis through behaviours designed to numb or suppress intensely uncomfortable or intolerable feelings. For instance, 'self-medicating' via food, alcohol, or other addictive substances or behaviours.

Methods targeting FEAR have included:

• Highly sensationalised headlines and news banners running 24/7, reinforcing fear and the constant triggering of anxiety
• Daily 'rituals', including briefings and continual replays to announce new numbers, restrictions, criteria and 'rules'
• Use of statistics to quote 'cases', 'infections' and 'deaths' – all without context
• Recurrent footage of sick, ventilated or dying patients in hospital (many of whom are 'crisis actors' who have been outed on social media and programs like Media Watch)
• Repetition of menacing slogans. For example, 'Covid will hunt you down', accompanied by alarmist images of emergency personnel in PPE, masks and visors
• Confusion – constant triggering of anxiety through changing of 'rules' and 'restrictions'
• Creating a 'fear of missing out' on your preferred vaccine due to scarcity created by limited or short supply
• The threat of loss of income, loss of one's business and livelihood – and

the ability to support oneself and one's family – which carries an extremely high existential threat
• Fear of loss of family, friendship and community relationships and support because of individual choices
• Threat of targeting and punitive disciplinary action from employers, and professional bodies, where individuals are told they are 'under investigation' for non-compliance
• Threat of future unemployability, inability to hold professional or business insurance
• Threat of loss of access to healthcare or being charged higher premiums.

2: Shame

Shame is another emotion that appears amongst research on methods used to manipulate human behaviour. In the case of Covid-19, 'virtue' was equated with adherence to government mandates and directives (such as wearing masks, using QR codes, getting tested even with no symptoms, and repeated vaccination). Those who resisted these directives were portrayed as the selfish, shameful and 'dirty' minority who were endangering the entire community (despite much scientific evidence to the contrary). Like fear, shame targets the primitive brain, causing distress in humans and all animal species that have an innate need to 'belong'. Most people have an unconscious desire to be accepted – to be perceived as useful and virtuous members of their community.

Methods targeting SHAME have included:
• Messaging that equates 'virtue' with adherence to restrictions, masking, vaccination
• Hijacking of colloquial idioms, such as, "It's your duty to 'roll up your sleeves' and get jabbed", (co-opting a phrase typically associated with 'working hard' and being a 'team player')
• TV advertisements using paid actors, celebrities and influencers to promote 'doing the right thing'
• Evoking sympathy for medical and hospital staff if you are not fully vaccinated and require their services – even for an accident, injury, scheduled surgery, or the ongoing treatment or monitoring of a health issue that's non-Covid related
• Shame and guilt for 'draining' the health system if you have not 'done your duty' and complied
• Targeting students and children with messaging that they are a threat to family, especially their grandparents.

3: Peer Pressure

Peer pressure has been utilised throughout the Covid-19 response to create division between and within families, workplaces and communities. Those who questioned 'rules' or 'mandates' have been painted as selfish and a danger to vulnerable members of the community, in contrast to those who have been compliant. The enforcement of wearing masks also served as a visible way for people to easily identify those who were 'compliant' from those who were not, allowing for maximum peer pressure and potential shaming to be utilised against non-mask wearers. This continues to occur, even with those who have valid mask exemptions.

Tactics such as labelling everyone who is 'hesitant' or who questions mandates, 'the science' or statistics as an 'anti-vaxxer', regardless of whether they have been vaccinated in the past, is another technique that uses the threat of loss, exclusion, and removal of privileges and rights to force compliance. Again, it targets the primitive part of the brain that equates being ostracised and cast out from the tribe with 'death'.

Methods targeting Peer Pressure have included:

• Labelling and shunning those who have queries as 'non-compliant' and 'anti-vaxxers'
• Installation of new 'accepted' rituals to replace previous habitual ways of being
• Repetition of the phrase, 'We're all in this together' – when there is the intentional fostering of division
• Categorising the 'non-compliant' and those asking questions and inviting debate as a deviant minority
• Recruiting businesses to track, identify, segregate or exclude 'rule breakers' and only serve 'rule followers'
• Inciting the public to polarise and to 'cancel' anyone who expresses opinions or concerns, or even references research that may be considered to be counter to the official mainstream narrative
• Encouraging the general public to use peer pressure to gain community compliance with their escalating restrictions, such as masking, tracking, QR codes, vaccine passports and testing. For example, families have been encouraged to exclude their non-compliant family members and friends from events, including holiday celebrations
• Narratives have been used to encourage blaming, scapegoating and to incentivise 'reporting' those who break the 'rules' (such as hotlines to 'dob in' colleagues and neighbours who attended a peaceful Freedom Rally, and even offering rewards)
• Making others – especially children – feel responsible, even guilty, for causing harm to others (e.g., their grandparents) is a deliberate and harmful manipulation.

In summary, to use nudges to encourage others to fear, shame, ostracise and apply peer pressure to any individual or group – and in particular, in ways that divide families – is unethical.

Ethical Questions

We have many ethical questions and concerns about the use of nudges on the Australian public which can loosely be grouped as follows:

1. Why is there a need for covert behaviour modification to implement Government policy rather than engage the Australian community in open debate?

2. How is lack of consent around the use of covert behaviour modification techniques (nudges) acceptable?

3. How is the harm inflicted on the Australian public, as a result of using nudge techniques based on fear, shame and peer pressure, justified or justifiable?

4. How is the lack of transparency around the use of these techniques appropriate? What possible justification can there be there for:

    • Engaging and incentivising partners to promulgate the messaging (including media, 'expert opinion', corporations, businesses, universities and institutions)
    • Conflicts of interest, including funding and sponsorship ('experts', media, heads of regulatory bodies, politicians, celebrities, influencers, etc.)
    • The ignoring and censorship of valid science that highlights significant concerns about the safety of the health directives
    • Lack of open debate – certain individuals are promoted as 'experts', while others, often far more qualified, are censored and silenced.

The position of various national, state and modality-specific Professional Associations including, but not limited to AHPRA, APS, ACA, PACFA, and HCCC

In Australia, the stance of professional bodies representing psychologists, mental health professionals and health professionals generally has been characterised by lack of support for members including:

• Advising psychologists and counsellors to recommend that their clients accept certain medical interventions, when this is outside their field of expertise, and it is not ethical for them to do so
• Threatening disciplinary action and suspending practitioners who ask questions, provide health advice, or voice opinions counter to public health policies and directives
• Not allowing health professionals to abide by long-held professional values such as 'informed consent'
• Failure to address responses to ethical questions raised by psychologists, including refusing to acknowledge 'mandatory reporting'
• Shutting down and targeting dissenting voices, and demanding they attend a 'psychiatric assessment', often administered by someone less qualified
• Terminating the employment of psychologists, counsellors, doctors, and other mental health providers who have queries regarding the official narrative and who are attempting to provide the best care for their individual clients and patients
• Making it difficult for students to get placements and fulfil requirements to complete their studies
• Limiting face-to-face sessions (and insisting on face coverings) in a growing mental health crisis creates ruptures in the therapeutic relationship and is perceived by clients as self-interest and a 'lack of care'
• Supporting 'rules' that exacerbate mental health conditions, versus working with their professional association members to support them to continue in their responsibilities to care for their clients and patients
• Severing client-patient relationships due to dismissal of practitioners, often with no allowance for closure, appropriate referrals and hand-over
• Refusing to acknowledge increasing suicide levels, alcoholism and major stress within our communities
• Promoting courses and resources that encourage 'shaming' and teaching techniques for 'persuading' and 're-educating' colleagues and clients who are hesitant
• Conflicts of interest – who 'owns' the heads and board members of these professional organisations – and dictates what is considered to be the accepted 'science'?

Supplemental Answer

Correspondence received in support of my answer, which I fully adopt and advance to the Committee, from Lindsay Spencer-Matthews, Registered Psychologist MAAPiBA (Soc Sci), Grad Dip (App Psych) Grad Cert (Acctg):

> I write this evidence with a sense of resignation and sadness. As a Registered Psychologist of over 27 years, as a human of over 70 years, and

as a "survivor" of the Covid years, I recognise that the forces aligned against common sense and the common good are highly intelligent, well resourced, implacably disinterested in their fellow humans, and relatively difficult to tell apart from we everyday humans. Having dealt with thousands of clients, and having been engaged in decades of academic study, professional development, and consideration regarding my profession, I fear that the worst within us might just be capable of overwhelming the best within us. The Covid years were an extraordinary experience for this 70-year-old man personally, socially, and professionally. I have seen genuine heroism demonstrated by a few, genuine malevolence shown by many, and genuine confusion and passivity evident in most. I write this submission in an attempt to give comfort to the few heroes, to spike the guns of the malevolent many, and to rescue the confused from themselves.

Part 1: Manipulation of and harm to citizens via government messaging

As the "lock-step" messaging (identical interpretations, identical inclusions/exclusions, even identical wording) began to flow in early 2020, it became obvious to me that there was a central reference point influencing those messages. I did not hear about the Trusted News Initiative until 2021. I became aware in mid-2020 that journalism no longer performed as I had perceived it in my earlier life. Now, in 2024, "Investigative journalist" sounds like an oxymoron outside of the emergence of "citizen journalists". As a psychologist I am acutely aware of how we humans tend to perceive, process, and interpret information. Most of this work is done by the primitive parts of our brains. I have spent my therapeutic career trying to alert clients to this phenomenon in order to reduce the harm it might continue to do to them, given that most people attending my rooms do so having already been harmed by their poor ability to perceive, process, and interpret information, in one way or another. Sadly, a cohort of my fellow psychologists find lucrative employment in the exploitation of these very normal limitations through the exercise of nudge techniques which take advantage of these very natural human frailties. The negative impact of the intentional use of nudge manipulation has been clearly evident throughout the Covid years.

Even today, the British Prime Minister swears on the Dispatch Box in Parliament (obviously under parliamentary privilege) that the "Covid vaccines are safe!". I note that he no longer asserts that they are "effective". Where are the investigative journalists seeking to find out what his definition of "safe" might be? It surely cannot be the widely accepted "without harm" that a reasonable person would expect. Whoever, or

whatever, it was that encouraged world leaders, mass media, celebrity "experts", and celebrities in general, to endlessly repeat the "safe and effective" mantra, certainly knew what they were doing. A lie uttered once is a lie, a lie uttered 1000 times starts to sound like the truth. After a thousand utterances of the lie, the truth becomes increasingly hard to demonstrate, or to believe.

We humans have a limited capacity to seek out, integrate, and act upon novel information. The reason that we survive the complex 21st century is that most of the novelty and danger are managed for us by entities that we are programmed to trust. Sadly, that trust has been shown to be misplaced in some important ways. The "Safe and Effective" narrative was an example of sophistry of the worst and most devious kind. Even those wondering at the absolute nature of that narrative might have been tempted to conclude that what was "actually meant" was that they were "safer than Covid19", even though time has not shown this to be the case.

As the draconian Covid19 reactions of governments began to emerge, and long before the experimental injections were developed, it was obvious to any who looked that the disease had an almost total preference for the lives of the old and the infirm, and that the early predictions of the Imperial College were hysterically overestimated. I find it fascinating that there appears to be no prior example of the Imperial College EVER getting a prediction right (as an example, see https://www.iedm.org/wp-content/uploads/2020/06/note032020_en.pdf for a stunning comparison of the Covid19 death predictions compared to actual deaths, and examples of previous spectacularly wrong overestimations. The most spectacular example for wildly wrong Covid19 death projections was for Taiwan, with an Imperial College prediction of 1.4 million deaths and an actual outcome of 7 deaths as of April 2020).

My experience was flavoured by my having been a passenger on the Diamond Princess on the cruise immediately before the one stranded off Japan due to it having Covid on board. I waited with trepidation for the disease to sweep through that population of disproportionately older people. My concern was a reaction to the Imperial College's modelling. In a floating incubator with shared air-conditioning and a population of over 4000 heavily skewed towards the aged, the total of 712 cases with 13 deaths fell far below even the most conservative projections.

If these early actual figures had been monitored and reported from the early days of the Covid years, would the draconian and experimental measures have ever been seen as politically palatable, let alone actually necessary? Why has it not yet been admitted widely that our "public health

messages" were the equivalent of Chicken Little saying that the sky was falling? Even today, after more than four years of Covid19, less than 1% of those diagnosed with Covid are, sadly, dying as a result. There have been almost as many people killed in car accidents over the same period, so why are we still allowed to risk our lives in motor cars, if raw death numbers can so powerfully influence health policy? Where was/is the due diligence, the journalism, the science? I suspect that it was hidden by the "lock step" messaging which could not have existed without some form of organised agreement, and some sort of diabolical psychological manipulation.

As I engaged with clients in those early months of 2020, I noted that the usual progress of therapy was often interrupted by my clients' fear of the new disease. As reporting of the raw numbers of deaths and positive PCR tests became a daily ritual of mainstream media and political briefings, it became obvious to me that my clients were not processing the actual threat in any way other than emotional. It became my habit to ask them "Do you know what percentage of the world's population have caught it so far, and how many have died?" The response was either admitted ignorance or incorrect and catastrophically wrong guesses. I followed the websites Our World in Data and Worldometer, and was able to cite these relatively reliable, and publicly available, sources. Such a reference to plausible, proportioned, and less alarmist, information almost always led to a moment of genuine relief for the previously agitated client. Sadly, the relief demonstrated by my clients when they gained a factual, unbiased, and relative view of the true risk was short lived, as most of them turned on the news that night and re-exposed themselves to the lockstep alarmist raw data endlessly reported by those purporting to be journalists. This was nudge messaging at an obscene level, carefully constructed to generate the most fear, the most compliance, and (potentially) the most profit.

Part 2: Violation of the right to freedom of thought without political interference

It seems almost nonsensical to have to consider this aspect of the Covid response. Had such rights NOT been violated, we would not have had 5 billion people subject themselves to repeated exposure to an experimental substance. Freedom of thought without political interference (such as denial of platforms to dissenting voices, cancellation of dissenters, blocking social media accounts, suspending and/or deregistering healthcare professionals) would have seen the dissenting voices, be they scientific, epidemiological, pharmacological, psychological, or educational, be heard. Once having considered such reasoned dissent, those 5 billion experimental subjects may have reached a different conclusion.

Part 3: Violation of psychological codes of ethics

I began my psychology studies in 1986. In that first year we were introduced to the scientific method, informed consent, and the ethical treatment of experimental subjects. All three fundamentals have been compromised over the Covid years (and perhaps before, but not as spectacularly, uniformly, or effectively). If adhered to, these principles negate the possibility of malevolent experimentation on humans.

The Covid years saw a cessation of evidence gathering unless it met the needs of the narrative. Raw numbers of infections and deaths may appear to be "evidence", but unless they are placed into context, they are easily misinterpreted, misunderstood, or misused. The gruesome daily counts of raw numbers were a device to feed into the fear and uncertainty which science, and the scientific method, would normally reserve for the kind of event which was, once, accurately called a "pandemic". Until recently a "pandemic" would have included a rise in all-cause mortality (ACM), followed by a dramatic fall in ACM. Due to Australia's dramatic border closures, and our island status, we did not suffer the initial increase in ACM seen in the non-island countries. We did not experience the initial "Wuhan" strain, had minimal exposure to "Delta", and most of our Covid19 infections have been of the much milder and more infectious "Omicron". We also had over 90% of our population injected with the "safe and effective" substances. Yet over 50% of us have caught Covid19, and our ACM has remained well above the pre-Covid baseline ever since.

My early studies at university included an examination of the Milgram, Asch, and Zimbardo experiments. I never expected to see Milgram replicated in real life, with otherwise ordinary people being forced by authority figures to abuse their innocent fellows (e.g., police arresting people for not wearing masks, just like subjects believing they were electrocuting others at Milgram's exhortation). I was not quite so surprised to see Asch replicated, showing the stupidity of the group overcome the wisdom of the individual (e.g., Queensland's Premier stating that the virus would "hunt down the unvaccinated", much like a subject stating something transparently false as a result of Asch's successful manipulation, via presentation of that transparently false response as a group's consensus position). I was, however, deeply disturbed to see Zimbardo echoed through the enthusiastic exercise of power both exerted, and complied with, by otherwise "good" people (e.g., ordinary people cutting family ties and contending that the unvaccinated should be denied medical care, much like the inhumane behaviour exhibited by those assigned to play "prison guards" in the Stanford Prison Experiment).

If these abuses were facilitated by clever psychologists working with nudge units, which I find appallingly credible, then my profession needs to hang its collective head in shame. We urgently need to review the training of emerging psychologists to ensure that the new generation refuses to comply, or be complicit, again. Of all the professions, psychologists (a) should have questioned the generally accepted premises from the start, (b) should have acted on their ethical obligation to safeguard people from psychological manipulation, and (c) should, courtesy of their training, have raised the flag of rational thought when others were rendered incapable of rational thought due to the fear that the nudging had inflicted upon them. Worst of all, we psychologists have an obligation to hold the regulatory authorities to account for having used their power to stifle any examples of such informed, intelligent and ethical dissidents and thereby usher in these terrible examples of humanity's inhumanity which once lived for me only in textbooks.

Part 4: Further observations and illustrative examples

Until recently I, as an average human and reasonably informed psychologist, believed that the phenomenon of "nudge" was the disreputable domain of advertising. To discover that our own governments and regulatory agencies have been employing such tactics is beyond abhorrent. We now have a large proportion of the community who live either in denial that they have been manipulated without any proper or ethical cause, or with an emerging awareness of such manipulation. The first group remain oblivious and, therefore, susceptible into the future. The second group are destabilised, distressed, and distrusting as a result. The adage "Fool me once, shame on you. Fool me twice, shame on me" is very applicable here. The discovery of having been "nudged" is akin to experiencing a betrayal. If the "nudge" is benevolent (e.g., my wife lies to me to keep my surprise birthday party secret), then I can reconcile myself to her deceit, but it remains deceit, even if well-intentioned and with acceptable outcomes. If the "nudge" is malevolent (e.g., my trusted doctor recommends an experimental treatment without telling me the risks and benefits) and the outcome then harms me (psychologically, socially, or physically) then I am unlikely to continue to invest such trust again.

Nudging people to obey widely held community mores, such as speed limits, drink driving, and "Stop" signs, is defendable. Marginalising behaviours such as domestic violence and paedophilia might even be noble. But shaming, intimidating, and coercing people into fearing a seasonal respiratory virus to such a degree that they agree to take part in the "biggest clinical trial in history" (as expressed by Mr Greg Hunt) is

beyond reprehensible. The contribution that my profession, psychology, has made to this state of affairs makes me embarrassed to be a psychologist. The fact that our regulators and professional bodies still adhere to these notions is malfeasant.

As a final personal and professional observation on this question, I am moved to note that nudging is a form of gaslighting. To gaslight someone is to act in ways which are intended to diminish, undermine, or take advantage of that person. Gaslighting can include overt and covert behaviours, and/or an intentional absence of behaviours. Gaslighting is far more difficult to counter than it is to commit. Gaslighting behaviours can include lies, partial truths, cherry picking, personal attacks and insults, social exclusion, unduly exaggerated emotional reactions, calls to questionable authority, cancellation, and many more techniques which were abundantly demonstrated in the nudge activities related to Covid19. For completeness I will provide examples of each of these behaviours as related to Covid19 messaging and behaviours.

Lies:

> "There are no alternative Covid19 management methods available."

This was an outright lie as, just one year earlier, in 2019, the WHO had developed specific guidelines to manage a respiratory virus pandemic which were completely opposite to what unfolded across the world. Without awareness of the whole truth, the nudge/gaslighting is persuasive and plausible. It would not even occur to the person in the street to question such an unequivocal statement (lie) from a previously trusted authority.

Partial truths:

> "Safe and Effective".

No one would argue that the experimental injections were totally unsafe or totally ineffective, but the degree of safety and effectiveness was not discussed. We were repeatedly and unequivocally told that they were "safe and effective". Digging beyond such hyperbole is beyond ordinary folk, particularly when they are being nudged/gaslit.

Cherry picking:

> "Studies show that masks are effective".

Citing a single study or a limited number of studies without noting that there are many more examples in the scientific literature that demonstrate the ineffectiveness of masks is cherry picking. For the uninformed, the distracted, and the lazy, such nudging provides the illusion of scientific consensus, and, in the absence of a platform, it is very difficult to counter.

Personal attacks and insults:

> "Anti-vaxxer" and "granny killer".

The sobriquets of "anti-vaxxer" and "granny killer" might be legitimate if the dissidents were unreasonable, unreliable, uninformed psychopaths. The fact that most dissidents had taken every vaccine prior to Covid19 completely negated the first insult, and the fact that granny would be protected by her own injections (IF those injections worked as "advertised") negated the second, yet these ad hominem attacks created via gaslighting a social division, existing to this day, which must have made the nudge units feel very proud.

Social exclusion:

> "No green tick, no service."

We are a social species for whom in history, anthropologically, exclusion from the tribe meant death. To exclude people from their day-to-day activities was overt coercion and a deliberate embarrassment tactic. Such abuse of power used to exclude a dissenting minority is a clear example of gaslighting.

Unduly exaggerated emotional reactions:

> "I would feel uncomfortable standing next to an unvaccinated person".

This statement stood out, to me, as one of the worst examples of gaslighting. For the NSW Premier to tacitly admit, as a "vaccinated" person, that the injections did not work (i.e., to protect her from the unvaccinated), did not appear to occur to anyone. This example of gaslighting demonstrates the irrationality of gaslighting. The absence of incredulity and outrage over this statement demonstrates the awful power of gaslighting. The emotionality in her gaslighting statement effectively hid its true meaning.

Calls to questionable authority:

"Wearing masks will slow the spread".

I was one of over ten thousand Queenslanders to sign a petition asking the then Health Minister, Yvette D'Ath, for the evidence that her expert advisors had presented to justify the mandating of masks. Her response was "it is widely accepted that masks slow the spread of airborne viruses". This dismissive reference to "the science" typified the gaslighting of Covid19. If Ms D'Ath had been provided with overwhelming evidence to support mask mandates, why would she not provide that evidence to her petitioners? Instead, she cited the unscientific, and minority, view as being a "consensus". Such gaslighting then places the obligations on those being gaslit to disprove the spurious "voice of authority".

Cancellation:

The AHPRA March 2021 Position Statement.

The most powerful tool available to a gaslighter is the ability to silence the voice of truth and reason. If you behave in any of the ways mentioned above, and then gag those you just gaslighted, you have sinned twice. The fact that many courageous healthcare workers who spoke out, telling the truth, are still suspended or deregistered is appalling. I know one psychologist who has been suspended for three years, even though her every statement has been shown to have been true and relevant. I know a previously famous and respected gynaecologist who now sells garden sheds because he dared to tell the truth about the impact that the Covid19 injections had on his patients. I was investigated, and issued with a warning, for encouraging people to think rationally. This final example of the behaviour of the gaslighting bully, cancellation, is perhaps the worst.

I write these remarks and observations from my own experiences, my observations of my clients, colleagues, and friends, and after having spent the last four years trying to prove myself wrong. I have never been so motivated to disprove my own hypotheses as I am now, and I have never been so unsuccessful in being able to disprove them. I have sought input from hundreds of medical doctors, nurses, psychologists, academics, and the public, and all I have received back has been a repeat of the gaslighting examples referred to above. Our politicians, bureaucrats, registration authorities, and media, all need to be held accountable for their roles in the world's largest, worst designed, most unethically carried out, and most egregiously camouflaged experiment in the history of mankind. If they are not held accountable, then I shudder to think what they might do next.

Recommendations

1. A truly independent and comprehensive evaluation of the ethics of deploying psychological 'nudges' on the Australian people – during public health campaigns and in other areas of government – is now urgently required.

2. Transparently acknowledge and inform the population about how 'nudges' have been used to influence their behaviour and to co-opt their compliance.

3. Identify strategies for repairing the many psychological harms that have been inflicted through the non-transparent application of 'nudge' and other behaviour modification techniques.

4. Provide funding for repairing the ruptures and rebuilding trust in the community at all levels, including between individuals and their medical and other health professionals, who have been denied the opportunity to speak truthfully to their patients.

Index

Reference: J

Index

A review and analysis of the functioning of Federal, State, and Territory government media liaison departments and activities during 2020, 2021, and 2022, in respect of:

i. any plans, strategies, policies, or activities involving the coordination of State and/or Territory and/or Commonwealth Government Covid-19 messaging amongst Australian governments;
ii. any plans, strategies, policies, or activities involving Federal, State, or Territory government Covid-19 messaging using Australian media outlets and companies;
iii. any plans, strategies, policies, or activities or relationships with Covid-19 vaccine suppliers and manufacturers with Federal, State, or Territory governments or officers concerning Covid-19 messaging;
iv. any plans, strategies, policies, or activities involving Federal, State, or Territory governments in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning the safety or efficacy of Covid-19 vaccines;
v. any plans, strategies, policies, or activities involving Federal, State, or Territory governments in the coordination of, involvement with, advising upon, the directing of, or the requesting of the censorship or 'taking down' of any information or messages from or by any persons or groups seeking to share via media, social media, or direct public engagement, opinions, views, scientific evidence, data or information questioning Federal, State, or Territory or Commonwealth Government mandate measures in response to Covid-19;
vi. any plans, strategies, policies, or activities involving Federal, State, or Territory governments and social media and media companies in respect of (iii) and (iv) above, including 'fact checker' organisations;
vii. any plans, strategies, policies, or activities involving Federal, State, or Territory governments and the Trusted News Initiative;
viii. systems and processes of review implemented by Australian governments to ensure that new and different and evolving scientific hypotheses, case reports, and scientific reports supporting alternative approaches in respect of pandemic management and the treatment of Covid-19 were not suppressed, and were shared with Australian health practitioners and the public.

Explanatory Memorandum

Index

An examination to confirm whether the activities of the Federal, State, and Territory government media liaison departments in respect of Covid-19 public messaging, including any actions undertaken to censor non-government public messaging throughout 2020, 2021, 2022, and 2023 were reasonable and proportionate and consistent with real-time Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known and shared amongst Australian governments.

Question(s) on Notice

Index

In respect of **Reference J**, please provide any further information concerning the functioning of Federal, State, and Territory government media liaison departments and activities during 2020, 2021, and 2022, in the context of Covid-19 public messaging.

Answer(s)

Index

Answer

The People's Terms of Reference:

Time constraints prevented a full and complete response to the above question which would have seen an extensive answer, had sufficient time been made available.

Term of Reference J continues to be advanced by The People's Terms of Reference.

Reference: K

Index

A systematic review of the funding from Australian governments to all bodies responsible for media collaboration and advertising in regard to Covid-19, including any contracts or incentives offered, including but not limited to:

i. the ABC;
ii. channels 7, 9, 10, and SBS;
iii. the RMIT;
iv. The Grattan Institute;
v. 'fact checker' organisations;
vi. the Actuaries Institute;
vii. the Australian Bureau of Statistics;
viii. the Australian medical colleges;
ix. AHPRA and the National Boards;
x. Universities;
xi. Medical research institutes;
xii. the TGA;
xiii. the Australian Academy of Science (AAS);
xiv. the Australian Academy of Health and Medical Science (AAHMS);
xv. the Australian Council of Learned Academies (ACOLA);
xvi. ATAGI.

Explanatory Memorandum

Index

An examination to confirm whether Australian government media contracts and collaborations relating to Covid-19 with non-government media companies and institutions, to assist Australian governments with influencing Australian citizens towards Covid-19 vaccination and compliance with Covid-19 mandates, were fair and unbiased arrangements that did not seek to restrict third parties sharing views that criticised or offered information in opposition to the Covid-19 messaging of Australian governments; and to further confirm such contracts and collaborations were reasonable and proportionate and necessary when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

An examination to confirm whether Australian government media contracts and collaborations relating to Covid-19 with non-government media companies and institutions, sought or required or influenced those media companies and institutions to challenge or possibly censor Australian citizens with differing

public views towards Covid-19 vaccines and mandates, and whether any such requirements or influence was reasonable and proportionate when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 adverse event reports;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference K**, please provide any further information concerning funding from Australian governments to any bodies or companies for media collaboration and advertising in regard to Covid-19, and particularly in respect of how any such funding could have or did in fact affect critical journalism in Australia during the same period, in respect of Covid-19.

Answer(s)

Index

Answer

The People's Terms of Reference:

This is information that Australian governments hold that requires a Covid Royal Commission to request for examination.

An example of the manipulation of the media is provided by the RMIT debacle:

> Facebook suspends RMIT FactLab after voice No campaigners criticise factchecker

Another example involved a failure by RMIT/ABC fact checkers to provide a response to FOI REF 202223-005 seeking the evidence and basis for claims by RMIT via the ABC, as a fact checker media comment, that there were no concerns over birth rate drops.

The above answer has been limited due to time constraints.

Index

Reference: L

Index

A review and analysis of Covid-19 national statements, policies, or directives created by Australian governments or their agencies for the attention and observance by health practitioners, and any possible risks, detriments, or impacts upon the delivery of health services caused as a consequence of any national statements, policies, or directives, including:

i. the 9 March 2021 joint statement issued by AHPRA and the National Boards, including an examination to confirm whether, prima facie, the AHPRA joint statement:
   a) impaired or infringed or obstructed or violated the doctor-patient relationship;
   b) unduly or unfairly or unreasonably or illegally censored doctors and health practitioners;
   c) caused or forced or coerced violations of the Codes of Conduct and Ethics;
   d) caused doctors and health practitioners to violate their Codes of Conduct and Ethics placing them in violation of the National Law;
   e) was a legally valid statement;
   f) was a statement that illegally employed coercion or duress for compelling health practitioners to violate Codes of Conduct and Ethics and in turn the National Law;
   g) was influenced by the International Association of Medical Regulatory Authorities (IAMRA)/Federation of State Medical Boards (FSMB);
   h) misled the Australian population into compliance with government measures by creating a false impression of medical and scientific consensus, through denial of access to a full range of informed and expert opinions;
ii. possible impacts on *valid* Informed Consent;
iii. the presence of any conflicts of interest with the authors of national statements; and
iv. an examination of the investigatory and disciplinary processes undertaken by AHPRA against health practitioners deemed or alleged to have acted in any manner contrary to the 9 March 2021 joint statement.

Explanatory Memorandum

Index

An examination to confirm whether statements, policies, or directives created by Australian governments or their agencies to be observed by health practitioners

were:

a) reasonable and proportionate and considered all available scientific evidence; and
b) involved fair and reasonable prior consultation with health practitioners; and
c) ensured by way of prior legal analysis that all statements, policies, or directives were legal and would not be causative of any legal infringements by health practitioners observing same; and
d) would not negatively impact upon *valid* Informed Consent being provided by Australian citizens.

An examination to determine whether any evidence considered by AHPRA was held to acceptable standards of reliability and validity. That is, whether it:

a) emanated from primary sources (such as clinical trials, real world data, biological science) rather than secondary sources (such as bureaucrats, government officials, press agencies and corporate actors);
b) whether it emanated from independent sources absent conflicts of interest;
c) whether it emanated from sources with the appropriate subject-matter expertise; and whether AHPRA ensured all of its evaluation of the science prior to the release of the 9 March statement was undertaken by persons with the appropriate range of expertise (microbiology, immunology, infectious disease, epidemiology, pharmacology, toxicology and nanotoxicology).

An examination to determine whether health practitioner directives were regularly reviewed and updated as new evidence regarding Covid-19 came to light.

Question(s) on Notice

Index

In respect of your joint submission and in particular index **Reference L**, concerning the 9 March 2021 joint statement issued by AHPRA which effectively gagged Australian doctors from sharing their concerns about Covid-19 vaccines with their patients, is there any legal basis to say that statement by AHPRA was illegal and was made illegally by AHPRA, where the consequence of AHPRA's statement was to cause all doctors who censored themselves with their patients, to breach their Codes of Conduct, thereby causing them to commit offenses under the National Law, possibly creating a basis for medical negligence lawsuits?

Answer(s)

Index

First Answer

Peter Fam, Co-Author:

The joint statement released by AHPRA and the National Boards on 9 March 2021 (**the March Statement**) saw an unprecedented imposition on the ability of doctors to practice in accordance with both their own professional judgment as well as in accordance with their own Code of Conduct.

Section 30 of the National Law contains the power for AHPRA to decide 'policies', but nowhere does or did AHPRA assert that the Position Statement was a 'policy' of AHPRA in the proper sense. AHPRA is required to publish all official Policy Directions and guidance on its website, and record them in its Annual Report. In the 2020-2021 Annual Report covering the period during which the March statement was released, AHPRA made no record seeking to place the March statement forward as an official policy.

As such, the March statement at its highest can only be called a 'joint statement' or 'position statement' published by AHPRA and the National Boards.

This means the March statement holds no special legal nature or force, nor does it appear possible to call the March statement a 'legislative instrument' or 'subordinate legislation'. Instead, the March statement appears to be nothing more than support for the national Covid-19 vaccination program, where in terms, it seeks to state on behalf of Australian governments 'what is expected' of registered practitioners.

It was used to discipline practitioners, but perhaps more worryingly, it was used to *frighten* practitioners, and it was very successful in doing so. Doctors across the country refused to issue valid contraindication certificates or to provide their patients with the opportunity to provide fully informed consent as a result of the March Statement, opening themselves up to liability for medical negligence, and potentiating serious physical and psychiatric harm for their patients.

In August of 2022, Julian Gillespie and I released a legal opinion elaborating on the above in detail. The opinion establishes that the March Statement was made in contravention of the ***Codes of Conduct*** which supersedes such a statement in law. Even if made with good intentions as the experimental gene-based Covid-19 injectables were rolled out in an atmosphere of great hope, its outcomes have been to undermine the ***Codes of Conduct***, the practitioner-patient/client relationship, and thwart the right of patients to fully-informed Informed Consent.

In short, the Legal Opinion, annexed hereto and marked Annexure 8, establishes the following:

a. The publication of the 9 March 2021 joint statement by AHPRA and the

National Boards was illegal.

b. At all times before and after publication of the March statement, Health Professionals were required to observe first their ***Codes of Conduct***, irrespective of the various coercive and threatening statements made in the March statement.

c. ***Codes of Conduct*** are subordinate legislation deemed Statutory Rules; a failure to strictly observe ***Codes of Conduct*** amounts to a breach of the ***National Law***.

d. Nothing in the March statement allowed any Health Professional to not observe their ***Code of Conduct*** in respect of the Covid-19 injectables.

e. Covid-19 injectables administered by a Health Professional who does or did not fully-inform patients of the known risks associated with the injectables, for the purpose of patients providing fully-informed Informed Consent, were and are in breach of the ***National Law***.

f. Health Professionals who do not and/or did not fully-inform patients of the known risks associated with the Covid-19 injectables for the purpose of patients providing fully-informed Informed Consent, are now legally liable to 'vaccine' victims for **Professional Negligence and/or Medical Negligence**.

g. No Australian government has put in place any indemnity or immunity for Health Professionals in respect of their potential liability to patients to whom they administered Covid-19 injectables.

h. As a consequence of the 9 March statement being illegal, the public officers within AHPRA and the National Boards responsible for the publication of the statement, now appear to be personally liable to Covid-19 'vaccine' victims. The reason for this would be due to the foreseeable harm arising from the statement 'gagging' Health Professionals from sharing evidenced-based information about the known risks associated with the Covid-19 injectables. This liability arises under the tort of **Misfeasance in Public Office**.

i. Lastly, Health Professionals who may indeed be professionally liable to 'vaccine' victims, may themselves be able to also sue the public officers within AHPRA and the National Boards responsible for the March statement, again by resort to the tort of **Misfeasance in Public Office**.

Index

Second Answer

Ros Nealon-Cook BPsychSc, Co-Author:

I have outlined in previous answers, the sequence of events in 2021 that led to the suspension of my psychology licence and with it, the destruction of my career, reputation and livelihood. My crime? Attempting to raise safety concerns in the public interest, firstly with regards to child safety and secondly regarding the lockstep media censorship of qualified Australian health professionals who were similarly trying to protect the public from dangerous government policy.

When I registered with AHPRA in 2010 and adopted the APS Psychological Code of Ethics, I understood that freedom of speech, informed consent, and non-coercive practices were the cornerstone of ethical psychological practice. I had no hesitation in adopting these ethical principles, since they represent values that I hold as extremely important on a personal level.

AHPRA's March 2021 Position Statement (the "Gag Orders") starkly conflicted with these principles, imposing restrictions that felt antithetical to the values I stood for. These directives essentially prohibited free speech and informed consent, disgracefully crafted by bureaucrats who were either missing critical safety data (negligent), or deliberately withholding it (malfeasance). Any Australian mental health professional who has undertaken the mandatory (and substantial) ethics training requirement of our profession would be immediately aware that the "Gag Orders" were not only highly coercive but had the potential to impact millions of lives. In the video which led to my suspension, **my request was simply that government and media allow relevant medical experts to openly debate this critically important information** ... *surely* not an unreasonable request with so many lives at stake?

Choosing to speak out, driven by a duty to protect and advocate for the vulnerable, especially in light of my mandatory reporting obligations, resulted in severe personal and professional repercussions. You will be aware that I was not alone in being 'disciplined' for speaking out, and no doubt, you are familiar with my fellow 'heretics'. Are you also aware of the large numbers of Australian health practitioners who voluntarily left their professions (deregistration and early retirement) after witnessing the campaign of bullying and persecution to which my colleagues and I were subjected? Good, honourable medical experts were terrorised into ending their careers before they could be similarly 'punished'. As the 'suspended psychologist', many of these fine professionals sought my support, all suffering significant distress. I have certainly spoken to more than a hundred health practitioners who left the profession due to fears of persecution from AHPRA – including two veteran medical doctors who were experiencing severe suicidal ideation. Courtesy of the governments stazi-esque 'gag orders'. Writing and remembering these experiences makes me utterly sick to the stomach.

I've been asked to provide a detailed account of what I experienced at the hands of the various government tentacles for doing no more than fulfilling my statutory obligation to protect my clients and the children of Australia. However revisiting those experiences has proved too traumatic these last few days and this time, I'm putting myself first. Summary points were that I was suspended, repeatedly threatened with criminal offences, stalked on social media and required to attend a psychiatric assessment. A psychiatric assessment because the government didn't like what I was saying – it would be brilliant Orwellian farce if it hadn't been so personally injurious.

Many of my suspended colleagues have been (or still are) involved with protracted legal battles with AHPRA in efforts to have their suspensions reverse. I've had countless requests to join class actions/fights against AHPRA however as a mother, for the sake of my own mental health and that of my family, I'm not willing to get involved in a game where I have zero faith that the hand is not entirely stacked against me. Remarkably, before facing the 2021 tribunal which stripped me of my license, I was counselled by two solicitors and a barrister, all independently advising against my even showing up. Their unanimous verdict? It would be an exercise in futility, a sham or in the words of one "a kangaroo court". That advice only cements my conviction that the current system is designed to fail us, to deny us a fair hearing. Sadly, my faith in receiving just treatment within this system remains utterly shattered.

I withdrew and wrote to AHPRA, HCCC explaining why. Of note:

> As a practitioner, I cannot ethically operate in an environment that promotes non-evidence-based government health policy above fundamental democratic freedoms and unalienable human rights. Similarly, I cannot ethically work in a system beholden to boards and bureaucracies that must either be ignorant of the existence of opposing information (indicative of incompetence) or complicit in suppressing that information (or possibly some combination of both).
>
> Although the addressees of this letter may find ways to avoid ethical imperatives whilst hiding behind corporate and political agendas, this does not obliviate any of you of your own professional ethical responsibilities – or your personal moral responsibilities. Have you not considered the *mens rea* piece here? *Why* would thousands of health professionals around the world, such as myself, have risked everything to raise awareness of these issues? Whether as mental health professionals, or a body that purports to 'represent' or 'regulate' our profession, it is critical to consider this.

Against this backdrop, I extend a heartfelt appeal to you, Senator Paul Scarr,

inspired by my great-grandfather, Sir Joseph Cook, and my grandfather, Justice Richard Cecil Cook. Both served our country as embodiments of truth and integrity during a time when Australia was guided by stronger principles. I take pride in my heritage and urge you to embrace these values in your work, ensuring a legacy that your descendants can equally be proud of. This shared legacy highlights the paramount importance of unwaveringly committing to what is right, even in the face of adversity and professional risk.

Index

Third Answer

Kara Thomas, Co-Author:

The Australian Health Practitioner Regulation Agency (AHPRA) issued a position statement warning health professionals against publicly questioning government public health directives, particularly regarding Covid. This statement threatened their registration, and it is viewed by the Australian Medical Professionals Society not only as a breach of Medical Ethics, international declarations and the Codes of Conduct, but probably illegal.

The joint position statement with the National Boards on March 9, 2021, which was distributed to registered health practitioners nationwide, restricted health practitioners from providing independent advice regarding the safety, efficacy, and risk-benefit of Covid vaccines if it contradicted the official promotion and encouragement of vaccination on the grounds that it may cause vaccine hesitancy. The statement limited the doctor-patient relationship and compelled practitioners to adhere solely to the official position of the government, disregarding their professional experience or what they deemed to be the best available scientific evidence.

Similarly, around August 2021, AHPRA and the Therapeutic Goods Administration (TGA) jointly issued a public statement further emphasising limitations on independent advice regarding Covid vaccines. This statement reinforced the requirement for health practitioners to adhere to government-approved information sources and prohibited them from swaying the public with disobedient opinions. Regardless of how accurately and thoroughly researched. It effectively prevented practitioners, through coercion, from providing comprehensive information to patients, hindering proper valid informed consent and discouraging open discussion and reporting of adverse effects following immunisation (AEFI). All this was on pain of potentially losing their registration to practice and as a result their employment.

AHPRA and the TGA were aware of the restrictions imposed by these statements,

which undermined the ability of health practitioners to provide essential information to patients for valid informed decision-making and reporting of AEFI. Despite the potential effect on patient safety and informed consent, the government enforced coercive measures that impeded the professional autonomy and ethical obligations of health practitioners.

The directive prohibits promotion of anti-vaccination statements that contradict scientific evidence or undermine the national immunisation campaign. Practitioners faced regulatory disciplinary action resulting in conditions on or suspension of their registration for challenging public health messaging, providing independent advice and patient advocacy regarding Covid-19 vaccination based on individual risk-benefit assessments, providing exemptions based on government and manufacturer data or prescribing early treatments supported by sound scientific evidence but not recommended by authorities. These facts and circumstances have never been encountered before in Western culture and require serious examination of anti-scientific disciplinary action taken by regulators against practitioners for expressing views contrary to government messaging, which requires consideration and an examination of the balance between public health interests and individual rights. Examples of this regulatory overreach were, unfortunately, exemplified by cases such as Dr. Melissa McCann, Dr. Paul Oosterhuis, Dr. Robert Brennan, Dr. Christopher Neil, Dr. Duncan Syme, Dr. Jeyanthi Kunadhasan, Dr. Mei Li, Dr. Sally Price and Dr. Hobart, where in each case the presumption of innocence was undermined and ignored, suspensions were swift and ruthless, followed by continuing and lengthy inquiry processes designed, it would appear, to keep conscientious doctors tied up in quasi-judicial procedures designed to wear them down and cause serious financial stress limiting their capacity to seek justice, all the while keeping them from their patients; patients who have been denied access to the learned medical opinions of *their* doctors, simply because the professional opinions of these doctors did not always accord with government health messaging that was in fact being *pushed*, (and continues to be), about what were unknown and unproven Covid-19 injectables in 2021 and 2022. Now in 2024, and every concern and caution and alternate treatment raised by the above persecuted doctors have, with the passage of time, been shown to be correct and reasonable.

The joint statements raise grave concerns about the lack of transparency in decision-making processes. There has been actual coercion of health professionals to comply with government policy, and the erosion of trust in the medical establishment resulting from regulatory actions. It calls for a return to ethical evidence-based medicine, transparent communication, and accountability within AHPRA's and the National Boards' regulatory framework.

Health professionals argue that directives contradict their oath to 'first, do no harm' and their commitment to valid informed consent and their code of conduct.

Compliance with public health messaging is seen as overriding the primacy of the patient, which is and always must be the principal concern of medical ethics and the Good Medical Practice Code of Conduct.

These statements need to be viewed with reference to historical contexts as well as with consideration of the importance of freedom of political communication and intellectual freedom. Citing the High Court's discussion on over-arching benefits of intellectual freedom, the Court's judgement in *Ridd v James Cook University* emphasises the societal importance of intellectual freedom and the duty to speak out for what one believes to be true. Medicine should never be under the total control of a rigid bureaucracy determined to support it at any cost.

The directives raise constitutional concerns about the right of political communication. Professor Augusto Zimmermann argues that the legislation suppresses freedom of political communication and imposes undemocratic control through enforced medical censorship. The controversy highlights the tension between transparency and repression. Practitioners argue that suppression of information appears to violate individuals' rights to fully informed valid consent.

This situation challenges the principles of evidence-based medicine, informed consent, and bodily autonomy. Practitioners perceive themselves as being compelled to enforce government guidelines rather than advocate patient welfare.

To protect the public and the integrity of medicine there needs to be much greater transparency, adherence to evidence-based medicine, protection of health professionals' rights to advocate on behalf of patients, and accountability in regulatory actions taken by AHPRA. It raises concerns about the potential politicisation of healthcare decisions and the erosion of trust in regulatory bodies where directives handed down as "advice" are not supported by independent science, and not open to challenge by cogent argument, and carry with them wholly unjustified capacity to punish.

In conclusion, the AHPRA Position Statement raises substantial ethical, legal, and constitutional issues, prompting concerns about intellectual freedom, freedom of political communication, patient advocacy, democratic principles and the blatant misuse of power. All of these matters are of critical national importance requiring thorough examination by a Covid-19 Royal Commission.

Index

Reference: M

Index

A review and analysis of Australian laws, policies, practices, and procedures concerning *valid* Informed Consent for medical treatments in the context of Covid-19 vaccines, including:

i. an assessment of any defects, faults, or failures in Australian citizens receiving all information necessary for the purpose of providing fully informed *valid* Informed Consent for agreeing to receive, or not receive, a Covid-19 vaccine;
ii. whether Australian governments and health authorities provided all necessary resources and information to health practitioners so the conditions for legally valid Informed Consent detailed in the Australian Immunisation Handbook were fully satisfied, including ensuring all Australians were informed about:
    a) the fact that mRNA Covid-19 vaccines are genetic vaccines that involve injecting foreign genetic material into the body;
    b) the new technology contained in the Covid-19 genetic vaccines had never before been used for vaccination, and involved recombinant technology satisfying Australian legal definitions for being properly called genetically modified organisms (GMOs);
    c) the fact all Covid-19 genetic vaccines had significantly limited and incomplete clinical studies;
    d) the fact all Covid-19 genetic vaccines had significantly limited short-term safety data, and had no medium or long-term safety data;
    e) that all Covid-19 vaccines were only *provisionally* approved by the Therapeutic Goods Administration due to the limited nature of the short-term, medium-term and long-term safety data;
    f) that the limited nature of the short-term, medium-term and long-term safety data meant that Covid-19 vaccines may have a greater number of unknown risks compared to other vaccines;
    g) that insufficient research had been done to ensure that the Covid-19 genetic vaccine products do not interfere with a recipient's genetic material and, therefore, that genotoxicity is a potential risk of these vaccines;
    h) the fact all Covid-19 genetic vaccines had not been tested for preventing transmission;
    i) the known risks and unknown risks associated with Covid-19 genetic vaccines;
    j) the known risks and unknown risks associated with the manufacture of Covid-19 genetic vaccines;

k) all other treatments, protocols, and preventative measures available instead of or in addition to a Covid-19 genetic vaccine;

iii. whether *valid* Informed Consent was affected by incentives provided by Australian governments or Australian health authorities;

iv. whether *valid* Informed Consent was affected by contracts with Australian media entered into by Australian governments or Australian health authorities;

v. whether *valid* Informed Consent was affected by any actual or threatened punishment by Australian governments or Australian health authorities;

vi. whether *valid* Informed Consent was affected by any actual or threatened coercion by Australian governments or Australian health authorities;

vii. whether *valid* Informed Consent was affected by any actual or threatened coercion by Australian companies who mandated Covid-19 vaccines for employees;

viii. whether the denial of medical exemptions affected *valid* Informed Consent; and

ix. an examination of recommendations, rules, and policies implemented by Australian governments and agencies in respect of the recognition of, and granting of medical exemptions from receipt of Covid-19 vaccines.

Explanatory Memorandum

Index

An examination of whether *valid* Informed Consent was possible for the novel and provisionally approved Covid-19 vaccines being administered in a setting where efficacy data and short-term, medium term, and long-term safety data were limited and incomplete, where coercive mandates and restrictions of freedoms based on vaccination status existed, and where restrictions had been placed on medical professionals in regards to the management of exemptions and the sharing of their knowledge regarding vaccine safety and efficacy.

An examination to confirm whether Australian governments and health practitioners fully ensured that *valid* Informed Consent was fully prioritised as a condition precedent before any Australian citizen received a Covid-19 vaccine throughout 2021, 2022, and 2023, and that all reasonable and ongoing efforts were undertaken by Australian governments to ensure health practitioners received and conveyed to Australian patients all information about the nature of Covid-19 vaccines, and updated in real-time Australian health practitioners with all reasonably available Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known by and shared between Australian governments, for advising Australian patients receiving Covid-19 vaccines.

Question(s) on Notice

Index

Mr Fam, in respect of index **Reference M** in your joint submission, and to your knowledge, in respect of Covid-19 vaccines, do you believe Australians were prevented from providing legally valid Informed Consent, due to information about Covid-19 vaccines that Australian governments failed to share with Australian citizens?

Answer(s)

Index

First Answer

Peter Fam LLB, Co-Author:

Australia has a long legal history of upholding the central medical tenet of fully informed and free consent.

The origins and development of Informed consent in Australian Law

Origins and Development of the Concept in Australia

The use and definition of "informed consent" as a legal concept has occurred over time through the common law, mostly in the context of claims for medical negligence.

The term "informed consent" first arose in North America in 1957[xiv] where it was introduced as a means of shifting practitioner emphasis away from medical paternalism towards a "duty" to respect the autonomy of patients.

The Australian and English courts were initially uninfluenced by this decision or concept, instead favouring the more conservative *Bolam* test,[xv] (summarily; that a doctor who reaches the standard of a responsible body of medical opinion is not negligent, whether or not they informed their patients of any risks).

The first major development in Australia occurred in *Sidaway v Board of Governors of Bethlem Royal Hospital [1985]*,[xvi] where it was held that "currently accepted practice" would not override or excuse the non-disclosure of a particular risk of serious adverse consequences to the patient, where it is "obvious to the prudent doctor" that such disclosure would be "necessary if the patient were to make a rational or informed choice as to whether to accept or reject the treatment

offered". Failure to do so, it was said, may provide grounds for negligence.

The second major development was *Rogers v Whittaker (1992).*[xvii] Here, the Court actually rejected the use of the expression "informed consent" as "apt to mislead", instead introducing the term "duty of disclosure". In doing so, the Court reaffirmed that doctors have a duty to disclose and warn patients of "material risk".[xviii] Furthermore, the basic duty to disclose was deemed to be present even when the patient does not seek information through specific questions. This was emphasised by Gaudron J when she wrote:[xix]

> where, for example, no specific inquiry is made, the [doctors'] duty is to provide the information that would reasonably be required by a person in the position of the patient

Gaudron J also pointed out that the duty to disclose or to warn of all material risks was a minimum, not a maximum. She added; "a patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned". Thus, disclosure of information to the patient must now take account of factors associated with the specific needs of the patient, be they wishes, anxieties or beliefs.[xx]

The current characterisation of informed consent in Australian Law

Statute

First, it is important to note that there is no statutory enshrinement of informed consent in NSW in a general sense. There are some statutes however which define or use the phrase for their purposes.

For example, the *Guardianship Act 1987 (NSW),*[xxi] in the context of consent for the carrying out of mental or dental treatment on patients under a guardianship order, implements several checks and balances which might be complied with by the guardian:

> 40 Consents given by persons responsible for patients
>
> (1) Any person may request a person responsible for a patient to whom this Part applies for that person's consent to the carrying out of medical or dental treatment on the patient.
>
> (2) Such a request shall specify—
>
> (a) the grounds on which it is alleged that the patient is a patient to whom

this Part applies,

(b) the particular condition of the patient that requires treatment,

(c) the alternative courses of treatment that are available in relation to that condition,

(d) the general nature and effect of each of those courses of treatment,

(e) the nature and degree of the significant risks (if any) associated with each of those courses of treatment, and

(f) the reasons for which it is proposed that any particular course of treatment should be carried out.

(3) In considering such an application, the person responsible for the patient shall have regard to—

(a) the views (if any) of the patient,

(b) the matters referred to in subsection (2), and

(c) the objects of this Part.

The above criteria seem to acknowledge the elements of informed consent as well as taking into account the judgment of *Rogers v Whitaker* above.

The *Mental Health Act 2007* No 8 (NSW) refers to "informed consent" only in the context of Electro Convulsive Therapy, stipulating "informed consent requirements" in that context as follows:

91 Informed consent requirements (cf 1990 Act, s 183)

(1) A person is taken to have given informed consent to the administration of electro convulsive therapy if the person gives a free, voluntary and written consent after this section is complied with.

(2) The following steps must be taken before consent is obtained—

(a) a fair explanation must be made to the person of the techniques or procedures to be followed, including an identification and explanation of any technique or procedure about which there is not sufficient data to recommend it as recognised treatment or to reliably predict the outcome of its performance,

(b) a full description must be given, without exaggeration

or concealment, to the person of any possible discomforts and risks of the treatment (including possible loss of memory),

(c) a full description must be given to the person of any expected benefits of the treatment,

(d) a full disclosure must be made, without exaggeration or concealment, to the person of any appropriate alternative treatments that would be advantageous to the person,

(e) an offer must be made to the person to answer any inquiries concerning the procedures or any part of them,

(f) the person must be given notice that the person is free to refuse or to withdraw consent and to discontinue the procedures or any part of them at any time,

(g) a full disclosure must be made to the person of any financial relationship between the person proposing the administration of the treatment or the administering medical practitioner, or both, and the facility in which it is proposed to administer the treatment,

(h) the person must be given notice of their right to obtain legal and medical advice and to be represented before giving consent,

(i) any question relating to the techniques or procedures to be followed that is asked by the person must have been answered and the answers must appear to have been understood by the person,

(j) a form setting out the steps in this subsection is to be given to the person and an oral explanation of the matters dealt with in the form is to be given to the person in a language with which the person is familiar.

(3) The regulations are to prescribe forms setting out the steps to be taken before obtaining informed consent to electro convulsive therapy.

The *Mental Health Act 2014 (Vic),* in contrast to NSW, has a very lengthy, very carefully drafted definition and criteria for informed consent as follows:

Part 5—Treatment

Division 1—Capacity and informed consent

68 Capacity to give informed consent under this Act

(1) A person has the capacity to give informed consent under this Act if the person—

(a) understands the information he or she is given that is relevant to the decision; and

(b) is able to remember the information that is relevant to the decision; and

(c) is able to use or weigh information that is relevant to the decision; and

(d) is able to communicate the decision he or she makes by speech, gestures or any other means.

(2) The following principles are intended to provide guidance to any person who is required to determine whether or not a person has the capacity to give informed consent under this Act—

(a) a person's capacity to give informed consent is specific to the decision that the person is to make;

(b) a person's capacity to give informed consent may change over time;

(c) it should not be assumed that a person does not have the capacity to give informed consent based only on his or her age, appearance, condition or an aspect of his or her behaviour;

(d) a determination that a person does not have capacity to give informed consent should not be made only because the person makes a decision that could be considered to be unwise;

(e) when assessing a person's capacity to give informed consent, reasonable steps should be taken to conduct the assessment at a time at, and in an environment in, which the person's capacity to give informed consent can be assessed most accurately.

69 Meaning of informed consent

(1) For the purposes of treatment or medical treatment that is

given in accordance with this Act, a person gives informed consent if the person—

(a) has the capacity to give informed consent to the treatment or medical treatment proposed; and

(b) has been given adequate information to enable the person to make an informed decision; and

(c) has been given a reasonable opportunity to make the decision; and

(d) has given consent freely without undue pressure or coercion by any other person; and

(e) has not withdrawn consent or indicated any intention to withdraw consent.

(2) For the purposes of subsection (1)(b), a person has been given adequate information to make an informed decision if the person has been given—

(a) an explanation of the proposed treatment or medical treatment including—

(i) the purpose of the treatment or medical treatment; and

(ii) the type, method and likely duration of the treatment or medical treatment; and

(b) an explanation of the advantages and disadvantages of the treatment or medical treatment, including information about the associated discomfort, risks and common or expected side effects of the treatment or medical treatment; and

(c) an explanation of any beneficial alternative treatments that are reasonably available, including any information about the advantages and disadvantages of these alternatives; and

(d) answers to any relevant questions that the person has asked; and

(e) any other relevant information that is likely to influence the decision of the person; and

(f) in the case of proposed treatment, a statement of rights relevant to his or her situation.

(3) For the purposes of subsection (1)(c), a person has been given a reasonable opportunity to make a decision if, in the circumstances, the person has been given a reasonable—

(a) period of time in which to consider the matters involved in the decision; and

(b) opportunity to discuss those matters with the registered medical practitioner or other health practitioner who is proposing the treatment or medical treatment; and

(c) amount of support to make the decision; and

(d) opportunity to obtain any other advice or assistance in relation to the decision.

The Victorian *Charter of Human Rights and Responsibilities Act 2006* (Vic) has the following provision relevant to informed consent:

10 Protection from torture and cruel, inhuman or degrading treatment

A person must not be—

(a) subjected to torture; or

(b) treated or punished in a cruel, inhuman or degrading way; or

(c) subjected to medical or scientific experimentation or treatment without his or her full, free and informed consent.

The *Australian Human Rights Commission Act 1986* (Cth), which among several international human rights covenants and treaties which it attaches via schedules, attaches article 7 of the ICCPR, being:

Article 7

No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without

his free consent to medical or scientific experimentation.

Though, this Article is not mentioned (or enshrined) in any other part of that Act.

Finally:

- the *Biosecurity Act 2015* (Cth) prohibits the use of force for vaccination (s95); and

- The *Biosecurity Act 2015* (Cth) prohibits vaccination or treatment without an individual Biosecurity Control Order with stringent requirements (s92).

Common Law

The common law which directly refers to informed consent is sporadic in the sense that 'informed consent' is generally raised as an element of wider proceedings and is taken as a given by the Courts rather than something which is explained, elaborated on, defined or argued over. Nonetheless the following extracts refer to informed consent in various ways:

Case	Extract	Ref
Malette v Shulman (1990) 67 DLR (4th) 321	"[a] competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternative form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community…it is the patient who has the final say on whether to undergo the treatment".	
Dr Noel Rodney Campbell v The Dental Board of Victoria [1999] VSC 113	[In the context of an appeal against the decision of a Dental Board for professional misconduct and negligence where one of the grounds was that he did not obtain his patients' informal consent for the use of an experimental drug]: I am satisfied that the appellant used the drug DMSA, in the treatment of the said four patients, without informing them of the status of the drug in Australia, it's possible adverse side effects (or the risk thereof) and the state of medical knowledge concerning DMSA. I should add that it was undisputed that there was material readily available from the manufacturer and in the US pharmacopoeia and other medical literature concerning possible adverse side effects which the appellant had not troubled to find. The appellant gave evidence before the Board that he had read "hundreds of references", but this seems most improbable (alternatively, it makes the position worse). Instead, it appears that the appellant had relied in the first instance on	56

	statistically limited and scientifically uncontrolled information derived from the experience of a New Zealand colleague and subsequently from his own experience of a like nature. I am satisfied that the appellant failed to obtain the informed consent of the four patients to their treatment with the drug and even failed (in the two cases where the form was available) to obtain their signature to the inadequate consent form which had been devised for the purpose. I am satisfied that the appellant failed to establish any protocol, let alone an adequate one, to monitor the condition of the four patients during their said treatment or to ask them to report any infection. I am persuaded, as a result of the uncontradicted and undisputed evidence of Dr Mashford, that a competent practitioner (whether a physician or a dentist) who took it upon himself to prescribe DMSA in all the circumstances of these four patients ought not to have failed to take all of the steps and precautions to which I have referred. The appellant conceded that he ought to have taken them, but he maintained that he acted in good faith, was ignorant of the potentially serious side effects (such as liver damage and neutropoenia) and relied upon the favourable experience of the said colleague and later upon his own experience.	
Hunter and New England are Health Service v A by his Tutor [2009]	Whenever there is a conflict between a capable adults' exercise of the right of self-determination and state's interest in preserving life – the right of the individual must prevail	17
Brightwater Care Group (Inc) v Rossiter [2009] WASC 229	In a Guardian Tribunal decision in WA, Senior Member Mr J Mansveld noted that: The common law was considered by the Supreme Court of Western Australia in Brightwater Care Group (Inc) v Rossiter [2009] WASC 229 (Rossiter). The following principles were stated at [23] to [27]: - an adult person is assumed to be capable of having the mental capacity to consent to, or refuse, medical treatment (reflecting the statutory presumption of capacity in s 4(3)(b) of the GA Act). - An adult person has the right of autonomy or self-determination, the right to choose how he or she should live his or her life.	23 - 27

	- The informed consent of the patient is required before any medical treatment can be undertaken lawfully (but note Pt 9D of the GA Act as it relates to the provision of urgent treatment). - An individual of full capacity is not obliged to give consent to medical treatment regardless of whether the reasons for the withholding of consent are rational, irrational, unknown or even non-existent (the withholding of consent is reflected in the definition of treatment decision in s 3 of the GA Act). - As to the factors to be considered in the ability to give informed consent, the decision in Rossiter included the capacity to comprehend and retain information given to the person in relation to his or her treatment, the capacity to weigh up that information, to weigh up alternative options, to understand the consequences of the treatment decision and the capacity of expressing reasons for the decision (although as stated, a capable person is not obliged to give reasons) (Rossiter at [13] and [14]).	
Wallace v Kam [2013] HCA 19	The common law duty of a medical practitioner to a patient is a single comprehensive duty to exercise reasonable care and skill in the provision of professional advice and treatment […] The component of the duty of a medical practitioner that ordinarily requires the medical practitioner to inform the patient of material risks of physical injury inherent in a proposed treatment is founded on the underlying common law right of the patient to choose whether or not to undergo a proposed treatment.	8
Reeves v the Queen [2013] HCA 57 18 December 2013 S44/2013	[A case where a victim of a botched medical procedure tried to argue that the doctor was negligent by way of not ensuring the patient gave informed consent, but both the CCA and the HC both instead ruled that 'informed consent' is a misconstrual of the test, which should actually instead be the test in Rogers v Whitaker (which is a lower bar)] *The directions on informed consent* The jury were supplied with written directions of law, which included directions on "informed consent". The oral directions on this topic were in the same terms as the written directions.	33 - 35

	Relevantly, the written directions stated. "There will not be 'lawful cause or excuse' for the surgery performed by the [applicant] if the Crown proves beyond reasonable doubt that the [applicant] did not honestly believe at the time of the operation that the patient had given her informed consent to the full extent of the operation, including removal of the labia and clitoris". (emphasis in original) Under the heading "What Does 'Informed Consent' mean?" the written directions included the following: "To be valid, consent must be 'informed'. This means that the medical practitioner must at least explain to the patient the purpose of the operation, the part or parts of the body to be cut or removed, the possible major consequences of the operation, and any options or alternative treatments which may be reasonably available." (emphasis in the original) *Consent to medical procedures* The Court of Criminal Appeal found, correctly, that it was an error to direct the jury in terms of "informed consent". Specifically, it was an error to direct that a medical practitioner must explain the "possible major consequences of the operation" together with "options" and "alternative treatments" before the patient's consent to the procedure will afford the medical practitioner lawful cause or excuse for performing it. The nature of the consent to a medical procedure that is required in order to negative the offence of battery is described in the joint reasons in Rogers v Whitaker. It is sufficient that the patient consents to the procedure having been advised in broad terms of its nature. Provided CDW was informed that the surgery involved the removal of her labia and clitoris, the applicant had a lawful cause or excuse for performing it. This was so regardless of any failure to inform CDW of its possible major consequences and any alternative treatments. A failure in either of these respects might be a breach of the applicant's common law duty of care exposing him to liability in negligence, but it would not vitiate the consent to the surgery.	
PBU & NJE v Mental Health Tribunal &	Contains a discussion of whether a patient lacked the capacity to give informed consent in the context of the Mental Health Act Victoria, and how that Act defines the concept. For e.g., see:	77

Ors [2018] VSC 564; 56 VR 141	Seeking, and presuming the capacity to give, informed consent It would be discriminatory and a grave violation of human rights to regard a person having mental illness as lacking capacity to give informed consent merely because the person has that illness and the legislation does not operate upon this basis. Section 70(2) provides that anyone seeking the informed consent of another to treatment or medical treatment must presume that the other person has the capacity to give informed consent. This is the position under the common law (see below) and applies to an authorised psychiatrist who considers that a person needs treatment for mental illness. Before treatment or medical treatment is administered, 'the informed consent of the person must be sought' (s 70(1)), unless the person does not have the capacity to give that consent at the relevant time (s 70(3)).	

Policy And Regulation

"Informed Consent" is referred to and defined as follows in various policies and regulations, issued primarily by regulatory bodies.

The ALRC states**:**

> 'Informed consent' refers to consent to medical treatment and the requirement to warn of material risk prior to treatment. As part of their duty of care, health professionals must provide such information as is necessary for the patient to give consent to treatment, including information on all material risks of the proposed treatment. Failure to do so may lead to civil liability for an adverse outcome, even if the treatment itself was not negligent.[xxii]

The *Health Care Complaints Commission* in NSW states that**:**[xxiii]

> Medical and dental treatment requires valid consent from the patient. Informed consent means a patient will be given clear information about what is involved in any proposed treatment and their treatment options. Health care providers need to obtain valid consent from a patient before examining or treating them. If a patient lacks capacity, consent should be sought from the person with the proper authority, except in situations where the treatment is urgent and necessary to save a person's life or prevent serious damage to their health.

For consent to be valid the provider needs to ensure that the patient has:

- the capacity to provide consent.
- a good understanding of any side-effects, risks, benefits and alternatives regarding the proposed treatment.
- been informed about the fees involved
- given consent voluntarily, without being pressured.

…

The Health Care Complaints Commission can assist with complaints based on concerns that valid consent was not obtained prior to treatment or care being provided to a patient. You can contact our Inquiry Service on 1800 043 159 for more information or make a complaint online.

The NSW Department of Health has a "Consent to Medical and Healthcare Treatment Manual" which has a section titled "Requirements for Consent"[xxiv]. It says:

Adults with capacity have a right to decide what happens to their own bodies. This means that they have the right to consent to treatment, refuse to consent to treatment for any reason, or withdraw their consent, even if refusal or withdrawal of treatment is likely to lead to serious injury or death. These principles are reflected in the law that governs consent to medical treatment. As a general rule, no operation, procedure or treatment may be undertaken without prior consent from the patient or, if the patient lacks capacity, from the patient's substituted decision maker.

The only exceptions are:

i. in an emergency when the patient lacks capacity and the patient's express wishes are unknown; or

ii. where the law otherwise allows or requires treatment to be given without consent.

Consent to the general nature of a proposed operation, procedure, or treatment must be obtained from the patient or, if the patient lacks capacity, from the patient's substituted decision maker.

Failure to do this could result in legal action for assault and battery against the Health Practitioner who provided the care, irrespective of whether the patient suffered harm as a result of the procedure.

Health Practitioners also have a legal obligation to provide patients (or substituted decision makers) with information, including warnings, about

any material risks involved in the proposed procedure or treatment.

Failure to do so may also give rise to legal action for negligence. For further information on material risks see section 4.8.

Obtaining consent and adequately informing patients about their treatment options and the risks and benefits arising are an established part of good clinical practice.

The oft quoted **Australian Immunisation Handbook** states:

Valid consent is the voluntary agreement by an individual to a proposed procedure, which is given after sufficient, appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to that individual.

As part of the consent procedure, people receiving vaccines and/or their parents or carers should be given sufficient information (preferably written) about the risks and benefits of each vaccine. This includes:

a. what adverse events are possible
b. how common they are
c. what they should do about them

Table. Side effects following immunisation for vaccines used in the National Immunisation Program schedule can be used to inform valid consent.

Criteria for valid consent

For consent to be legally valid, the following elements must be present:

i. It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of receiving a vaccine.
ii. It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
iii. It must cover the specific procedure that is to be performed.
iv. It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.
v. The person must have the opportunity to seek more details or explanations about the vaccine or its administration.

The information must be provided in a language or by other means that the person can understand. Where appropriate, involve an interpreter or cultural support person.

Obtain consent before each vaccination, after establishing that there are no medical condition(s) that contraindicate vaccination. Consent can be verbal or written.

Consent on behalf of a child or an adolescent

In general, a parent or legal guardian of a child has the authority to consent to that child being vaccinated.

Some Australian states and territories have legislation that addresses the issue of a child's consent to medical treatment. Check with your state or territory health authority about these laws.

The common law applies in the states and territories that do not have specific legislation relating to children's consent to medical treatment. This common-law position is often referred to as Mature Minor or Gillick competence.

For certain procedures, including vaccination, a child or adolescent may be determined to be mature enough to understand the proposed procedure, and the risks and benefits associated with it. These young people may have the capacity to consent under certain circumstances.

If a child or adolescent refuses a vaccination that a parent or guardian has given consent for, respect the child's or adolescent's wishes, and inform the parent or guardian.

Consent on behalf of an adult lacking capacity

Carefully assess an adult's capacity to give valid consent to vaccination. If the adult lacks capacity, refer to relevant state and territory laws for obtaining consent from a substitute decision-maker. For example, this may occur for influenza vaccination of an elderly person with dementia.

See the enduring guardianship legislation in your state or territory for more details.

Resources to help communicate the risks and benefits of vaccines

Use plain language when communicating information about vaccines and their use. The person to be vaccinated (or their parent or guardian) must:

a. be encouraged to ask for more details
b. have enough time to decide whether to consent
c. Provide printed information to supplement any verbal explanations.

Evidence of consent

General practice or public immunisation clinics

People can give consent either in writing or verbally, according to the protocols of the health facility. All consent must meet the criteria for valid consent:

i. Document evidence of verbal consent in the clinical records.
ii. For electronic medical records, include a typed record of verbal consent in the person's file, or scan a copy of written consent into the file.

iii. If the practice or clinic routinely follows a standard procedure, show that the provider followed the procedure by using a stamp, a sticker or the provider's signature.

People need to give explicit verbal consent before receiving any vaccine, even if they gave written consent at previous vaccination encounters for the same vaccine. Document verbal consent in the person's file each time they give it.

School-based vaccination programs

Consent is required to provide individual vaccines or a vaccine course through school-based vaccination programs.

In school-based, and other large-scale, vaccination programs, the parent or guardian usually does not attend with the child on the day they receive the vaccine. Written consent from the parent or guardian is desirable in these circumstances.

If the parent or guardian cannot provide written consent, or if they need further clarification, they can give verbal consent to the immunisation provider by telephone. Clearly document this on the child's consent form.

In some states and territories, older adolescents may be able to provide their own consent for vaccinations offered through school-based vaccination programs. See Consent on behalf of a child or an adolescent.

> Consent requirements and vaccines offered in these programs vary between jurisdictions. See your state or territory school-based vaccination program guidelines for more details.

The Australian Commission on Safety and Quality in Health Care says that "ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating professionals and supports person-centred care".[xxv]

The Tangential Concept of Bodily Integrity

Simultaneously, case law in Australia around the notion of "bodily integrity" has developed, along with the suggestion that a breach of said integrity can constitute an assault and/or battery.

There are several authorities which point towards bodily integrity as a fundamental right:

a. *Collins v Wilcock* [1984], for example, which says that "the fundamental principle, plain and incontestable, is that every person's body is inviolate. It has long been established that any touching of another person, however slight, may amount to a battery…The breadth of the principle reflects the fundamental nature of the interest so protected";[xxvi] and, from Blackstone's Commentaries[xxvii],[xxviii]

b. The law cannot draw the line between different degrees of violence, and therefore totally prohibits the first and lowest stage of it; every man's person being sacred, and no other having a right to meddle with it, in any the slightest manner. The effect is that everybody is protected not only against physical injury but against any form of physical molestation.

c. Probably most relevant of all, *Marion's Case, 233*[xxix] (**Marion's Case**), in which it was adjudged that:

> "every man's person is sacred', points to the value which underlies and informs the law: each person has a unique dignity which the law respects and which it will protect. Human dignity is a value common to our municipal law and to international instruments relating to human rights"; and

d. That there is a fundamental right, arising from the common law, to personal inviolability:[xxx]

> As we have indicated, the conclusion relies on a fundamental right

to personal inviolability existing in the common law, a right which underscores the principles of assault, both criminal and civil, as well as on the practical exigencies accompanying this kind of decision which have been discussed.

e. The most famous quote from the case in general is that, as held by the majority, "consent ordinarily has the effect of transforming what would otherwise be unlawful into accepted, and therefore acceptable, contact. …The factor necessary to render a [medical treatment] lawful when it would other be an assault, is therefore, consent".

All in all, it can be said without doubt that informed consent **does exist in Australian law** and it is an example of a human right which Australia has covenanted into via an international treaty (Part III, Article 7 of the ICCPR) which has been enshrined into our domestic law.

Given the above, which must be described as a comprehensive and consistent approach in Australian law, it is remarkable that so many Australian citizens underwent a provisionally approved medical treatment in circumstances where they did not fully understand the material risks associated with that treatment and whilst subjected to significant social and economic pressures to undergo that treatment. We submit that *nobody in Australia* was capable of providing fully informed and free consent to vaccination against Covid-19, given the pressure being exerted daily by employers, media and politicians, and the inaccurate and incomplete information being made available to them.

This poses the question of whether the law on informed consent in Australia has been bypassed or ignored, and if so, how and why this was allowed to occur.

Children

With respect to children, consent is much more important. Obviously, there is a point in life where the ability to consent to anything, including medical procedures, passes from parent to offspring. Until that time, a parent acts as their child's guardian; making the decision that they deem best in all the circumstances. The age and capacity of minors to give consent is therefore a critical issue at law.
The age at which a person becomes an 'adult' in Australia, and at which time they can give valid consent for medical treatment, is 18 years. Consent for people under the age of 18 is therefore to be provided by the child's parents. Although there are circumstances in which a child less than 18 can give valid consent, these circumstances are extremely limited, and much more limited than was suggested by various Government departments and individual politicians during Covid-19. We elaborate on this below.

The Legislation

Two states in Australia, New South Wales and South Australia, have legislation going towards the ability of children to consent to medical procedures.

New South Wales

In New South Wales, the *Minors (Property and Contracts) Act 1970* (**the MPC Act**), at Section 49, provides a defence in actions for assault and battery against minors aged less than sixteen years "where medical treatment…is carried out with the prior consent of the parent or guardian". The MPC Act does not provide said defence in circumstances where a parent has **not** provided their consent, even if their child has.

Section 49 (2) also states that a medical practitioner who provides treatment with the consent of a child 14 years or over will have a defence to any action for assault or battery. In saying that, the MPC Act does not assist a medical practitioner in a situation where there is a conflict between a child and their parent, and a parent can still generally override a child's consent to treatment. It is also worth noting that "consent" is not defined in the MPC Act, and the ability of a child aged 14 years and above to give *valid* consent will depend on the application of the common law principles explained below to the individual circumstances of that child's case.

South Australia

In South Australia, the *Consent to Medical Treatment and Palliative Care Act 1995* (**the CMPA**) states, at Part 2, Division 1, Section 6, that a person over the age of 16 years can "make decisions about his or her own treatment as validly and effectively as an adult". South Australia, therefore, is the only state in Australia where it is clear that a child aged between 16 and 18 could lawfully consent to vaccination in the absence of parental consent. In saying that, even here, consent must still be informed and valid; a child must have capacity to give consent, like any adult, in order to be capable of giving it. So, therefore, the common law principles still have some application even here.

Additionally, in regard to children who are under the age of 16, the CMPA states the following:

> Division 4—Medical treatment of children
> 12—Administration of medical treatment to a child
> A medical practitioner may administer medical treatment to a child if—
> (a) the parent or guardian consents; or
> (b) the child consents and—

(i) the medical practitioner who is to administer the treatment is of the opinion that the child is capable of understanding the nature, consequences and risks of the treatment and that the treatment is in the best interest of the child's health and well-being; and
(ii) that opinion is supported by the written opinion of at least one other medical practitioner who personally examines the child before the treatment is commenced.

As the name implies, this section is intended to relate to "medical treatment". Treatment implies the administering of medicine for an illness or ailment that somebody already has, as opposed to a medical intervention designed to be preventative. In addition, in terms of the administering of vaccinations in schools, the checks and balances this section provides, such as seeking the written opinion of another medical practitioner, are unlikely to occur.

The Common Law

The common law is the primary guide in Australia as to the limited circumstances in which a child has capacity to give consent to medical intervention in the absence of parental consent of same. Even in NSW and South Australia, where there is some legislation on this issue, the common law is required to clarify its application. In all other states and territories, we are completely reliant on the common law to determine the issue in its totality, as there is no applicable legislation on this point.

The Concept of a 'Mature Minor', or 'Gilick Competency'

The case often referred in regard to a child's ability to give consent to a medical procedure or treatment is *Gilick v West Norfolk and Wisbech Area Health Authority* (**Gilick**).[xxxi]

First, it must be noted that Gilick was a case in which it was debated whether a 15-year-old could consent, without parental knowledge, to a prescription for the contraceptive pill. So, the circumstances are quite different to consent for an invasive medical procedure such as vaccination.

Nonetheless, in Gilick, Lords Scarman and Fraser agreed that in most cases it is in the child's best interests for parental consent to be obtained. They said, however, that "exceptional" and "special" circumstances could exist where minors could consent to medical treatment on their own, provided certain conditions were met. Lords Scarman and Fraser provided their own versions of these conditions.

Problematically, this decision was over-simplified in the context of Covid-19

vaccination to suggest that as long as a minor has a "sufficient understanding and intelligence to enable him or her to fully understand what is proposed"[xxxii] that a child will be capable of giving lawful consent. This is often referred to as 'Gillick Competence'.

What is often ignored is the complexity inherent within the test Lord Scarman proposes. As Lord Scarman himself notes, to be deemed competent to make a decision without parental consent or knowledge, a minor must fully understand the moral, emotional and familial, long, and short term implications of the decision they are purporting to make.[xxxiii] Put another way, it is very difficult to determine the time at which, and the circumstances where, a child will be capable of "fully understanding" a medical procedure.

This is particularly true in the case of vaccination against Covid-19, which, to be frank, no child (nor adult) could "fully understand" due to the lack of long-term safety data available. Though we will elaborate below, our own High Court has noted that the test for Gillick Competence is a "very high threshold"; described as the ability to exercise a "wise choice",[xxxiv] and one that medical doctors have expressed as "higher than they would expect from some competent adults".[xxxv] Another implication of Lord Scarman's test is that competency will differ from child to child, pursuant to their own capacity and circumstances. Quite a forensic assessment of that child would need to occur in order for the threshold of Lord Scarman's test to be reliably met. Finally, and again oft ignored, was the requirement Lord Scarman proposed for the doctor to first try to persuade the child to include their parents in the decision-making process.[xxxvi]

Lord Fraser gave his own version of the conditions which must be met for 'Gilick Competence', or for a 'mature minor', to be capable of consenting to medical treatment absent his/her parents. His Lordship described the following steps a health professional should follow to determine whether to give treatment to a minor without parental consent. Again, this judgment was made specifically in the context of contraceptive treatment, so the steps are relevant to that scenario:[xxxvii]

> [The practitioner must be satisfied of the following matters]:
>
> (1) that the [child] will understand his advice;
>
> (2) that he cannot persuade [the child] to inform her parents or to allow him to inform the parents that [the child] is seeking contraceptive advice;
>
> (3) that [the child] is very likely to begin or to continue having sexual intercourse with or without contraceptive treatment;

> (4) that unless [the child] receives contraceptive advice or treatment [their] physical or mental health or both are likely to suffer; and
>
> (5) that [the child's] best interests require him to give [the child] contraceptive advice, treatment or both without the parental consent.

So, this test makes clear, too, the high threshold that must be met. To be 'satisfied of understanding' is no simple thing when it comes to a child, and further, the role of the parent is not negated completely given the requirement to attempt to persuade the child to seek their parents' consent. In addition, and importantly, there are requirements around the detriment to be suffered if the child does *not* receive the treatment, as well as the child's best interests. Both of these matters are, on a conservative view, at the very least unclear in the case of Covid-19 vaccination. The evidence is clear that there is a very low risk to children of severe or long-term illness from the virus,[xxxviii] and unclear with respect to whether the vaccines currently available will detriment their health, at the very least in the long term.

Marion's Case

In Australia, *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)*[xxxix] examined "whether a child, intellectual disabled or not, is capable, in law or in fact, of consenting to medical treatment on his or her behalf".[xl]
In determining this question, Marion's Case laid the following foundations:

- First, Section 63F(1) of the *Family Law Act 1975* (Cth) recognises and empowers parents as guardians and custodians of children until they attain the age of 18 years;[xli]

- Second, that "the responsibilities and powers of parents extend to the physical, mental, moral, educational and general welfare of the child…they extend to every aspect of the child's life";[xlii] and

- Third, "A fortiori, if the child is incompetent to give consent, whether by reason of age, illness, accident or intellectual disability, the parents have the responsibility and power to authorize the administration of therapeutic medical treatment".[xliii]

Importantly, the High Court emphasised the extreme care that must be taken if parental consent is to be set aside, quoting an established precedent as follows:[xliv]

> In exercising the jurisdiction to control or to ignore the parental right the court must act cautiously, not as if it were a private person acting with regard to his own child, and acting in opposition to the parent only when judicially satisfied that the welfare of the child requires that the parental right should be suspended or superseded. **There must be some clear justification for a court's intervention to set aside the primary parental responsibility for attending to the welfare of the child.**

And, Brennan J even cast doubt on whether Gilick, in laying out the test for competency, placed enough emphasis on the parents' view, stating that "I would respectfully doubt whether the primacy of parental responsibility was sufficiently recognised in the leading English case of Gilick".[xlv]

So, in summary, the legal position can be distilled into the following principles:

- Parental consent is generally essential to any medical procedure for somebody under the age of 18;
- There are exceptional circumstances where somebody under the age of 18 can give consent absent their parents, subject to strict conditions which will rarely be met;
- Such conditions would need to be met on a case-by-case basis; and
- If such conditions aren't met, medical treatment provided absent parental consent is likely to constitute liability for battery and/or negligence.

What happened during Covid-19 was a complete abdication of these principles. Schools and teachers should **not** have discussed Covid-19 vaccination with their students. Students should not have been encouraged to undergo vaccination by their schools or their teachers, who themselves are not medical professionals in any event, and whose duty of care is supervisory, but does not extend to the provision of medical care, treatment or procedures.

Further, the provision of 'pop-up clinics' and 'vaccination buses' to schools was highly problematic. None of the Covid-19 vaccines, which are still in Phase IV trials, have been added to the National Immunisation Program Schedule (**the Schedule**). Generally, vaccines on the Schedule are administered at schools, but only subject to strict parental consent given in writing.

In addition, recommendations made by politicians and even reputable medical journals relied on oversimplifications and distorted interpretations of the law on this point.

Children should be left, with their parents and guardians, to attend their Doctor for advice and treatment according to law. It is important that the concept of 'Gilick

Competency' is not used to bypass the very important protections which exist in Australia for the purpose of protecting children as well as the integrity of the parents' role as guardian and caregiver.

Endnotes: For all answers
Index

Second Answer

Elizabeth Hart, Proposed Witness:

In my opinion, there has been *no valid consent* for any of the 69.3 million Covid-19 vaccinations/medical interventions reportedly administered in Australia.

This mass population medical intervention has been undertaken against a disease it was known from the beginning wasn't a serious threat to most people, even the highly conflicted WHO admits this for those who can read between the lines.

The medical profession has unaccountably largely supported coercive and mandated medical interventions - in a supposed free country! The Royal Australian College of General Practitioners, the Royal Australasian College of Physicians and the Australian Medical Association have all collaborated with coercive/mandated Covid-19 vaccination. The medical profession is in ruins with its failure to defend voluntary informed consent for vaccination.

I've sent many emails pleading for voluntary informed consent to be upheld, see links on this webpage: https://vaccinationispolitical.net/vax-australia/

After much persistence on my part, the regulator of practitioners, the Australian Health Practitioner Regulation Agency (AHPRA), finally sent me a letter in September 2021, confirming that:

> 'Practitioners have an obligation to obtain informed consent for treatment, including vaccination. Informed consent is a person's *voluntary* decision about health care that is made with knowledge and understanding of the benefits and risks involved.' (emphasis added)

Also in September 2021, then Victorian Premier Daniel Andrews announced:

> "There is going to be a vaccinated economy, and you get to participate in that if you are vaccinated...We're going to move to a situation where, to protect the health system, we are going to lock out people who are

not vaccinated and can be".

In November 2021, Chris Perry, the Queensland President of the Australian Medical Association, said:

> "If you're not vaccinated, it's going to be very, very hard to maintain a job, to be able to go anywhere. People having weddings are going to have to weed out the unvaccinated. The pubs and clubs are going to have to find out whether people are vaccinated before they allow them in. Otherwise, their businesses will go bankrupt."

And in January 2022, then Western Australian Premier, Mark McGowan said:

> "Life will be very difficult for the unvaccinated from January 31. No pub, no bottle shop, no gym, no yoga class, no gig, no dancefloors, no hospital visits."

There it was, all laid out by members of the National Cabinet and the Australian Medical Association - 'No Jab, No Life'.

Where was the outcry? From AHPRA for instance? Why didn't AHPRA jump up and down and say registered practitioners must not collaborate with coercive/mandated vaccination, this violates voluntary informed consent? Not a peep out of AHPRA ... or the medical colleges.

AHPRA had already effectively mandated practitioners to support the government's Covid-19 vaccination rollout via the AHPRA Position Statement of 9 March 2021, which I challenged in my email to AHPRA CEO Martin Fletcher and Anne Tonkin, Chair of the Medical Board of Australia, and others, see: Reckless disregard for voluntary informed consent - the AHPRA Position Statement 9 March 2021.

I also raised this matter with Attorney-General Mark Dreyfus, questioning if health practitioners are in effect being conscripted to participate in the Australian Government's Covid-19 vaccination rollout, in contravention of the Australian Constitution, i.e. paragraph xxiiiA of s51, see my email: Are health practitioners in effect being conscripted to participate in the Australian government's Covid-19 vaccination rollout, in contravention of the Australian Constitution?

Australia's Chief Medical Officer, Paul Kelly, and the AHPPC, broke the ethical principle of voluntary informed consent for vaccination in June 2021, when they capitulated to the demand of then Prime Minister Scott Morrison and the Premiers and Chief Ministers in the National Cabinet to 'recommend' compulsory vaccination for residential aged care workers. This set the precedent for a flood

of vaccination mandates around the country. See my notification to AHPRA about CMO Paul Kelly violating voluntary informed consent for more background.

This is the biggest scandal of all time. The entire country was pressured, coerced and manipulated to submit to the Covid-19 injections at the behest of politicians, medical/health officers, the medical profession, academics, and the mainstream media.

Probably millions have submitted to the jabs under Covid mandates to maintain their livelihoods and participate in civil society - 'No Jab, No Job'...'No Jab, No Life' - No valid informed consent.

The judicial system has supported these mandated medical interventions, apparently unaware of practitioners' legal and ethical obligation to obtain valid voluntary informed consent for vaccination.

And the practitioners do *not* have specific medical indemnity for administering the Covid jabs. They might think they do, but they don't, because the Morrison Government lied to them about this, around the time of the AstraZeneca blood clots emerging in 2021.

Meanwhile, in November 2022, the Department of Health and Aged Care also confirmed to me:

> "Informed consent should be obtained for every Covid-19 vaccination, as per usual consent procedures for other vaccinations."

Who knew?!

Apparently not the practitioners who have administered the 69.3 million jabs across a population that has been subjected to coercion and vaccination mandates.

There is no objective and independent mainstream media to break the story. And the taxpayer- funded ABC, chaired by Scott Morrison's 'captain's pick' Ita Buttrose, and SBS, have been worse than useless, performing as a propaganda machine for the vaccine industry.

There's been no critical analysis of the Covid debacle which has stolen the Australian people's freedom, looted them, and put them into enormous debt ... enriching who exactly via this manufactured phony crisis?

And all thanks to the Commonwealth Government's taxpayer-funded Covid-19 vaccination rollout, that former Prime Minister Scott Morrison wanted to be "as

mandatory as you can possibly make it".

This isn't just about Covid-19 vaccination, the entire ever-increasing taxpayer-funded vaccination schedule must be investigated, the lucrative 'womb to tomb' schedule that is mired in conflicts of interest, with little or no transparency and accountability.

It is essential that a Royal Commission investigate and call to account those parties who collaborated in the destruction of voluntary informed consent for Covid-19 vaccination.

Index

Reference: N

Index

A systematic review of all roles performed by the Australian Defence Force (ADF) and Australian military personnel in response to Covid-19 throughout 2020, 2021, and 2022, including:

i. the use of troops in the community;
ii. an examination of the chain of command from the Department of Home Affairs (DHA) to the ADF via Emergency Management Australia (EMA), including:
    a) the process by which DHA, via its EMA, formulated requests to the ADF and ADF personnel under Operation Covid-19 Assist, including due diligence with respect to the medical, scientific, legal and human rights aspects of those requests and any other advice and instructions;
iii. an examination of the initiating steps and operational planning undertaken by the ADF for Operation Covid-19 Assist, including:
    a) whether a Joint Military Appreciation Process was undertaken;
    b) whether the operational level commander received strategic level direction from a higher commander, for example, a Chief of the Defence Force (CDF) Planning Directive or CDF orders, and the source and personnel involved in respect of any such orders; or
    c) whether the operational level commander-initiated operation planning on their own initiative and whether a CJOPS Planning Directive was issued, the content of any such directive and the personnel involved and planning undertaken in respect of any such directive; and
    d) what accredited training was provided to ADF personnel to undertake the wide range of pandemic medical tasks involved with Operation Covid-19 Assist, and what evaluation and validation was undertaken to ensure these tasks were effectively executed;
iv. an examination of the strategies employed by the ADF to support "compliance measures" as noted on the Department of Defence website;
v. an examination of any co-ordination or consultation by the ADF with international security services, particularly with respect to compliance measure strategies, use or threat of force, troops in the community, and advice or training for local police forces;
vi. whether ADF personnel were deployed:
    a) to assist any Australian police force and the nature of any such assistance;
    b) to assist any Australian police force wearing uniforms or insignia that did not identify them as ADF personnel;
    c) to use force against non-violent protesters and members of the

public;

vii. the use of troops in remote areas and indigenous communities;
viii. the involvement of the ADF in the development of Covid-19 vaccines;
ix. the involvement of the ADF arising from any international arrangements or agreements in respect of medical countermeasures in relation to SARS-CoV-2 and Covid-19;
x. the involvement of the ADF in US Department of Defense medical countermeasure activities for the manufacture and supply of Covid-19 vaccines;
xi. the total cost of ADF involvement in Covid-19 activities.

Explanatory Memorandum

Index

An examination to confirm whether the role and involvement of the ADF was reasonable and proportionate and necessary when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known prior to the initiation of ADF activities involved in the rollout of Covid-19 vaccines across Australia, and known throughout the ADF's activities in respect of Covid-19 vaccines, as continually updated by Australian governments, and whether the involvement of the ADF was required and reasonable and proportionate and necessary when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 adverse event reports;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference N**, please provide any further information concerning the roles performed by the Australian Defence Force (ADF) and Australian military personnel in response to Covid-19 throughout 2020, 2021, and 2022.

Answer

Dr Lissa Johnson, Co-Author:

As far as I am aware, key publicly available information regarding the roles performed by the ADF and Australian military personnel in response to Covid-19 throughout 2020, 2021, and 2022 are listed below. The list is far from exhaustive, but aims to provide a representative selection of the kinds of activities that Defence personnel undertook in response to Covid-19. The majority of the publicly available information describes the activities of ADF and military personnel in relatively broad terms, for instance as "contact visits" or providing assistance with compliance measures, without offering substantive specific detail about what each of those activities entailed.

23 March 2020: Covid-19: Defence sends troops to state health authorities: an article on The Mandarin describing ADF assistance to state, territory and national health authorities. State assistance included logistics, transport, health, contact tracing and general planning assistance. The article quotes then Defence Minister Linda Reynolds as saying that Defence had been helping the Department of Health with logistics and specialist staff, and had been providing clinical and epidemiological support to the Department of Health's National Incident Room (now the National Incident Centre) since early February.

Date unknown (25 March or later): 'Operation Covid-19 Assist' – a post on the Department of Defence website providing an overview of Defence initiatives in response to Covid-19. It reads:

> Operation Covid-19 Assist is the Australian Defence Force contribution to the whole-of-government response to the Covid-19 pandemic. [See my answers to Questions on Notice regarding Reference E for further detail on the whole-of-government response.]
> The operation is part of a wider Defence effort led by the Covid-19 Taskforce, which ensures that Defence is well prepared to continue to defend Australia and its national interests.
> From March 2020, Operation Covid-19 Assist contributed to the whole-of-government response to the Covid-19 pandemic with customised support for state and territory authorities. Assistance from the ADF was coordinated through the emergency management whole-of-government response to Covid-19.
> Operation Covid-19 Assist responded to a range of contingencies and

supported various initiatives, including:

- Mandatory state and territory hotel quarantine program assistance for returning Australians and other international travellers.
- Emergency response planning assistance via reconnaissance support teams.
- Police border controls logistics support.
- Frontline Covid-19 swab testing support at testing facilities
- Contact tracing teams helping trace and understand the spread of the virus in the community.
- Logistical support for civilian authorities.

Although not noted in the post, Operation Covid-19 Assist was established on 25 March 2020.

29 March 2020: Defence support to mandatory quarantine measures commences: a media release on the Defence Ministers website announcing that:

> The Australian Defence Force (ADF) has deployed teams across the country to work in partnership with state and territory law enforcement agencies to conduct Covid-19 quarantine compliance checks.

1 April 2020: Expansion of ADF Support to Covid-19 Assist: a media release on the Defence Ministers website providing further information on both Operation Covid-19 Assist and the broader Covid-19 Taskforce.

The media release explains that Operation Covid-19 Assist was being led by Major General Paul Kenny, DSC, DSM, who had previously served as Director General of Special Operations and Counter Terrorism Operations. Operation Covid-19 Assist involved seven state-and-territory based task groups, to provide "customised support to state and territory authorities".

The release adds that the broader Covid-19 Taskforce had been established on 9 March, and was being led by Lieutenant General John Frewen, DSC, AM, to coordinate Defence's internal response to Covid-19, as well as supporting the whole-of-government effort.

At the time of the release there were "around 570 ADF members providing support including contact tracing, planning assistance, and assisting police with mandatory quarantine arrangements for international air arrivals," according to the Minister for Defence, Senator the Hon Linda Reynolds.

15 April 2020: ADF rolls out online training package for Covid-19 response: a post on the Department of Defence website describing medical training and activities for ADF personnel, "designed to quickly prepare ADF personnel, who

do not have a medical background, to conduct medical support tasks and other duties as part of Operation Covid-19 Assist." Those medical support tasks included working in health facilities as orderlies, while other duties included quarantine compliance measures. The ADF medical training was being provided to over 52,000 Defence personnel and had been offered to Australia's international military partners.

31 July 2020: ADF expands Victoria Covid-19 response: a post on the Defence Minister's website describing deployment of 1,400 ADF personnel to Victoria, and the establishment of 'Command and Coordination' advice to Victoria's Department of Health and Human Services (DHHS). It reads:

> Minister for Defence Linda Reynolds said… "In addition to the Joint Task Force personnel in Victoria, we have embedded senior ADF officer, Commodore Mark Hill RAN, in DHHS to provide advice on command and coordination arrangements to boost their capacity to respond to the crisis".

The ADF activities in Victoria included: assisting DHHS in contact tracing, data management, logistics and planning; supporting Victoria Police at checkpoints, in logistics, planning, the Police Assistance Phone Line, and "CBD community engagements"; public health testing; training with Ambulance Victoria to assist paramedics; visiting homes to provide infection notifications; and providing planning support to the Victoria State Control Centre.

26 August 2020: Voluntary submission to the Covid-19 Hotel Quarantine Inquiry: a submission to the Covid-19 Hotel Quarantine Inquiry, providing general information on the mechanisms by which ADF provided assistance to States, and some specifics of ADF compliance-related activities.

The submission explains that on 21 March 2020, the Chief of Defence Force (CDF), General Angus Campbell AO DSC, directed the ADF to support all States and Territories with their response to Covid-19. Deployments to States and Territories under Operation Covid-19 Assist were coordinated through the Defence Assistance to the Civil Community (DACC) process, enabled by the Australian Government Disaster Response Plan 2017 (COMDISPLAN), which is prepared and maintained by Emergency Management Australia (EMA), a division of the Department of Home Affairs (DHA).

The submission includes a transcript of a Prime Minister's Press Conference on 27 March 2020 in which then Prime Minister Scott Morrison said:

> "...we will be supporting them [States and Territories] also by providing

> members of the Australian Defence Force to assist in the compliance with
> these [quarantine] arrangements. Now, I want to stress that members of the
> Australian Defence Force are not authorised as enforcement officers regarding prosecution in States and Territories. That is the responsibility of law enforcement officers so sworn in those jurisdictions. The ADF will be there to support those enforcement authorities. And so we will be turning out the defence forces to support compliance with these new arrangements. It will require that cooperative and facilitative support and I have no doubt the defence forces will do that in the most sensitive way they can, but it is necessary.
> The other thing we are doing is we will be supporting the States and Territories in the important work they have of enforcing the existing isolation arrangements for people who are already here. The ADF will be supporting those States and Territories with compliance checks to ensure that people are at their residences, that they have so sworn that they would be at. To ensure we get compliance with the self-isolation. Again, if there is a situation where people are non-compliant, of course the enforcement authority is the State jurisdiction and the relevant law enforcement agency in that State. But the ADF will be there to put boots on the ground, to support them in their enforcement efforts, and I thank the ADF for their great support in turning up to this task. We believe these important actions are the most important we can take right now because of what you've done, Australia."

Appendix 1 of the submission is a Task Order issued to ADF personnel regarding the performance of quarantine and home isolation compliance checks. It states:

> "THE ADF MEMBER ARE ONLY BE ABLE [sic] TO VISIT AND ENTER PRIVATE PROPERTY (NOT ENTER PREMISES) AND STATE THEIR PURPOSE – QUOTE SUPPORT TO POLICE IN THE CONDUCT OF QUARANTINE COMPLIANCE CHECKS END QUOTE. WHERE AN ADF MEMBER IS FACED WITH INSTANCES OF NON-COMPLIANCE, OR OBJECTION, FROM THE PUBLIC, THE ADF MEMBER WOULD BE REQUIRED TO NOTE THE OUTCOME OF THEIR COMPLIANCE CHECK, LEAVE THE PREMISES, AND REPORT TO THE CIVILIAN AUTHORITIES FOR FOLLOW-UP. 3.C.3.C. ROE. IAW REF C. USE OF FORCE IS NOT PERMITTED, EXCEPT IN CASES OF SELF-DEFENCE."

The task order included a set of "endorsed media talking points", which were

consistent with the Prime Minister's statements at the press conference of 27 March.

19 April, 2021: The fight continues one year on: a post on the Defence website describing police checkpoints, compliance measures, testing and contact tracing, supplying medicines and PPE, staffing a hospital emergency department and administering vaccines**.** In a review of one year of Operation Covid-19 Assist, the post notes that ADF activities over the previous year had included: supporting police vehicle control points, quarantine compliance, making over 35,000 contact visits, production of medical supplies, designing and producing personal protective equipment, Covid testing, contact tracing, operating a hospital emergency department, and administering Covid vaccines in nursing homes (also reported in a *Guardian* article here). The post describes Operation Covid-19 Assist as the ADF's largest ever domestic operation.

2 July 2021: Mission: to get us all vaccinated: a post on the Department of Defence website describing Operation Covid Shield, whose aim was to maximise Covid vaccine uptake during 2021. A team of military planners had been appointed to assist the Department of Health with logistics and contingency planning, and to accelerate the vaccine rollout using the "military appreciation process."

A second aim of Operation Covid was to build public confidence in the vaccination campaign. The Commander of the Operation said, "In a few weeks, you're going to start seeing ad campaigns to motivate people who are now eligible… We want to inspire the nation to get it done this year – get it done in 21." One of the approaches to inspiring the nation was to promote vaccination as way for "Australians to 'get back on with their livelihoods' and the freedoms they enjoy."

21 July 2021: Scientists assess reactions to Covid-19: a post on the Department of Defence website describing work by a psychologist and Defence scientist to understand Australians' responses to Covid restrictions. The aim of the work was to develop "strategies that policy makers can employ to improve our readiness for lockdowns and other impositions." The research sought to adapt for civilians a "cognitive fitness" model being used by the Defence Science and Technology Group to improve soldier task performance. The aim of the project was to provide "options for assessing mental readiness for public health emergencies such as pandemics", assess "people's mental wellbeing and how they might cope with further lockdowns or other challenging events", and predict "readiness for another lockdown."

29 July 2021: Australian Defence Force support for Greater Sydney: a post on

the Defence website describing assistance with compliance measures and policing, reading:

> This afternoon Defence received a request from [DHA's] Emergency Management Australia on behalf of the NSW State Emergency Operations Centre to provide Australian Defence Force personnel to support the NSW Police with their response to the Covid-19 situation in Greater Sydney ... Up to 300 Defence personnel will deploy in the coming days to assist NSW authorities with Covid-19 restriction compliance measures.

The post adds that over 13,000 ADF personnel had been deployed around Australia as part of Operation Covid-19 Assist to date.

30 July 2021: **Covid in Sydney: Military deployed to help enforce lockdown**: a BBC article explaining that the deployment of ADF soldiers to NSW was aimed at helping enforce lockdown. It read:

> Australian Defence Force soldiers will undergo training on the weekend before beginning unarmed patrols on Monday… Soldiers will join police in virus hotspots to ensure people are following the rules, which include a 10km (6.2 miles) travel limit… The Australian Lawyers Alliance, a civil rights group, called the deployment a 'concerning use' of the army in a liberal democracy.

3 August 2021: **Op Covid SHIELD National Covid Vaccine Campaign Plan**: a document on the Department of Health Website describing the National Covid-19 Vaccine Campaign Plan ('the Plan'), which was part of the Defence Department's Operation Covid Shield. It explained that implementation of the Plan was being coordinated by the National Covid Vaccine Taskforce (NCVTF), led by Lieutenant General (LTGEN) John Frewen.

The NCVTF's goals are described in the document as ensuring public confidence in the vaccine rollout and ensuring that as many Australians as possible are vaccinated. In addition to coordinating and leading Australia's vaccination program (supply, distribution and administration), the Defence's NCTVF was to lead the public information campaign, with a goal of motivating eligible people to receive at least the first Covid vaccine dose by 20 December 2021.

The document notes that, "successful implementation will require drawing in several stakeholders, including industry actors."

In a section on motivating the Australian population to take the Covid vaccine, the document describes using both communication strategies and incentives. It advises that, "the Commonwealth will leverage key incentives to drive vaccine up-take",

including "providing vaccinated people with greater personal freedoms." Under the heading 'incentives' the document reads:

> Incentives can play an important role in persuading individuals to get vaccinated. On 2 July 2021, the Prime Minister announced the 'Roadmap to a CovidSafe Australia'. This roadmap detailed multiple incentives to promote uptake of vaccines, including allowing vaccinated individuals to quarantine at home and easing domestic border restrictions…
> The use of incentives will need to be coordinated across the public, private and community sectors. This includes:
> - Coordinating the use of incentives between the Commonwealth, States and Territories as part of the ongoing review cycle with jurisdictions. Where possible, incentives will be made consistent across jurisdictions.
> - Coordinating the use of incentives by industry – The Motivate workstream will collaborate with the Industry Liaison Cell (ILC, detailed in Annex H) to coordinate any use of incentives by industry partners. Through the ILC, the Motivate workstream will closely monitor the use of incentives in the private sector.

With respect to communications, the document describes a four-phase public advertising campaign, amongst other messaging strategies. It advises public leaders to coordinate their messages such that they, "speak to the same expert advice about vaccine availability, eligibility, safety and risks (e.g. side effects)." With respect to side effects the report notes that, "The first 48 hours is critical in responding to any adverse event. Pre-planning and rapid response plans (e.g. communications templates) should be developed as soon as possible to prepare for adverse events."

Which begs the question as to why Operation Covid Shield would be concerned about pre-planning communications templates for adverse events when the vaccine was being billed as safe.

3 August 2021: **ADF boosts support to Covid-19 effort**: a post on the Defence website describing compliance measures, food distribution, vaccination and testing. Compliance measures included ensuring stay-at-home orders were observed and assisting police with compliance checks. The post also describes ADF attendance at Covid testing centres, vaccination stations, and welfare checks.

23 August 2021: **ADF helps with vaccinations in western NSW**: a post on the Defence website describing vaccine administration in rural, remote and indigenous communities. The post describes sending Vaccination Outreach Teams to remote locations and establishing a mass vaccination centre in Dubbo, NSW.

1 September, 2021: Letter reveals what Scott Morrison told John Frewen when he gave him vaccine role: a *Guardian* article reporting on a letter from then Prime Minister Scott Morrison to Lt Gen John Frewen, Coordinator General of the National Covid Vaccine Taskforce and its Covid Vaccination Plan, under Operation Covid Shield. In the letter Morrison conveyed his expectation that Lt Frewen would exert "a direct command and control structure" in leading the nation's vaccination campaign. The letter gave Lt Frewen, "direct operational control of all relevant assets and resources across all Commonwealth government departments and agencies engaged in the direction and implementation of the national Covid vaccination program." Morrison told the Vaccine Coordinator General to "ensure that you have the support you require" from the Health Department Secretary, Brendan Murphy.

3 December 2021: Streamlining the vaccine rollout: a Defence Science and Technology post describing assistance provided to the Department of Health's Vaccine Operations Centre, including drawing on Defence personnel's operations analysis and command-and-control expertise, to improve the centre's efficiency.

1 February 2022: ADF driving support to Victoria: a post on the Defence website describing ambulance and paramedic assistance, policing and hotel quarantine: The post reads:

> Responding to an Emergency Management Australia request, the ADF is providing 20 ambulance drivers to Ambulance Victoria and six planners to Emergency Management Victoria from January 2020. The ADF personnel working as ambulance drivers will partner with paramedics on non-urgent tasks after being trained at the Ambulance Victoria Training Centre.

It adds that the ADF had also previously "supported the Victorian Department of Health, Victoria Police and hotel quarantine", noting that over 7,000 ADF personnel had been deployed to Victoria since 2020.

Footage capturing use of force

In addition to material on government websites and in the media, citizen footage of law enforcement compliance activities, support for which is listed as one of the ADF and Defence personnel's main responsibilities, has captured unprovoked use of force against non-violent and unarmed citizens.

Video 1 (Victoria, Australia): Ambush / tackling to the ground by

personnel dressed in military garb.

Potential questions for a Covid Royal Commission arising from the above include:

A. Did the ADF have any role in training or equipping or supporting local police forces for militarised activity, including the use of rubber bullets, tear gas, pepper spray and armoured vehicles, and/or where force was used? If so, what did that training involve? Was it undertaken with the support, coordination, or involvement of any international bodies, agencies or private partners?
B. What do the daily Joint Task Force 629 Situation Reports reveal about the details of the ADF or Defence Department activities with respect to compliance measures in 2020 and 2021? Is there any reference to use of force, or to supporting civilian police in or preparing them for use of force?
C. What complaints, if any, were received from members of the public in relation to Defence personnel's compliance-related activities, such as home visits, lockdown compliance, quarantine compliance or at vehicle checkpoints?
D. What training did Defence personnel receive to prepare them for compliance-related activities such as such as home visits, quarantine compliance, vehicle check points, and responding to protests, or to prepare them for assisting local law enforcement in these activities? When did that training occur? What was its content? Who or what body provided it? Was there any coordination in this respect with international partners, agencies, governments or private bodies?
E. What is meant by terms, "CBD community engagements", "support[ing] the NSW Police with their response to the Covid-19 situation in Greater Sydney", and "assisting [State] authorities with Covid-19 restriction compliance measures"? Did they pertain to actions against protesters? What are the details of these activities?
F. If ADF had no authority to enforce compliance with Covid measures such as stay at home orders, or quarantine, or police vehicle checkpoints, what was the purpose of accompanying civilian authorities to these incidents? In practical terms, how did the "boots on the ground", as the Prime Minister described it, assist, other than potentially intimidating citizens?
G. What due diligence or measures were undertaken with respect to Operation Covid-19 Assist, the Covid-19 Taskforce, and Operation Covid Shield to avoid intimidating civilians into compliance with medical interventions such as Covid testing and vaccination by the mere presence of Defence personnel?
H. How did operations, procedures, practices and frameworks change in agencies or bodies within the Department of Health as a result of input, training, coordination, or leadership from the Department of Defence and its personnel or divisions?
I. What due diligence or measures were undertaken with respect to Operation Covid-19 Assist, the Covid-19 Taskforce, and Operation Covid Shield to avoid militarising medical care?

J. What steps were taken to safeguard the role of specialist medical and public health subject-matter authority, expertise and experience in the context of command-and-control authority over a public health intervention being granted to non-medical Defence Department personnel?

K. What is the list of "endorsed media talking points" (Attachment 1, p.2) that the ADF issued with respect to its activities under Operation Covid-19 Assist and the Covid-19 Taskforce? In what ways, if any, did this shape public messaging by non-Defence officials regarding Covid-19, such as Ministers (state and federal) and Chief Medical Officers?

L. Is the Defence work on assessing and predicting Australians' readiness for pandemics and further "lockdowns and other impositions" being used, or has it been used, to inform or guide any policies, communication strategies, planning, information operations or other undertakings by any state, territory or federal government bodies or officials, or their partners with respect to future pandemics, health emergencies, lockdowns or other impositions? If so, what are the details?

M. What other Defence Department work, if any, is being undertaken or has been undertaken with respect to psychological aspects of, or messaging regarding, lockdowns and other curtailments of citizens' rights and freedoms? What is the intended application of that work?

N. Given that the Defence Department's Operation Covid Shield (with its National Covid-19 Vaccine Campaign Plan – 'the Plan') took charge of public messaging and incentives to drive up vaccination rates Australia, was this an information operation or psychological operations campaign? What other agencies or bodies, whether within the Australian Government or within the Five Eyes network if any, and/or their external contractors or private partners if any, contributed to crafting and/or executing the messaging and incentive strategies?

O. Why was Operation Covid Shield concerned about developing pre-planned communications templates for adverse events when the vaccine was being billed as safe?

P. Given that Operation Covid Shield advised public leaders to coordinate their messaging and speak to the same "expert advice" on vaccine safety and risks, to what extent were public leaders offering the Australian public honest, well-researched, and science-based information on Covid vaccines, and to what extent were they following a script?

Q. What scientific due diligence did the Department of Defence undertake regarding the scientific reliability and validity of its messaging that the Covid vaccines were safe and effective? What is the full list of scientific experts, bodies, research papers, and literature consulted by the Defence Department (including its divisions, mechanisms and personnel) to guide its messaging and advice?

R. How was the "safe and effective" mantra, which was central to the Operation Covid Shield messaging campaign, reconciled with the numerous lines of

evidence to the contrary? Such as the fact that no long-term safety data existed with respect to Covid vaccines? Or the fact that the European Medicines Agency wrote in its own Pfizer/BioNTech approval documentation that "vaccine-associated enhanced disease, including Vaccine-associated enhanced respiratory disease" were "important potential risks that may be specific to vaccination for Covid-19"? And that a "statistically certain conclusion cannot be drawn" about whether the vaccine "protects against severe Covid-19"? Or the Lancet paper of April 2021 explaining that the purported ~90% efficacy rates claimed by vaccine manufacturers were in fact in the order of ~ 1% when the entire study sample was taken into account, as sound statistical practice demands? (These are but a few examples of a long list of related lines of evidence).

S. Given these and other known scientific controversies regarding Covid vaccines' necessity, efficacy and safety, how can the Department of Defence ethically and scientifically justify ignoring such scientific complexities in order to stick with the simplistic 'safe and effective' mantra?

T. What communication or information regarding vaccine necessity, efficacy and safety, if any, did Operation Covid Shield and/or its personnel or subdivisions receive from concerned members of the public? Whether in written correspondence or on social media or in oral form. How did it respond to those communications?

U. What other Defence Department work besides Operation Covid Shield, if any, is being undertaken or has been undertaken with respect to psychological aspects of, or messaging regarding, future pandemic vaccination campaigns? What is the status of that work?

V. Who were the industry actors that the Defence Department called in to assist with Operation Covid Shield? What was their involvement, role and activities?

W. Given that Covid vaccines were not expected to prevent transmission (with a Pfizer executive ultimately admitting as much to the European parliament), how could the Department of Defence justify incentivising vaccine uptake by making citizens' freedom of movement contingent upon vaccination?

X. What due diligence was undertaken to differentiate between coercion (i.e. a carrot and stick strategy, with lockdowns as the stick and freedom as the carrot) versus non-coercive incentivisation?

Y. What involvement did Operation Covid Shield and/or its personnel or subdivisions, or the Covid Taskforce, have in the vaccine mandates implemented around Australia, if any? What communications took place between Operation Covid Shield and any and all actors involved in the vaccine mandates?

Z. Did Operation Covid Shield or any other Defence Department bodies, initiatives or personnel contribute to any messaging or incentivisation regarding vaccine mandates? If so, what are the details? Was there any exploitation or manipulation of emotion (fear, shame, guilt, anger / blame) involved?

AA. Given that Operation Covid Shield's mission was to maximise vaccine uptake, what due diligence was undertaken to assess whether issuing communication "templates" in the immediate aftermath of adverse events risked minimising the nature, severity and/or incidence of those events, and therefore misleading the Australian public into risking harm? Did the Operation's mission cause a conflict of interest in dealing with adverse events?

Index

Reference: O

Index

A review and analysis of clinical studies available to Australian governments and health departments (and their advisory committees) in 2020, 2021, and 2022 containing data concerning the safety and efficacy of repurposed drugs used in the treatment of SARS-CoV-2 illness (Covid-19), including but not limited to:

i. Hydroxychloroquine alone or in combination (for example with Azithromycin/ Doxycycline/Zinc);
ii. Ivermectin alone or in combination (for example with Azithromycin/ Doxycycline/Zinc);
iii. Azithromycin alone or in combination;
iv. Vitamin D alone or in combination (for example with Azithromycin/ Doxycycline/Zinc);
v. Povidone Iodine (Nasodine®).

Explanatory Memorandum

Index

An examination of the deliberations and assessments undertaken by the TGA and Dept of Health and the extent to which the TGA/DOH included external expert advices and studies in respect of the use of repurposed drugs for SARS-CoV-2.

An examination of the deliberations and assessments process undertaken by the National Clinical Evidence Taskforce (NCET) for the recommendations made by the NCET, particularly the authorship for each recommendation, and the role of the MAGIC Evidence Ecosystem Foundation (administrators of https://app.magicapp.org/#/guidelines) in the creation NCET recommendations as well as the development, administration and clinical governance of the Covid19evidence.net.au website used as the central repository for the protocols that were recommended.

Question(s) on Notice

Index

Professor Brighthope, in respect of index **References O & Q**, there has existed great controversy since 2020 about the use of repurposed drugs for the prevention of Covid-19 illness, and if ill, for treating patients with repurposed drugs, some of which like Vitamin D and intravenous Vitamin C have been used safely for nearly 100 years, and others like Ivermectin and Hydroxychloroquine, which have proven to be incredibly safe and effective for treating prior coronaviruses.

My questions to you Professor Brighthope are:

1. Did Australians only need to receive these incredibly safe repurposed drugs to protect against getting sick with Covid-19, and if they got sick, would they have quickly got Australians feeling well again, without any side-effects?

2. Secondly, if these long established and well known repurposed drugs had been used from the beginning, would there have been any need for the experimental Covid-19 gene therapy drugs containing GMOs to be administered to Australians, with all the massive side effects and deaths they have caused?

Answer(s)

Index

First Answer

Professor Brighthope, Co-Author:

In answer to Question 1.

> Did Australians only need to receive these incredibly safe repurposed drugs to protect against getting sick with Covid-19, and if they got sick, would they have quickly got Australians feeling well again, without any side-effects?

The 'drugs' in question are Ivermectin, Hydroxychloroquine, azithromycin, doxycycline, vitamin C, vitamin D and zinc.

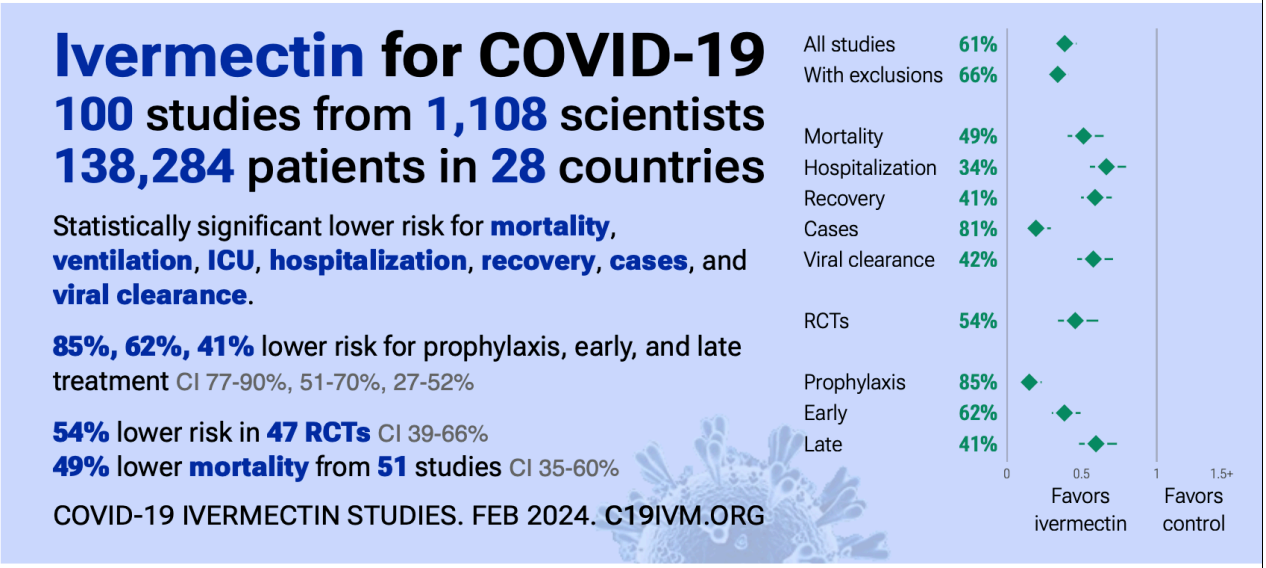
These incredibly safe, effective, cheap and readily available drugs, if given to Australians at the outset of the pandemic, would have prevented the majority of Australians from getting sick, permitted them to quickly develop natural immunity to the virus, and given the Australian population natural herd immunity, the most profound and long-lasting immunity achievable. In fact, raising the population's vitamin D status to the level for optimal immunity will also reduce the risk of some brain diseases, cancers, autoimmune disease etc. You cannot achieve these beneficial side effects with expensive risky GMO-based experimental vaccines.

The repurposed medicines, if used in symptomatic patients, would return them to health very quickly. The use of vitamin C intravenously in very sick patients would save requirements for hospitalisation or intensive care.

Ivermectin as a Repurposed Drug for Covid

All Peer Reviewed studies collected here:

Ivermectin for Covid-19: real-time meta-analysis of 100 studies



It is important to look at the totality of evidence from all sources when deciding whether to use a particular treatment approach. Many medical groups around the world used the totality of evidence approach when deciding on whether to recommend ivermectin as a potential treatment for Covid-19. When ivermectin was used, it was successful in prevention of Covid, effective in early treatment, effective in late-stage treatment and more recently been found to be effective in both long covid and covid vaccination reactions. It was banned in Australia.

There have been and remains fraudulent claims about Ivermectin's safety and efficacy. These claims have resulted in the underuse of one of the safest lifesaving medicines ever.

Ivermectin was adopted in all or part of 22 countries (39 including non-government medical organizations). It was banned in Australia.

Statistically significant lower risk is seen for mortality, ventilation, ICU admission, hospitalisation, recovery, cases, and viral clearance. All remain significant for higher quality studies. 60 studies from 54 independent teams in 24 different countries show statistically significant improvements.

Hydroxychloroquine as a Repurposed Drug for Covid

In the very early days of the SARS-CoV-2 pandemic, hydroxychloroquine (HCQ) was found to be a safe, versatile medicine. It had been used to treat hundreds of millions of people for many diseases over seven decades. Numerous controlled observational studies

and meta-analyses had demonstrated that HCQ could help people with Covid-19. To argue against its use because it hadn't undergone the usual randomised studies was reckless. Hundreds of drugs have been approved by the U.S. FDA on the basis of observational studies, especially when conducted in large numbers and subject to meta-analysis. As a matter of medical practice and especially in a pandemic emergency, it is not the case that only randomised controlled trials can justify adopting a treatment. HCQ should have been more widely recommended, prescribed and promoted to treat Covid-19. HCQ was banned in Australia for no scientific reason.

Note the Lancet has previously published fraudulent and misleading papers on Hydroxychloroquine. See: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext

Use in Multi-Drug Protocols in August 2020

By this time it was common knowledge that Hydroxychloroquine was being used in Multi-Drug Protocols in the US in combination with Zinc and Azithromycin (Publication Aug. 06, 2020)

Covid-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study

See: https://pubmed.ncbi.nlm.nih.gov/33122096/ A Publication OCT 26, 2020
See a published Clinical Guide from back in November 2021 https://tribeqr.com/v/c19osguides

The Australian study using repurposed medicines and nutraceuticals:

> **Therapies to Prevent Progression of COVID-19, Including Hydroxychloroquine, Azithromycin, Zinc, and Vitamin D3 With or Without Intravenous Vitamin C: An International, Multicenter, Randomized Trial**

A very positive study but ignored by the Minister for Health despite being funded by the Rinehart Medical Foundation.

Letter from the Federal Health Minister Mr. Greg Hunt to Ms. Gina Rinehart in response to the above Covid Study.

The Hon Greg Hunt MP
Minister for Health and Aged Care

Ref No: MC21-033377

Mrs Gina Rinehart
Executive Chairman
Hancock Prospecting Pty Ltd

19 OCT 2021

Dear Mrs Rinehart Gina

I refer to your correspondence of 27 September 2021 concerning a recently released report from the National Institute of Integrative Medicine describing the ALLIANCE study of medicines to prevent COVID-19 progression underway in a number of Turkish hospitals.

I thank you for bringing these preliminary findings to my attention and understand from the report that there is a plan to progress the study into stage 2 to obtain further evidence. As there is very little information in the report in how the trial was conducted, I would strongly encourage the authors to submit the study for peer-review and publication in a major international journal when they are able. Applying the rigour of peer-review to the findings will be important for the clinical and scientific community to better understand this study in the context of the other available evidence.

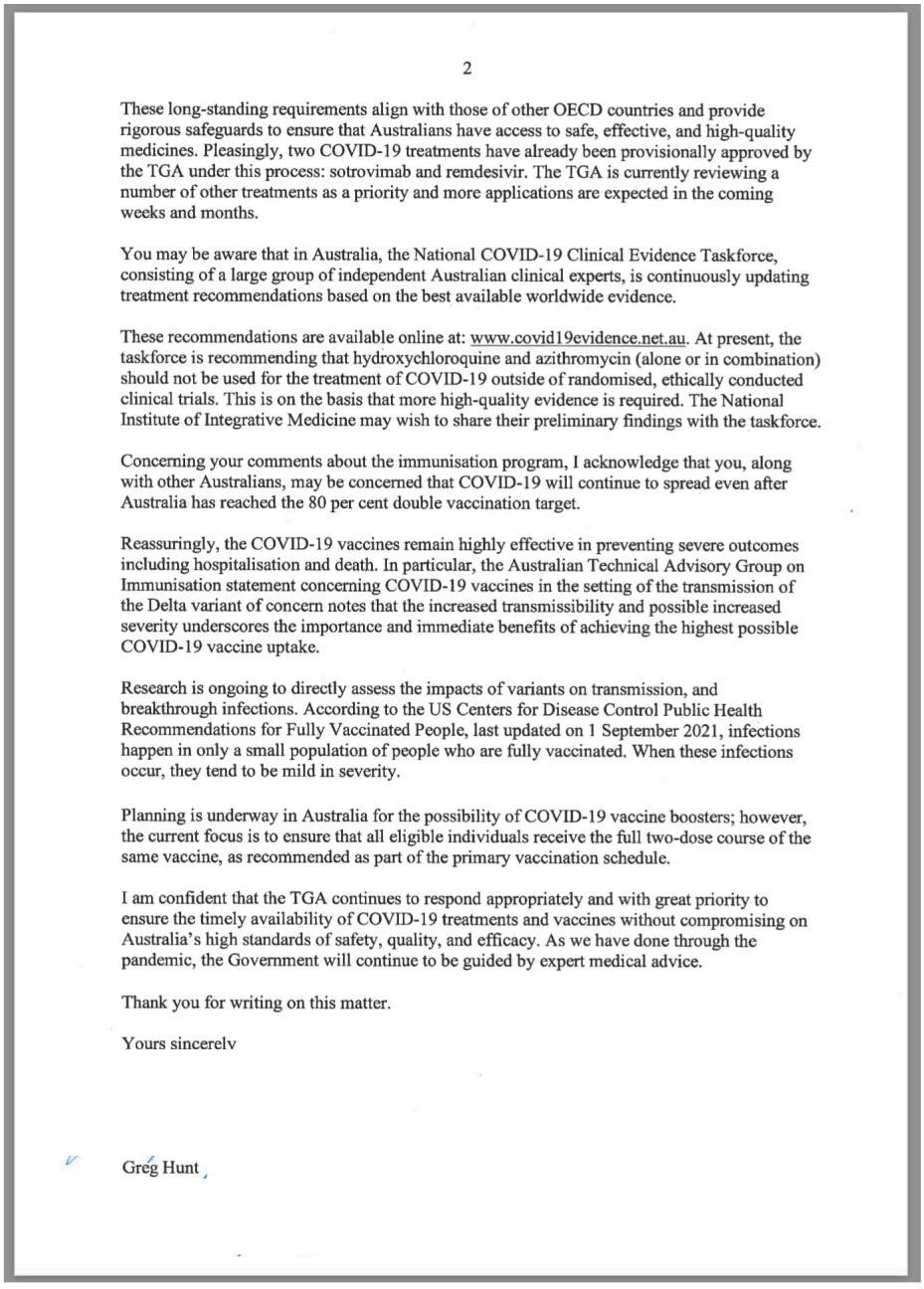
I can assure you that the Australian Government is committed to ensuring that Australians have access to the safest and most effective treatment options for COVID-19 and is closely monitoring clinical research being conducted in Australia and overseas.

My Department, which includes the Therapeutic Goods Administration (TGA), is regularly meeting with researchers, developers and manufacturers about a wide range of medicines for the prevention and treatment of COVID-19 in a variety of clinical scenarios. The TGA welcomes and encourages discussions with prospective sponsors about the regulation process for potential COVID-19 treatments.

I note that the medicines mentioned in the report, including hydroxychloroquine, azithromycin, zinc, vitamin D, vitamin B12 and intravenous vitamin C are not yet approved as COVID-19 treatments in Australia or any comparable Organisation for Economic Co-operation and Development (OECD) country. As with any medicine, before a COVID-19 treatment can be lawfully supplied in Australia it must be evaluated by the TGA and included in the Australian Register of Therapeutic Goods (ARTG). Although medicines, such as those above, may already be registered in Australia for other uses, it does not automatically mean that they are safe and effective when used to treat another condition.

It is important to clarify that if a sponsor holds the appropriate evidence, they are welcome to make an application at any time to the TGA to register their medicine/s on the ARTG. However, the Government is unable to compel a sponsor to make an application for registration. In order for a sponsor to make an application, they are required to submit a comprehensive dossier to support safety, quality and efficacy. The application must also include a source of product manufactured to pharmaceutical Good Manufacturing Practice standards.

Parliament House Canberra ACT 2600 Telephone: (02) 6277 7220



2

These long-standing requirements align with those of other OECD countries and provide rigorous safeguards to ensure that Australians have access to safe, effective, and high-quality medicines. Pleasingly, two COVID-19 treatments have already been provisionally approved by the TGA under this process: sotrovimab and remdesivir. The TGA is currently reviewing a number of other treatments as a priority and more applications are expected in the coming weeks and months.

You may be aware that in Australia, the National COVID-19 Clinical Evidence Taskforce, consisting of a large group of independent Australian clinical experts, is continuously updating treatment recommendations based on the best available worldwide evidence.

These recommendations are available online at: www.covid19evidence.net.au. At present, the taskforce is recommending that hydroxychloroquine and azithromycin (alone or in combination) should not be used for the treatment of COVID-19 outside of randomised, ethically conducted clinical trials. This is on the basis that more high-quality evidence is required. The National Institute of Integrative Medicine may wish to share their preliminary findings with the taskforce.

Concerning your comments about the immunisation program, I acknowledge that you, along with other Australians, may be concerned that COVID-19 will continue to spread even after Australia has reached the 80 per cent double vaccination target.

Reassuringly, the COVID-19 vaccines remain highly effective in preventing severe outcomes including hospitalisation and death. In particular, the Australian Technical Advisory Group on Immunisation statement concerning COVID-19 vaccines in the setting of the transmission of the Delta variant of concern notes that the increased transmissibility and possible increased severity underscores the importance and immediate benefits of achieving the highest possible COVID-19 vaccine uptake.

Research is ongoing to directly assess the impacts of variants on transmission, and breakthrough infections. According to the US Centers for Disease Control Public Health Recommendations for Fully Vaccinated People, last updated on 1 September 2021, infections happen in only a small population of people who are fully vaccinated. When these infections occur, they tend to be mild in severity.

Planning is underway in Australia for the possibility of COVID-19 vaccine boosters; however, the current focus is to ensure that all eligible individuals receive the full two-dose course of the same vaccine, as recommended as part of the primary vaccination schedule.

I am confident that the TGA continues to respond appropriately and with great priority to ensure the timely availability of COVID-19 treatments and vaccines without compromising on Australia's high standards of safety, quality, and efficacy. As we have done through the pandemic, the Government will continue to be guided by expert medical advice.

Thank you for writing on this matter.

Yours sincerelv

Greg Hunt

In respect of vitamins D and C and Zinc

The following article titled 'PANDEMIC FREE' and its messages were published and widely disseminated to the community, politicians, medical leaders and the media during 2020.

PANDEMIC FREE IN 6 TO 8 WEEKS

> **Nutritional medicine could save hundreds of millions of lives and create new wealth for the globe**

The world will be free of future pandemics only when we come to the realization that the known scientific fundamentals have not been applied to the current SARS- CoV-2 (Covid-19) and we react positively. Whilst the social distancing, hygiene, testing, tracking and tracing have been effective, this approach is too late and is a reflection of the failure to plan and manage infectious disease.

Waiting and hoping for effective, safe vaccines and antiviral drugs is almost farcical. The question must be asked 'are we going to continue to wait for vaccines and drugs when the next, and possibly highly lethal virus pandemic strikes?'

Currently, the innate strength of the human immune system is completely ignored.

It is the most powerful defence we all have against Coronaviruses and every other pathogenic microbe. The function of the immune system depends mostly on the individual's nutritional status and genetic makeup. It's the basic building blocks of amino acids, fatty acids, vitamins, mineral and trace elements that determine how powerful the immune system will respond to an infectious agent such as a virus, bacteria or fungus. Any deficiency or imbalance of a single nutrient will weaken the response and permit invasion, infection, multiple organ damage, severe disease and death.

Doctors practicing nutritional medicine understand how important the diet, nutritional supplementation and the elimination of excesses such as sugar, alcohol and saturated fats are to preventing most diseases. For decades now, nutritional medicine (NM) experts have been quietly defeating infectious diseases especially when orthodox medicine has failed. They have been successfully preventing and treating influenza, severe herpes simplex, coronavirus infections, intractable bacterial infections and pneumonia for over 5 decades using nutrients that are essential for improving the immune response and suppressing the viral load, including killing the viruses responsible.

The advent of Covid-19 saw panic, pandemonium, economic destruction and death.

The world's health authorities were completely unprepared for it. They should have had superior strategies than the application of simple epidemiological tools. The scientific evidence and experience that NM has accumulated over the decades has been and still is, completely ignored.

Practitioners of NM have universally attempted making the authorities aware of how powerful it is but the preference of hoping for a vaccine has dominated. Meanwhile, unnecessary deaths and destruction have prevailed. January 2020

saw the commencement of the ‘CD-Zinc Campaign’. It consisted of public health recommendations for the entire population to take Vitamins C and D
and the trace element Zinc, the most critical, effective, safe and readily available nutrients for optimal immunity and virus elimination.

The common cold is typically caused by respiratory viruses. Regular oral supplementation with Vitamin C has been found to reduce the duration and severity of common colds in adults and children. Vitamin C deficiency results in impaired immunity and higher susceptibility to all infections. Also, infections significantly impact on vitamin C levels due to enhanced inflammation and metabolic requirements. Supplementation with vitamin C both prevents and treats respiratory and systemic infections.

Covid-19 causes more serious conditions such as pneumonia, acute lung injury (ALI), acute respiratory distress syndrome (ARDS), septic shock and multiple organ failure.

Some patients develop serious co-infections of bacteria and fungi. ARDS is characterised by severe low-blood oxygen, uncontrolled inflammation, oxidative damage and damage to the air sac barrier leading to death. Infections and sepsis cause the ‘cytokine storm’. This leads to fluid accumulation in the airways. Increased oxidative stress is a key factor in pulmonary injury including ALI and ARDS.

Vitamin C has many functions for Covid-19 prevention and treatment. Vitamin C can reduce the incidence and severity of bacterial and viral infections. Vitamin C increases white blood cell activity, the replication of viruses, production of interferons, enhances killer and helper cell proliferation and increases antibody formation.

It is a very powerful antioxidant that can protects cells and tissues. Its anti-viral effects have been demonstrated in influenza, herpes viruses, pox viruses and coronaviruses.

Vitamin C can ameliorate hypoxia-induced ALI and attenuate hypoxia-induced white blood cell dysfunction. Vitamin C prevents the cytokine surge damaging the lungs. Vitamin C eliminates alveolar fluid by preventing the activation and accumulation of neutrophils, special white blood cells.

High dose intravenous Vitamin C (HDIVC) is instrumental in recovery from influenza and ARDS and other serious complications of serious viral infections. Patients on life support (ECMO) with a poor prognosis have been rapidly and successfully recovered using HDIVC, with no evidence of lung fibrosis. IV Vitamin C use in septic shock reduces mortality. It also reduces the length of stay

in ICU and significantly shortens the duration of mechanical ventilation. HDIVC does not cause kidney stones or kidney damage, an excuse used by opponents to justify refusal to use the treatment. A rare side effect is preventable break down some of the red blood cells.

In March 2020, the Shanghai government announced its official recommendation that Covid-19 should be treated with high doses of IV Vitamin C. The experience of thousands of doctors around the world who have used HDIVC is that this molecule is one of the most powerful in virtually all human conditions, including physical and mental illnesses and trauma. It should be used as the treatment of first choice in every epidemic.

Vitamin D is the sunlight vitamin. When ultraviolet light falls on the skin, it manufactures a precursor of vitamin D that goes to the kidneys and liver that make active vitamin D; more accurately a hormone called calcitriol. Deficiency of vitamin D results in Ricketts in children, bone disease in adults such as osteoporosis and a greatly weakened immune system. Cod liver oil is a rich source of vitamin D. It was used extensively for children in the past during winter to protect against cold and flus.

This ‘sunlight ’Vitamin D is essential for strong anti-viral immunity. Lack of exposure to sunlight in winter increases the prevalence of Vitamin D deficiency. The seasonal increase in Vitamin D deficiency amplifies the risk from respiratory viruses, including the Covid-19 coronavirus.

A large number of clinical trials of vitamin D supplementation for the prevention of acute respiratory tract infection have been conducted over the last 2 decades. Over 25 randomised controlled trials have showed an overall protective effect of vitamin D supplementation against acute respiratory tract infections including influenza and coronaviruses. In fact, the benefit was greater in those receiving daily vitamin D than the benefits from influenza vaccination. The protective effects against acute respiratory tract infections were strongest in those with profound vitamin D deficiency. However, those with low levels of vitamin D have greater protection with supplementation.

People with vitamin D deficiency are much more likely to suffer serious outcomes and death from exposure to respiratory viruses than people with optimal Vitamin D levels. In particular, elderly people, especially those in aged-care, are at risk from the consequences of Vitamin D deficiency, unless given adequate Vitamin D supplementation to maintain optimal levels of vitamin D. Others who cannot manufacture enough include people of colour, people restricted to indoors, the obese, diabetics and others with chronic diseases.

The Nordic countries have public health policies of Vitamin D supplementation

and food fortification. They also have among the lowest mortality rates attributed to the SARS –COV2 coronavirus. Thus, Vitamin D adequacy in the general population allowed for a much lower mortality. Countries that do not have any public health policy of Vitamin D supplementation in winter and spring create at risk groups to viral respiratory infections. Accordingly further surges in cases and deaths from influenza-like viruses including Covid-19 occur.

Public health programmes of vitamin D supplementation protect elderly people and healthcare workers from serious illness and death and allow for a much less severe lock-down and much less economic destruction. In fact, overall, it leads to greater productivity and economic gains.

Vitamin D supplementation is extremely safe, effective, cheap and readily available.

No toxicity has been reported with doses of 10,000 iu per day or less. The myriad of mechanisms of action of Vitamin D are understood. In fact, it has now been reclassified as a hormone (I call it Hormone D or its proper name Calcitriol). Logically, if that is the case, then routine testing of people at risk of insufficiency should be conducted. If the level of Hormone D (calcitriol) is low, it should be medically corrected with supplementation, just as is done with insulin in diabetes and thyroid hormone in hypothyroidism. If vitamin D was a drug, it would be prescribed extensively by the medical profession. Change the name to calcitriol and let's see what happens.

The immediate introduction of public health measures to improve vitamin D status globally is essential, particularly in settings where insufficient levels and profound vitamin D deficiency is common. Finally, to zinc, a critical trace element in the fight against Covid-19 and future pandemics. It plays a fundamental role in protecting us against invaders. It is like the moat, turrets, gates and locks to the fort. Without it we are completely unprotected.

Zinc creates killer mucous lining our airways from the nose to the airway's final passages. It holds our lining cells together. Without zinc, our white cells cannot produce antibodies and our genes cannot express and repair themselves for any viral onslaught. It has been shown to be effective in Covid-19, as has vitamin s C and D.

There is absolutely every reason for the global health authorities to execute a CD-Zinc supplementation world-wide program. There is no excuse to deny the people of the world a new, cheap, available scientifically based approach to be pandemic and pandemonium free. We cannot wait for all the clinical studies to emerge when the experience around the current science is proof. We cannot wait while watching the bodies drop.

'Discovery consists of seeing what everybody has seen and think what nobody has thought' (Albert Szent-Gyorgyi, the discoverer of vitamin C) and now acting differently in every way for the health of the entire planet

Ian Brighthope
October 2020

The Critical Nutrients for Prevention and Treatment

1. Zinc

Summary

The importance of the trace element zinc for the development and function of the immune system across all kinds of species has been proven in many studies. As zinc deficiency results in altered numbers and dysfunction of all immune cells, subjects with suboptimal zinc status have an increased risk for infectious diseases, autoimmune disorders, and cancer. In addition to malnutrition, risk groups for zinc deficiency include the elderly and patients with various inflammatory and autoimmune diseases. As mild zinc deficiency is largely sub-clinical, it is unnoticed in most people. However, the World Health Organization (WHO) assumes that at least one third of the world population is affected by zinc deficiency. The fact that zinc deficiency is responsible for 16% of all deep (severe) respiratory infections world-wide provides strong evidence of zinc deficiency with the risk of infection and severe progression of Covid-19 and suggests potential benefits of zinc supplementation.

The most common symptoms of Covid-19 are impaired smell and taste (and long Covid-19), fever, cough, sore throat, general weakness, pain as aching limbs, runny nose, and in some cases diarrheaa. Most of those symptoms may be attributed to altered zinc homeostasis and explain how zinc might prevent or attenuate those symptoms, and thus should be regarded as a promising cost-effective, globally available therapeutic approach for Covid-19 patients, for which minimal to no side effects are known.

In clinical nutritional immunological practice, zinc is used globally to prevent respiratory and non-respiratory infections.

Zinc is thus a critical trace element in the fight against Covid-19 and future pandemics. It plays a fundamental role in protecting us against invaders. It is like the moat, turrets, gates and locks to a fort. Without it we are unprotected.

Zinc significantly influences immune function. Altered resistance to infections occurs

when zinc is deficient. Approximately 30 percent of the community have insufficient or deficient levels of zinc, leaving them susceptible to infection.

Zinc is known to play a central role in the immune system and zinc-deficient persons experience increased susceptibility to a variety of pathogens. Zinc affects multiple aspects of the immune system and is crucial for the normal development and function of cells mediating nonspecific immunity such as the white blood cells and natural killer cells.

Zinc deficiency also affects the development of acquired immunity, the activation of T lymphocytes and B lymphocytes. It helps B lymphocyte development and antibody production, particularly immunoglobulin G. Zinc deficiency adversely affects the function of macrophages.

The impact of zinc supplementation on Covid-19 is very well known and the experience of its use by thousands of physicians worldwide supports its routine use in Covid prevention and treatment. Zinc deficiency results in altered numbers and the dysfunction of all the immune cells. Suboptimal zinc increases risk for infectious diseases, autoimmune disorders, and some cancers.

Supplementation is safe, effective, cheap and readily available with minimal to no side effects.

57.5% of the elderly and nursing home residents in the U.S. have a significantly decreased zinc intake. Zinc supplementation is able to reconstitute immune function in the elderly and zinc deficient individuals. The Journal of Infectious Diseases has documented poor outcomes in Covid patients with zinc deficiency. These zinc deficient patients develop more complications, and the deficiency is associated with a prolonged hospital stay and increased mortality.

Zinc creates a virus killing mucous mask lining our airways from the nose to the airway's final passages. It holds our lining cells together. Without zinc, our white cells cannot produce antibodies and our genes cannot express and repair themselves for any viral onslaught. It has been shown to be effective in Covid-19, as has vitamin s C and D and these 3 nutrients are extremely synergistic.

Following are some of the many peer-reviewed articles in support of the above.

Twice-Daily Oral Zinc in the Treatment of Patients With Coronavirus Disease 2019: A Randomised Double-Blind Controlled Trial

Clin Infect Dis. 2023 Apr 17;76(8):1532. doi: 10.1093/cid/ciad014.

Methods: We conducted a prospective, randomised, double-blind, placebo-controlled multi-centre trial. Patients who were tested positive for Covid-19 without end-organ failure were randomised to oral zinc (n = 231) or matching placebo (n = 239) for 15 days. The primary combined outcome was death due to Covid-19 or intensive care unit (ICU) admission ≤30 days after randomisation. Secondary outcomes included length of hospital stay for inpatients and duration of Covid-19 symptoms with Covid-19-related hospitalisation for outpatients.

Results: 190 patients (40.4%) were ambulatory and 280 patients (59.6%) were hospitalised. Mortality at 30 days was 6.5% in the zinc group and 9.2% in the placebo group (OR: .68; 95% CI .34-1.35); ICU admission rates were, respectively, 5.2% and 11.3% (OR: .43; 95% CI .21-.87). Combined outcome was lower in the zinc group versus the placebo group (OR: .58; 95% CI .33-.99). Consistent results were observed in pre-specified subgroups of patients aged <65 years, those with comorbidity, and those who needed oxygen therapy at baseline. Length of hospital stay was shorter in the zinc group versus the placebo group (difference: 3.5 days; 95% CI 2.76-4.23) in the inpatient group; duration of Covid-19 symptoms decreased with zinc treatment versus placebo in outpatients (difference: 1.9 days; 95% CI .62-2.6). No severe adverse events were observed during the study.

Conclusions: Our results showed that, in Covid-19 patients, oral zinc can decrease 30-day death, ICU admission rate and can shorten symptom duration. Clinical Trials Registration.

Covid-19: Poor outcomes in patients with zinc deficiency

International Journal of Infectious Diseases 100 (2020) 343–349

Zinc is a trace element with potent immunoregulatory and antiviral properties and is utilized in the treatment of coronavirus disease 2019 (Covid-19). However, we do not know the clinical significance of serum Zinc levels in Covid-19 patients. The aim of this study was to determine the clinical significance of serum zinc in Covid-19 patients and to establish a correlation with disease severity.

Methods: This was a prospective study of fasting zinc levels in Covid-19 patients at the time of hospitalisation. An initial comparative analysis was conducted between Covid-19 patients and healthy controls. Covid-19 patients with zinc deficiency were compared to those with normal zinc levels.

Results: Covid-19 patients (n = 47) showed significantly lower zinc levels when compared to healthy controls (n = 45): median 74.5 (interquartile range 53.4–94.6) mg/dl vs 105.8 (interquartile range 95.65–120.90) mg/dl ($p < 0.001$). Amongst the Covid-19 patients, 27 (57.4%) were found to be zinc deficient.

These patients were found to have higher rates of complications (p = 0.009), acute respiratory distress syndrome (18.5% vs 0%, p = 0.06), corticosteroid therapy (p = 0.02), prolonged hospital stay (p = 0.05), and increased mortality (18.5% vs 0%, p = 0.06). The odds ratio (OR) of developing complications was 5.54 for zinc deficient Covid-19 patients.

Conclusions: The study data clearly show that a significant number of Covid-19 patients were zinc deficient. These zinc deficient patients developed more complications, and the deficiency was associated with a prolonged hospital stay and increased mortality.

Reduction of covid mortality

The following is a publication on Sunday, September 26, 2021in Pharma Market.

Supplementing with zinc could reduce mortality in the Covid-19 patient

With more than 10 million people vaccinated in Spain, research on how to improve the situation of hospitalised and seriously ill patients due to Covid-19 does not stop. Now a new study led by Dr. Robert Güerri, Covid-19 hospitalisation coordinator at the Hospital del Mar in Barcelona, and researcher Rubén Vicente, from the Biophysics of the Immune System group at Pompeu Fabra University, concludes that zinc supplementation could reduce mortality in this disease.

The Potential Impact of Zinc Supplementation on Covid-19 Pathogenesis

Front. Immunol., 10 July 2020 | https://doi.org/10.3389/fimmu.2020.01712

As zinc is essential to preserve natural tissue barriers such as the respiratory epithelium, preventing pathogen entry, for a balanced function of the immune system and the redox system, zinc deficiency can probably be added to the factors predisposing individuals to infection and detrimental progression of Covid-19. Finally, due to its direct antiviral properties, it can be assumed that zinc administration is beneficial for most of the population, especially those with suboptimal zinc status.

Nutritional approach for increasing public health during pandemic of Covid-19: A comprehensive review of antiviral nutrients and nutraceuticals

Health Promot Perspect. 2021; 11(2): 119–136. Published online 2021 May 19.

Conclusion: The most important nutrients which can be considered for Covid-19 management are vitamin D, vitamin C, vitamin A, folate, zinc, and probiotics. Their adequacy should be provided through dietary intake or appropriate supplementation. Moreover, adequate intake of some other dietary agents including vitamin E, magnesium, selenium, alpha linolenic acid and phytochemicals are required to maintain the host

immunity.

Clinical Significance of Micronutrient Supplementation in Critically Ill Covid-19 Patients with Severe ARDS

Nutrients **2021**, *13*, 2113. https://doi.org/10.3390/nu13062113

Taken together, the present findings strengthen the notion on a clinical significance of adequate Se and Zn supply for critically ill patients with severe Covid-19 ARDS. Commonly observed deficiencies can be effectively compensated by applying the outlined supplementation strategy. Se and Zn might be involved in the reduction in inflammation and the restoration of critical lymphocyte counts for the cytotoxic immune response, which may further translate into clinical improvement. However, the results need to be considered within the limits of an observational study, so that adequately designed trials are encouraged to fully elucidate the clinical relevance of micronutrient supplementation in patients with severe Covid-19.

20-Week Study of Clinical Outcomes of Over-the-Counter Covid-19 Prophylaxis and Treatment

Journal of Evidence-Based Integrative Medicine Volume 26: 1-13

Abstract
Objectives and Setting. As the lethal Covid-19 pandemic enters its second year, the need for effective modalities of alleviation remains urgent. This includes modalities that can readily be used by the public to reduce disease spread and severity. Such preventive measures and early-stage treatments may temper the immediacy of demand for advanced anti-Covid measures (drugs, antibodies, vaccines) and help relieve strain also on other health system resources. *Design and Participants.* We present results of a clinical study with a multi-component OTC "core formulation" regimen used in a multiply exposed adult population. Analysis of clinical outcome data from our sample of over 100 subjects comprised of roughly equal sized regimen-compliant (test) and non-compliant (control) groups meeting equivalent inclusion criteria demonstrates a strong statistical significance in favor of use of the core formulations. *Results.* While both groups were moderate in size, the difference between them in outcomes over the 20-week study period was large and stark: Just under 4% of the compliant test group presented flu-like symptoms, but none of the test group was Covid-positive; whereas 20% of the non-compliant control group presented flu-like symptoms, three-quarters of whom (15% overall of the control group) were Covid-positive. *Conclusions.* Offering a low cost, readily implemented anti-viral approach, the study regimen may serve, at the least, as a stopgap modality and, perhaps, as a useful tool in combatting the pandemic.

Zinc and immune function: the biological basis of altered resistance to infection
A H Shankar 1 , A S Prasad

The American Journal of Clinical Nutrition
Volume 68, Issue 2, August 1998, Pages 447S-463S

Zinc is known to play a central role in the immune system, and zinc-deficient persons experience increased susceptibility to a variety of pathogens. The immunologic mechanisms whereby zinc modulates increased susceptibility to infection have been studied for several decades. It is clear that zinc affects multiple aspects of the immune system, from the barrier of the skin to gene regulation within lymphocytes. Zinc is crucial for normal development and function of cells mediating nonspecific immunity such as neutrophils and natural killer cells. Zinc deficiency also affects development of acquired immunity by preventing both the outgrowth and certain functions of T lymphocytes such as activation, Th1 cytokine production, and B lymphocyte help. Likewise, B lymphocyte development and antibody production, particularly immunoglobulin G, is compromised. The macrophage, a pivotal cell in many immunologic functions, is adversely affected by zinc deficiency, which can dys-regulate intracellular killing, cytokine production, and phagocytosis. The effects of zinc on these key immunologic mediators is rooted in the myriad roles for zinc in basic cellular functions such as DNA replication, RNA transcription, cell division, and cell activation. Apoptosis is potentiated by zinc deficiency. Zinc also functions as an antioxidant and can stabilise membranes. This review explores these aspects of zinc biology of the immune system and attempts to provide a biological basis for the altered host resistance to infections observed during zinc deficiency and supplementation. *Am J Clin Nutr* 1998; 68(suppl):447S–63S.

2. Vitamin D

Summary

Vitamin D deficiency represents a serious global pandemic afflicting more than one billion individuals across all age groups worldwide.

The current serious deadly pandemic of vitamin D deficiency collided with the milder Covid-19 pandemic and radically increased the number of deaths because of vitamin D insufficiency.

Vitamin D supplementation has been used with significant benefits in reducing the risk of respiratory infections, particularly acute respiratory infections (ARIs). Several systematic reviews and meta-analyses of randomised controlled trials (RCTs) have reported on the protective effects of vitamin D supplementation against ARIs, especially in individuals with insufficient and deficient vitamin D levels. Here are some key benefits of Vitamin D supplementation in relation to respiratory infections. A reduction in risk of acute respiratory Infections. Multiple systematic reviews and meta-analyses have shown that vitamin D supplementation can reduce the risk of acute respiratory tract

infections, especially in individuals with low baseline vitamin D levels.

Studies have suggested that vitamin D supplementation can have a more pronounced effect on bacterial infections compared to viral ones in children under 6 years old. Some evidence also indicates that a dose of 80 IU/kg/day may provide significant protection against acute respiratory infections in this age group. Vitamin D supplementation has been found to be safe and effective in protecting against acute respiratory tract infections overall. It was particularly beneficial for patients who were very vitamin D deficient and those not receiving large, infrequent doses. Vitamin D supplementation has shown potential benefits in preventing respiratory tract infections, including conditions such as pneumonia and influenza, which are leading causes of death in children worldwide.

Vitamin D plays a role in modulating the immune system and enhancing innate immunity by up-regulating the expression and secretion of antimicrobial peptides, which can help boost mucosal defences against respiratory pathogens.

BOOK: VITAMIN D IN THE PREVENTION OF Covid-19

July 2020

Even a former director of the Centers for Disease Control and Prevention, Dr. Tom Frieden, proposed using vitamin D to combat the Covid-19 pandemic on March 23, 2020. There have been many recent calls for widespread high-dose vitamin D supplementation in the prevention and mitigation of Covid-19.

Unfortunately for reason I can explain, the experts without specific experience, have condemned vitamin D in favour of lockdowns, masks and vaccines.

Vitamin D and Covid-19: Synopsis and Key Points

1. The best defence against viral infections is a strong immune response.
2. An optimal level of the 'sunlight' **Vitamin D** is essential for strong anti-viral immunity.
3. Lack of exposure to sunlight in winter in latitudes greater than 35^{o} North or South, increases the prevalence of Vitamin D deficiency in winter and spring seasons. Melbourne's latitude is 38^{o} south.
4. People with vitamin D deficiency are much more likely to suffer serious outcomes and death from exposure to respiratory viruses than people with optimal Vitamin D levels.
5. The seasonal increase in Vitamin D deficiency amplifies the risk from respiratory viruses, including the SARS –COV2 coronavirus, in all sub-groups of people regarded as being at-risk for influenza-like illnesses.
6. Vitamin D deficiency is correlated with higher mortality and more serious illness in patients hospitalised with Covid-19 infection. Those with adequate vitamin D status have a much lower mortality and milder illness.

7. In particular, elderly people, especially those in aged care, are at risk from the consequences of Vitamin D deficiency, unless given adequate Vitamin D supplementation to maintain optimal levels of vitamin D.
8. For strong anti-viral immunity, vitamin D levels in blood tests should be within a target range of
   120 – 150 nmol/L.
9. Correction of vitamin D deficiency with supplementation has been shown to protect against viral respiratory infections and influenza in numerous clinical trials.
10. Clinical trials of supplementation with Vitamin D3 are underway with results awaited.
11. The Nordic countries have public health policies of Vitamin D supplementation and food fortification. They also have among the lowest mortality rates attributed to the SARS –COV2 coronavirus, in contrast to most other higher latitude countries.
12. Sweden's mortality rates from Covid-19 in April and May increased in its elderly aged-care population in whom supplementation rates have been inadequate (less than 20%). Prior to that, Vitamin D adequacy in the general population allowed for much lower mortality and a much less economically damaging lock-down policy against the Covid-19 coronavirus epidemic.
13. Southern Australia does not have any public health policy of Vitamin D supplementation in winter and spring, so that at-risk groups most susceptible to viral respiratory infections including the Covid-19 coronavirus and influenza, remain vulnerable to vitamin D deficiency.
14. Accordingly, as Vitamin D levels further decline in winter, Melbourne and other parts of southern Australia are likely to experience a further surge in cases and deaths from influenza-like viruses, including Covid-19, until seasonal sunlight exposure increases again in early summer, unless an urgent programme of vitamin D supplementation for most at risk groups is expedited.
15. Such a public health programme of supplementation with adequate doses of vitamin D3, would protect elderly people and healthcare workers from serious illness and death from Covid-19 and other respiratory viruses, and allowed for a much less severe lock-down and much less destructive economic effects.
16. Vitamin D3 supplementation is very safe. No toxicity has been reported with doses of 10,000 iu per day or less, nor at serum levels below serum levels of 300 nmol/L.
17. The mechanisms of action of Vitamin D have been extensively researched and reported in readily accessible scientific journals.
18. Good vitamin D levels will somewhat reduce the chance of contracting Covid-19. More
    importantly these levels greatly reduce the risk of serious symptoms and greatly reduce the rate of vital shedding - so reducing the rate of transmission. If everyone had these levels, then there would be no need for lockdowns, vaccines or masks for Covid-19 and there would be numerous other health benefits, including much less sepsis, ARDS and severe influenza.
19. Availability: Vitamin D3 is available in pharmacies in liquid and capsules for infants and children (1000iu dose) and 7000iu capsules suitable for adult loading doses.
20. Cost: Vitamin D3 supplements are relatively inexpensive on a daily average dose

basis.

21. Average weight individuals need about 0.125mg (5000IU) D3 a day to attain protective levels 125 nmol/L. This is a gram every 22 years and the ex-factory cost is less than AUD $4.00 a gram, before final manufactured dosage form.

Vitamin-D and Covid-19: time for the profession to take a stand
https://doi.org/10.1016/j.aimed.2021.01.003

Adequate Vitamin-D levels are of great importance in the prevention and severity of acute respiratory infections. Vitamin-D protects against pathogens including viruses via the innate and adaptive immune system, involving white blood cells and T-cells. It is known, that a large proportion of Australians are Vitamin-D deficient, specifically older people. Research has proven Vitamin-D supplementation to be a key to alleviate Vitamin-D deficiency, and subsequently prevent the onset and severity of acute respiratory tract infections, and reduce morbidity and mortality. Supplementation of 4000 IU Vitamin-D and up to 10,000 IU daily for several months are considered safe and effective in alleviating Vitamin-D deficiency and optimising plasma Vitamin-D levels.
Urgent action by the medical profession in Australia is needed to raise awareness about Vitamin-D and promote Vitamin-D supplementation.

Vitamin D for Covid-19: real-time meta-analysis of 154 studies

Covid Analysis, Dec 26, 2021, Version 125

Typical meta-analyses involve subjective selection criteria, effect extraction rules, and study bias evaluation, which can be used to bias results towards a specific outcome. In order to avoid bias we include all studies and use a pre-specified method to extract results from all studies. This provides an overview of all research.

For sufficiency studies, different studies use different levels as the threshold of sufficiency, and some studies measure risk only within hospitalised patients, which excludes the risk of a serious enough case to be hospitalised, however 91 of 97 studies present positive effects. 49 of 57 treatment studies report positive effects. Studies vary significantly in terms of treatment delay, treatment regimen, patients characteristics, and (for the pooled effects analysis) outcomes, as reflected in the high degree of heterogeneity. However, treatment consistently shows a significant benefit. The treatment studies not showing positive effects are mostly prophylaxis studies with unknown dosages. The only non-prophylaxis studies reporting negative effects are a small unadjusted retrospective *[Assiri]*, and *[Murai]* which is a very late-stage study using cholecalciferol. This result also has very low statistical significance due to the small number of events, and the other reported outcomes of ventilation and ICU admission, which have slightly more events and higher confidence, show benefits for vitamin D. Calcifediol or calcitriol, which avoids several days delay in conversion, may be more successful, especially with this very late-stage usage.

Covid-19 Mortality Risk Correlates Inversely with Vitamin D3 Status, and a Mortality Rate Close to Zero Could Theoretically Be Achieved at 50 ng/mL 25(OH)D3: Results of a Systematic Review and Meta-Analysis
Results of a Systematic Review and Meta-Analysis. *Nutrients* **2021**, *13*, 3596.

'The datasets in this study provide strong evidence that low D3 is a predictor rather than just a side effect of the infection. Despite ongoing vaccinations, we recommend raising serum 25(OH)D levels to above 50 ng/mL (125 nmol/L) to prevent or mitigate new outbreaks due to escape mutations or decreasing antibody activity.'

Effect of calcifediol treatment and best available therapy versus best available therapy on intensive care unit admission and mortality among patients hospitalised for Covid-19: A pilot randomised clinical study.

The Journal of Steroid Biochemistry and Molecular Biology
Volume 203, October 2020, 105751

This study clearly demonstrated that administration of a high dose of Calcifediol or 25-hydroxyvitamin D, a main metabolite of the vitamin D endocrine system, significantly reduced the need for ICU treatment of patients requiring hospitalisation due to proven Covid-19. Calcifediol seems to be able to reduce the severity of the disease. Larger trials with groups properly matched will be required to show a definitive answer.
Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data

BMJ 2017;356:i6583 http://dx.doi.org/10.1136/bmj.i6583

This 2016 study reports a major new indication for vitamin D supplementation: the prevention of acute respiratory tract infections. We also show that people who are very deficient in vitamin D and those receiving daily or weekly supplementation without additional bolus doses experienced particular benefit. The results add to the body of evidence supporting the introduction of public health measures such as food fortification, and supplementation, to improve vitamin D status, particularly in settings where profound vitamin D deficiency is common and at times of risk of severe respiratory infections.
3. Vitamin C

Summary

All infections significantly impact on vitamin C levels due to enhanced inflammation and metabolic requirements. Supplementation with vitamin C both prevents and treats respiratory and systemic infections. Vitamin C has many functions for Covid-19 prevention and treatment. Vitamin C reduces the incidence and severity of all viral infections, including severe Covid-19. Vitamin C increases white blood cell activity,

reduces the replication of viruses, increases the production of interferons, enhances killer and helper cell proliferation and increases natural antibody formation. It is a very powerful antioxidant that protects cells and tissues. Its anti-viral effects have been demonstrated in influenza viruses, herpes viruses, pox viruses and coronaviruses. Vitamin C can ameliorate the hypoxia-induced Acute Lung Injury (ALI) and it attenuates hypoxia-induced white blood cell dysfunction. Vitamin C prevents the cytokine surge damaging the lungs. Vitamin C eliminates alveolar fluid (fluid in the lung air sacs) by preventing the activation and accumulation of neutrophils, which are specialised white blood cells. It is thus close to being the ideal agent for the prevention and treatment of Covid-19.

High dose intravenous Vitamin C (HDIVC) is instrumental in recovery from influenza, ARDS (Acute Respiratory Distress Syndrome) and other serious complications of serious viral infections. Seriously ill patients on life support (ECMO) with a poor prognosis have been successfully recovered using HDIVC, with no evidence of lung fibrosis. Septic shock occurs in very sick Covid patients. IV Vitamin C use in septic shock reduces mortality. It also reduces the length of stay in ICU and significantly shortens the duration of mechanical ventilation. It probably also helps to reduce the damage caused by intubation. HDIVC does not cause kidney stones or kidney damage, a false reason used by opponents to justify refusal to use the treatment. A rare side effect is preventable break down of some red blood cells.

Covid-19 and Vitamin C Peer Review References Located Here

In answer to Question 2:

> Secondly, if these long established and well known repurposed drugs had been used from the beginning, would there have been any need for the experimental Covid-19 gene therapy drugs containing GMOs to be administered to Australians, with all the massive side effects and deaths they have caused?

The argument for using safe, effective drugs for treating serious infectious diseases, rather than new and experimental medicines that carry a high degree of risk, is multifaceted and grounded in both ethical and practical considerations. This argument is particularly relevant in the context of infectious diseases, where the stakes are high due to the potential for widespread transmission and significant morbidity and mortality.

The following describes the first and wisest principles of ethical and moral medical and medicine practices and should always be followed.

First and foremost, the primary argument for using established drugs is their proven safety and efficacy profile. Safe, effective drugs have undergone rigorous testing through clinical trials and have been used in the population, providing a wealth of data on their safety, efficacy, and potential side effects. This contrasts with new and experimental medicines, which, despite promising high-level claims, may not have been thoroughly

tested, posing unknown risks to patients. The uncertainty surrounding these drugs can lead to unintended consequences, including adverse reactions or ineffective treatment, which can exacerbate the spread of infectious diseases.

From a public health perspective, the use of safe and effective drugs is crucial in controlling outbreaks and reducing the transmission of infectious diseases. Established drugs can provide immediate benefits by effectively treating infections and preventing their spread, thereby protecting the broader community. On the other hand, the deployment of experimental medicines with uncertain outcomes could delay effective control measures, potentially leading to larger outbreaks and higher mortality rates.

The cost-effectiveness of using established drugs is another significant factor. These drugs are often more affordable and accessible, making them a practical choice for large-scale treatment programs, especially in resource-limited settings. In contrast, new and experimental medicines can be prohibitively expensive and may not be readily available, limiting their utility in addressing public health emergencies.

Harm reduction strategies, such as scientifically-based vitamin and mineral supplementation, demonstrate the effectiveness of integrating safe practices with the use of established drugs such as antibiotics to mitigate the spread of infectious diseases among vulnerable populations. The argument for using safe, effective drugs for the treatment of serious infectious diseases is compelling. It is grounded in the principles of safety, efficacy, public health impact, cost-effectiveness, and harm reduction. While the allure of new and experimental vaccines with high-level claims is understandable, the priority must be to protect patient safety and public health. Therefore, the focus should be on utilising established drugs with proven track records, supported by harm reduction strategies, to effectively combat infectious diseases and mitigate their impact on society.

Had these long established and well known repurposed drugs and vitamins been incorporated quickly, easily and cheaply from the beginning, there would have been no need for more than one short sharp lockdown at most, no need for masking and absolutely no need or desire for the experimental Covid-19 gene therapy drugs containing GMOs to be administered to any Australian. The risk of the GMO vaccines was too great, and we have been witness to all the massive side effects and deaths they have caused. They are also potentially a sinister global pollutant. The use of modRNA in any biological system should be outlawed worldwide for the good of EVERY biological system and the factories manufacturing same, shut down.

Index

Second Answer

Prof. Robyn Cosford, Co-Author:

Nasal sprays and mouth washes were always a simple, safe, highly effective, and affordable prophylaxis against and early treatment for Covid-19 but were ignored by Australian health authorities when they should have been recommended.

Polyvinyl Pyrrolidone or Povidone Iodine (PVP-I) is a strong microbicidal agent having 99.99% virucidal efficacy in only 0.23% concentration, including SARS-CoV-2 in vitro.[xlvi] As the first step in the development of COVID-19 is the adherence and colonisation of SARS COV-2 to the nasopharyngeal and oropharyngeal mucosa, and then attachment to the ACE receptors and internalisation, intranasal and intra oral application of Povidone Iodine offers a practical measure for prevention and early treatment.

In Japan, 0.45% PVP-I throat spray has long been used for the prevention of colds, sore throat treatment, and prevention of acute exacerbations of chronic respiratory disease[xlvii] and gargling and throat sprays are included in their national respiratory guidelines.[xlviii]

Results from trials to date using nasal application of PVP-I have been indicative but not conclusive. A small pilot trial of 0.4% PVP-I nasal spray showed poor virucidal activity, with significant reduction of viral titres in only some 50% of trial subjects, unlikely to reduce transmission of SARS-CoV-2 in prophylaxis use.[xlix] A randomised controlled trial (RCT) in 45 subjects using either saline, low dose PVP-1 (0.5%) or 2 % PVP-1, demonstrated reduced viral load and improved olfaction in all groups, but with no significant difference between saline and low dose PVP-1. Higher dose (2%) was more effective as a virucidal but produced a high rate of nasal burning as a side effect.[l] [An RCT of 32 patients comparing 0.5% PVP-I nasal spray and gargle to distilled water demonstrated an effect on reducing nasopharyngeal and oropharyngeal viral loads in COVID-19 patients[li]. A larger prospective RCT of 120 patients randomised to either no irrigation, nasal irrigation (NI) with saline, NI with povidone-iodine (PVP-I) 1%, NI with a mix of hypertonic alkaline and PVP-I 1% demonstrated benefit in all intervention groups in reduction of nasopharyngeal viral load, most effective being the PVP-I 1% with hypertonic alkaline solution.[lii] On the basis of all these results, a larger clinical trial of 189 subjects is currently being recruited to compare various strengths of PVP-I ,both by nasal irrigation and via nasal spray, comparing to distilled water placebo[liii].

An early trial with Nasodine gave positive results. Nasodine is a commercial formulation of 0.5% PVP-I that has been evaluated for safety and efficacy in human trials as a treatment for the common cold. It has been demonstrated to be safe for nasal mucosa for up to 30 minutes' exposure[liv]. In cell culture, the PVP-I formulation was found to rapidly inactivate SARS-CoV-2 isolates in vitro in short timeframes (15 seconds to 15 minutes) consistent with the minimum and maximum potential residence time in the nose. The Nasodine formula was also found to be more effective than 0.5% PVP-I in saline[lv]. Nasodine has been found extremely effective in biofilm disruption in chronic rhino sinusitis.[lvi]

While nasopharyngeal irrigation or sprays is one route to reduce viral load and entry, another route is via oral gargles and rinses, to reduce oropharyngeal viral load. A review published in September 2022 including 33 studies (11 in vivo and 22 in vitro) showed that povidone-iodine is the most efficacious intervention in vivo in terms of reducing the SARS-CoV-2 salivary viral load, compared to several different oral antiseptics, with a reduction in the viral load of 86%. Povidone-iodine- based oral and nasal preparations showed favourable results in terms of reducing SARS-CoV-2 viral loads both in vivo and in vitro.[lvii]

A review in 2022 of 27 studies found that Povidone-iodine, cetylpyridinium chloride, and essential oils were effective in vitro, while povidone-iodine, and sorbitol with xylitol, amongst other oral antiseptics, were effective in vivo, the conclusion being that "more studies are needed to determine the real antiviral effect of these different mouthwashes against SARS-CoV-2."[lviii]

Another review of 11 studies up to October 2022, concluded that mouthwashes are effective at reducing the SARS-CoV-2 viral load in human saliva. Povidone iodine was one of the antiseptics reviewed and was found effective in 5 of the 8 trials. They stated that further studies should be performed on larger populations and that the overall quality of evidence was high.[lix]

A further review published in 2023 of nine randomized controlled trials (RCTs) investigating the efficacy of different mouth rinses in reducing salivary SARS-CoV-2 loads indicated positive results. Various active ingredients have been tested in these trials including 0.5%,1% and 2% povidone-iodine. However, saline was also used as a control in several of these studies,[lx] and saline itself has been demonstrated effective[lxi]. This may have confounded the results: there was reduction in the salivary levels of the virus compared to baseline, however the majority of the examined trials failed to show a difference between active groups and water/saline. Povidone iodine itself was generally seen to be effective. The conclusion was that 'Although promising, these results should be confirmed by larger trials'.[lxii]

A recent 2023 trial, a single-center, randomized, double-blind, six-parallel-group, placebo- controlled clinical trial investigated the effect of four mouth rinses (1% povidone-iodine, 1.5% hydrogen peroxide, 0.075% cetylpyridinium chloride, and 80 ppm hypochlorous acid) on salivary SARS-CoV-2 viral load relative to the distilled water and no-rinse control groups. It would appear that the act of rinsing is key, as a reduction of viral load was found also with distilled water but not the no rinse groups. Povidone iodine was found effective.[lxiii]

A further trail of 120 lab confirmed COVID-19 positive patients were tested using saline, povidone iodine or chlorhexidine, with no benefit seen for the antiseptics over saline.[lxiv]

A review of trials up to 3 March 2023 included 5 RCTs of 454 patients and nine

interventions) showed that, in comparison with no rinse, sodium chloride (NaCl) was the most effective mouth rinse for reducing the viral load, followed by povidone-iodine (PVP-I).[lxv]

The most recent review up to June 2023, of thirty-five studies (14 RCTs, 21 in vitro) found that overall, the mouthwashes were effective in decreasing the salivary viral load both clinically and in vitro. The risk of bias was judged to be high for 2 clinical and 7 in vitro studies. The most commonly tested product was chlorhexidine alone or in combination with other active ingredients, followed by povidone-iodine, hydrogen peroxide and cetylpyridinium chloride.[lxvi]

In summary, in answer to the question regarding data available for povidone-iodine either as a nasal spray or a mouth wash, it can be said that there is only 1 in vitro trial currently available for Nasodine for the reduction of SARS-COV-2 virus in the nasal cavity, which was positive, and was noted to be more effective than other povidone-iodine (PVP-I) formulations in saline. However, there are numerous trials for either PVP-I or other antiseptics as mouth washes, which generally show effect although it cannot be clearly stated that the effect of PVP-I is significantly greater than for essential oils, other oral antiseptics, or even saline.

As PVP-I and Nasodine have been demonstrated to be safe and have at least some degree of efficacy, it would be prudent to routinely advise nasal spray or irrigation and oral rinsing or gargling to help reduce viral loads. The key issue appears to be the use of fluid to wash the nasopharyngeal and oropharyngeal mucosa. Even saline rinsing has been demonstrated to be of benefit. Further studies are required however to confirm the optimal route and combination and measure the effectiveness of each intervention.

Endnotes: For all answers
Index

Reference: P

Index

A review and analysis of any decision and the evidence basis for any decision by Australian governments' health departments (and their advisory committees) to limit access to repurposed drugs for use in the treatment of SARS-CoV-2 illness after March 2020, including any changes to guidelines or recommendations in respect of the use of antibiotics.

Explanatory Memorandum

Index

An examination to understand the evidential basis for decisions made, particularly against the use of long established protocols for the treatment of Coronaviruses and secondary pneumonia/vascular effects following viral infection.

Question(s) on Notice

Index

In respect of **Reference P**, please provide any further information concerning the evidence basis for any decision by Australian government health departments suspending or restricting access to repurposed drugs in the prevention of Covid-19 illness, and the treatment of Covid-19 illness, including any changes to guidelines or recommendations in respect of the use of antibiotics for treating Covid-19 illness.

Answer(s)

Index

First Answer

The People's Terms of Reference:

The evidence base for the treatment of Covid-19 was changed in April 2020 by the introduction of covid19evidence.net.au (now abrogated) and the introduction of the COVID living guidelines.

Both of these were generated from the "MAGICapp" which was endorsed by the WHO and distributed to multiple countries.

The author of the "MAGICapp" was Per Olav Vandvik who runs the MAGICapp company and is loosely affiliated with the University of Liverpool.

Professor Mark Morgan testified before the Legal and Constitutional Affairs Reference Committee on 1 February 2024, that he chaired the guidelines committee with over 130 doctors. We have it on good authority that it is physically impossible to create a 620-page guideline with input from that number of doctors, or to create it singlehandedly in the timescale. Further, there is no authorship on the document.

The first version of the document recommended:

> For patients with COVID-19 illness, only administer antiviral medications or other disease-modifying treatments in the context of clinical trials with appropriate ethical approval.

As well as "early endotracheal intubation" which was entirely inappropriate and likely resulted in excess deaths.

By July 2020 the document had become an unmanageable 215 pages, still with no authorship (v15) and by December 2020 (v30) was 453 pages.

All versions failed to recommend antibiotics for prevention and early treatment of bacterial secondary pneumonia.

Of 17 members of the therapeutics committee, at least 8 had documented ties to the pharmaceutical industry.

A thorough investigation and examination is required to determine the methods and processes involved in the *COVID-19 living guidelines*, as the guidelines issued ran counter to long established medical treatments for respiratory illnesses for coronaviruses, some of which treatments (or the denial of) appear to have resulted in many preventable deaths of Australians.

The answer above has been limited due to time constraints.

Index

Second Answer

Dr Phillip Altman, co-author:
As referred to in the Altman *et al* TGA submission of 26 Sept 2022 to relax the restrictive prescribing of Ivermectin (see Annexure 9), the stated reasons for the Scheduling change to introduce restrictive prescribing of Ivermectin were as

follows:

a) "persons taking Ivermectin in an effort to prevent Covid-19 consider themselves to be protected against the disease, elect not to be vaccinated as part of the national Covid-19 vaccination program"…

b) "it is possible that oral Ivermectin will be in shortage in Australia" [if used to manage Covid-19]. and

c) "Oral Ivermectin also has the potential to cause severe adverse events in persons, particularly when taken in high doses that have recently been described in social media and other sources for the prevention or treatment of Covid-19 infection".

Never before has a therapeutic agent been essentially banned from use because it might be considered an alternative treatment.

Ivermectin is a generic drug and available through various manufacturing sources. Claims of a potential Ivermectin shortage were based on supposition.

The TGA previously evaluated the safety of Ivermectin. Ivermectin is known to have a wide margin of safety compared to most drugs including many non-prescription medications.

Prior to the pandemic, the TGA previously had no significant concerns regarding the safety of Ivermectin. According to the TGA Australian Public Assessment Report for Ivermectin – 2013:

Page 11: "Escalation to a single dose of 120 mg (up to 2 mg/kg), 10 times the approved dose and 5 times the anticipated head lice dose, also produced no mydriatic effect. This supports the safety of Ivermectin at the proposed dose and provides a significant margin of safety."

Page 18: the drug "showed good tolerability and no safety concerns at doses ranging from 30 to 120 mg, that is, up to 10 times the proposed dose of 200 µg/kg for treatment of scabies".

Page 39: The TGA clinical evaluator found that there were no significant safety concerns reported with the use of Ivermectin in any of the published studies.

Index

Third Answer

Julian Gillespie, co-author:

As the materials referenced by Dr Altman evidence Ivermectin has a long history of established safety.

Ivermectin is also extremely cheap and can be manufactured quickly and in large quantities. The TGA failed to mention these considerations when restricting use of the drug.

The Australian Medical Professionals Society (AMPS) also provided a submission to the TGA seeking to have Ivermectin rescheduled and made available again for off-label prescribing by general practitioners. On pages 9-10 of the AMPS submission the following paragraph is of note:

Ivermectin has documented pharmacological mechanisms that led

clinicians to believe this extremely safe medicine could be repurposed effectively for the treatment of Covid-19. It has been known for over 10 years that ivermectin demonstrated antiviral activity against several RNA viruses by blocking the nuclear trafficking of viral proteins[29]. A comprehensive systematic review summarises the antiviral effects of ivermectin, including in vitro and in vivo studies over the past 50 years [30]. Another paper titled, "Ivermectin: an award-winning drug with expected antiviral activity against Covid-19" put forward that Ivermectin, an FDA-approved broad-spectrum antiparasitic agent, had demonstrated antiviral activity against a number of DNA and RNA viruses, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)[31]. As well as ivermectin's antiviral benefits there is also research literature that outlines its recognised "anti-inflammatory capacity"[32].

A review titled "Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of Covid-19" concluded:

> *"Meta-analyses based on 18 randomized controlled treatment trials of ivermectin in Covid-19 have found large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance. Furthermore, results from numerous controlled prophylaxis trials report significantly reduced risks of contracting Covid-19 with the regular use of ivermectin. Finally, the many examples of ivermectin distribution campaigns leading to rapid population-wide decreases in morbidity and mortality indicate that an oral agent effective in all phases of Covid-19 has been identified [33]."*

With due and appropriate cynicism, the Committee should take further note that none of the new Covid-19 vaccines provisionally approved by the TGA – AstraZeneca, Pfizer, and Moderna – could have been granted provisional approval and fast-tracked for Australian release, had any pre-existing drugs registered in Australian been shown to prevent and/or treat SARS-CoV-2/Covid-19 better than the proposed new Covid-19 vaccines.

In brief, the legislative pathway for the provisional approval of the Covid-19 vaccines involved a sponsor making a provisional application under Section 22C then Section 22D of the TG Act, which required the TGA to look to the legal criteria under Regulation 10L of the TG Regulations, which states (emphasis added):

(1) For the purposes of subsection 22D(2) of the Act, the criteria are all of the following:

(a) an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

(b) either:

(i) no therapeutic goods that are intended to treat, prevent or diagnose the

condition are included in the Register (except in the part of the Register for goods known as provisionally registered goods); or

(ii) **if one or more therapeutic goods that are intended to treat, prevent or diagnose the condition are included in the Register** (except in the part of the Register for goods known as provisionally registered goods) **-- there is preliminary clinical data demonstrating that the medicine** [a Covid-19 vaccine] **is likely to provide a significant improvement in the efficacy or safety of the treatment, prevention or diagnosis of the condition compared to those goods;**

(c) there is preliminary clinical data demonstrating that the medicine is likely to provide a major therapeutic advance;

As the submissions to the TGA by Dr Altman and AMPS evidence, clinicians in early 2020 had already shown Ivermectin to be a safe and extremely prophylactic against Covid-19, and a highly effective early treatment for those with Covid-19 illness.

Despite the mounting peer reviewed literature in favour of Ivermectin as the safest and best known treatment for preventing or treating Covid-19, the TG Act without any noticeable prior consultation with Australian doctors was amended on 23 July 2021, effectively excluding Ivermectin (and any other repurposed drugs) from possibly being a bar to the provisional approval of Covid-19 vaccines, when the following was inserted into regulation 10L:

(2) However, paragraphs (1)(b) and (c) do not apply if:

(a) the application under subsection 22C(1) of the Act is made on or after the commencement of this subregulation; and

(b) an indication of the medicine is the treatment or prevention of the disease known as coronavirus disease (Covid-19).

Had the 23 July 2021 amendment not occurred, the success of Ivermectin in the treatment of Covid-19 shown in clinical studies in Australia and in protocols established overseas, would have continued to expose the TGA provisional approval of Covid-19 vaccines to legal challenge, for failing to properly consider all relevant information for the purpose of a proper application of the criteria under Regulation 10L.

Specifically, had application been made to the TGA for Ivermectin to be rescheduled to also include the *indication* (the illness or disease a drug can be used to treat) Covid-19, then based on the many clinical studies showing the significant benefit of Ivermectin to reduce Covid-19 caused deaths by up to 75%, (when used as an early treatment), the TGA would have not been able to provisionally approve the Covid-19 vaccines.

Unfortunately, no applications were made to the TGA for the rescheduling of Ivermectin before applications for provisional approvals were lodged by Covid-19 vaccine sponsors.

Australia was not the only country where regulatory authorities took unprecedented steps against Ivermectin in order to clear the way for the new and relatively untested Covid-19 vaccines.

In the USA similar legislative provisions prevent a new drug from being approved for Emergency Use Authorisation (EUA), (fast tracking), if a pre-existing drug can be shown to provide the same of better treatment outcomes. In 2020 Ivermectin had not been rescheduled in the US to include the *indication* of Covid-19, which cleared the way for Covid-19 vaccines. However, the FDA did not have the authority to restrict the prescribing of Ivermectin by general practitioners like the TGA. Undaunted, the FDA instead reverted to false and misleading media claims concerning the safety and efficacy of Ivermectin for treating or preventing Covid-19.

The US attack on Ivermectin and other repurposed drugs was investigated by Douglas Peterson, the Attorney General for the State of Nebraska in the United States of America. His report dated 14 October 2021 is required reading for evidencing a concerted campaign within the USA to discredit Ivermectin at all costs, which the co-authors here believe the TGA was a party to. The highly questionable and unethical campaign against Ivermectin and other repurposed drugs for treating Covid-19 appears to have been coordinated globally, however only a Covid-19 Royal Commission is capable of confirming this statement with any certainty.

Index

Reference: Q

Index

A review and analysis of treatment methods and protocols for SARS-CoV-2 illness, including prophylaxis, treatment methods, and protocols against SARS-CoV-2 illness, with supporting clinical data evidencing safety and efficacy, that were presented to Australian governments in 2020, 2021, and 2022 by appropriately qualified Australian and overseas medical and science experts, and an examination of the scientific basis for why some treatment protocols presented, proposed, or undertaken were either stopped, not advanced further, or not adopted in relation to, but not limited to:

i. Hydroxychloroquine (HCQ) alone or in combination (for example with Azithromycin/ Doxycycline/Zinc/IVC/IVM/Vitamin D);
ii. Ivermectin (IVM) alone or in combination (for example with Azithromycin/ Doxycycline/Zinc/IVC/HCQ/Vitamin D);
iii. Vitamin D alone or in combination (for example with Azithromycin/ Doxycycline/Zinc/IVC/HCQ/IVM);
iv. high dose intravenous Vitamin C (IVC) to prevent hospitalisation and for use in Intensive Care Units for Covid-19 patients in combination with other drugs (for example with Azithromycin/ Doxycycline/Zinc/Vitamin D/IVM/HCQ);
v. the scientific evidence basis advanced by the National Clinical Evidence Taskforce for Covid 19 recommending Remdesivir despite the drug's known adverse clinical history;
vi. the basis for recommending Paxlovid in persons vaccinated with other Covid-19 vaccines, together with an examination of the statistical basis for showing benefit from Paxlovid in the Recovery Trial; and
vii. any Australian treatment programs for Covid-19 initiated by Australian medical experts that were halted by Australian health authorities, and the reasons why;
viii. any treatment programs or studies proposed by Australian medical experts in relation to flight travellers not adopted by Australian health authorities, and the reasons why;
ix. any studies proposed by Australian medical experts in relation to the use of Ivermectin (IVM) as a prophylaxis against Covid-19 not adopted or supported or advanced by Australian health authorities, and the reasons why.

The examination of the scientific basis for why treatment protocols (i)-(iv) were not adopted, or were restricted, or were rejected or were said to be not effective against SARS-CoV-2 should include statements and reasons and scientific evidence relied upon by, but not limited to:

a) the Prime Minister;

b) the Commonwealth Health Minister;
c) the Commonwealth Chief Medical Officer;
d) the Secretary of Health;
e) the TGA;
f) the Australian Medical Association;
g) the Royal Australian College of General Practitioners;
h) the Medical Board of Australia.

Explanatory Memorandum

Index

An examination to understand the evidential basis for decisions made by Australian governments against the use of long established protocols for the treatment of Coronaviruses, for example, the submitted studies and protocols of Prof Ian Brighthope detailing the use of Vitamin D and the use of IVC; the submitted studies and protocols of Professor Robert Clancy detailing the use of IVM; the submitted studies and protocols of Professor Thomas Borody detailing the use of Vitamin D and IVM, doxycycline and zinc.

Question(s) on Notice

Index

Professor Brighthope, in respect of index **References O & Q**, there has existed great controversy since 2020 about the use of repurposed drugs for the prevention of Covid-19 illness, and if ill, for treating patients with repurposed drugs, some of which like Vitamin D and intravenous Vitamin C have been used safely for nearly 100 years, and others like Ivermectin and Hydroxychloroquine, which have proven to be incredibly safe and effective for treating prior coronaviruses.

My questions to you Professor Brighthope are:

1. Did Australians only need to receive these incredibly safe repurposed drugs to protect against getting sick with Covid-19, and if they got sick, would they have quickly got Australians feeling well again, without any side-effects?

2. Secondly, if these long established and well known repurposed drugs had been used from the beginning, would there have been any need for the experimental Covid-19 gene therapy drugs containing GMOs to be administered to Australians, with all the massive side effects and deaths they have caused?

Answer(s)

Index

Answer

The People's Terms of Reference:

Time constraints prevented a full and complete response to the above question which would have seen an extensive answer, had sufficient time been made available.

The Committee is instead alerted to the answers provided for the Question on Notice for Reference O.

Term of Reference Q continues to be advanced by The People's Terms of Reference.

Index

Reference: R

Index

A review and analysis of any involvement of Australian scientists in the origins of the SARS-Cov-2 virus and any involvement of Australian scientists in the field of gain of function viral and bacterial research in the decade prior to the pandemic.

Explanatory Memorandum

Index

An examination to confirm whether evidence placed before US Congress investigating the Wuhan lab leak shows participation by Australian scientists in efforts to conceal the origins of SARS-CoV-2, and if so, an examination of any such US evidence and any further Australian evidence for confirming the nature and extent of Australian involvement.

Question(s) on Notice

Index

In respect of **Reference R**, please provide any further information concerning any involvement of Australian scientists in the origins of the SARS-Cov-2 virus and any involvement of Australian scientists in the field of gain of function viral and bacterial research in the decade prior to the pandemic.

Answer(s)

Index

Answer

The People's Terms of Reference:

Both Prof Edward Holmes (of Sydney University) and Prof Dominic Dwyer were involved in producing articles in relation to the origins of the Coronavirus/SARS-CoV-2 which attempted to portray a false story that it was of natural origin.

This became a subject of a US Congressional investigation with particular focus on Prof Holmes:

US Lawmakers Pursue Australian Virologist in Covid-19 "cover-up" Probe

As a consequence, Australian lawyer Tony Nikolic submitted two FOIs to Sydney University for emails relevant to the investigation of the origins of the Coronavirus/SARS-CoV-2 and both FOIs were denied.

Professor Holmes is known to be associated with the Ecohealth Alliance, the suspected developers of the Coronavirus backbone for the creation of SARS-CoV-2, via his publications with Dr Zengli Shi, Hume Field, Danielle Anderson and the CSIRO including Gary Crameri.

The above answer has been limited due to time constraints.

Index

Reference: S

Index

A review and analysis of the legal criteria required to be fulfilled or satisfied for the provisional approval and registration of Covid-19 vaccines in Australia, including the extension of those approvals to different age groups, and including:

i. whether and which Covid-19 vaccines required licencing approval by the Office of the Gene Technology Regulator (OGTR);
ii. whether and which Covid-19 vaccines required OGTR licencing approval before seeking provisional approval by the TGA;
iii. whether and which Covid-19 vaccines satisfied being deemed Gene Therapy drugs under TGA guidelines;
iv. if any Covid-19 vaccines required OGTR licencing and/or satisfied Gene Therapy definitions what, if any, further testing and assessment requirements were applicable;
v. an examination of the definition of a 'vaccine' in Australia and whether Covid-19 vaccines fulfilled all relevant criteria for being properly deemed a vaccine.

Explanatory Memorandum

Index

An examination to confirm whether TGA Regulation 10L was ever satisfied particularly for persons under 65 years, considering SARS-CoV-2 epidemiological studies.

An examination to confirm whether the OGTR fulfilled its statutory mandate in respect of Covid-19 vaccines.

Question(s) on Notice

Index

In respect of **Reference S**, please provide any further information concerning the legal criteria required to be fulfilled or satisfied for the provisional approval and registration of Covid-19 vaccines in Australia.

Answer(s)

Index

First Answer

Dr Angela Jeanes, Co-Author:

In answer to the Question on Notice in respect of Term of Reference S, please note that I am also an expert witness in Australian Federal Court Proceedings Julian Fidge v. Pfizer Australia Ptd Ltd and Anor: Case File Number: VID510/2023.

My answer encompasses all parts of Terms of Reference S.

From March 2022 to the present, I have contributed my knowledge in molecular biology, cell biology, and embryology, to a range of projects seeking to understand the nature of the COVID-19 so-called "vaccines". What I have come to learn through extensive reading and consideration of the literature and data is very concerning. I will provide some insight into the nature of **genetically modified organisms** (GMOs) from a biological perspective, and how these characteristics of GMOs relate to the design of the mRNA products (specifically, Comirnaty by Pfizer and Spikevax by Moderna).

What is a GMO?

A GMO is first and foremost an organism. Most biologists would agree that an organism be defined as a living entity that can grow, metabolise and replicate i.e. transfer its genetic material to create another living entity. An organism is the unit of life, as it acts as an autonomous entity.

Organisms that contain modified genetic material eg. modified DNA or RNA, are known as genetically modified organisms. There are many examples of GMOs and these are commonly found in a laboratory setting, such as bacteria containing modified DNA. The controversial Oxitec OX5034 mosquitos released in Florida, USA, and other locations is also an example of a GMO, in this case it is a genetically modified mosquito.

The nature of the modification can be different in each GMO case; however, the common underlying fact is that the genetic material of the organism has been altered through a targeted process involving gene technology, or a technique to modify genetic material.

Does the Pfizer and Moderna mRNA products contain genetically modified RNA?

Yes.

Pfizer and Moderna have utilised an entirely new platform technology to create a so-called "vaccine". Previous vaccine technologies have injected humans with either dead viruses, or attenuated (weakened) live viruses, or proteins that are derived from viruses, to create an immune response in the human to defend against viral infection. Pfizer and Moderna have instead injected humans with a messenger ribonucleic acid (mRNA) code, contained within a lipid nanoparticle (LNP), with the idea that the LNP will directly

deliver the mRNA to human cells, whereby the RNA code instructs the human cell to produce the SARS-CoV-2 spike protein, which then activates the immune response in the human.

For clarity, the mRNA code found in Comirnaty (Pfizer) and Spikevax (Moderna) to encode for spike protein production in humans **IS NOT THE SAME AS THE RNA CODE FOUND IN SARS-CoV-2 VIRUS**. Instead, the Pfizer and Moderna mRNA code is highly modified and will be referred to as "modified mRNA" (**modRNA**). The modRNA differs from the SARS-CoV-2 code in a number of ways, including:

1. **Codon optimisation:** A technique called **"**codon optimisation**"** was used in the Pfizer and Moderna mRNA products. The genetic code (nucleotides A, U, C, and G in RNA) is interpreted in groups of three letters, which is called a codon. Each codon instructs the cell on which amino acid will be inserted to build the protein. This is the process of translation where the cell uses the RNA and creates the spike protein. There can be different combinations of letters that can instruct the cell to use the same amino acid. The purpose of codon optimisation is to increase the amount of protein that can be produced from a given amount of starting RNA.

   Conclusion: the amount of spike protein produced from the Pfizer and Moderna mRNA products is expected to be far greater than the amount of spike that would have been present if they had used the exact same sequence derived from the SARS-CoV-2 virus.

2. **Substitution of Uracil (U) for N1-Methylpseudouridine (m1Ψ):** During the production process for Comirnaty and Spikevax, a process called *in vitro* transcription (IVT) was used, which allowed them to insert a modified version of the letter "U" in the mRNA sequence. This new letter was N1-Methylpseudouridine (m1Ψ), which is a highly modified version of the "U". The purpose of using m1Ψ is to evade the innate immune response, in favour of an adaptive (antibody) immune response. M1Ψ also allows for more protein to be produced from a given amount of modRNA. However, problems such as "stop codon readthrough" and "altered translation fidelity" arise, whereby the protein made from the modRNA does not stop where it is supposed to, or have the correct amino acids inserted. More recently, a study has shown that the presence of m1Ψ also drastically affects how the modRNA is read; a nucleotide can be skipped in the reading of the code, leading to a whole new, unrelated and unexpected, protein may be produced (Mulroney'23).

   Conclusion: m1Ψ drastically alters the outcomes of protein production through having the right protein, in the right amount. Additionally, m1Ψ can lead to the creation of nonsense proteins, which Mulroney et al. demonstrated can lead to off-target immune activation (Mulroney'23).

3. **Addition of 3'UTR and 5'UTR:** Instead of encoding just the spike protein sequence into the modRNA, Pfizer and Moderna added extra sequence at the start (5' untranslated region; 5'UTR) and at the end (3' untranslated region; 3'UTR) of the spike sequence. The extra code was a little different between the two products (Comirnaty vs Spikevax), but in both cases it involved sequence encoding human genes, which was attached to the modified version of the viral spike gene. Both modRNA products contained the extra code for the same reason: it increased the stability of the modRNA and enhanced the protein production. Given the risk of "*stop codon readthrough*" mentioned above, if any of the human sequence was incorporated into a protein also containing the spike sequence, it is conceivable that an immune response targeted against the human protein component may ensue, leading to an autoimmune response.

   Conclusion: Addition of extra human sequence within the modRNA will increase the amount of spike protein produced. These extra human sequences, if translated along with spike sequence, may lead to autoimmune complications.

In summary, the modRNA found within the Pfizer and Moderna products is a highly modified version of the mRNA encoding the SARS-CoV-2 spike protein. These modifications include changes to the fundamental code (codon optimisation), changes to the letter "U" in the code (use of N1-Methylpseudouridine; m1Ψ), and addition of human sequence attached to the modified viral sequence.

What is the modRNA-LNP?

Pfizer and Moderna have created modified versions of mRNA code for spike protein and packaged this modRNA into minuscule lipid carriers called lipid nanoparticles (LNPs). The LNP contains many of the lipid molecules you find on the cell surface. This allows the LNP to be readily taken up into any cell. The LNP acts as a transfectant, which enables the delivery of the modRNA from within the LNP to cross the membrane of human cells. The purpose of the LNP is to ensure the modRNA does not degrade quickly; it is required inside the human cell to produce the spike protein.

The LNP does not target specific cells in the way that SARS-CoV-2 targets cells with the ACE2 receptor, but, rather, can be taken up by any cell. This makes the LNP a very effective vehicle for "**transferring genetic material**".

Discovery of DNA contamination in the Pfizer and Moderna Covid-19 injections

In early 2023, a highly experienced genomics researcher in the USA, discovered modDNA contamination within the Pfizer and Moderna products. In a series of studies, Kevin McKernan and his team discovered that the modDNA contamination far exceeded the allowable limits, as ascribed by the major regulatory agencies in the world (the U.S. Food and Drug Administration (FDA), the Therapeutic Goods Administration (TGA)

and the European Medicines Agency (EMA)).

The DNA contamination is a consequence of a second manufacturing process, which was adopted by both Pfizer and Moderna to scale up production. This second process produced the modRNA from a bacterial DNA template (plasmid) derived from live bacteria. The modDNA and bacterial constituents were supposed to be completely removed by purification steps; however, this does not appear to have been the case. Both Pfizer and Moderna have failed to filter out the bacterial modDNA[lxvii] from their second manufacturing process, meaning the products are now contaminated with bacterial modDNA, which also contains sequences of viral DNA origin.

The presence and quantities of modDNA contamination has been reproduced in multiple batches in different labs located throughout the world. In addition, the modDNA contamination contained fragments of viral SV40 sequence linked to cancer development.

Finally, McKernan's team demonstrated that the modDNA contamination was encapsulated inside the LNPs (modDNA-LNP). If this DNA contamination is inside the LNPs, then it is likely that huge quantities of modDNA contamination have also been delivered directly to cells all around the human body, thereby transferring this genetic material.

In summary, both the modRNA-LNP and modDNA-LNP complexes fit the legal definition of GMOs as they are "*biological entities*" that "*transfer modified genetic material*".

Further in-depth analysis of the genetic changes and their potential consequences are covered in my expert report submitted to the Australian Federal Court for Case File Number: VID510/2023 Julian Fidge v. Pfizer Australia Ptd Ltd and Anor. My report can be found at p19 as Annexure 1 in the Criminal Brief of Evidence submitted to the Commonwealth Director of Public Prosecutions on 4 December 2023.

Instructing solicitor Katie Ashby-Koppens responds further to the GMO definitions and the *Gene Technology Act 2000* in the Second Answer, below.

Endnotes: For all answers
Index

Second Answer

Katie Ashby-Koppens, LLB, Co-Author:

My name is Katie Ashby-Koppens, I am a lawyer in New South Whales.

In July 2023, on instruction from Dr Julian Fidge, an aggrieved person[lxviii], I commenced injunction proceedings in the Federal Court, Melbourne Registry (VID510 of 2023), against Pfizer Australia Pty Ltd (**Pfizer**) and Moderna Australia Pty Ltd (**Moderna**) on the basis that their Covid-19 injections satisfied the legal definition of genetically modified organism, which requires a licence from the Gene Technology Regulator, which both companies failed to obtain.

In bringing the civil action against Pfizer and Moderna, I caused to be briefed by Dr Angela Jeanes, PhD, Molecular and Cellular Biology. Dr Jeanes is a scientist specialising in the molecular, cellular and environmental aspects of health and disease, specifically relating to embryonic development. In supplying this answer to questions on notice, Dr Angela Jeanes speaks to certain aspects the subject of her expertise.

Pursuant to questions on notice, I have been asked to provide the legal definitions of generically modified organisms (**GMO**).

In Australia, GMOs are regulated by the *Gene Technology Act 2000* (Cth) (**GT Act**).

The GT Act, s 10, defines ***genetically modified organism***, ***gene technology*** and ***organism*** to mean:

- A ***genetically modified organism*** as *(a) an organism that has been modified by gene technology* where ***gene technology*** *means any technique for the modification of genes or other genetic material.*

  On 26 October 2023, the Gene Technology Regulator confirmed that both the Pfizer and Moderna injections for Covid-19 were manufactured using gene technology.[lxix] Dr Bhula's statement was:

  > *'If, indeed, the mRNA was being manufactured here—and it's correct that gene technology was used in the modification of the mRNA—then, under the Gene Technology Act, an approval would have been required for that manufacturing step.'*

  Pfizer[lxx] and Moderna[lxxi] have also confirmed that the Covid-19 mRNA injections used gene technology in their manufacture.

  Dr Jeanes in response to the First Question of Reference S, has also confirmed that gene technology was used.

- An ***organism*** means "*any biological entity"* that is ... *"(c) capable of transferring genetic material".*

  The Pfizer and Moderna injections for Covid-19 are:

- Biological entities, each sponsor submitted a *"new biological entity"* application[lxxii] for provisional registration from the Therapeutic Goods Agency, which was approved. Further Dr Jeanes in response to the First Question of Reference S, has also confirmed that the modRNA-LNP and modDNA-LNP complexes fit the legal definition of GMOs as they are "biological entities".

- Capable of transferring genetic material as outlined in the First Answer to Questions on Notice reference: S above as detailed by Dr Angela Jeanes.

Section 32 GT Act, outlines that it is an aggravated criminal offence to 'deal with' a GMO without a licence in Australia and under section 38 carries a penalty of 5 years or 2000 penalty units.

Section 10 ***deal with***, prohibits dealing with a GMO without a licence in several ways, relevantly:

> *(a) conduct experiments with the GMO;*
> ...
> *(g) import the GMO;*
> ...
> *and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).*

- As to (a) conduct experiments with the GMO: Both Pfizer and Moderna's Covid-19 injections were subject to the Provisional Approval process from the TGA.[lxxiii] Further, both were required by the TGA to participate in the 'Black Triangle' program, facilitated by the TGA.[lxxiv] Provision approval and the Black Triangle program are reserved for novel drugs which lack sufficient safety data to receive full regulatory approval. This approval process required both Pfizer and Moderna to collect and return clinical safety data to the TGA within specified timeframes. Each approval process was predicated on the assumption, or hypothesis, that the mRNA drugs, for which each accused sponsored the approval process with the TGA, were safe and effective. As the drugs were an entirely novel class of drugs for widespread distribution, whether they were safe and effective for widespread use was yet unknown. The hypothesis, method of distribution and administration, the collection of clinical data to determine the results, constituted an experiment.

- As to (g) import the GMO: Both Pfizer and Moderna were the sponsors listed on the TGA Register of Therapeutic Goods[lxxv] who can import the Covid-19 injectables, as confirmed on Australian Border Force requirements.[lxxvi]

Endnotes: For all answers

Index

Third Answer

Julian Gillespie LLB BJuris, Co-Author:

The following describes the Provisional Approval pathway used by Covid-19 vaccine sponsors who applied to the Therapeutics Goods Administration (TGA).
In brief, the legislative pathway for the provisional approval of the Covid-19 vaccines involved a sponsor making a provisional application under Section 22C then Section 22D of the Therapeutic Goods Act (TG Act), which required the TGA to look to the legal criteria under Regulation 10L of the TG Regulations, which states (emphasis added):

> (1) For the purposes of subsection 22D(2) of the Act, the criteria are all of the following:
>
> > (a) an indication of the medicine is the treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;

The TGA provisionally approved the Covid-19 drugs of Pfizer, Moderna, and AstraZeneca using the above criteria.

Several issues of concern are immediately apparent.

First, the TGA as Australia's national drugs regulator must be deemed to have always possessed knowledge of the Infection Fatality Rate (IFR) in respect of SARS-CoV-2. The subject of IFRs is dealt with in greater detail in answer to the Question on Notice for Reference A.

An appreciation of the real risk posed by Covid-19 illness always required an appreciation and knowledge of the clinical risk, a duty of the TGA, exemplified in the statistical tool known as the Infection Fatality Rate (IFR). The IFR for Covid-19, particularly for how this tool shows Survivability, is shown below.

Infection Fatality Rate: Rates of Death from SARS-CoV-2 Infection

Age Groups	IFR %(Infection Fatality Rate)[1]	Survivability Rate % (100 – IFR)
0-19	0.0003	99.9997
20-29	0.003	99.997
30-39	0.011	99.989
40-49	0.035	99.965
50-59	0.129	99.871
Median 0-59	0.035	99.965

60-69	0.501	99.49
Median 0-69	0.095	99.905
70+ Elderly community-dwelling[2]	2.9	97.1
70+ Elderly overall[3]	4.5	95.5

The above table requires little interpretation. Children 0-19 years experienced nearly a 0% rate of death when infected by SARS-CoV-2.

Conversely, children 0-19 years experience a nearly 100% chance of surviving Covid-19 infection.

This data does not evidence Covid-19 as a statistically significant life-threatening illness in children 0-19 years. Indeed, there is no available evidence to show Covid-19 illness as life-threatening in children 0-19 years, nor is it a substantially life-threatening illness in healthy populations 69 years and younger.

Significantly, the IFR data shown in the table above was gathered during the decidedly more lethal Delta variant of SARS-CoV-2, and even more severe variants pre-dating Delta.

From December 2021 and throughout 2022 the Omicron variant and its sub-lineages dominated. The risk of death[4] from Omicron was established to be 66% lower as compared to Delta.

Consequently, the IFR numbers shown above for those aged under 70 years must be further and significantly ***reduced***.

That it was the elderly (>69 years who faced a 2,230 to 3,769 x greater IFR risk than children 0-19 years was confirmed by Australian data[5], where from January 2020 through 31 August 2022 (34 months), SARS-CoV-2 had proven to be a disease mostly affecting the elderly, with the median age of death being **85.3** years. During the same 34-month period 64 deaths were recorded in those aged 0-39 years, compared to 8,248 in those aged 70+ years.

The above data makes clear that SARS-CoV-2 and Covid illness simply did not represent an existential threat to the lives and health of Australians.

Rather, the above data confirms the IFR for SARS-CoV-2 to have been about the same as for Influenza, for which Australia has never introduced new and largely untested experimental drugs, let alone Gene Therapies containing GMOs.

Moreover, for most of the Australian population SARS-CoV-2 and its Covid-19 illness simply was not ‘life-threatening’, nor in 2020, 2021, and 2022 was there any evidence to

show those who fell ill with Covid-19 experienced a 'seriously debilitating condition', at least not anything beyond perhaps the experience of a severe bout of Influenza.

As a consequence, the TGA when provisionally approving Covid-19 drugs was ***never able to satisfy*** Regulation 10L based upon available IFR data known to the TGA at the time of each application. An argument was available based on the same IFR data for provisionally approving these drugs for persons 70 years an older, but no basis existed for those under 70 years of age. None.

But, as shall be further detailed below, the TGA never had any clinical data upon which it could safely release Covid-19 vaccines to old and frail persons, namely and often, persons 70 years and older.

In respect of Australia's youngest aged 0-19 years, the TGA can be said to have failed utterly in its duty owed to this age cohort, for whom Covid-19 statistically represented perhaps a case of 'the sniffles', yet the TGA robustly extended the indication of Pfizer and Moderna to Australian children, and worked with ATAGI to create untrue statements impressing upon Australian parents the importance and need for their children to receive Covid-19 vaccines. The media campaign targeting Australian parents and children was a hideous deception that led to preventable Covid-19 vaccine injuries and deaths.

Next, and both Pfizer and Moderna were provisionally approved for:

'Active immunisation to prevent Covid-19 caused by SARS-CoV-2'

See the Pfizer AusPAR provisional approval document at pages 7, 8, 10, 30, 36, 37, 38, and 39.

Approved therapeutic use: *Comirnaty (BNT162b2 (mRNA)) COVID-19 vaccine has provisional approval for the indication below:*

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older.

See the Moderna AusPAR provisional approval document at pages 7, 8, 11, 58, 60, 61, and 62.

Approved therapeutic use: *Spikevax (elasomeran) COVID-19 vaccine has provisional approval for the indication below:*

Active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 18 years of age and older.

However the TGA failed to mention to the Australian public that this purported *active immunisation* lasted only 5 weeks at best, and that data only came from monkeys, not humans. Page 14 of the Pfizer AusPAR revealed the problem:

- Antibodies and T cells in monkeys declined quickly over 5 weeks after the second dose of BNT162b2 (V9),[18] raising concerns over long term immunity, which will be assessed by clinical studies according to the sponsor.

As regards the Moderna product, on the one hand the TGA was spruiking *active immunity* from Covid-19 from SARS-CoV-2, but buried within the same AusPAR at page 14, the TGA acknowledged this active immunity was achieved for ***the original strain of SARS-CoV-2 present only in early 2020***, but there was little to no data showing active immunity in subsequent strains in circulation at the time the product was released to Australians … in other words, Australians were asked and coerced to take a drug for which *active immunity* was unknown:

The Spikevax COVID-19 mRNA-1273 vaccine in a lipid nanoparticle (LNP) formulation (2 new excipients) was immunogenic in young and old mice, rats, hamsters and rhesus macaques. A prime/booster dosing regimen (3 to 4 weeks dosing interval) induced strong humoral and cellular immune responses. Antibodies neutralised the wildtype SARS-CoV-2 virus strain isolated at the beginning of the pandemic. There were no data on activity against the new variants (for example, alpha (α), beta (β), gamma (γ) and delta (δ)). In monkeys, antibodies declined 2 weeks after the second dose, raising long-term immunity concerns.

While all along both the Moderna and Pfizer clinical trial data submitted to the TGA contained absolutely No Data on efficacy, let alone safety, when:

Taken by pregnant or breast-feeding women
Taken by immunocompromised people
Taken with other vaccines including other Covid-19 vaccines
Taken by frail subjects with unstable health conditions, which includes almost all old, aged persons

Pfizer page 31:

Missing information	Use in pregnancy and while breast feeding
	Use in immunocompromised patients
	Use in frail patients with co-morbidities (for example, chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)
	Use in patients with autoimmune or inflammatory disorders
	Interaction with other vaccines
	Long term safety data

Moderna page 55:

Missing information	Use in pregnancy and while breast-feeding
	Long-term safety
	Use in immunocompromised subjects
	Interaction with other vaccines
	Use in frail subjects with unstable health conditions and co-morbidities (for example, chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders)
	Use in subjects with autoimmune or inflammatory disorders

Yet, the TGA and ATAGI and Australian governments continually extolled the dire need for the above persons to receive Covid-19 vaccines as a priority – yet neither the TGA nor ATAGI nor Australian governments had any safety data for these very people.

Pregnant, breast-feeding, immunocompromised, and frail and aged Australians were told these product were *Safe and Effective*, yet there was a complete absence of any clinical data upon which to ground these claims .. rather, these claims were known by Australian governments and health agencies to be baseless.

The recommending of taking any drug or substance to prevent a certain outcome is illegal under Australian law whenever there is an absence of clinical trial data to support such recommendations. The TGA and ATAGI and Australian governments broke these laws and must be called to account before a Covid-19 Royal Commission.

Perhaps the most egregious failure of the TGA and Australian governments surrounds the approval of the Pfizer product, when quite simply, provisional approval was granted to a Covid-19 product ***for which there was absolutely No Clinical Trial Data***.

In short, Pfizer submitted clinical trial data results for the efficacy and safety of a Covid-19 vaccine that was not the Covid-19 vaccine given to Australians.

Pfizer used a very specific manufacturing process to create the product used in the clinical trials from which it provided a host of data to the TGA when seeking provisional approval.

But, the Pfizer product imported to Australia and received by millions of Australians used a vastly different manufacturing process.

The clinical trial product was tested on 44,000 people to obtain the greater than 94% efficacy number much touted throughout the media by Australian governments, however the product received by Australians, made by a vastly different manufacturing process, was ***only tested on approximately 250 people***, where Pfizer never provided the safety and efficacy data from that 250 person trial to the TGA. Consequently the TGA had no efficacy and safety data ***whatsoever*** for the Pfizer drug product pushed onto to millions of Australians.

Again the devil is in the details. There were drug product batches manufactured for the clinical trials, and there was the final drug product manufactured for '*commercial scale batches*', for which commercial scale manufacturing the TGA had no safety or efficacy data. The TGA acknowledge this at pages 14 and 41:

- Additional data should be provided in relation to process validation of commercial scale batches.

The above statement within the Pfizer AusPAR when interpreted clearly, means the TGA was seeking at the time of provisionally approving the Pfizer product, additional data, namely safety and efficacy data that was never supplied by Pfizer nor further sought again by the TGA. In other words, ***the TGA approved a phantom product***.

The above change in the manufacturing process and the supply of data for a product that was never released to global markets is now commonly referred to as the Pfizer *Bait and Switch*. It would be all so criminal, and perhaps it actually is, were it not for the fact the TGA knew implicitly the *Bait and Switch* had occurred, just like all other drugs regulators knew, yet they all rolled out efficacy and safety data and claims to their citizens based on a non-existent product.

More information on the Pfizer Bait-and-Switch can be read in the following articles:

Covid-19: Researchers face wait for patient level data from Pfizer and Moderna vaccine trials

The list of defects in the TGA provisional approval process and false claims arising out of that process could go on for many more pages here, drawing upon expert witness testimony filed in two separate proceedings that sought to bring these issues into the public domain, namely the Federal Court matter of *AVN* NSD52/2022 NSD 496/2022, and the High Court matter of *Parry* S162/2022. Both cases while extremely strong on pleadings and evidence, were kept from full hearings in both Courts due to a perverse decision on legal standing in the AVN matter, and a perverse decision in The Australian Babies case, where though preventable deaths and injuries to Australians was specifically pleaded, the High Court believed hearing such a matter would *not be a good use of the Court's resources*. Both cases await further scrutiny by legal scholars as to whether they mark a loss of the Separation of Powers doctrine in our country.

In the meantime, a Covid-19 Royal Commission must lay bare all of the allegations and evidence mentioned above, and much more, to understand the depths to which Australia's TGA and Secretary of Health responsible at the time, Dr Brendan Murphy, failed the TGA's core mission to:

> provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.

Index

Reference: T

Index

With regards to the Covid-19 vaccines received by Australians, a review and analysis of the application materials submitted by sponsors, including the clinical safety and efficacy data and references submitted by Covid-19 vaccine manufacturers and relied upon by the Therapeutic Goods Administration for the provisional approval of the Covid-19 vaccines, including:

i. data that was withheld or not disclosed by Covid-19 sponsors at the time of submitting applications for provisional approval, and subsequent to provisional approval being granted, including;
   a) plasmid DNA maps;
   b) open reading frames (ORFs);
   c) translation issues associated with codon optimisation;
   d) residual DNA levels and tests used to quantitate same;
   e) residual Endotoxins and tests used to quantitate same;
   f) omissions or irregularities in Clinical Trials and the consequences from same;
   g) any other information requested by regulators but not supplied by sponsors;

ii. an examination of the review process undertaken by the TGA for assessing and verifying the references provided and comparative claims made by sponsors;

iii. an examination of the raw patient level data from Covid-19 vaccine Clinical Trials requested by the TGA for independent analysis, including;
   a) all correspondence and communications between the TGA and FDA in respect of the FDA's monitoring and auditing of Covid-19 vaccine Clinical Trials;
   b) all correspondence and communications between the TGA and FDA identifying issues, complaints, or concerns raised in respect of Covid-19 vaccine Clinical Trials monitored and audited by the FDA;
   c) the extent to which the TGA independently reviewed and requested information from Covid-19 vaccine sponsors in respect of any issues, complaints, or concerns brought to the attention of the TGA in respect of Covid-19 vaccine Clinical Trials;
   d) an examination of the legislative basis upon which the TGA was not required to independently assess and audit and examine Covid-19 vaccine Clinical Trials, including patient level data from those trials.

Explanatory Memorandum

Index

An examination to confirm whether there was any regulatory oversight by the TGA in context of Covid-19 drugs developed in record time, approved in record time, for use in a national vaccination campaign.

An examination to confirm the inquiries undertaken by the TGA in respect of Pfizer performing clinical trials using a drug from one production method, then supplying a different drug produced by a different production method.

An examination to confirm and understand the regulatory justifications for not insisting upon a range of studies prior to a national rollout of Covid-19 drugs.

Question(s) on Notice

Index

In respect of **Reference T**, please provide any further information concerning the application materials submitted by sponsors, including the clinical safety and efficacy data and references submitted by Covid-19 vaccine manufacturers and relied upon by the Therapeutic Goods Administration for the provisional approval of the Covid-19 vaccines.

Answer(s)

Index

First Answer

Dr Jeyanthi Kunadhasan, co-author:

I am an anaesthetist and peri-operative physician in Victoria. I am current Treasurer of the Australian Medical Professionals Society.

Additionally, I am also a member of the Daily Clout Pfizer research volunteers. We have investigated the data from trial C4591001 that formed the basis of the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) of the Pfizer -BioNTech's BNT162b2 mRNA Covid Vaccine in December 2020.

I co-authored Pfizer reports 42 and 76, available on dailyclout.io. I wrote about the evaluable efficacy population, and the timing of their accrual in the Australian Spectator. I also contributed as a co-author of "Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial." This analysis of the Pfizer's Covid vaccine represents the inaugural examination of the original trial data by a group unaffiliated with clinical trial sponsor. I have also

written a letter to the Attorney General of Texas, the Honourable Ken Paxton highlighting **undisclosed vaccinated subjects deaths from trial C4591001** at the Vaccine and Biological Products advisory Committee (VRBPAC) December 10th 2020 meeting, This December 10th VRBPAC meeting issued the EUA for the Pfizer Covid 19 vaccine after examining the results of trial C4591001.

Part 1: Efficacy Data analysis

Whilst Phase 2/3 of trial C44591001 involved 44,060 subjects, the 95% efficacy claim of the Pfizer Covid-19 vaccine was based on the results of just 170 patients, also known as the evaluable efficacy population.

Table 6. Final Analysis of Efficacy of BNT162b2 Against Confirmed COVID-19 From 7 Days After Dose 2 in Participants Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population

Pre-specified Age Group	BNT162b2 N[a] = 18198 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a] =18325 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)	Met Predefined Success Criterion*
All participants	8 2.214 (17411)	162 2.222 (17511)	95.0 (90.3, 97.6)[e]	Yes
16 to 55 years	5 1.234 (9897)	114 1.239 (9955)	95.6 (89.4, 98.6)[f]	NA
>55 years	3 0.980 (7500)	48 0.983 (7543)	93.7 (80.6, 98.8)[f]	NA

*Success criterion: the posterior probability that true vaccine efficacy > 30% conditioning on the available data is >99.5% at the final analysis
[a] N = number of participants in the specified group.
[b] n1 = Number of participants meeting the endpoint definition.
[c] Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
[d] n2 = Number of participants at risk for the endpoint.
[e] Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.
[f] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively (Table 7).

23

https://www.fda.gov/media/144416/download (page 23)

The evaluable efficacy population was the primary endpoint of Pfizer's trial upon which the EUA was granted. An endpoint is a measurable outcome used to determine whether a drug under investigation is beneficial or not. To qualify to be part of the evaluable efficacy population, all eligible, randomized participants must:

- Receive all vaccinations - a 2 dose vaccination regimen at this point of the trial) as randomized within the predefined window. (In the trial protocol, the dosing interval between dose I and 2 was 21 days with an allowed variance of 19-23 days.
- Have no evidence of Covid infection prior to seven days after the second dose of the vaccine.
- Have the efficacy measurement (i.e., the test confirming symptomatic Covid-19

infection) only after seven days following the second vaccine dose.

- Have no other major protocol deviations as determined by the clinician.

A major protocol deviation excluded a participant from the evaluable efficacy population from the date that it occurred through the participant's remaining follow-up. Vaccine efficacy is measured by calculating the risk of disease among the vaccinated and placebo groups and determining the percentage reduction in disease between the two groups.

In the 170 patients, five had dosing interval irregularities, one did not receive the correct dose of the investigational product, and another received a blood product within 60 days (a confounding event for infection), all of which should have disqualified them from being part of the evaluable efficacy population. Two others had been withdrawn from the trial prior to issuance of the Emergency Use Authorization (EUA). These disqualified patients would have brought the final number of cases to fewer than the 164 target patient threshold that Pfizer had set, thus bringing into question if an EUA application could have been made, much less approved.

Earlier phases of this trial only evaluated this drug with a dosing window of three weeks. In fact, patients outside this dosing window were removed during the Phase 1 trial. However, when the EUA was approved, the dosing interval which was previously 21 days in the protocol, had been inexplicably changed to 42 days .

Table 2. Efficacy Populations, Treatment Groups as Randomized

Population	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Participants without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Participants excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Participants without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Participants without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Participants excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion[c]			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Participants excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Participants excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

[a] n = Number of participants with the specified characteristic.
[b] These values are the denominators for the percentage calculations.
[c] Participants may have been excluded for more than 1 reason.
Note: 100 participants 12 through 15 years of age with limited follow-up are included in the randomized population (49 in the vaccine group and 51 in the placebo group). Some of these subjects were included in the denominators of efficacy analyses, depending on the population analyzed, but did not contribute primary endpoint cases and do not affect efficacy conclusions for ages 16 years and above.

https://www.fda.gov/media/144416/download (page 18)

This allowed at least 1410 patients whose results would have ordinarily have to be discontinued from any efficacy analysis (that is, excluded), to be included. It is important to note, that when drug regulatory agencies allowed a doubling of the dosing interval of this novel drug, they did so without any studies to back the efficacy of the drug with a different dosing interval that had previously been studied.

Protocol 19-23 days	Enrolled	No Dose	Dose 1	Delta	Dose 2	<8 Nov	< 19 Days	> 23 + 7	> 14 Nov 2020	Deviation	Eligible
BNT162b2	21,717	54	21663	1,147	20516	19439	171	775	1,077	2,023	17,416
Placebo	21,730	45	21685	1,197	20488	19443	174	806	1,045	2,025	17,418
Total	43,447	99	43,348	**2,344**	41,004	38,882	345	1,581	2,122	**4,048**	**34,834**

Protocol 19-42 days	Enrolled	No Dose	Dose 1	Delta	Dose 2	<8 Nov	< 19 Days	> 42 + 7	> 14 Nov 2020	Deviation	Eligible
BNT162b2	21,717	54	21663	1,147	20516	19,439	171	96	1077	1,344	18,095
Placebo	21,730	45	21685	1,197	20488	19443	174	75	1,045	1,294	18,149
Total	43,447	99	43,348	**2,344**	41,004	38,882	345	171	2,122	**2,638**	**36,244**
Recapture								**1,410**	**0**	**1,410**	**-1,410**

https://dailyclout.io/report-41-the-170-clinical-trial-participants-who-changed-the-world-pfizer-ignored-protocol-deviations-to-obtain-emergency-use-authorization-for-its-Covid-19-mrna-vaccine/

Part 2: Safety Analysis

Below are the summary points from the first peer reviewed paper looking into the original trial data of study C4591001, that I co-authored:

1. The C4591001 placebo-controlled randomized clinical trial of 22,030 vaccinated and 22,030 placebo subjects were the world's only opportunity for an unbiased evaluation of the Pfizer/BioNTech BNT162b2 vaccine.
2. Unblinding of placebo subjects starting in Week 20 terminated the placebo-controlled clinical trial, thereby ending all unbiased evaluation of possible adverse event signals.
3. The modRNA-LNP platform is novel, not previously phase 2/3 tested in humans, and the toxicity of Spike protein was unknown. Taken together, a 20-weeks placebo-controlled clinical trial is NOT sufficient to identify anything except for the most basic of safety concerns.
4. The number of all-cause deaths is NOT decreased by BNT162b2 vaccination.
5. Of the 38 deaths reported in the 6-Month Interim Report of Adverse Events, 21 BNT162b2 vaccinated subjects died compared to 17 placebo subjects.
6. Delayed reporting of the subject deaths in the BNT162b2 group into the Case Report Form, which was in violation of the trial protocol, allowed the EUA to proceed unchallenged.
7. The number of subject deaths was 17% of the expected number, based on age-adjusted US mortality. One possible explanation could lie in the 395 subjects that were "Lost to Follow-up".
8. There was a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine *versus* the placebo.
9. Of the 15 subjects who were Sudden Adult Deaths (SAD) or Found Dead (FD),

12 died of a cardiac event, 9 of whom were BNT162b2 vaccinated.

10. The cardiac adverse event signal was obscured by delays in reporting the accurate date of subject death that was known to Pfizer/BioNTech in the subject's Narrative Report. See the VRBPAC meeting and NEJM publication.

To further elucidate on point 10, the delays in reporting of deaths that were uncovered in the forensic analysis were in contravention of legal and ethical obligations of the clinical trial sponsor. This is clearly explained in my letter to Attorney General Ken Paxton. The forensic analysis into the trial data revealed that as of the data cut-off date of November 14, 2020, a total of 11 deaths (six deaths in vaccinated arm of the study and five in the placebo arm) were recorded. This stands in contrast to the six deaths (2 vaccinated and 4 placebo) publicly disclosed at the VRBPAC meeting. The capture rate seems to be 33% in the vaccinated arm (two reported deaths out of six) and 80% in the placebo arm (four reported deaths out of five). How did we get to a situation that we are unable to track accurately the people who died in this trial?

By painstakingly going through all the documentation available for each of the 38 dead subjects in this trial, my co-authors and I could identify first the 6 patients whose deaths were publicly disclosed. This allowed us to look even deeper into those who died before the data cut-off date, but whose deaths were not disclosed.

In a death notification, the onus obviously falls to the loved ones/emergency contact to inform the trial site of the death. Once informed of the death, as per the protocol, this was to be entered into Pfizer Safety Vaccine SAE form within 24 hours, and under no circumstances exceed 24 hour. As such, if there were delays in recording a death, it could be because of a delayed notification by a loved one to the clinical site.

By going through all the publicly available documentation for the undisclosed deaths at the point of the EUA approval for the 5 remaining patients (4 vaccinated and 1 placebo), we found evidence that loved ones had in fact called the clinical site for two (2) of these patients on the day they died .

Subject 11141050, from Kansas, from the vaccinated arm of the trial, was a 63 year old lady who was overweight with depression who was found dead on 19 October, 2020. Her emergency contact notified the clinical site on October 19th that the patient had died. This death occurred well before the data cut-off date of Nov 14th and should have been disclosed publicly. Interestingly, this patient also had an autopsy done, of which the cause of death was '*sudden cardiac death*'. The specific diagnosis of 'sudden cardiac death' was found in the patient's notes on 9 December 2020 , (the day before the VRBPAC meeting), leading one to a conclusion that this undisclosed death from the vaccinated arm possibly had an autopsy result available the day prior to the VRBPAC meeting . This autopsy result is not publicly available for independent evaluation.

In a clear violation of the clinical trial protocol and legal requirements, despite the

clinical site being informed of this patient's death on the day of death (19 October 2020), this was only entered into the patient's notes on 25 November 2020. This was presumably the method of circumventing needing to publicly disclose this death, as this was now after the data cut-off date of 14 November 2020. This was still before the VRBPAC approval meeting of Dec 10th, and there was documented receipt of a death that occurred well within the trial reporting period. The clinical trial investigators chose not to disclose this death with the autopsy result of "sudden cardiac death" to the regulators.

Subject 11121050, a 58 year female subject from the vaccinated arm of the trial died in her sleep on 7 November 2020. Her husband called the clinical site on 7 November informing them of her death. On the patient's CRF, it is explicitly stated that the notification of the death happened on 7 November 2020. This patient was not one of the 6 deaths publicly disclosed. It is troubling in light of established facts of being notified of the death that occurred well within the reporting period, that this death was not disclosed publicly to regulators at the point of consideration of vaccine approval. There was no autopsy performed for this patient. This patient was not seen in the hospital and the coroner was called to pronounce her death. The cause of death in her death certificate was cardiac arrest. The clinical investigators and Pfizer came to the conclusion that there was no reasonable possibility that her cardiac arrest was related to the study intervention, concomitant medications or clinical trial procedures. Astonishingly, the FDA and other drug regulatory agencies including the TGA seemed to agree.

This pattern of delaying death notification strikes a big blow to safety reporting in this trial.

If these two deaths highlighted above were disclosed at the time of the EUA approval the cardiac signal in the vaccinated would have been apparent, as the first 4 deaths that occurred in this trial in the vaccinated arm were in those aged 56 to 64 who were found dead.

Regulators such as the FDA and The TGA could have pieced together all this with the information available to them, as this is from the data the FDA scrutinised to grant the emergency use authorisation in December 2020. Did the TGA with its own purportedly *rigorous process*, find similar reporting delays by Pfizer, but ignore them like the FDA? Similar level of documentation is not available for the remaining 3 undisclosed deaths at the time of the EUA approval.

I hope the issues the I have highlighted here will help somehow compel Pfizer-BioNTech and the clinical trial sites to provide all available information to establish the facts and a correct timeline. There needs to be accountability for what has happened. The deceit on the clinical trial participants and members of public has been monumental.

While finally, what role did Australia's TGA play in this data cover-up by Pfizer

especially if they themselves had found the undisclosed deaths at the point of the EUA approval .. what went wrong with the TGA that it would approve a drug that killed more people in the trial who received it, than those who received a placebo?

Index

Second Answer

Dr Geoff Pain PhD, Proposed Witness:

Areas of Relevant Expertise and Personal Pandemic Experience

I was infected with the Wuhan Covid19 original strain in early 2020 while visiting the Monash Medical Precinct in Clayton, Victoria [Wuhan Covid19 Arrival in Victoria].

The Wuhan Covid19 strain had a very high Lethality due to its ability to force Lung Cell Merging resulting in Death through Viral Pneumomia [Wuhan Syncytia]. The Omicron strain appeared less lethal because it was less efficient at forcing cell merger and also because the most vulnerable had already died as a result of the Wuhan strain.

I refused to be injected with the experimental products that clearly are not capable of generating Mucosal Immunity and therefore do not prevent Infection, Transmission [Asymptomatic Spread of Covid19], Hospitalization or Death from the Coronavirus that includes the Bioweapon insert known as the Furin Cleavage Site [FCS, also published with permission by DailyClout [Pfizer used Synthetic Life]. Please note I had nothing to do with, and do not endorse, the advertising of the Foster Coulson controlled "The Wellness Company Spike Support" pills next to any of my articles.

The fact that the Covid19 injections were not preventing infection and spread of the disease and suffered "waning" of circulating antibodies in days to weeks prompted the state governments of Queensland and Western Australia to commission a study to model what would happen when all border restrictions were eliminated for economic reasons. The advice recommended deliberate spread of the Omicron variant as quickly as possible. "National Cabinet" clearly endorsed this strategy of belated generation of "herd immunity" by exposure to the whole virus. I was one of a very few who shared news of this plan, which was published in March 2022.

Because I refused injections, I was prevented from participating in society and discriminated against for wanting to uphold my fundamental human right to refuse a medical intrusion into my body.

I was prevented from entering other states and territories of Australia or traveling overseas.

I was prevented from attending a memorial service for my late father at Melbourne University who had donated his body for medical research.

The Australian government paid the profiteers behind social media Twitter (account since restored by Elon Musk with 7,292 followers) and Facebook (not restored) to suspend my accounts because I shared accurate factual science regarding the effects of the Coronavirus and various treatments offered, or viciously mandated. I therefore established new accounts at Gettr (3,962 followers) and Substack (2,281 subscribers) and continued at ResearchGate (544 followers) where I could continue initiation of, and participation in, scientific discussions. A chronological list of links to my 64 Questions at ResearchGate is available for convenience.

One of the reasons I was targeted for suppression was my social media posts on the AusVaxSafety survey that showed the new injections were causing massive harms to millions of Australians. If you search X (formerly Twitter) you will find very few references at all to AusVaxSafety, which was designed to reduce the flood of adverse event reporting to the TGA.

I witnessed unprecedented numbers of injured and Dead injectees reported to the Australian Database of Adverse Event Notifications (DAEN). I became interested in the ingredients and manufacturing processes used in the various injections based on Chimpanzee Adenovirus such as AstraZeneca and the mRNA products from Pfizer and Moderna as well as Insect cultured synthetic Spike Protein used in Novavax. I sought answers to the apparent differences in Toxicity and Relative Lethality of the different brands of injections.

I shocked Senator Rennick by revealing that the Australian Bureau of Statistics met with a representative of the World Health Organization (WHO) to discuss the expected Deaths arising from use of AstraZeneca and that the ABS redacted the agreed WHO Code for Covid19 Injection Induced Death. This code was clearly not circulated to medical practitioners or Hospital Registrars or Coroners, resulting in under-reporting of such Deaths.

Resulting from my published articles and questions, I was invited to join a group who were in the privileged position of reviewing Pfizer documents as they began to be released under US Court Order. I was helped by a large network of new friends, some of whom were experts in so-called “Deep Diving” into complex, very large and unusually formatted documents. At my request some of the documents were converted from scans to much more useful searchable text generated by Optical Character Recognition. I contributed to early drafts of documents later published without me listed as co-author by the “Naomi Wolf Team 3”. With Naomi’s husband, I was able to confirm that ongoing Genomic Modification of Coronavirus and subsequently Dengue Virus was part of the Pfizer business plan under the term Directed Evolution. Some of my contributions were published by DailyClout, controlled by Naomi Wolf and others.

Education and Training

I graduated from Monash University with PhD and BSc(Hons) degrees.
As an undergraduate I studied Biochemistry, Chemistry, Information Science, Mathematics, both Pure and Applied, including Statistics and Physics. The first new chemical that I synthesized was Chiral, existing as Right- and Left-handed enantiomers and I have separated optical isomers.

At the request of Telecom Australia (now Telstra) I completed a Graduate Diploma in Business Management with Deakin University majoring in Strategy and Innovation. This broadened my formal qualifications to include Economics and Law of Negligence.

My post-doctoral career was varied and equipped me with detailed knowledge and hands on use of numerous scientific instruments including those used to characterize viruses, nanoparticles, micelles, and determination of the structures and solution dynamics of new chemicals and solid state materials that I created. I have expertise in the design and operation of cleanrooms and the effectiveness of masks [Mask Capture of Exhaled Virus] and high efficiency air filtration techniques that are used to reduce transmission of airborne pathogens. I was trained in the use of Reverse Transcription Polymerase Chain Reaction (RT-PCR) amplification of genomic sequences found in RNA and DNA and design of primers essential to that analysis.

In 2011, I was co-author of a paper that dealt with incorporation of foreign genomic sequences into the Human Genome [Reverse Transposition].

My expertise is widely recognized with 1,324 citations and an h-index score of 21 [CV] and I have experience as an expert witness and membership of government expert panels by ministerial appointment.

I have recently been invited by a peer-reviewed journal to give my assessment of a narrative review of Covid19 Spike Protein and the impact it has on the human system in Synergy with **Endotoxin**.

In 2014 Ugur Sahin and Özlem Türeci, co-founders of BioNTech, along with their colleague Katalin Karikó, mentioned the problem of Endotoxin as a contaminant in their planned mRNA injections.

I am collaborating with international researchers developing new test methods to reveal the true Endotoxin content of Covid19 injections, which is masked by Lipid Nanoparticles in the mRNA injections negating the conventional Limulus Amebocyte Lysate (LAL) test employed by manufacturers and regulatory authorities including the Therapeutic Goods Administration (TGA) as part of Batch Release legal requirements in Australia [TGA Endotoxin Batch Release]. The LAL test was developed by one of my

distant cousins.

I recently contributed a chapter to a book published by the Australian Medical Professionals Society following their presentations at Parliament House Canberra [Too Many Dead Chapter 4]. Due to space limitations this covered only a small amount of my published material relevant to this Inquiry.

I have shown that over 10,000 different types of Adverse Reaction reported in Pfizer Periodic Safety Update Reports (PSURs) match exactly what is known and recorded in the US Government Comparative Toxicogenomics Database (CTD) for Endotoxin Diseases.

I have supplied the current Inquiry with the OCR searchable text versions of Pfizer PSUR3 Appendices listing numbers of reports for each Adverse Reaction and Deaths arising as attachments to my independent submission.

I have written a large number of reports listing numerous peer-reviewed studies linking Endotoxin to Adverse Reactions and Deaths of special interest, including Endotoxin Induced Myocarditis (EIM), Pericarditis, Anaphylaxis, Atrial Fibrillation, as the most common cause of Sudden Death, delayed Anaphylaxis due to the Sanarelli-Shwartzman effect, Blindness caused by AstraZeneca and the mRNA injections, special vulnerability of injectees with people with Nickel allergy to the Covid19 products, Autoimmune Diseases, Guillain-Barré Syndrome (GBS), Parkinson's Disease. I was the first person to point to the mechanism of Tinnitus and Hearing Loss suffered by unprecedented numbers of people after mRNA injections.

Women and their Foetuses are hit especially hard by the Covid19 injections resulting in Placenta, Umbilical Cord and Foetus Damage, Reduced Birthrate, Spontaneous Abortion, Stillbirth, Preeclampsia, Premature Birth, Maternal and Foetal Death.

Pfizer has already reported a terrifying range of Birth Defects and has an ongoing post-marketng Teratology study. Pfizer reported 17 cases of Autism Spectrum Disorder from their Covid19 injections to June 2022 and this is easily explained by experiments in non-human primates and Human studies of Brain Damage caused by Endotoxin in other types of injections. Brain Damage caused by injections can be expressed as Narcolepsy with Suicidal Inclinations, as has been determined in Court cases.

In 2010 the State Food and Drug Administration (SFDA) of China announced a "voluntary" Recall of Rabies injections produced by the Wuhan Institute of Biological Products due to Endotoxin contamination. Note that China participated in BioNTech/Pfizer Covid19 clinical trials and rejected the opportunity to expose its population to these injections.

Postmenopausal haemorrhage is easily explained by Endotoxin.

The "new" pathology of conformal long "rubbery" material pulled by embalmers from the veins and arteries of the deceased reported since 2021 can be explained by the known effects of Endotoxin.

My answer to the Question on Notice in respect of Reference T is as follows:

The Specific Failures of the TGA to protect the health of Australian citizens from the Adverse Effects of the Covid19 injections include:

TGA failed to reveal that the SV40 Promoter from the Simian Vacuolating Virus 40 was deliberately inserted into the Pfizer/BioNTech Covid19 injection. That fact and the known hazards have created international furore and opened the way for litigation.

TGA and other government bodies lied to the Australian public about the Covid19 mRNA injections, knowing that the intended target was the Lymphatic System and not the Muscle. This predictably resulted in massive numbers of people suffering Lymphadenopathy.

TGA Failed to tell the Australian public that Ivermectin was used in the Pfizer clinical trials to successfully rescue hospitalized trial subjects. If the TGA had revealed this information, Emergency Use Authorization would have been exposed as illegal.

No effort was made to warn of a correlation between Infection, Hospitalization or COVID-19 Death rates and prior Influenza Vaccine coverage through weakening the immune system, as had been reported by US Military studies.

TGA Failed to withdraw AstraZeneca injections as soon as Vaccine-induced Immune Thrombocytopenia and Thrombosis (VITT called TTS by the TGA) was identified and it was clear that Polysorbate 80 and its degradation products and Sodium Edetate were the major causes.

TGA failed to inform the Australian public that Pfizer knew its injections also cause VITT.

TGA Failed to arrange pre-injection testing for allergy to any injection component.

TGA Failed to consider the impacts of Water Fluoridation as it is known that Fluoride Inhibition of Activation-induced deoxycytidine deaminase could interfere with Somatic Hypermutation required for Immunity to COVID-19.

COVID-19 injections kill and injure people. Instead of a compassionate Indemnity and Compensation system as implemented in Japan, Australia instituted a cruel system designed to reduce claims.

TGA Failed to investigate the Relative Lethality of COVID-19 injections by brand or Batch.

TGA Failed to tell the Australian public that the Pfizer injection purchased was not tested on any more than 252 trial subjects and that a New Production Process using E. coli Bacteria known as Process 2, introduced the known hazard of uncontrolled Endotoxin and Plasmid DNA contamination. Pfizer knew how to remove foreign DNA in 2011 but chose not to as a means of increasing profits.

TGA failed to tell the Australian public that Pfizer's "preferred adjuvant" is the supertoxin Endotoxin Lipid A.

TGA authorized a new formulation of the Pfizer injection, with no clinical trial data, containing toxic Tromethamine, known to cause Anaphylaxis.

It was clear by November 2021 that the Covid19 injections were demonstrating Negative Effectiveness due to Original antigenic sin, otherwise known as Immune Imprinting involving IgG4 switching. TGA continued to recommend further "boosting" against a virus variant that no longer existed!

TGA failed to announce that reactivation of dormant viruses including Herpes Zoster is an expected outcome of Covid19 injections.

TGA approved the Pfizer injection without any Toxicity studies of (4-hydroxybutyl) azanediyl) bis(hexane-6,1-diyl) bis(2-hexyldecanoate) ALC-0315 - which has two Chiral centres. Recall that the Thalidomide Disaster was due to just one of the optical isomers of the drug.

TGA approved the Pfizer and Moderna injections without any Toxicity studies of 2-[(polyethylene glycol)- 2000]-N,N-ditetradecylacetamide ALC-0159.

TGA knows that Truncated expression of RNA is caused by Aldehydes forming Adducts with mRNA and the E. coli toxin RE1E, an Endoribonuclease that intervenes when Ribosomes get "stuck", chopping off incompletely translated product, but has not investigated the effects of the truncated proteins on Human health before unleashing the injections. The Aldehydes arise from the oxidation of residual Ethanol, breakdown of Polysorbate 80 and some of the chemicals used to make Lipid Nanoparticles including ALC-0315.

TGA failed to warn of the Nickel Allergy hazard that can develop from remnant stainless steel shards left in the arm after repeated injections and that Nickel Allergy predisposes people to more severe reaction to subsequent injections, including Death from Anaphylaxis and Stroke because it involves the same Toll-like Receptor, TLR4, as

Endotoxin and induces disastrous processes including NETosis.

TGA has not investigated the Toxicology of Sucrose (Sugar, the main ingredient of the mRNA injections) or its probable degradation products Fructose and Glucose when injected into Muscle or the Lymphatic system. Can toxic Liposaccharides be formed from injected Sucrose?

TGA has failed to publish Endotoxin measurements on any Batch of any brand of Covid19 injection or state what they consider to be an acceptable amount of the supertoxin. I am confident that all their secret Endotoxin measurements are gross underestimates due to masking by other injection components. Preliminary measurements by my collaborator Kevin McKernan have found Endotoxin levels of up to 19 EU/ml in a batch of Pfizer Covid19 injection and the technique for unmasking is being further developed in his laboratory.

TGA knows from research conducted in Australia that Covid19 injections have contaminated and altered the contents of donated Blood and its products but has allowed and encouraged Blood Banks to take no action to prevent harm to recipients.

TGA has failed to investigate the widespread reports of Discoloured Breastmilk reported by injected mothers.

Index

Reference: U

Index

A review and analysis, as of the date each Covid-19 vaccine was provisionally approved, of the safety studies completed by the manufacturers, and any safety studies not performed or completed by the manufacturers, or the TGA, at the time of provisional approval, and:

i. peer reviewed studies that supported the claims of manufacturers as to safety;
ii. peer reviewed studies that subsequently contradicted earlier safety claims published by their manufacturers.

Explanatory Memorandum

Index

Examine TGA reasoning for not requiring inclusion historically required historic studies into consideration of safety.

Question(s) on Notice

Index

In respect of **Reference U**, please provide any further information concerning safety studies completed by the manufacturers, and any safety studies not performed or completed by the manufacturers, or the TGA, at the time of provisional approval of Covid-19 vaccines.

Answer(s)

Index

First Answer

Dr Astrid Lefringhausen, Co-Author:

Pharmacokinetic studies with regards to the lipid nanoparticle (LNP) component of the mRNA vaccines were, as reported by the TGA in the TGA's "Nonclinical Evaluation Report" of the Pfizer vaccine dated January 2021, short studies and the mRNA content of the LNP-mRNA complexes in those studies was coding for luciferase, instead of the spike protein. The study outcomes for mRNA/expression, protein distribution and degradation were summarised as follows:

> Sensitivity of the imaging detection system was low. Distribution to other tissues, e.g. draining lymph nodes, is highly likely (Lindsay et al. 2019), but the level was probably below the limit of detection of the imaging system." ... "**There are no data on the kinetics of BNT162b2 mRNA degradation**. In mice injected with the luciferase mRNA, the absence of expressed protein by 9 days after dosing indicates that mRNA has been degraded. (p.10).

All following quotes are also from the TGA's January 2021 Nonclinical Evaluation Report for the Pfizer vaccine.

It must be noted here that unlike the mRNA in the above studies, vaccinal mRNA coding for the spike protein was genetically altered for stability by exchange of uridine, a standard building block of RNA, with N1-methylpseudouridine. In reality there is no data available regarding how long the spike protein is produced, the data we have for standard RNA cannot be compared with the genetically modified RNA that has vastly increased stability. The TGA stated in conclusion of the study:

> In summary, the limited **pharmacokinetic studies** indicate that the vaccine LNP formulation is expected to deliver the mRNA effectively in vivo, and the antigen expressed mainly at the injection site, liver and probably in draining lymph nodes. The limited studies showed slow elimination of ALC-0315 and retention in liver, and complete elimination of ALC-0159 in 14 days, with the latter eliminated in faeces most likely by biliary excretion." (p.11)

By their own words the TGA admits that only limited studies were done.

The TGA report for the **toxicity study** states:

> The dosing interval was not optimal given that the immune response peaks 2-3 weeks after dosing, and the clinical dosing interval is 3 weeks. In addition, the novel lipid excipients have long elimination half-lives. Repeat dose toxicity studies with a dosing interval of 2 or 3 weeks would be more appropriate for investigating the potential toxicity of the vaccine. The Sponsor indicated that "As platform data was available, a shortened administration paradigm was used in the repeat dose toxicity studies in order to assess the toxicity of the vaccine with a shortened study timeline allowing more rapid transition into clinical trials." Platform data were not provided to the TGA for review. Given the availability of clinical data, another repeat dose study in animals is not considered necessary. The shortcoming of the repeat dose toxicity study design should not preclude approval of the vaccine. (p.11)

Regarding **genotoxicity studies**, the TGA decided to trust the manufacturer's words:

> No genotoxicity studies were conducted for the vaccine. This is in line with relevant guidelines for vaccines. There were also no genotoxicity studies with the novel excipients. The sponsor stated that the novel lipid excipients are not expected to be genotoxic based on in silico analysis (Derek Nexus 6.1.0, Derek Knowledgebase 2020 version 1.0 and Sarah Nexus 3.1.0, Sarah Model 2020.1 Version 1.8) of the novel lipids and their primary metabolites (reports not provided). (p.13)

The comments regarding the lack of **carcinogenicity studies** show a concerningly low level of understanding of the effect that the mRNA modifications have on its half-life and consequently the length of exposure of vaccinated individuals to LNP-mRNA complex components and their genetic product:

> Carcinogenicity studies were not conducted. This is acceptable based on its duration of use. The novel lipid excipients are not expected to be carcinogenic based on the low exposure, duration of exposure, absence of structure alerts for mutagenicity (see discussion above). (p.13)

There was a **reproductive study on 44 rats only**, with 22 females/group committed for caesarean sectioning at the end of gestation and the remaining 22 females/group allowed to litter and raise pups until weaning prior to sacrifice and examination. Post-natal development of pups until weaning was also assessed. This was deemed enough data to proceed to vaccination of pregnant woman. No repeats of the study were done.

No dedicated **immunotoxicity study** was conducted.

It is actually true that mRNA degrades quickly. standard mRNA produced in human cells has a half-life of minutes to maybe a couple of hours, depending on sequence and structure of the molecule. This is however not the case for the modified mRNA used in the Pfizer and Moderna vaccines. A study by Bansal et al. (2021)[lxxvii] showed that the spike proteins are circulating presented on exosomes for more than four months after vaccination. To my knowledge Pfizer never performed studies to measure the duration or the amounts of spike protein produced.

The alterations of the mRNA, only one of which is the substitution of uridine with N1-methylpseudouridine (Morais et al. 2021)[lxxviii], are alterations of the genetic code and mean the population was injected with a genetically modified construct. Genetically modified organisms or drugs have to be evaluated by the Gene Technology Regulator, an assessment that would have to be much more stringent regarding safety than that for a standard vaccine. However, the Gene Technology Regulator was never involved in the safety evaluation of the mRNA vaccines.
A study published in 2020 by Peter Doshi in the *British Medical Journal (BMJ)* titled "Will covid-19 vaccines save lives? Current trials aren't designed to tell us"[lxxix], already alerted readers to the fact that the vaccine trials performed are not testing for

efficacy. There are no study endpoints looking at protection from severe illness and hospitalisation nor was tested if the vaccine interrupts viral transmission. According to Doshi the current phase III trials are not actually set up to prove either (Figure 1).

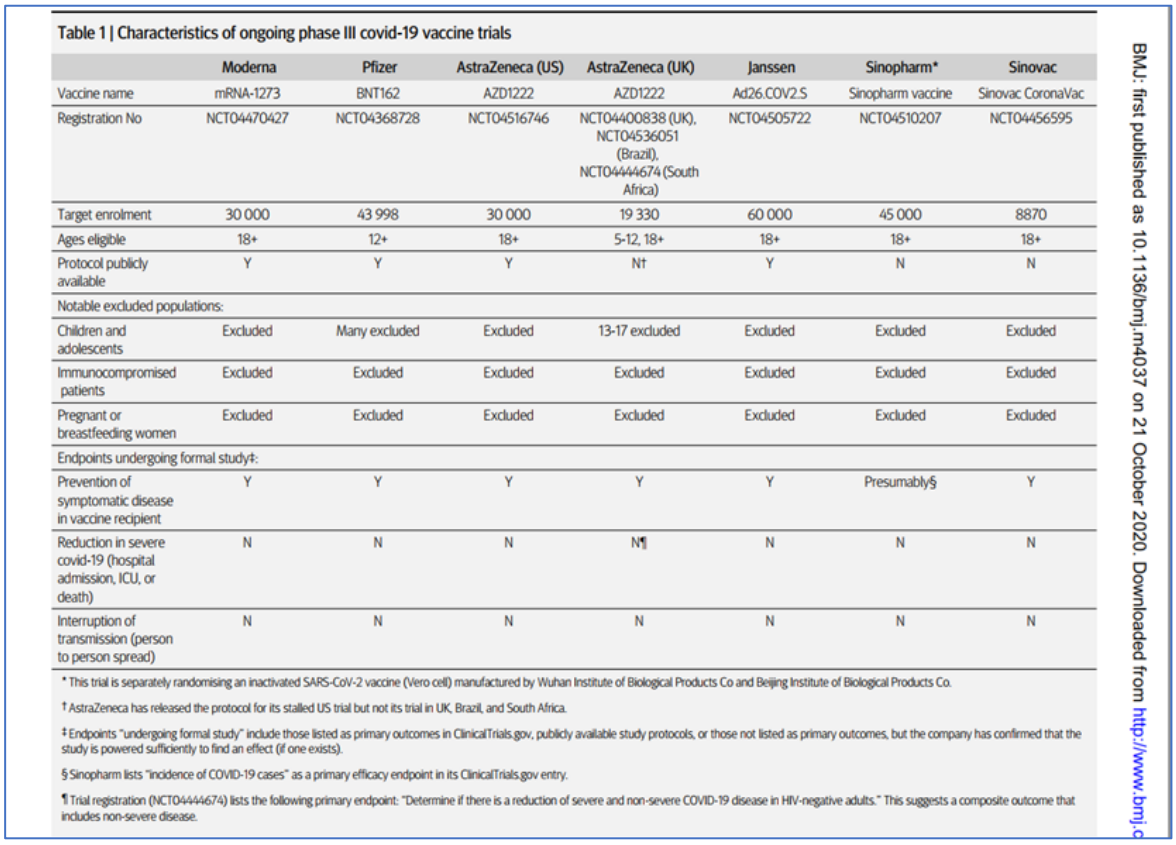


Table 1 | Characteristics of ongoing phase III covid-19 vaccine trials

	Moderna	Pfizer	AstraZeneca (US)	AstraZeneca (UK)	Janssen	Sinopharm*	Sinovac
Vaccine name	mRNA-1273	BNT162	AZD1222	AZD1222	Ad26.COV2.S	Sinopharm vaccine	Sinovac CoronaVac
Registration No	NCT04470427	NCT04368728	NCT04516746	NCT04400838 (UK), NCT04536051 (Brazil), NCT04444674 (South Africa)	NCT04505722	NCT04510207	NCT04456595
Target enrolment	30 000	43 998	30 000	19 330	60 000	45 000	8870
Ages eligible	18+	12+	18+	5-12, 18+	18+	18+	18+
Protocol publicly available	Y	Y	Y	N†	Y	N	N
Notable excluded populations:							
Children and adolescents	Excluded	Many excluded	Excluded	13-17 excluded	Excluded	Excluded	Excluded
Immunocompromised patients	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded
Pregnant or breastfeeding women	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded	Excluded
Endpoints undergoing formal study‡:							
Prevention of symptomatic disease in vaccine recipient	Y	Y	Y	Y	Y	Presumably§	Y
Reduction in severe covid-19 (hospital admission, ICU, or death)	N	N	N	N¶	N	N	N
Interruption of transmission (person to person spread)	N	N	N	N	N	N	N

* This trial is separately randomising an inactivated SARS-CoV-2 vaccine (Vero cell) manufactured by Wuhan Institute of Biological Products Co and Beijing Institute of Biological Products Co.

† AstraZeneca has released the protocol for its stalled US trial but not its trial in UK, Brazil, and South Africa.

‡ Endpoints "undergoing formal study" include those listed as primary outcomes in ClinicalTrials.gov, publicly available study protocols, or those not listed as primary outcomes, but the company has confirmed that the study is powered sufficiently to find an effect (if one exists).

§ Sinopharm lists "incidence of COVID-19 cases" as a primary efficacy endpoint in its ClinicalTrials.gov entry.

¶ Trial registration (NCT04444674) lists the following primary endpoint: "Determine if there is a reduction of severe and non-severe COVID-19 disease in HIV-negative adults." This suggests a composite outcome that includes non-severe disease.

Figure 1: Table 1 from Doshi et al. *BMJ* October 2020.
https://www.bmj.com/content/371/bmj.m4037

The TGA states with certainty that the mRNA cannot be reverse-transcribed and inserted into the DNA of our cells. This old "Central Dogma" was proved wrong not only empirically but confirmed by a 2021 paper by Chandramouly et al[lxxx]. They discovered a unique DNA polymerase-helicase fusion protein called Polymerase θ, which functions as an RNA-templated DNA repair enzyme. Furthermore eight percent of human DNA consists of remnants of ancient endogenous retroviruses[lxxxi], which were reverse transcribed and the resulting cDNA integrated into the human genome[lxxxii]. In February 2022 it was established in an *in vitro* study that SARS-CoV-2 RNA can be reverse-transcribed and integrated into the genome of human cells[lxxxiii]. No studies were done to see if the mRNA is integrated into our DNA, even though both relevant literature and historical data already showed the potential[lxxxiv].

Pfizer ended their clinical trials prematurely by unblinding participants and offering the vaccine to the placebo group, thus effectively making it impossible to observe long-term effects of the vaccine on the human body. What is urgently needed is an unvaccinated control group that can be followed for the next decade and compared to the vaccinated majority to assess the real risks posed by the genetic vaccines.

Second Answer

A/Prof Peter Parry, Co-Author:

This is not a direct answer to the QoN but supplies some relevant background with respect to **item (ii) in Term of Reference U**: *peer reviewed studies that subsequently contradicted earlier safety claims published by their manufacturers*.

The obvious case with regard to the 'safe and effective' Pfizer and Moderna mRNA Covid-19 vaccines, is the publication by Fraiman et al. (2022) in the journal *Vaccine*, of data analysis of the phase III clinical randomised controlled trials (RCTs) data from clinicaltrials.gov that contradicts the results, conclusion and narrative emanating from the sponsors' write ups of the same RCT data in *The New England Journal of Medicine*, upon which global health vaccine policy was predicated. This is described in greater depth in **Reference Z.**

What is important to convey here is the historical context. That vital discrepancies in the academic medical literature with far-reaching consequences is not an aberration reserved for the Covid-19 epidemic. Rather it is a systemic problem for which there is a large medical literature saying the medical literature is untrustworthy. How to fix it has been described but so far not enacted, and unlikely to be anytime soon due to entrenched vested interests and habits.

Over six decades, between 1953 and 2013, 462 medicinal products were recalled from the market by regulators due to adverse drug reactions. That total over the past decade may well have surpassed 500 but no-one has updated the research. It is therefore common for peer-reviewed studies and case reports in the medical literature, as well as pharmacovigilance databases reports of adverse events to lead to withdrawal of products that earlier studies (almost invariably sponsored by the manufacturers) had led regulators such as the FDA, TGA etc to initially approve.

Two decades ago, a meta-analysis study in the *British Medical Journal (BMJ)* found that across 18 different drugs from a range of medical specialities, the odds ratio (OR) of a clinical trial finding in favour of a manufacturer's drug compared to an independent study of the same drug was 4.05. In other words, there was a 4-fold chance of results reporting better safety and efficacy if the study was sponsored by the manufacturer. Figure 1 is the table from the meta-analysis.

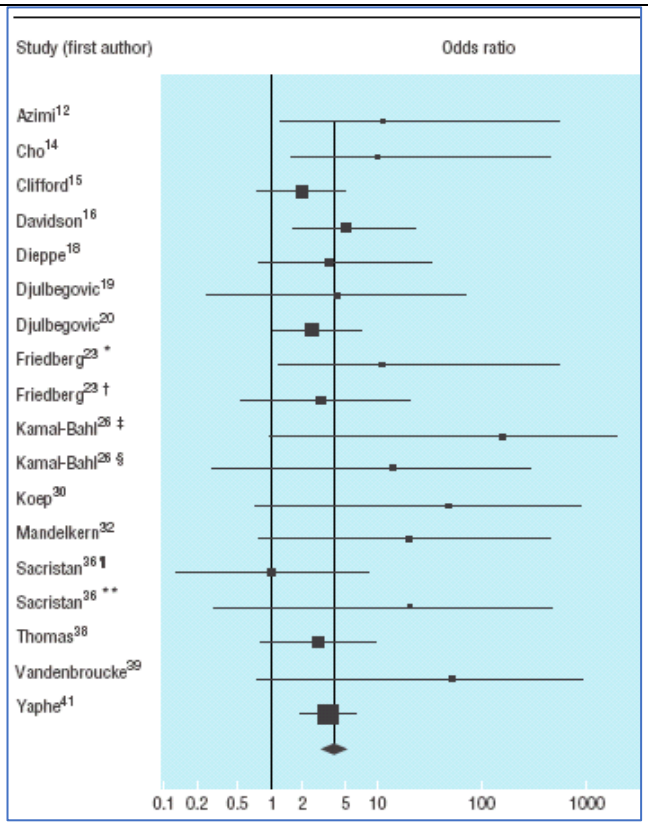


Figure 1: From Lexchin et al *BMJ* 2003 Pharmaceutical industry sponsorship and quality: a systematic review. https://www.bmj.com/content/326/7400/1167.long

In the case of RCTs for the Covid-19 vaccines, only the manufacturers have conducted them and published them in the prestigious *The New England Journal of Medicine*. Fraiman et al. could review the data from clinicaltrials.gov, but no independent RCT of these vaccines has been done.

As part of my PhD research, I analysed internal pharmaceutical industry documents. What I found was disturbing. Our paper: "From evidence-based medicine to marketing-based medicine: evidence from internal industry documents" was based on reading over 400 company documents from six pharmaceutical companies. These documents were released after discovery in litigation for criminal convictions, for which the industry has been fined significant amounts (Figure 2). Many of these fines concern data fraud and fraudulent marketing of products.

Violation Tracker Industry Summary Page

Industry: pharmaceuticals
Penalty Total since 2000: **$114,618,579,333**
Number of Records: 1,255
Note: The totals include only those entries matched to a parent company. The industry designation is the primary one for the parent's operations overall. The totals are adjusted to account for the fact that each parent's entries may include both agency records and settlement announcements for the same case; or else a penalty covering multiple locations may be listed in the individual records for each of the facilities. They are also adjusted to reflect cases in which federal and state or local agencies cooperated and issued separate announcements of the outcome. Duplicate or overlapping penalty amounts are marked with an asterisk in the individual records list below.

TOP 10 CURRENT PARENT COMPANIES	TOTAL PENALTY $	NUMBER OF RECORDS
Johnson & Johnson	$24,347,662,770	87
Pfizer	$10,948,368,523	98
Merck	$10,710,366,831	88
Teva Pharmaceutical Industries	$10,118,294,929	94
GlaxoSmithKline	$9,572,803,406	50
Purdue Pharma	$9,278,372,787	11
AbbVie	$7,509,289,954	82
Takeda Pharmaceutical	$3,987,516,447	32
Endo International	$2,847,090,667	29
Eli Lilly	$2,831,299,676	26

Figure 2: From https://violationtracker.goodjobsfirst.org/summary?major_industry_sum=pharmaceuticals

However, as per figure 3, the fines appear to be more than compensated for by profits.

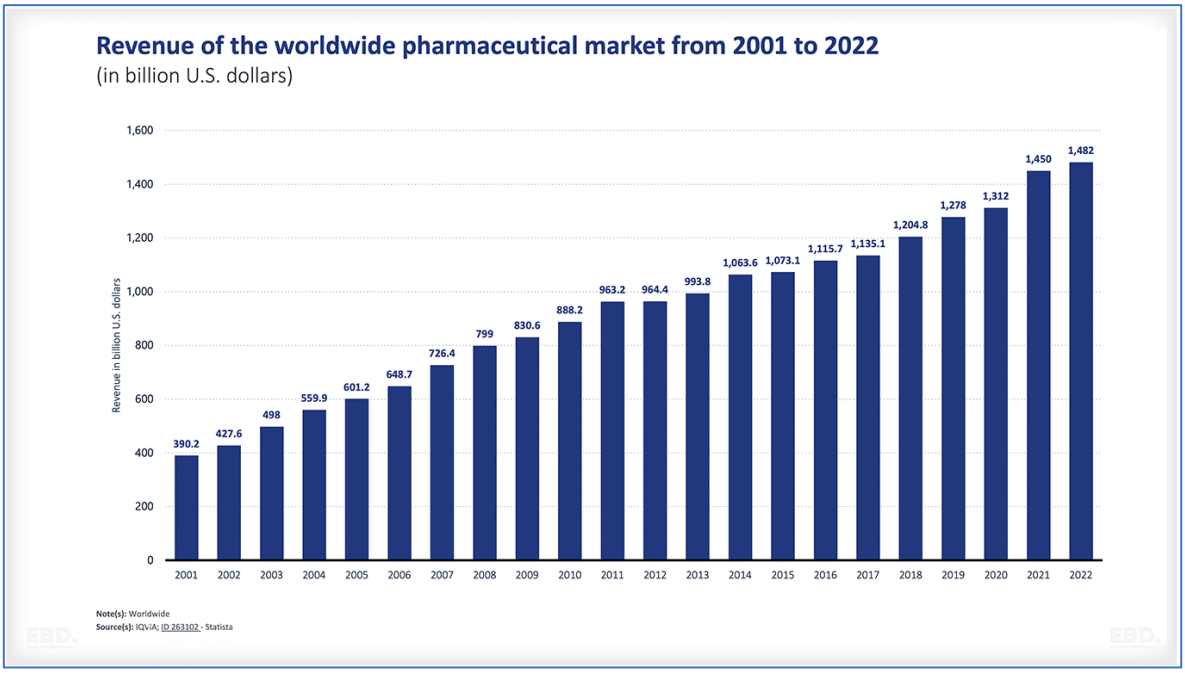


Figure 3: Revenue of the pharmaceutical market in $Billions USD
https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/

Just one of numerous such internal company documents is an internal AstraZeneca email thread about its antipsychotic Seroquel (quetiapine), where they "buried" adverse clinical trial data including whole RCTs (Figure 4).

From: Tumas John JA
Sent: Monday, December 06, 1999 11:45 PM
To: Owens Judith J; Jones Martin AM - PHMS; Litherland Steve S; Gavin Jim JP
Cc: Holdsworth Debbie D; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP; Wilkie Alison AM; Murray Michael MF; Rak Ihor IW; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM; Woods Paul PB; Holdsworth Debbie D; De Vriese Geert; Shadwell Pamela PG
Subject: RE: 2 EPS Abstracts for APA

Please allow me to join the fray.

There has been a precedent set regarding "cherry picking" of data. This would be the recent Velligan presentations of cognitive function data from Trial 15 (one of the buried trials). Thus far, I am not aware of any repercussions regarding interest in the unreported data.

That does not mean that we should continue to advocate this practice. There is growing pressure from outside the industry to provide access to all data resulting from clinical trials conducted by industry. Thus far, we have buried Trials 15, 31, 56, and are now considering COSTAR.

Figure 4: Internal AstraZeneca email in: 2 EPS Abstracts for APA. 2008 November 25, Seroquel Litigation Documents. https://www.industrydocuments.ucsf.edu/drug/docs/#id=yqkw0221

Many clinical trials that have unfavourable results are not published. This skews the literature to make drugs appear more efficacious and safer than they are. With time, the medical community and patients, through clinical experience, along with reports of adverse events to pharmacovigilance databases such as the FDA's FAERS, the CDC's VAERS, the TGA's DAEN etc, work out the real-world safety and efficacy of products. This has led to market recalls of ~500 medicinal products. But many patients suffer morbidity and mortality in the interim.

A 2014 review article in the *The Lancet* calculated the costs in terms of $billions of health dollars and millions of lives affected (Figure 5).

	Type of biased dissemination	Effects
Oseltamivir	Trials with 60% of patient data not reported Full study reports inaccessible for 29% of trials Missing modules for 16 of 17 available full study reports Discrepancies between published articles and full study reports	Billions of dollars spent worldwide (US$3·3 billion in 2009 alone) to stockpile a drug that did not necessarily reduce hospital admissions and pulmonary complications in patients with pandemic influenza, and that had unclear harms
Rosiglitazone	Unfavourable trials and sponsor's meta-analysis not reported Increased risk of myocardial infarction confirmed by independent meta-analysis of 56 rosiglitazone trials, which included 36 unreported trials for which data were obtained from the sponsor's trial registry	Number needed to harm of 37–52 for 5 years translates into 6000–8000 additional myocardial infarctions in 325 000 patients taking rosiglitazone in the USA and UK in 2010 About 83 000 additional myocardial infarctions potentially attributable to rosiglitazone in the USA from 1999 to 2006
Gabapentin	Negative trials for off-label indications not reported or reports delayed Selective reporting of positive primary outcomes for off-label uses in published reports, with suppression of negative outcomes	In 2002, $2·1 billion (94% of total sales) spent in the USA alone on prescriptions for off-label uses promoted by sponsor despite poor evidence of efficacy
TGN1412	Phase 1 trial that showed serious adverse effects from a similar antibody in 1994 not reported	Serious adverse effects in a study of TGN1412 in 2006, with six previously healthy volunteers admitted to hospital
Paroxetine	Selective reporting of four positive post-hoc outcomes and suppression of four negative protocol-specified outcomes in highly cited published report of a trial of children with depression Two trials and two observational extension studies showing increased harms (eg, suicidal ideation) and poor efficacy in children not reported Systematic review showed that balance between risk and benefit no longer favoured the drug when unreported trials were included	In 2002, about 900 000 prescriptions (costing $55 million) written for children with mood disorders in the USA for a drug with potential harms and poor evidence of efficacy
Lorcainide and class I antiarrhythmic drugs	Trial done in 1980 showing increased mortality with lorcainide (nine [19%] of 48) versus placebo (one [2%] of 47) not reported Mortality risk for this class of drugs remained unknown until subsequent trials with similar findings were reported in 1989 and 1992	20 000–70 000 preventable deaths every year in the 1980s in the USA alone because of widespread use of harmful antiarrhythmic drugs
Rofecoxib	Sponsor's internal meta-analysis of two trials showing increased mortality in Alzheimer's disease not reported; 2 year delay in reporting of the results to regulators Selective exclusion of placebo-controlled trials from three reported meta-analyses done by the sponsor, showing no overall increase in cardiovascular events, by contrast with a subsequent independent meta-analysis that included all trials (made available through litigation) Selective omission of cardiovascular harms from report of arthritis trial	88 000–144 000 additional myocardial infarctions for 107 million prescriptions filled in the USA from 1999 to 2004 About 400 000 users in the UK in 2004
Celecoxib	Selective reporting of favourable 6-month harms data in trial report, with suppression of unfavourable 12–15-month data (identified via publicly accessible regulatory documents) that no longer showed benefit for reduction of gastrointestinal ulcers Discrepant reporting of cardiovascular mortality data between regulatory report and two published reports of the same trial	In 2004, 600 000 users in the UK and more than 14 million prescriptions filled in the USA for an expensive drug with questionable benefit rather than cheaper alternatives
Ezetimibe-simvastatin	Report of randomised trial showing no benefit of ezetimibe-simvastatin versus simvastatin alone delayed by 2 years	Billions of dollars spent worldwide during publication delay ($2·8 billion in 2007) for costly combination drug not known to be better than cheaper alternatives
Vitamin A and albendazole	Report of a clinical trial of 2 million children showing no benefit of vitamin A and deworming on mortality delayed for 5 years	Millions of children dewormed (>300 million in 2009) and given vitamin A supplementation (77% of preschool children in 103 countries) on the basis of global policies although benefits were unclear

See appendix pp 1–3 for references.

Table: **Examples of selective reporting for different drugs and the estimated effects**

Figure 5: From Chan et al. Increasing value and reducing waste: addressing inaccessible research. *The Lancet*: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62296-5/abstract

Two of the medications in the table in *The Lancet* provide clear examples for **item ii in Reference U**: *peer reviewed studies that subsequently contradicted earlier safety claims published by their manufacturers*. These are 1) rofecoxib (brand name Vioxx) manufactured by Merck, which I have described to some extent in answers for **References Z, EE and FF.** And 2) paroxetine, an SSRI antidepressant. It is now off-patent but when on-patent was made by SmithKlineBeecham now known as GlaxoSmithKline or GSK. GSK's brand names for paroxetine were Paxil (USA), Seroxat (UK), Aropax (Australia);

Of additional note regarding court discovery of Merck documents relating to Vioxx, was in a Federal Court in Melbourne where internal company emails showed the company drew up a list of critics among scientists and clinicians who were aware and speaking out about Vioxx's increased risk of cardiovascular adverse events. The emails discussed putting financial pressure on the clinicians and scientists' institutions to further pressure the clinicians and scientists into silence. An article by Ray Moynihan (now an A/Prof, Bond University), in the *BMJ* titled "Court hears how drug

giant Merck tried to 'neutralise' and 'discredit' doctors critical of Vioxx" reports on Merck's email discussions of a "list of 'problem' physicians that we must, at minimum, neutralise". Similarly British cardiologist Aseem Malhotra, speaking on GB News TV, disclosed that a colleague from an elite British cardiology research unit said they had data of serious coronary artery inflammation linked to the Covid-19 vaccines but "were not going to publish their findings for fear of losing their research funding from the drug industry".

Paroxetine for adolescents suffering depression was studied by SKB/GSK in two studies "Study 329" and "Study 377" with identical methodologies. There was no good data for the product from Study 377, so the company decided to suppress that data. There was some beneficial data on secondary endpoints in Study 329, so the company decided to publish that beneficial data, which it later did in a 2001 article by Keller et al in the *Journal of the American Academy of Child & Adolescent Psychiatry (JAACAP)*. Figure 6 shows how internal company communications decided to suppress adverse data because "it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine". By "commercial ... profile" they meant profit.

SB CONFIDENTIAL - FOR INTERNAL USE ONLY

October 1998

conducting clinical trials in adolescent depression. Available published data are limited, derived from small open studies in adolescent depression (McConville et al; 1996; Tierney et al; 1995)

TARGET

To effectively manage the dissemination of these data in order to minimise any potential negative commercial impact.

PROPOSALS

- Based on the current data from Studies 377 and 329, and following consultation with SB country regulatory and marketing groups, no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time. However data (especially safety data) from these studies may be included in any future regulatory submissions, provided that we are able to go on and generate robust, approvable efficacy data. The rationale for not attempting to obtain a safety statement at this time is as follows;

  i) regulatory agencies would not approve a statement indicating that there are no safety issues in adolescents, as this could be seen as promoting off-label use

  ii) it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.

- Positive data from Study 329 will be published in abstract form at the ECNP (Paris, November 1998) and a full manuscript of the 329 data will be progressed.

Figure 6: SmithBeecham Seroxat/Paxil Adolescent Depression – Position piece on the phase III clinical trial, p. 5 of 6, October 1998. https://www.industrydocuments.ucsf.edu/drug/docs/#id=xrfw0217

However, after GSK was fined $3.1 billion USD for data fraud involving paroxetine, GSK allowed an independent group of researchers restricted access to the raw data on Study 329. These researchers published their analysis of the data in the *BMJ* as LeNoury et al in 2015 and the findings were the opposite of Keller et al in *JAACAP*, as per a PowerPoint slide of mine in Figure 7.

Figure 7: Comparison of two peer-reviewed articles in prominent medical journals based on the same raw data but with opposite findings and conclusions.

A similar issue can be presented regarding the Pfizer and Moderna Covid-19 vaccines as in Figure 8.

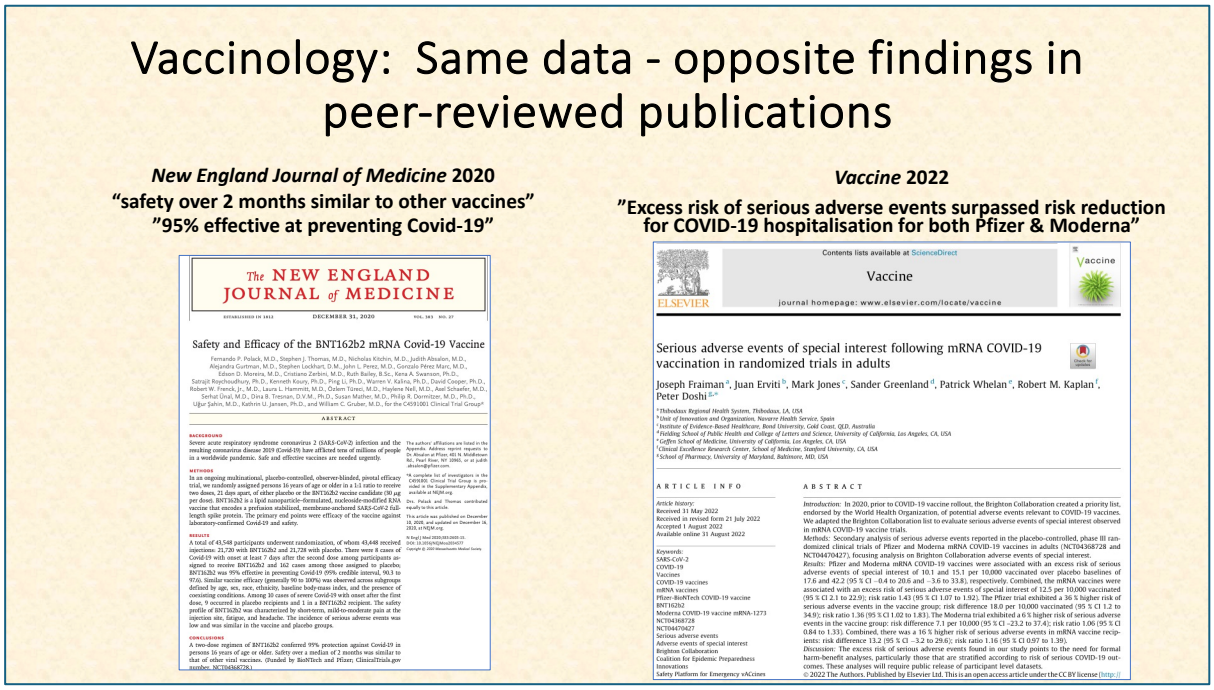


Figure 8: Ostensibly same data for the Pfizer and Moderna mRNA phase III clinical trials, published with different safety risk conclusions in two prominent peer-reviewed medical journals.

It is not only Fraiman et al. in the journal *Vaccine*, but as listed in Reference Z many other peer-reviewed papers *that subsequently contradicted earlier safety claims published by their manufacturers* – in the seminal papers on the AstraZeneca, Pfizer,

Moderna and Janssen Covid-19 vaccines published in *The New England Journal of Medicine*.

A highly cited paper by Ioannidis in the respected journal *PLoS Medicine* titled "Why most published research findings are false" notes that perhaps 50% of the published medical literature is wrong due to various forms of bias including commercial vested interest.

Doshi et al in 2013 in the *BMJ* wrote that the heart of the problem is lack of access to raw data. A figure from that paper conveys the issue showing that clinicians, medical scientists, health bureaucrats and policy makers are just like the man in the boat, only data presented as icebergs above the water in published papers is visible. This data can be at odds with the submerged data (Figure 9).

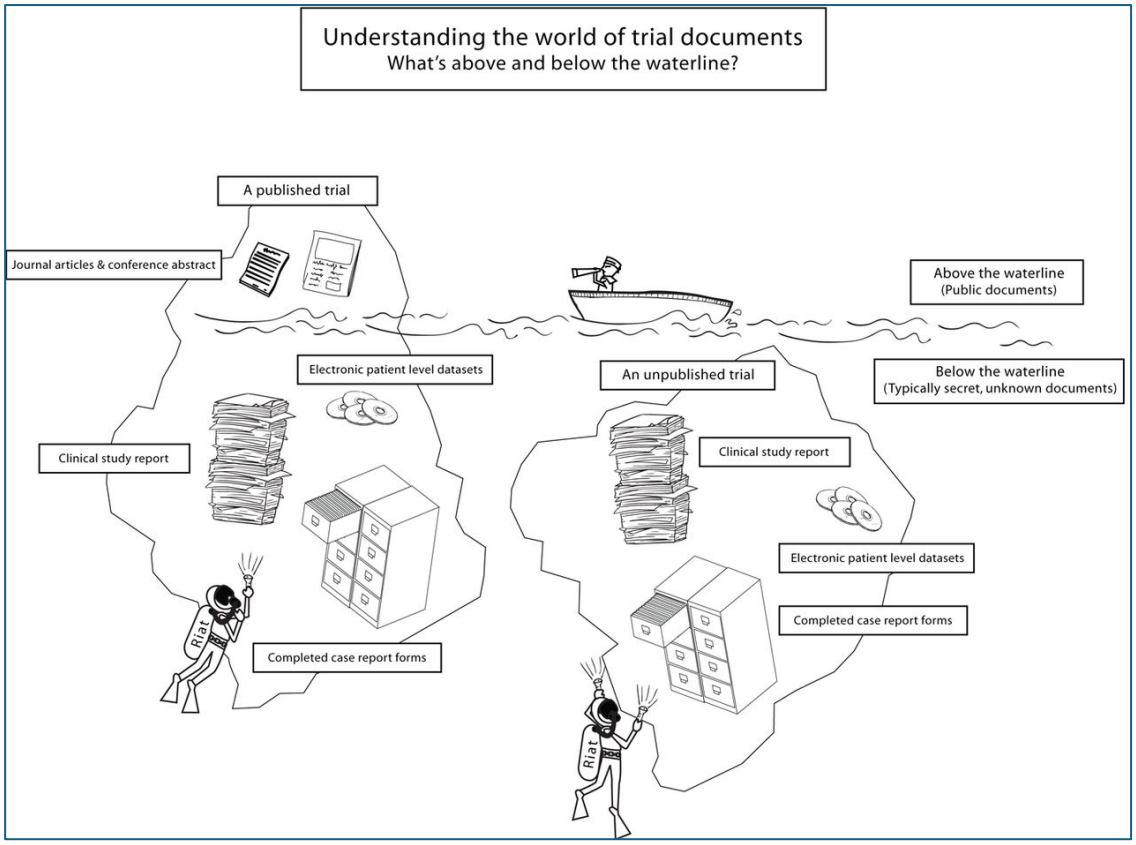


Figure 9: From Doshi et al. Restoring invisible and abandoned trials: a call for people to publish the findings. https://www.bmj.com/content/346/bmj.f2865

Aware of this data credibility issue as it applies to the Covid-19 vaccines, senior editor at the *BMJ* Dr Peter Doshi along with immediate past and current chief-editors of the *BMJ,* Fiona Godlee and Kamran Abbasi, published an editorial titled "Covid-19 vaccines and treatments: we must have raw data, now". That was 19 January 2022. Access to the FDA's copies of the Pfizer and Moderna clinical trial data has been achieved by US court-ordered enforcement of FOI request by Public Health and Medical Professionals for Transparency, and volunteers have started analysing and

publishing – but this is not in the mainstream 'big' journals.

This problem of failure in integrity of the academic medical system, due to widespread vested interests is one of the several 'elephants in the room' of the Covid-19 pandemic.

A 2022 paper in the *BMJ* by Jureidini and McHenry argued that we only have "The illusion of evidence based medicine" because "evidence-based medicine has been corrupted by corporate interests, failed regulation, and commercialisation of academia". The only female chief-editor of *The New England Journal of Medicine,* Marcia Angell, resigned and thereafter wrote an article titled "Drug companies & doctors: a story of corruption". My co-author and former director of a Qld ICU, Dr Peter Rhodes, and I have a peer-reviewed paper in the Elsevier journal *Pathology – Research and Practice* titled "Gene-based Covid-19 vaccines: Australian perspectives in a corporate and global context" that cites further literature on the credibility problem.

A Royal Commission needs to be aware of the publications credibility problem. It needs to consider this as the general contextual backdrop to much of what has occurred regarding pharmaceuticals (both drugs and vaccines) in the Covid pandemic.

Index

Third Answer

Dr Geoff Pain PhD, Proposed Witness:

The TGA forwarded details of Adverse Event reports from Australia regarding Covid19 injections that have been published in the US VAERS database, but are withheld from view on its own DAEN webpage. The TGA has also admitted to the Parliament that it has deleted or hidden an unknown number of Adverse Event reports, including Deaths, with the excuse that their publication might discourage further injection with products that are known to be ineffective in preventing Infection or Transmission.

The TGA should immediately publish all Periodic Safety Update Reports from all Covid19 injection manufacturers. These can then be compared with the thousands of peer-reviewed medical Case Reports and mechanistic studies of injection harms that have appeared since 2020.

The TGA could ask the Critical Intelligence Unit of the NSW Health Department to make its huge database of the scientific literature available to all. Members of the public could then submit new publications to assist building a usable resource that is updated weekly.

I was recently invited by a prestigious scientific journal to review a submitted manuscript that contained over 250 references relevant to the Synergistic Toxicity of Endotoxin that binds to natural and synthetic Covid19 Spike Protein. I pointed out to the editors that a single author could not possibly keep up with the rate of new papers appearing, or afford to purchase those behind paywalls.

In my individual submission to this TOR Inquiry, I list some further suggested actions that are necessary, which hopefully will be recommended by the Royal Commission.

I request that my submission be made public.

Index

Reference: V

Index

An examination of each State's Covid-19 vaccination and infection statistics that were relied upon for creating legislation that impinged upon freedom of movement of the population. This should include the availability of any data set that was published by a State authority showing infection or mortality statistics by vaccination status, and which data should be auditable and be able to be reconciled with the published documents, including:

i. an examination of the use and accuracy by Australian governments of WHO International Classification of Diseases (ICD-10) codes U07.1 and U07.2 for classifying persons with Covid-19 for compiling Covid-19 data;
ii. an examination of the stratification of Covid-19 cases, hospitalisations and deaths classified under WHO ICD-10 codes U07.1 and U07.2, in particular, a review of the breakdown of cases and deaths recorded under these codes that did and did not present with symptoms of SARS-CoV-2;
iii. an examination of the classification of vaccination status in hospitals and other health settings, by State authorities, and in statements made by the media, in particular, clarification of the definition of an 'unvaccinated' case, hospitalisation or death when reporting infection statistics;
iv. all deaths data on persons dying within 14 days, 21 days, and 28 days of receipt of a Covid-19 vaccine;
v. all scientific data relied upon for deeming a death within 14 days, 21 days, or 28 days of receipt of a Covid-19 vaccine being:
vi. due to Covid-19;
vii. not due to a Covid-19 vaccine;
viii. by reference to a random selection and analysis of deaths fitting the above criteria from each State and Territory;
ix. any other data or information relied upon.

Explanatory Memorandum

Index

What is important here is to gain an understanding of how authorities knew vaccination status, the timing and accuracy of this information, and how these factors impacted the reporting of vaccination and infection statistics to the Australian public, and the development and adoption of legislation that impinged upon freedom of movement of the population.

For example, there were periods in NSW where it was clear the categories 'Unknown' and '0 Dose were being mixed.

There were also periods in NSW where the terms ‘unvaccinated’ and ‘no effective dose’ were used interchangeably in State government and media reports of the same data. In such cases, both terms referred to individuals including those who had ‘received their first dose of a two-dose (Covid-19) vaccination course less than 21 days prior’ to the outcome being measured. These individuals were then compared to ‘vaccinated’ individuals to evaluate vaccine efficacy. However, recent vaccination may confound the Covid-19 vaccine outcome measures being used to assess vaccine efficacy. In response to a Senate estimates question the TGA has provided data indicating that, where time since vaccination is known, approximately 60% of deaths reported following Covid-vaccination occur within 2 weeks. The inclusion of recently vaccinated individuals in an ‘unvaccinated’ or ‘no effective dose’ comparison group potentially confounds Covid-19 outcome data by assigning the short-term serious and fatal impacts of vaccinations to this group, and therefore biasing outcome measures to indicate vaccine benefit and mask vaccine harms.

A thorough re-examination of Covid-19 vaccination and its temporal relationship with Covid-19 infection and other health outcomes is needed where vaccination status is clearly and consistently defined and where only those individuals who have not received the Covid-19 vaccine ‘treatment’ are included in the ‘unvaccinated group’ and compared against the various treatment levels (no effective dose, 1 dose,2 dose, 1 booster, 2 booster etc).

This examination should give regard to the impact of the use of ICD-10 codes U07.1 and U07.2 in the classification of cases and deaths.

In respect of the use of ICD-10 code U07.1:

The WHO ICD-10 recommends to ‘use this code when Covid-19 has been confirmed by laboratory testing irrespective of severity of clinical signs or symptoms. Use additional code, if desired, to identify pneumonia or other manifestations’.

Under this code, a person could have no symptoms of Covid-19 infection and be classified as a Covid-19 case, hospitalisation and/or Covid death, based on a positive test result alone. In the absence of symptoms, and a relevant estimate of the false positive rates of the PCR and other test used to identify Covid-19 cases, it is uncertain whether a case defined this way was valid or had any clinical significance.

Application of this classification code may have inflated case counts significantly and rendered hospitalization, ICU and death data constantly published by Australian governments potentially misleading and uninterpretable.

This issue was exacerbated in NSW where the classification of cases, hospitalisations and deaths included back-capturing positive Covid-19 test results from 14 to 28 days prior to presentation at hospital, regardless of Covid-19 status when presenting to hospital.

In respect of the use of ICD code U07.2:

The WHO ICD-10 recommends to ‘use this code when Covid-19 is diagnosed clinically or epidemiologically but laboratory testing is inconclusive or not

available. Use additional code, if desired, to identify pneumonia or other manifestations'.

However, it has been well established that Covid-19 shares many clinical characteristics with other respiratory disorders such as influenza, viral pneumonia or multi-system inflammatory disease. The clinical (observational) diagnoses of individuals using this code in the absence of a positive laboratory test, may therefore have inflated case counts significantly and engendered the hospitalization, ICU and death data constantly published by Australian governments potentially misleading and uninterpretable.

Additionally, there have been claims that medical professionals were instructed by State governments not to test for influenza infection at certain periods during 2021 and 2022, regardless of symptom presentation, and to only test for Covid-19 infection. If any such directives were issued, they likely led to inflate the false categorisation of individuals as Covid-19 infections under ICD code U07.2 through restricting the ability to identify alternative diagnoses with over-lapping clinical presentation and may explain a drop in influenza cases and non-Covid-19 respiratory infections reported in 2021.

An understanding is needed of the systems that were being used to merge data from different repositories, for identifying any data processing limitations that may have affected Covid-19 statistics reported to the public. In respect of legislation that impinged upon freedom of movement, how such laws were created when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of that submission and in particular index **Reference V**, can you please inform the committee whether Australian governments were transparent and providing reliable and timely public access to data scientists like yourself, to Covid-19 infection or mortality statistics by vaccination status, and whether that data was being accurately used for the assessment of cases, hospitalisations and Deaths due to Covid-19?

Answer(s)

Index

First Answer

Dr Andrew Madry, Co-Author:

The answer varies across agency, and I will address three of those agencies.

Firstly, the Australian Bureau of Statistics (ABS) provides data on all-cause mortality (ACM), and mortality categorised by different diseases. I have found that the ABS provides data to a high-quality and professional standard. They also provide a paid data consultancy service that I can say from first-hand experience I can say is professional.

However, the ABS is limited by the timeliness with which it receives data from other agencies. For example, mortality data which already lags by three months is affected by delayed reporting, and so the mortality counts increase over time, taking a further three months to stabilise. There has been a change in reporting of doctor certified deaths and coroner certified deaths. There seems to be an inordinate length of time (sometimes more than 12 months) for the provision of coroners reports that needs to be addressed.

In contrast, the quality of data provided by our front-line health and pharmacovigilance agencies in relation to the Covid-19 pandemic can only be described as haphazard.

New South Wales (NSW) provided the most granular data regarding Covid-19 infections, hospitalisations and deaths. It also provided data, for a period of time, categorising infections, hospitalisations and death by vaccination status.

Unfortunately, NSW Health data reporting was subject to changes to categorisations mid-stream, and mis-categorisations of important data like vaccination status. The categorisation of **unvaccinated** was mixed with **unknown vaccination** status and **one dose** (or not fully vaccinated). This failure to categorise correctly makes the job of the analyst very difficult.

As example, towards the end of 2021, NSW Health reported Covid-19 infections by vaccination status. These regular reports indicated that those vaccinated were being infected at a rate greater than the unvaccinated, noting that this is not controlled data but observational and therefore subject to limitations. However, it was clear that it was not a "pandemic of the unvaccinated". NSW Health then shut down reporting of this statistic when it did not fit the narrative.

At one point all hospitalisations were of vaccinated people only and subsequently reporting of this statistic was also discontinued, at the end of 2022.

I am acutely aware of the limitations of observational data, but trying to provide data only to support a narrative that vaccination is more protective than it actually is does not serve the health of Australians.

Clearly, our elderly population is at most risk, and a broad range of measures are needed to protect them. Vaccines alone are not the sole solution, and overestimation of their safety and effectiveness will lead to a false sense of security and ultimately more deaths.

For other states this sort of information was not available to the public at all. The Doctors against Mandates court case against the Queensland Chief Health Officer uncovered important information from the Queensland Health Department, which should have been made available to the public without the necessity of a court case to extract the information.

Documents made public as a result of this court case showed that the first deaths from locally acquired Covid-19 in Queensland were of vaccinated people. A death of a young person involved in a car crash was temporarily classified as Covid-19. Data also showed high rate of infections in vaccinated people.

With respect to the classification of hospitalisations and deaths from Covid-19 the international ICD-10 codes, created for Covid-19 disease by the WHO, were applied. The public has no visibility on the application of the Covid-19 ICD codes in Australia.

A Royal Commission needs to audit this process and check alignment with other countries. These codes include a categorisation U07.1 where the patient may have no symptoms but has a positive PCR test. When assessing the impact of the pandemic measures on all-cause mortality the different categorisations of Covid-19 need to be understood.

In April 2021 a Sydney Morning Herald article titled "NSW adds 331 previously unreported deaths to Covid-19 toll" reported:

> *Health authorities have added more than 300 deaths to the state's Covid-19 toll following a review of data from Births, Deaths and Marriages, including 66 people who died from the virus in the home.*

It appears that many of these extra deaths were elderly people dying at home or in palliative care. The process of attributing Covid-19 as a cause of death is very opaque. Combined with uncertainty of determination of vaccination status, this can lead to dubious claims of medication effectiveness being made on erroneous data.

Index

Second Answer

Dr Suzanne Niblett, Co-Author:

The level of detail provided by Australian governments regarding the identification of Covid-19 cases, hospitalisations and deaths was inadequate for valid and reliable independent analyses by non-government researchers. The data generated was also not presented in a way that facilitated evaluation of the impacts of Covid-19 infection or the impact of Covid-19 vaccination on Covid-19 infection. Rather the data provided lacked clearly defined methodology and was inconsistently analysed and presented in a way liable to misinterpretation. Where methodology was known, it was deficient.

Classification of cases

A core component of evaluating the impact the Covid-19 infection has had on the health of the Australian population is the accurate and reliable identification of health outcomes resulting from Sars-CoV-2 infection including infection rates, hospitalisations, admissions to Intensive Care Units (ICU), and deaths. The latter is, in turn, dependent on the availability of reliable and valid criteria for classifying Covid-19 cases.

The validity and reliability of the classification of cases of Sars-CoV-2 infection in Australia, the base that informed the publication of these statistics, was and remains highly questionable, a factor that seriously impacts the ability to draw valid interpretations from case identification outcomes and any analyses stemming from these.

The classification process in Australia involved both laboratory testing using a polymerase chain reaction (PCR) test developed for the detection of segments of the Covid-19 virus's genetic material, a test touted as the gold standard for use in identifying Covid-19 cases, hospitalisations, and deaths, together with the application of the ICD-10 codes recommended by the WHO – U07.1 and U07.2.

The PCR tests

The polymerase chain reaction (PCR) test for Covid-19 is a complex analysis requiring substantial professional training and the employment of strictly controlled standardized methodology that includes the control of factors related to sample collection and storage, laboratory processing, and equipment management, including the settings used for temperature and cycle thresholds. However, with the exception of guidelines provided by the WHO (https://www.who.int/publications/i/item/10665-331501), a standardized protocol for the conduct of PCR tests to identify Covid-19 viral particles has been lacking and the rapid expansion of laboratories conducting these analyses raises concern as to whether staff conducting these tests are appropriately trained and how this, and a lack of methodology standardization may be impacting the accuracy and comparability of test results emanating from different laboratories. Further to this

is a lack of understanding of the rates of false positives and false negatives associated with the test and how various factors, including symptomatic status and cross-reactivity of the test with other microbes or compounds, impact these rates and thereby the validity and reliability of the test findings. These concerns impact the ability to reliably interpret any statistics that stem from these analyses, a factor that will continue to be a problem until such matters are identified and the limitations are both acknowledged and addressed.

Classification of cases and deaths using the ICD-10 codes

Over the past few years, individuals have been classified as cases of Covid-19 infection, and deaths classified as Covid deaths, when assigned one of two ICD-10 codes – ICD-10 codes U07.1 and U07.2. However, closer inspection of these codes reveals how their definitions may impact and potentially inflate case numbers and the numbers of hospitalisations, ICU admissions and deaths.

The U07.1 classifies individuals as Covid-19 cases if there is a laboratory confirmation of infection with Covid-19, irrespective of clinical signs and symptoms. Under this code, a person can have no symptoms of Covid at all and be classified as a Covid-19 case or a Covid death, purely based on a positive test result. In the absence of symptoms, it is arguable whether a positive test result represents a clinically significant infection at best or a false positive test result at worst. This classification inflates counts by an unknown amount and makes the hospitalization, ICU and death data potentially misleading and uninterpretable. It is uncertain what, if any, role Covid-19 had in any of the presentations to hospital, ICU or deaths.

This issue is exacerbated in NSW where the classification of hospitalisations includes back capturing of "diagnoses" from 14 days (reduced from 28 days) prior to presentation at hospital (or ICU or death) regardless of whether Covid symptoms were present or whether an individual is currently testing as “positive” for Covid-19.

The clinical relevance and/or accuracy of positive laboratory test results for Covid-19 have already been discussed above. Of relevance here is the recognised variable sensitivity and specificity of diagnostic tests currently being used to diagnose infection. The PCR test has been criticised by many for its employment of additional amplification cycles beyond that considered to give a valid result. It has also been criticised because it cannot ascertain whether a person is infected with the disease or not. Having a molecule of virus does not mean it is going to result in infection, a factor adding to the effective false positive rate from a clinical standpoint.

The U07.2 classifies individuals as Covid-19 cases if they are suspected of having

Covid-19 but laboratory testing for Covid-19 is inconclusive or unavailable and a clinical determination of Covid-19 has instead been made. The clinical diagnoses of individuals under this code, even in the face of negative test results, when the symptomology of the condition shares so many clinical characteristics with other respiratory disorders such as influenza (Coronavirus disease (Covid-19): Similarities and differences between Covid-19 and Influenza (who.int)), viral pneumonia, and a myriad of vaccine injuries such as multi-inflammatory disease and myocarditis, is also concerning and has the potential to inflate figures.

Classification of vaccination status

A core component of evaluating the impact the Covid-19 vaccination on Covid-19 infection rates, and hospitalization and deaths is the clearly defined and accurate classification of individuals who have not received the treatment (effectively the control group) and individual who have received the treatment (the vaccine) including clear identification of what type and dosage level of vaccine they have received.

The classification of vaccination status conducted by Australian governments was inconsistent and not well defined and as such was difficult to examine and prone to misinterpretation.

One issue was the inclusion of individuals in the unvaccinated or “no effective dose” group who have received their first dose less than 21 days prior to hospital admission, ICU admission or death. This makes it impossible to draw any effective inference re impact of vaccination on any of the outcome variables presented. Contamination of the "control" (non-vaccinated, non-treatment) group with individuals that have potentially had one, two or more doses of the "vaccine"/treatment renders any comparison to ascertain effectiveness critically confounded and arguably scientifically useless. This is especially the case here where the treatment (vaccination) can impact each of the outcome variables negatively (as in, increase counts). The first 21 days after injection are a period of high risk for experiencing a severe adverse reaction that may require hospitalization or result in death. As mentioned in the Explanatory Memorandum for Reference V, the TGA has provided information in response to a question on notice from Senator Gerard Rennick that indicate that approximately 60% of deaths reported following Covid-19 vaccination, where time since vaccination is known, occurred within 2 weeks (Portfolio question number: SQ23-000281). AusVaxSafety data also report that between 37% and 56% of people of almost 7 million people who returned a survey 3 days after their first dose of vaccine reported an adverse event and that between 0.7% and 2.3% of those who responded to the survey reported visiting a GP or emergency department as a result of symptoms, they experienced following the vaccine (based on the adult participants data). Regarding the latter, it should be noted that this data only

included the period up to day 3 after vaccination. It would be expected to be much higher by day 21.

Other Issues

There are other data analyses issues impacting the validity of data presented to us to assess the impact of vaccination on infection and symptom status.

For example, the timelines over which data was being processed. For example, early in the vaccination program, case numbers, hospitalisations, ICU admissions and deaths were summed across months and then compared to point estimates of current vaccination rates. This is an incorrect methodology to apply for the purpose of analysing vaccination outcomes when variable rates of vaccination exist across the time period being reviewed and is a method subject to misinterpretation with a bias to an increase representation of cases, hospitalisations and deaths in the unvaccinated group. The fact that a large proportion of the population was unvaccinated in the early months and thus would have been expected to contribute to the numbers of cases etc for the unvaccinated group throughout this period.

Another issue was how percentage vaccination rate data was presented especially in media releases where cases with unknown vaccination status were included in the denominator of percentage calculations, but this practice was not specified in the media release. This, arguably, was designed to reduce the apparent percentage of vaccinated cases and give the impression that they were under-represented and thus that the vaccines were effective. For example, one media release reported that 65% of Covid-19 cases were vaccinated, inferring (but not specifying) that 35% were unvaccinated which, to the lay person, would likely be interpreted as an over-representation of unvaccinated cases. What this media release did not mention was that the unvaccinated group was 15% and that 20% of cases had an unknown vaccination status. When the percentage of vaccinated cases was calculated for the cases of known vaccination status only, it was found that they represented 82% of the group and the unvaccinated (which include people who have had the first dose under 21 days) represented the remaining 18%. The media would also make many statements about the 95% vaccination rate in the population with minimal reference to this being specific to the age group 16 years and over. This may have contributed further to misinterpretation of the infection rates in the vaccinated individuals, leading people to compare the 65% to that figure that the media provided to the 95% figure and to think that the vaccinated group was not only under-represented but well underrepresented. However, the case numbers provided were whole population numbers, so the rate should have been compared to the whole population vaccination rate which was at the time around 80%. Once the correct comparisons were applied, the vaccine group was proportionately represented at 82% vs approximately 80%.

As stated in the Explanatory Memorandum, as a result of these issues, and others, "a thorough re-examination of Covid-19 vaccination and its temporal relationship with Covid-19 infection and other health outcomes is needed where vaccination status is clearly and consistently defined and where only those individuals who have not received the Covid-19 vaccine 'treatment' are included in the 'unvaccinated group' and compared against the various treatment levels (no effective dose, 1 dose, 2 dose, 1 booster, 2 booster etc)."

Index

Reference: W

Index

A review of epidemiological data relied upon by Commonwealth, State and Territory governments during the Covid-19 pandemic, relating to data collection, data integrity, data availability, data timeliness and data analysis to inform policy and justify Covid-19 mandates.

Explanatory Memorandum

Index

To identify the status of data records, the extent of any centralized national relational databases, and publicly available SQL facilities for data downloads, and to investigate the extent to which epidemiological data was relied upon, and the quality of the epidemiological data.

Question(s) on Notice

Index

In respect of **References W and CC**, please provide any further information concerning Australian epidemiological data being compiled and published and relied upon by Commonwealth, State and Territory governments during the Covid-19 pandemic from early 2020 into 2023, the manner in which the data was being collected, the integrity of the data, the availability of the data to non-government health experts, and how that data was being used transparently to inform government policy on the need for Covid-19 vaccines to the exclusion of all other repurposed drugs, and for justifying Covid-19 mandates.

Answer(s)

Index

First Answer

Dr Suzanne Niblett, Co-Author:

Refer also to the response by Dr Suzanne Niblett at Reference V.

In addition to the above response, it is difficult to make an assessment of the epidemiological data being "compiled …and relied upon by the Commonwealth,

State and Territory governments during the Covid-19 pandemic from early 2020 into 2023, the manner in which the data was being collected", and "the integrity of the data" due to a complete lack of transparency and access to the raw data or any of the details of its collection, analyses and/or interpretations. How that data was being used "to inform government policy on the need for Covid-19 vaccines to the exclusion of all other repurposed drugs, and for justifying Covid-19 mandates" is also unclear, again due to a complete lack of transparency and access to the key information necessary to make such an evaluation.

Regarding the availability of data for-non-government experts, as stated above no detailed or raw data has been made available to independent health experts or scientists to enable an independent review of the processes and interpretation of the various levels of governments and the government agencies. This is something that needs to be addressed through the Terms of Reference for a Royal Commission into the Covid-19 response. The data that has been made available has been published inconsistently across the various states and territories and is minimal in detail and ill-defined and variable in its categorisations. Whether data and in fact even any analysis exists other than that which has been published as summary reports or via the media exists is uncertain, but what is certain is that none of the government data, methodology, results, or interpretations have been properly peer-reviewed. If the data relied upon by governments to inform policy in any way resembled the data which has been published, then there could well be reason for serious concerns that these policies have been informed by biased and inaccurate analyses.

Index

Second Answer

Rebekah Barnett BA (Comm), Proposed Witness:

One of the problems was that it appeared that state governments in fact were *not* looking at their own data to inform their own decision making.

For example, the New South Wales Health Respiratory Surveillance Reports frequently included a boiler plate statement to the effect that "people who are not vaccinated remain more likely to suffer severe Covid-19" in weeks when there were zero unvaccinated patients in hospital or ICU.

In another example, Susan Pearce, Secretary of NSW Health, stated in a Senate hearing, on 07 September 2022, that NSW Health ICU data provided "irrefutable" evidence that the Covid-19 vaccines limit the severity of illness with Covid-19. This was stated in justification of the Health Ministry supporting ongoing workplace vaccination mandates.

Yet, the ICU data for the preceding months showed that in fact the unvaccinated were underrepresented in ICU. Conversely, those with three, four or more doses of Covid-19 vaccination were consistently overrepresented, proportionally.

Both Secretary Pearce's office and NSW Health refused requests to provide a data source alternative to the publicly available Surveillance Reports, which clearly showed that patients with more vaccinations were overrepresented in ICU. This is suggestive that Secretary Pearce and NSW Health were not paying close attention to their own data when forming and assessing health policies.

Index

Reference: X

Index

A review and analysis of the use of social media including celebrities by Australian governments and health authorities to transmit information to the public regarding:

i. Covid-19 case incidences;
ii. Covid-19 vaccine effectiveness statistics;
iii. Covid-19 vaccination advertising.

Explanatory Memorandum

Index

An examination to confirm the nature and extent of social media campaigns employed by health authorities, the accuracy of the data communicated, the transparency of data sources, and degree if any, that Covid-19 social media campaigns were coordinated amongst Australian governments, and whether any censorship tactics were employed by Australian governments through social media against views or opinions or comments that did not support Australian government messaging and narratives.

Question(s) on Notice

Index

In respect of **Reference X**, please provide any further information concerning the use of social media including celebrities by Australian governments and health authorities to transmit information to the public regarding Covid-19 vaccines and Covid-19 cases, and the science and data sources relied upon for all incidences of such social media and celebrity messaging.

Answer(s)

Index

Answer

The People's Terms of Reference:

Use of Australian government paid celebrities to influence the pubic to receive

Covid-19 vaccines:

> From Elvis to Dolly, celebrity endorsements might be the key to countering vaccine hesitancy
> Published: March 10, 2021 10.42am AEDT
>
> Australian music legends join forces in 'vax the nation' campaign
> 6 September 2021
>
> Influencers and incentives: How Australia can get its COVID vaccine campaign back on track
> July 1, 2021

Australian "Nudge units" expert Deborah Lupton, SHARP Professor and leader of the Vitalities Lab, University of New South Wales (UNSW) Sydney:

> Conceptualising and Managing COVID-19 Risk: The Six Phases in Australia·
> Oct 11, 2021

The answer above has been limited due to time constraints.

Index

Reference: Y

Index

A review and analysis of claims made by health authorities, Prime Ministers, Premiers, Ministers, health officials and spokespersons of Australian governments in respect of Covid-19 vaccines, including by Covid-19 vaccine sponsors, that Covid-19 vaccine(s):

i. are safe and effective;
ii. stop person-to-person transmission of the SARS-CoV-2 virus;
iii. are effective at stopping people getting very sick if they catch Covid-19;
iv. stay at the injection site;
v. protect against reinfection from Covid-19;
vi. are particularly important for protecting persons who are immunocompromised or have comorbidities;
vii. ingredients are quickly broken down by the body;
viii. do not shed their ingredients or by-products;
ix. do not cause autoimmune disease;
x. 'do not' (then changed to) 'may' cause a small and temporary change to menstrual cycles;
xi. do not cause sterilisation or infertility;
xii. protect against Long Covid;
xiii. can be safely administered with other vaccines;
xiv. do not enter the nucleus of cells;
xv. do not impact fertility or cause any problems with pregnancy, including the development of the placenta;
xvi. cannot affect or combine with human DNA; and
xvii. an examination of the designation of these genetic technology products as vaccines rather than genetic technology or gene therapies; and
xviii. an examination of epidemiological and statistical findings by pharmacovigilance departments within Australian governments in relation to the safety of Covid-19 vaccines at the time public statements as to the safety of Covid-19 vaccines were being made.

Explanatory Memorandum

Index

An examination to confirm the nature and type and extent of Covid-19 vaccine claims and assertions by the TGA and other Australian health departments, the scientific basis for the claims made compared to available peer reviewed literature, and the possibility of conflicting real-time data being observed by pharmacovigilance departments within Australian governments.

Question(s) on Notice

Index

In respect of **References Y**, please provide any further information concerning the veracity, accuracy, and scientific basis for the many medical statements made by Australian politicians and health bureaucrats and agencies concerning Covid-19 vaccines.

Answer(s)

Index

First Answer

Dr Conny Turni, Co-Author:

Let me address each point separately. I will concentrate on the earlier research that already gave us all the data about this vaccine that should have alerted us to stop vaccination immediately. Retrospectively it is hard to judge but it was all out there already, and doctors and scientists were warning us. After all, Australia was one of the lucky ones that had the vaccine roll out very late and the data of other countries was there to be analysed.

i. are safe and effective

These vaccines are neither effective nor safe.

Vaccination gives insufficient protection against variants of the virus[lxxxv]. Hence, we had so many booster vaccinations in Israel. We are seeing breakthrough cases all over the world and the data from Public Health England (PHE) also shows that between 1 February and 19 July 2021, of all the people who died within 28 days of testing positive for the delta variant, 49% (224) had two vaccine doses. Almost all of these people (220) were aged 50 or older[lxxxvi].

The fact is that even if we achieve over 80% vaccination rates, we are still not safe from variants of this virus. There are currently many variants according to the World Health Organisation, with Alpha to Delta being variants of concern, while Eta to Mu are variants of interest. These variants might be spread regardless of the vaccination status of people[lxxxvii]. This really means that vaccination is not going to be the solution, as durability of the protection of vaccinations cannot be predicted[86]. We are now in the Omicron and we still seeing infections of the vaccinated.

I am a senior research fellow with a PhD in veterinary immunology and work with

respiratory disease-causing bacteria. When we inject the Apx toxin of Actinobacillus pleuropneumoniae into pigs without the bacteria the host shows the same disease signs as if the bacterium has infected the animal[lxxxviii]. The same is true for the SARS-CoV-2 virus. The S1 subunit of the SARS-CoV-2 spike protein when injected into transgenic mice overexpressing human ACE-2 caused a Covid-19 like response (a decline in body weight, dramatically increased white blood cells and protein concentrations in bronchoalveolar lavage fluid (BALF), upregulation of multiple inflammatory cytokines in BALF and serum, histological evidence of lung injury, and activation of signal transducer and activator of transcription 3 (STAT3) and nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB) pathways in the lung)[lxxxix].
Jiang and Mei (2021)[xc] found that the SARS–CoV–2 spike protein significantly inhibits DNA damage repair by hindering the recruitment of crucial DNA repair proteins to the damage sites, which might be a mechanism to prevent adaptive immunity. Their conclusion was that full-length spike protein vaccines induce lower antibody titers due to the weakening of the DNA repair system and hinder the V(D)J recombination and adaptive immunity. They came to the conclusion that an antigenic epitope of the spike protein as vaccine candidate might be a more efficient and safer vaccine. Their study also points to a potential side effect of mRNA vaccines.

These Covid vaccines are still in the experimental stage and therefore the long-term health implications are not yet evident. There were concerns in the peer-reviewed literature as early as 2021 about consequences following Covid-19 vaccination such as autoimmune disease, antibody-dependent enhancement (ADE) and neurodegenerative diseases to name just a few[xci].

A study by Lyons-Weiler (2021)[xcii] revealed that there is considerable homology between human and viral proteins which can lead to vaccine-induced autoimmunity. The author found over 1/3 of the SARS-CoV-2 proteins have homology to key proteins in the human adaptive immune system which might lead to autoimmunity against these proteins.

Hasan et al. (2021)[xciii] analysed data from the National Health Service published by Public Health England and showed that the death rate due to the Delta variant infection was eight times higher in infected people that were fully vaccinated compared to unvaccinated infected people. The authors suggest that in a subset of individuals the pre-existing anti-S-IgG induced by vaccination may be sub-neutralizing and leading to accelerated infectivity via ADE, which is displayed as higher death rates.

Kelleni (2021)[xciv] reports the potential risk of the vaccine to induce auto-immune diseases such as thrombocytopenia, myocarditis and immune induced thrombosis and thromboembolism which might lead to fatal outcomes and might be a reason for some of the post vaccination sudden death reports.

The potential risk factors of the Pfizer vaccine are sequences that can induce TDP-43 and

FUS to aggregate into prion configuration, which might lead to neurodegenerative diseases, such as Alzheimers. The spike protein encoded by the mRNA binds to the ACE2 receptor which releases zinc molecules. Zinc also causes TDP-43 to transform into a pathological prion[xcv]. The link with neurodegenerative disease is attributed to the spike protein being able to interact with the heparin binding amyloid forming proteins. A study indicated that the S1 protein forms a stable bond with the aggregation-prone proteins which might initiate aggregation of brain proteins and thereby accelerate neurodegeneration[xcvi]. Finisterer and Scorza (2021)[xcvii] further stated that SARS-CoV-2 vaccines trigger neurological adverse reactions and mild and severe neurological side effects have been occasionally reported. Studies support the concept that the onset and progression of neurodegenerative diseases such as Alzheimer and Parkinson disease, including TDP-43 proteinopathy, are associated with propagation of protein aggregates between neuronal cells[xcviii].

Scientific studies have raised serious concerns about the safety of AstraZeneca after reports of cerebral venous sinus thrombosis and a variety of other thrombotic events after AstraZeneca vaccination with studies reporting such events in medical journals[xcix]. Kircheis (2021)[99] reported that other serious conditions have been reported for Covid vaccines such as capillary leakage syndrome (AstraZeneca) and coronary myocarditis (Pfizer).
Some concern about vaccinating pregnant women was raised by Anand and Stahel (2021)[c]. Walsh et al. (2021)[ci] reported that the results of the Pfizer vaccine demonstrate a broad immune response to vaccination with stimulation of neutralizing antibody responses, stimulation of CD4+ cells and growth of effector memory CD8+ T cells in men and women. Anand and Stahel (2021)[100] hypothesised that one could assume this would also happen in pregnant women as well. This would not be favourable for a perinatal outcome and might lead to preterm birth and fetal loss, as a good outcome relies on amplification of helper T cell type 2 and regulatory T cell activity coupled with decreased Th1 response[cii]. Evidence has suggested that mothers with variant CD4+ T cell responses give birth to babies that may suffer enduring adverse consequences[ciii].

A study concluded and I quote: “mRNA vaccines dramatically increased inflammation on the endothelium and T cell infiltration of cardiac muscle and may account for the observations of increased thrombosis, cardiomyopathy and other vascular events following vaccination”[civ].

We do not know the exact figures of people that have had severe side effects of the vaccine, all we know is that 10,000 people have filed a law suit for compensation for their severe side effects[cv].

In a study from Saudi Arabia[cvi], which was done through a survey, 2,601 people who had received one dose of BNT162b2 (Pfizer vaccine), of whom 456 completed the second dose, and 1,569 people who had received a single dose of ChAdOx1 (Astra Zeneca) were questioned about side effects of the vaccination received. ChAdOx1 vaccinees reported

ChAdOx1 vaccinees reported mild, moderate, severe and critical side effects in 30.13, 28.62, 29.73, and 1.53%, respectively. In contrast, mild side effects were recorded among the majority of BNT162b2 vaccinees (63.92%) while moderate, severe, and critical side effects were 27.67, 7.68, and 0.72%, respectively[106]. If we translate this to severe side effects per 100,000 this would be 7,680 vaccinees with severe and 720 with critical side effects per 100,000 vaccinees for the Pfizer vaccine and 29,730 with severe and 1,530 with critical side effects per 100,000 vaccinees for Astra Zeneca. We must also remember that in this study done purely by survey, death and paralysis would not have been captured. This study despite its lack of medical confirmation indicates that there are many reported side effects.

ii. stop person-to-person transmission of the SARS-CoV-2 virus

A study has found that the increases in Covid-19 cases are unrelated to levels of Covid-19 vaccination across 68 countries and 2,947 counties in the United States. On the contrary, it appears that countries with higher vaccination rates have higher numbers of cases. Let me quote one sentence of the study: "Across the US counties too, the median new Covid-19 cases per 100,000 people in the last 7 days is largely similar across the categories of percent population fully vaccinated."[cvii]

A report from August 2021[cviii] about 469 Covid-19 cases associated with multiple summer events and a large public gathering in Massachusetts revealed that 346 cases occurred in fully vaccinated people of which 274 cases were symptomatic. When the Ct value of real time PCR results of specimen from 127 vaccinated persons with breakthrough cases were compared to the Ct specimen of 85 people who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown, there was no significant difference. Even though more studies are needed, the authors concluded that the viral load of vaccinated and unvaccinated persons infected with SARS-CoV-2 is also similar[108]. A study from the UK[cix] revealed even though vaccination can reduce the risk of delta variant infection in a household and accelerates viral clearance, the peak viral load of breakthrough infections in vaccinated people is not different to unvaccinated people and both can effectively transmit the virus to vaccinated people. A review of the literature about transmission of the virus tells us that virus shedding based on PCR testing is very variable and can be prolonged, however, detection of viral RNA does not necessarily correlate with infectivity as the duration of shedding by viral culture suggests a shorter duration[cx]. We know that the PCR test will come up positive in naturally infected people long after they recovered, which might be due to the SARS-COV-2 RNAs reverse-transcribed and integrated into the DNA of human cells. In tissue from patient evidence it was seen that large fractions of the viral sequence are transcribed from integrated DNA copies of viral subgenomic sequences, which cannot produce the infectious virus, but might yield positive PCR results[cxi].

A study done on cases in the San Francisco Bay area[cxii] revealed that the differences in viral loads were non-significant between unvaccinated and fully vaccinated persons

overall. The authors concluded that vaccine breakthrough infections were caused by antibody-resistant Covid-19 variants and these infections transmit Covid-19 just as efficiently as unvaccinated infections.

The vaccine does not prevent the spread of the virus. All this vaccination that is injected into the arm is designed to do is to decrease the disease severity. It will not prevent disease, as we can see from studies such as the one at the University of California where 76% of the workforce had been fully vaccinated with mRNA vaccines by March 2021 and 86.7% by July 2021. In July 75.2% of the fully vaccinated workforce had symptomatic Covid[cxiii]. The vaccines are supposed to prevent severe disease and death. It is even questionable if the current mRNA vaccines are able to do this, as so many fully vaccinated people ended up in hospital due to the delta variant and there were also deaths recorded in the fully vaccinated[cxiv].

iii. are effective at stopping people getting very sick if they catch Covid-19

There seems to be a trend that the more boosters the less protection.

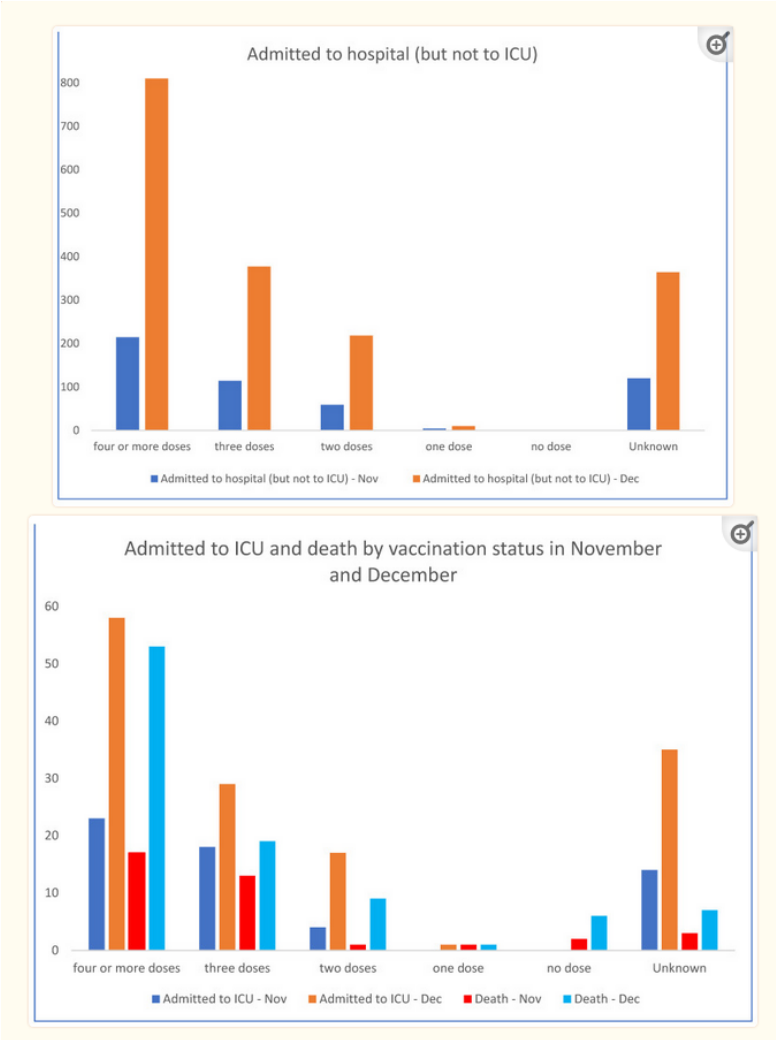


Figure 1: NSW Australia hospitalisations, ICU admissions and deaths last 6 weeks 2022 by vaccination

status. NSW Health. Bar charts derived from the numbers in official government report.

iv. stay at the injection site

The current main Covid-19 vaccine used in Australia consists of mRNA encapsulated by nanoparticles. The vaccine was assumed to stay at the injection site and generate a protective immune response. However, the vaccine does not stay at the injection site. On the contrary, it travels throughout the body, in the Pfizer rat studies we have seen that the vaccine can be found in nearly all organs. In Japan there is a disproportionately high incidence of death due to cerebral venous sinus thrombosis and intracranial haemorrhage and researchers, despite not being able to prove a causal link with vaccines, as no autopsies were performed, still believed that a link with vaccines is possible and warrants further analysis[cxv]. However, there are 1100 case studies linking the vaccine to adverse events in all parts of the body. A list is found in the review of Turni and Lefringhausen (2022)[cxvi].

We know very well that nanoparticles can cross the blood-brain barrier[cxvii] and the blood-placenta barrier[cxviii], so it came as no surprise that the European Medicines Agency assessment report for the Moderna vaccine on page 47 (https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-Covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf) also noted that mRNA could be detected in the brain following intramuscular administration at about 2% of the level found in the plasma.

v. protect against reinfection from Covid-19

I work at the University of Queensland and all the staff and students have been vaccinated twice in my work group, yet many of them had Covid not only once but twice.

vi. are particularly important for protecting persons who are immunocompromised or have comorbidities

If a vaccine is safe then this is probably true, however, if the vaccine evokes similar symptoms to the disease then this is not the case. According to researchers the risk of dying from the vaccine does not seem to outweigh the risk of dying from Covid-19. According to Dopp and Seneff (2022)[cxix], adults aged 40 to 49 are 5 times more likely to die after vaccination. People in the group aged 50 to 59 are still twice as likely to die after vaccination than after Covid-19. Only when over 60 years of age is the chance of death equal for both causes. Even when over 80 years old the likelihood of dying from Covid innoculation is just 0.13% lower than the risk of dying from the infection.

In 2021, Kostoff questioned the cost benefit scenario, as according to Kostoff et al (2021)[cxx] there are five times the number of deaths attributed to the vaccination verses

those attributed to Covid-19 and that is in the most vulnerable group, the age group over 65 years of age.

What needs to be further emphasised is that the majority of deaths with and from Covid-19 occur in the elderly with multiple comorbidities and generally weaker immune systems. Yet, they are vaccinated with an injection that amplifies underlying disorders (Fig 2 below) and is dependent on a strong immune response. Ironically, the survival of many of those patients is probably due to their immune system not being able to mount a significant response to the induced spike protein production (Turni and Lefringhausen, 2022)[cxxi].

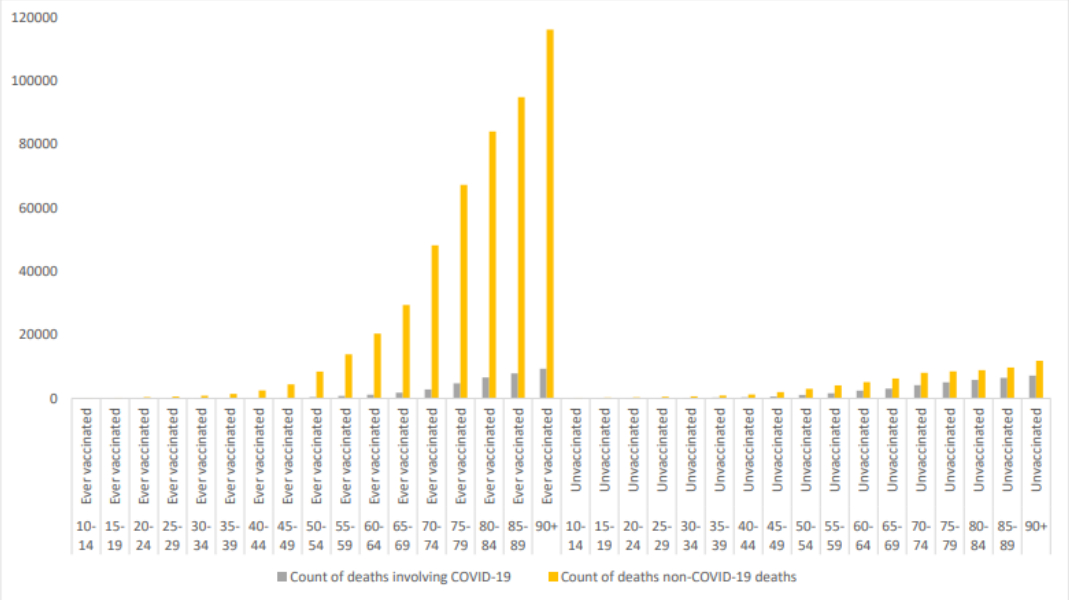


Figure 2: Death rate due to Covid and other causes comparing the vaccinated (at least one vaccination) and unvaccinated in each age group. The data of deaths occurring was for the period of the 1st of January 2021 to 31st of May 2022 in England (https://www.ons.gov.uk/)

vii. ingredients are quickly broken down by the body

According to literature, the ingredients are not broken down quickly and over four months later the spike proteins are still presented on exosomes circulating through the body[cxxii]. This study was four months long, hence we do not know how long the spike protein is produced. If the mRNA has integrated into the genome of the cells then the spike protein could be produced longer.

viii. do not shed their ingredients or by-products

A discussion paper by Domazet-Loso (2022)[cxxiii] raises the point everybody ignores, that biological and evolutionary evidence clearly demonstrates the integration of mRNA molecules into the genomes of murine and human populations. Yet when it comes to this vaccine the statement is simply that this cannot happen. If this integration occurs in the

reproductive cells, such as the sperm cells, egg cells and cells from very early embryos, then this change would be passed on to the next generation and these reproductive cell changes might cause events that will not be seen until years later, by which time the undesirable effects have already been passed on to the next generation.

ix. do not cause autoimmune disease

A study by Lyons-Weiler (2021)[cxxiv] revealed that there is considerable homology between human and viral proteins which can lead to vaccine-induced autoimmunity. The author found over 1/3 of the SARS-CoV-2 proteins have homology to key proteins in the human adaptive immune system which might lead to autoimmunity against these proteins.

x. 'do not' (then changed to) 'may' cause a small and temporary change to menstrual cycles

Several papers have reported abnormal bleeding after Covid vaccination[cxxv,cxxvi,cxxvii]. The most commonly reported signs were excessive bleeding (heavy, prolonged, or intermenstrual). Muhaidat et al (2022)[127] also listed side effects such as irregular menstruation, menstrual cramps, increased period frequency, menstruation stopped and worsening of premenstrual symptoms. Lee et al (2022)[125] reported 42% of the participants bled more heavily than usual.

xii. protect against Long Covid

Covid-19 is a respiratory infection, affecting foremost the respiratory system and only if it compromises the lung is it actually going systemic. Unless Covid-19 has gone systemic, there should only be respiratory problems and off course fever due to the inflammation. However, the vaccine created problems are due to the distribution of the vaccine effects systemically. From our knowledge we know that the vaccine has many side effects and that could easily be classed as long Covid-19. Hence our priority is to figure out if long Covid is not only a vaccine side effect.

xiii. can be safely administered with other vaccines

As the vaccine is not safe, it should not be administrated at all.

xiv. do not enter the nucleus of cells

It is naïve to think that the mRNA cannot enter the nucleus. It was stated with certainty that the mRNA cannot be reverse-transcribed into the DNA of our cells. This old "Central Dogma" that this cannot happen was proven to be wrong not only historically but by a paper in 2021 by Chandramouly et al. (2021)[cxxviii] when they discovered a unique DNA polymerase-helicase fusion protein called Polymerase θ, which functions as

an RNA-templated DNA repair. Furthermore, eight percent of human DNA consists of remnants of ancient endogenous retroviruses[cxxix], which were translated by reverse transcription and then integrated into the human genome.

Endnotes: For all answers
Index

Second Answer

Dr Astrid Lefringhausen, Co-Author:

I will address each point under Term of Reference Y separately.

i. are safe and effective

Health authorities failed to define their meaning of safe and effective. The lay person will always interpret safe and effective as "100% safe" and "100% effective". However, similar to the producers' 95% effectivity of the vaccines, which was in fact a relative protection factor which the general public understood to describe absolute protection, safety and efficacy as used by health authorities meant in comparison to what the modelling predicted as an outcome if people were not vaccinated. As we know now, those models were inflating projected casualties and morbidity of COVID infection well beyond reality. Presumptions of efficacy have been sustained by Covid-19 modelers, and reiterated by health authorities, medical publications, and the media. This is exhibited by Watson et al., (2022) in "Global impact of the first year of Covid-19 vaccination: a mathematical modelling study", published in The Lancet Infectious Diseases[cxxx]. The authors estimate around 14.4 million lives saved related to vaccination benefits that include protection against infection and transmission, both now recognised to be unfounded. This suppositional estimate by Watson et al. persists as an accepted fact, whereas real-world infection fatality rate (IFR) data speak against the need for vaccination in the non-elderly. Accurate estimates of lives saved or lost as a result of the Covid-19 gene-based vaccines would have required long-term studies in vaccinated compared to unvaccinated individuals. Pfizer, Moderna, AstraZeneca and Janssen eventually vaccinated almost all placebo subjects and thus lost their control group. This was based on ethical principles given the fear of Covid-19[cxxxi], but the loss to scientific integrity of only having short-term placebo-controlled trials was noted by the WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Evaluation (2020)[cxxxii]. A worldwide Bayesian causal Impact analysis suggests that Covid-19 gene therapy (mRNA vaccine) causes more Covid-19 cases per million and more non-Covid deaths per million than are associated with Covid-19[cxxxiii]. An abundance of studies has shown that the mRNA vaccines are neither safe nor effective.

ii. stop person-to-person transmission of the SARS-CoV-2 virus

The vaccine was never meant to prevent the spread of the virus, but to decrease disease severity. A study at the University of California followed up on infections in the workforce after 76% had been fully vaccinated with mRNA vaccines by March 2021 and 86.7% by July 2021. In July 2021 75.2% of the fully vaccinated workforce had symptomatic Covid[cxxxiv]. A study by Chau et al. reported a seminal nosocomial outbreak occurring in fully vaccinated Hospital Care workers (HCW) in Vietnam in 2021[cxxxv]. A second study described an outbreak in a Finnish hospital where the virus spread among HCWs and patients[cxxxvi]. In this study the Delta variant of the virus was introduced by an inpatient. Both symptomatic and asymptomatic infections occurred among vaccinated HCWs. Secondary transmissions were observed from those with symptomatic infections despite the use of personal protective equipment. Acharya et al. (2021) and Riemersma et al. (2021) both showed that the vaccinated have very high viral loads similar to the unvaccinated and are therefore as infectious[cxxxvii,cxxxviii]. Brown et al. (2021) and Servelitta et al (2021) suggested that vaccinated people with symptomatic infection by variants, such as Delta, are as infectious as symptomatic unvaccinated cases and will contribute to the spread of Covid even in highly vaccinated communities[cxxxix,cxl]. A study published by the Cleveland Clinic in 2023 found that with Omicron strains becoming predominant, the risk of contracting Covid-19 was lowest for individuals who opted to not get vaccinated, while vaccinated individuals were at increasingly higher risks of contracting Covid-19, the more injections they had received prior[cxli].

iii. are effective at stopping people getting very sick if they catch Covid-19

Australian State Government (NSW) health data from November and December 2022[cxlii] (Figures 1 and 2) demonstrate that the unvaccinated are almost not represented in the hospitalisation data while the most vaccinated are over-represented. The proportion of unvaccinated in NSW was low at 3.2%; however, the proportion of unvaccinated with severe Covid-19 is lower than this in late 2022 at 2.9%. Even accounting for more Covid-19 vaccine boosters in the elderly and vulnerable, the data do not suggest significant efficacy against hospitalisation, ICU admission and death, at least after the emergence of the Omicron strain.

For weeks 51 and 52 of 2022, the NSW government data document nil hospitalizations and six deaths for unvaccinated persons, but 1415 hospitalisations and 82 deaths in known vaccinated persons. NSW Health no longer publishes vaccination status.

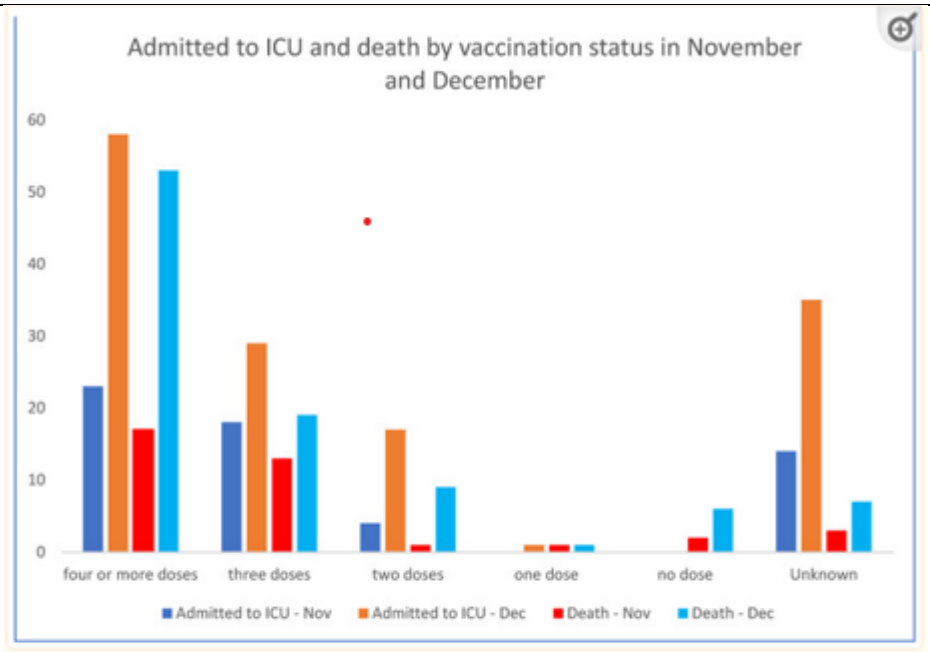


Figure 1

NSW Australia hospitalisations, ICU admissions and deaths last 6 weeks 2022 by vaccination status. NSW Health. Bar charts derived from the numbers in official government report excerpt of posted as Figure 2 [21].

These data do not support the premise, that the vaccinations have 'saved millions of lives', but instead indicate correlations between more doses with severe Covid-19 illness. A study from the US found that increases in Covid 19 cases are unrelated to levels of Covid-19 vaccination across 68 countries and 2,947 counties in the United States. On the contrary, it seems that countries with higher vaccination rates have also higher caseloads. It was shown that the median of new Covid-19 cases per 100,000 people was largely equivalent to the percent of the fully vaccinated population[cxliii].

iv. stay at the injection site

The lipid-nanoparticle, the carrier for synthetic mRNA, is potentially inflammatory in its own right, crosses membranes and distributes widely in the body. It crosses both the blood-brain barrier and the blood-placenta barrier. The EMA report on the Moderna vaccine showed "that mRNA could be detected in the brain following intramuscular administration at about 2% of the level found in plasma"[cxliv].

A/Prof Byram Bridle, Canadian virologist-vaccinologist, obtained Pfizer rodent study biodistribution data from the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) via a FOI request in 2021[cxlv]. Judicial Watch, a US independent watchdog foundation, obtained the same Pfizer study report via FOI lawsuit to the US Department of Health and Human Services after the FDA and CDC refused to comply[cxlvi]. A more recent FOI request to the Australian TGA (FOI reply 2389-6), reveals on page 45 of the TGA's "nonclinical evaluation report: BNT162b2 Covid-19 vaccine" that the same study was part of the TGA's evaluation in January 2021 prior

to its provisional authorisation[cxlvii].

Table 4-2. Mean concentration of radioactivity (sexes combined) in tissue and blood following a single IM dose of 50 µg mRNA/rat

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181
Adrenal glands	0.27	1.48	2.72	2.89	6.80	13.77	18.21
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687
Bone marrow (femur)	0.48	0.96	1.24	1.24	1.84	2.49	3.77
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112
Heart	0.28	1.03	1.40	0.99	0.79	0.45	0.55
Injection site	128.3	393.8	311.2	338.0	212.8	194.9	164.9
Kidneys	0.39	1.16	2.05	0.92	0.59	0.43	0.42
Large intestine	0.013	0.048	0.09	0.29	0.65	1.10	1.34
Liver	0.74	4.62	10.97	16.55	26.54	19.24	24.29
Lung	0.49	1.21	1.83	1.50	1.15	1.04	1.09
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.366
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.26
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112
Spleen	0.33	2.47	7.73	10.30	22.09	20.08	23.35
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456
Whole blood	1.97	4.37	5.40	3.05	1.31	0.91	0.42
Plasma	3.96	8.13	8.90	6.50	2.36	1.78	0.81
Blood:plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540

The Pfizer biodistribution study involved 63 Wistar Han rats of whom 42 (21 male, 21 female) were injected with the human equivalent of 50 ug mRNA per animal, and an additional 21 male rats were injected with the equivalent of a Moderna Covid-19 vaccine dose of 100 ug mRNA per animal. The mRNA coding for Luciferase was encapsulated in liquid nanoparticles containing radiolabelled cholesterol, injected into the gluteal muscle and monitored for 48 h. As indicated in the table above, the biodistribution data showed the lipid-nanoparticles, which were designed to pass easily through biological tissues and membranes, travel to all organs. By 48 h, 75% had left the injection site for elsewhere[144,143].

Although the highest levels went to the spleen and liver, where high cell turnover helps timely repair of any cytotoxic damage, the lipid-nanoparticle, and by implication the mRNA, went to seemingly all organs, particularly the ovaries and adrenal glands but also the brain, eyes, heart, testes, uterus, pituitary gland, spinal cord, thymus and bone marrow.

The Pfizer rat biodistribution study has been corroborated. Chinese researchers injected mice with lipid-nanoparticle-mRNA complexes (mRNA-LNPs) encoding the firefly luciferase gene and biodistribution from the injection site "became rapidly distributed throughout the body with a large presence in the liver" and the "non-linear relationship between the LNP exposure and the protein expression level varies in different tissues and organs"[cxlviii] (p. 114). Smaller mRNA-LNP complexes transfected further and relatively smaller amounts of mRNA in the liver and lymph nodes produced higher rates of encoded bioluminescent protein than at the injection site muscle. The authors stated:

> *"The duration and kinetics of transgene expression are affected by the pharmacokinetics and biodistribution of the delivery systems. The pharmacokinetic-pharmacodynamic relationship of mRNA-LNPs is highly complex, making the prediction of gene expression and efficacy (pharmacodynamics) unlikely just based on LNP exposures in tissue (pharmacokinetics)".*[cxlix]

Effectively the lipid-nanoparticle, and presumably its mRNA payload, distributes throughout the whole body and gene expression varies unpredictably[146,cl,145].

v. protect against reinfection from Covid-19

There is no doubt that the vaccines do not protect against re-infection, in fact, most health regulators made sure to classify the freshly vaccinated as unvaccinated or "not up to date" until 2 or sometimes 3 weeks post injection to avoid making it too obvious too early. Seneff et al[cli] enumerated Covid-19 vaccine effects on the innate immune system, importantly a decrease of type I interferon signaling, which can lead to a wide variety of disorders, such as reactivation of viral infections and reduction of the immune system's ability to not only fight disease but to keep tumors and autoimmune reactions suppressed[clii].

A case report by Glas et al from[cliii] illustrates the effects of a disseminated viral infection on an immune-suppressed patient: in this instance fatal multiorgan failure associated with disseminated Herpes simplex virus-1 infection. Reactivation and spread of dormant viral infections including Herpes simplex and Herpes zoster are listed as side effects from both mRNA injections as well as the Astra Zeneca vaccine, and Covid-19 is one of the most cited side effect of the SARS-CoV-2 vaccines.

Injection of mice, bred to have human-like ACE-2 receptors with spike protein S1/RBD unit was found to induce Covid-19-like acute pulmonary pathology, indicating it is the spike protein that is a cytotoxin primarily responsible for the severity of the SARS-CoV-2 respiratory infection[cliv]. This, in retrospect, means it has been a particularly poor choice for vaccine development purposes. In a preprint, McKernan et al.[clv] quantify the

pharmacokinetics of the mRNA vaccines as creating greater numbers of spike proteins than the SARS-CoV-2 virus, and more systemically in most people not prone to overwhelming Covid-19 viral infection:

> *"The pharmacokinetics of injection are different from an infection; 30–100 mg per injection (90–300 mg for those boosted) of Spike mRNA equates to 13 trillion to 40 trillion mRNA molecules injected in a few seconds with each injection. The pharmacokinetics of this bolus injection differs from that of viral replication that occurs over the course of a few days. If each of these mRNAs can produce 10–100 spike proteins and you have 30–40 trillion cells, there may be a far greater quantity and a much longer duration of spike protein exposure through the vaccination route than by natural infection".*[152] (p.12)

Exposure like this renders the recipient of the mRNA vaccines more likely to experience viral or bacterial infections – including Covid-19.

vi. are particularly important for protecting persons who are immunocompromised or have comorbidities

The vaccine was meant to protect the over age 60 with the greatest risk of mortality from Covid-19, yet a risk analysis by Dopp and Seneff (2022)[clvi] showed that the likelihood of dying from the injection is only 0.13% lower than the risk of dying from the infection in those aged over 80 years.

Furthermore, natural aging is accompanied by changes in the immune system that compromise the ability to effectively respond to new antigens. Similar to age-stratified responses to viruses, this means vaccines become less effective in inducing immunity in the elderly resulting in a reduced ability to fight novel infections[clvii]. Two-dose Covid-19 mRNA vaccination conferred limited adaptive immune response among aged mice, making them susceptible to SARS-CoV-2 infection[clviii]. The risk of severe disease among US veterans after vaccination remained associated with age according to a study by Vo et al., (2022)[clix]. The risk of breakthrough infections was also higher if immunocompromising conditions were present.

vii. ingredients are quickly broken down by the body

The lipid-nanoparticle carrier of the mRNA and the associated PEG that make the mRNA-LNP complexes are more stable and resistant to degradation, and have their own toxic effects; the lipid-nanoparticles primarily via pro-inflammatory effects and PEG by anaphylaxis in susceptible individuals. The LNPs are too big to be excreted via the kidneys and there is no study showing how, and if, they leave the body. Some LNP components are synthetic, and it is unclear if the human body can metabolize them – and it has never been looked into. Since they become part of the transfected cell membranes, they might stay in the body and be recycled in other cells membranes. It is unknown

whether and to what extent this happens and what the effects might be.

Röltgen et al.[clx] found the integration of N1-methylpseudouridine stabilised mRNA in the Covid-19 vaccines and spike proteins was produced for at least 60 days. Naturally occurring mRNAs have a half-life of minutes to a couple hours. The genetically modified mRNA used in the Pfizer and Moderna vaccines can be found in the blood of vaccinated individuals for at least 2 weeks post injection still producing spike protein[clxi]. Other research on retroposition of the genetic code[clxii] and substantial plasmid DNA contamination, suggests the possibility that such production of a foreign pathogenic protein could potentially be lifelong or even transgenerational.

viii. do not shed their ingredients or by-products

Non-degradable nanoparticles can stay in human tissue systems for an extended period of time[clxiii,clxiv] or can be excreted in saliva, sweat, and breast milk[clxv]. None of this has been studied with regards to the LNP-modRNA particles in the Moderna and Pfizer vaccines, in spite of the fact that none of the cited studies is new and these must have been facts well known to regulators. It is not only possible, but likely, that the LNP part of the vaccines – if not accumulating in the human body – will find its way into the environment via wastewater, skin and intimate contact, breast milk and food waste. The nucleic acid part of the vaccines as well as the product, the spike protein, can be spread throughout the body and to other people via exosomes. Exosomes are EVs with a size range of ~40 to 160 nm (average ~100 nm) in diameter and have the same structure as the LNP's in the Covid mRNA vaccines which are approximately 100 - 400 nm in size. Spike protein, LNPs and mRNA can all find their way into the environment by different routes, be it over breath, urine, faeces, sweat or other bodily fluids like breast milk. Shedding has been shown to occur with attenuated vaccines as well as with toxoid vaccines like Diphtheria, in fact, it was known as a risk to the producers of the mRNA vaccines. The Pfizer protocol Phase I/II/III trial of Covid-19 mRNA vaccines begun in May 2020[clxvi] states clearly on page 59 that men participating in the trial or even exposed to the vaccines by inhalation or skin contact risked exposing their female partners before or around conception and should abstain from physical contact.

Furthermore, breastfeeding women were also to report exposure immediately, meaning there were expectations of spike containing exosomes in breastmilk. Exposure was defined as being a recipient of the vaccines directly or if she was "exposed to the study intervention by inhalation or skin contact." When inhaled, specific sizes of NSPs (nano-sized particles, i.e. LNP's/exosomes) are efficiently deposited by diffusional mechanisms in all regions of the respiratory tract. The small size facilitates uptake into cells and transcytose across epithelial and endothelial cells into the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen, and heart[clxvii].

ix. do not cause autoimmune disease

Pharmacokinetic factors contribute to the pathophysiology. As mentioned, the Pfizer biodistribution study (where 75% of lipid-nanoparticle carrier molecules left the deltoid for all organs within 48 h) for the Japanese PMDA was known to the Australian TGA before the provisional authorisation of the mRNA Covid-19 vaccines for the Australian population[clxviii]. Because they cause replication of the spike protein in many organs, the gene-based vaccines act as synthetic viruses. The inevitable attack of the immune system on those transfected cells that display the foreign spike protein on their surface is nothing else but an autoimmune reaction – and is factored into the standard working procedure of the mRNA vaccines. If the LNPs stayed at the injection site as postulated by pharma and health agencies, this would mean the loss of muscle cells but nothing else. Since they carry the mRNA and plasmid DNA contaminants to all organs of the body, the immune attack will have unpredictable consequences.

There is also problematic homology of the spike protein to key proteins in the adaptive immune system leading to autoimmunity if vaccinated with the mRNA producing spike protein. Molecular mimicry contributes to autoimmune responses. Among the 41 immunogenic penta-peptides within the SARS-CoV-2 spike protein, 27 share homology with human proteins involved in oogenesis, placentation and/or decidualization. Autoantibodies formed due to molecular mimicry are potential contributors to female infertility[clxix]. This is yet to be definitively documented for the Covid-19 modRNA vaccines.

There are a multitude of publications and case studies showing re-activation or new onset of autoimmune diseases like MS, Psoriasis, Autoimmune hepatitis and encephalitis, Lupus and Rheumatoid arthritis following vaccination with the mRNA SARS-CoV-2 vaccines. Even the FDA was aware of this potential before the public release of the gene-based Covid-19 vaccines. It is the 16th slide from a PowerPoint presentation of the "Vaccines and Related Biological Products Advisory Committee (VRBPAC) 22 October 2020, Meeting"[clxx]. What is striking is the predictive accuracy of these mostly neurological, cardiovascular, and autoimmune "possible adverse events" with those reported to VAERS and other global vaccine injury databases.

x. 'do not' (then changed to) 'may' cause a small and temporary change to menstrual cycles

Several papers have reported abnormal bleeding after Covid-19 vaccination[clxxi],[clxxii],[clxxiii]. The most reported symptom was excessive bleeding (heavy, prolonged, or intermenstrual). Muhaidat et al.[170] also listed adverse effects such as irregular menstruation, menstrual cramps, increased period frequency, menstrual cessation and worsening of premenstrual symptoms. Lee et al.[168] reported 42% of the participants bled more heavily than usual.

Breakthrough, or post-menopausal bleeding was observed in respondents who for

various reasons usually do not menstruate. According to Issakov et al.[169] the risk of abnormal uterine bleeding increased by 2.5% for every year of a women's age but decreased by 8% for every child born to her.

In two large self-reporting population-based cohorts (n=21,925), Covid-19 vaccination was found to be associated with new onset heavy menstrual bleeding in ordinarily non-menstruating women.[clxxiv] The age-adjusted hazard ratios were 3.0 (post-menopausal), 4.2 (peri-menopausal) and 4.7 (premenopausal) within 28 days of a first vaccination. The association was stronger for women without pre-existing gynecological conditions or hormonal therapy. This post-vaccination cohort was found to be less likely to seek medical care, compared with the pre-vaccination women. Interestingly, this paper alluded to a mechanism related to the spike protein per-se across these reproductive age groups, with a 32% differential bleeding risk noted in the use of the high dose modRNA vaccine Spikevax (100ug) compared to Cominarty (30 ug) in premenopausal women. To date, the published vaccine trials, all of which excluded pregnant women, only covered adverse symptom reports for seven days post-trial, yet many reports of bleeding went well past seven days after vaccination[clxxv]. A Pfizer clinical trial of BNT162b2 vaccine in pregnancy was conducted but no results have been forthcoming, despite considerable passage of time[clxxvi].

This observation of prolonged menstrual bleeding may be consistent with other adverse effects of Covid-19 genetic vaccines. A 2022 paper by Taieb and Mounira described Covid-19 vaccines being associated with pituitary disruption and other endocrinopathies[clxxvii]. Case studies of pituitary disease show that onset is one to seven days after vaccination[clxxviii,clxxix,clxxx,clxxxi,clxxxii,clxxxiii]. Endocrinopathies can cause ovulatory dysfunction by hypothalamic pituitary ovary axis disruption.

xi. do not cause sterilisation or infertility

The Federal Institute for Population Research of Germany published a study showing a strong association between the launch and uptake of the Covid-19 vaccination programs and decline in fertility nine months later and that this decline in the first months of 2022 in Germany and Sweden was remarkable. The number of live births dropped by some 15% in Germany and close to 10% in Sweden, as compared to fertility levels in previous years. Both these countries were not affected by any birth rate decline during the Covid-19 pandemic in 2020 and most of 2021[clxxxiv].
Kuhbander and Reitzner[clxxxv] report the number of stillbirths as a proportion of live births in Germany "increased by 9.4% in the second quarter of 2021, and by 19.4% in the fourth quarter of 2021" and has remained high to the third quarter of 2022 but is yet to be updated with complete data since then.

Covid-19 vaccine nanoparticles constituents may potentially also be linked with stillbirth. The same components of nanoparticles and closely related chemical components have been administered to pregnant women in Australia since 2014. A

pertussis immunization vaccination containing polyoxyethylene (80) sorbitan monooleate ('Boostrix' ®) was introduced into 2nd trimester care into Australian states progressively from August 2014-2015, being recommended between mid 2nd trimester and early 3rd trimester of each pregnancy by the Australian Government Department of Health and Aged Care Immunization Handbook. In 2016, 2nd trimester stillbirth rates began to rise even though third trimester stillbirth rates continued a downward trend. (Australian definition of stillbirth: those born at 20 weeks' gestation or more, and/or weighing 400 grams or more.) As of 2020 Australia's total perinatal mortality rate is the highest since 2011. Total stillbirth rates have reached their highest figure since 2000, despite a downward trend prior to 2016. The cause of this trend remains unreported. On its webpage for "stillbirths and neonatal deaths", last updated November 29, 2022, the Australian Institute of Health and Welfare (AIHW) has an incomplete perinatal data spreadsheet for 2021. Thus, it is not yet possible to examine if Covid-19 vaccination has had a statistical impact in this country.

A multicenter retrospective investigation of the effect of Covid-19 modRNA (Pfizer) vaccine on semen parameters at 15-45, 75-125 and over 145 days post second vaccination in 37 Israeli sperm donors showed declines in semen concentration. Semen volume and sperm motility were not impaired. The authors concluded systemic immune responses after the modRNA vaccine to be a reasonable cause for a transient impact on semen parameters. The authors considered long-term prognosis for recovery to be good even though full recovery had not occurred or been documented in any subject by the 145-day mark[clxxxvi]. In contrast, a study measuring sperm parameters in 47 subjects before vaccination and at approximately 70 days post second Pfizer Covid-19 vaccine dose, did not find any significant differences[clxxxvii].

xii. protect against Long Covid

It is unclear if the vaccines have any protective effect against long Covid – there are suggestions that long Covid is either chronic Covid infection or chronic spikeopathy – the negative effects of the spike protein from either infection or vaccination. Long Covid seems to be more prevalent in the vaccinated population but there are no reliable statistics, so this point remains nebulous. However, if long Covid is an effect of the infection or chronic infection, we know that the majority if not all negative effects are caused by the spike protein. It is highly unlikely that converting the human body into a spike production factory will have any positive effect. At best it could cause an immune shift to immune tolerance - the immune response after the initial modRNA vaccine injection mainly causes production of proinflammatory subclasses IgG1 and IgG3, however, from the second vaccination, spike–specific antibodies are increasingly composed of noninflammatory IgG4[clxxxviii]. This would remove the symptoms of disease or long Covid without affecting the root cause. A third modRNA injection and/or SARS-CoV-2 variant breakthrough infection seems to boost this shift towards IgG4. Among all spike-specific IgG antibodies they rose, on average, from 0.04% shortly after the second vaccination to 19.27% late after the third vaccination. Increasing IgG4 is associated with

rising immune tolerance towards SARS-CoV-2 spike protein. IgG4 blood levels are generally elevated in individuals after chronic or recurrent exposure, e.g., a desensitization program.

This could indicate that there is no elimination of the spike protein by the immune system, but instead a tolerance is developing such as in overexposed individuals after an allergen desensitization program. This could allow the spike-induced inflammation to continue unabated but also remove all semblance of symptoms of either infection or spikeopathy. While the abating of long Covid symptoms will be a relief to sufferers, if this relief is a result of immune tolerance unwanted and potentially dire consequences are likely. A study from Italy[clxxxix] demonstrates that:

> 'in agreement with other published investigations both natural and spike protein may still be present in long-Covid patients, thus supporting the existence of a mechanism that might cause the persistence of spike protein in the human body for much longer than predicted by early studies. According to these results, all patients with long-Covid syndrome should be analyzed for the presence of vaccinal and viral spike protein.'

xiii. can be safely administered with other vaccines

It is unlikely that administration of mRNA vaccines in combination with other vaccines will change the effects on the injected individual. The genetic vaccines will likely flush the body with spike protein, a reaction that will overshadow that to any other standard vaccine given at the same time. It is improbable that a standard vaccination in combination with SARS-CoV-2 mRNA vaccination will yield results like immunity for the individual, and any immune reaction will probably be drowned out by the reaction to the auto-produced spike protein. Combination of several genetic vaccines – depending on the nucleic acid load and vector used - carries the potential to overload the immune system and cause more serious side effects than the Covid-19 vaccines already do. Since the Covid-19 vaccines themselves have to be deemed unsafe, no combination with additional vaccines will make them any safer. However, I am not aware of any scientific study currently attempting to answer this question.

xiv. do not enter the nucleus of cells

While the government website claims that "it (mRNA) never enters the nucleus…" a study by Sattar et al. clearly demonstrated that, in the context of infection, the spike protein from SARS-CoV-2 has the capacity to enter the cell nucleus[cxc]. The spike protein contains a nuclear localization signal (NLS) not present in other coronaviruses. Evidently, the spike mRNA from SARSCoV-2 co-localized with the spike protein in the nucleus, leading the authors to surmise that the spike mRNA may bind the spike protein to shuttle across the nuclear membrane. While Sattar et al. were focused on SARS-CoV-2 infection, this finding lends weight to further investigations being required of the

modRNA coding vaccines. Further knowledge on the localization of spike protein came following the release of the Nonclinical Evaluation Report from the Therapeutic Goods Administration (TGA)[cxci]. Transfection of HEK293 cells with BNT162b2-RNA, led to the detection of spike protein in the endoplasmic reticulum/Golgi apparatus, as expected, as well as in the nucleus. These data corroborated findings from Jiang et al. (retracted) whereby a His-tagged expression construct of spike protein localized to the nucleus[cxcii]. Thus, considerable doubt is now cast upon the claim that neither the spike nor the modRNA that encodes the spike, enter the nucleus.

xv. do not impact fertility or cause any problems with pregnancy, including the development of the placenta

At a Congressional inquiry organized by US senator Ron Johnson, the lawyer Thomas Renz presented three US military doctors, Drs. Samuel Sigolo , Peter Chambers, and Theresa Long. The doctors had sworn under oath that there was a 300% increase in miscarriages in the military above the five-year average in the first 10 months of 2021 after the Pfizer Covid-19 vaccine was rolled out in December 2020. The inquiry also revealed a 156% increase of children's congenital malformations of military personnel and a 471% increase of female infertility[cxciii].

Monitoring and accounting for spontaneous abortion (miscarriage) is not performed in all countries. For example, under the United Kingdom law, loss of a baby in the uterus, namely miscarriages (under 20 weeks) or stillbirths prior to 24 weeks of pregnancy, are not recorded as deaths. In line with this, miscarriages and related conditions prior to 24 weeks are not classified as fatal by MHRA and the event is considered to relate to the mother rather than the fetus. Because this number would not be included in the total fatality count at the bottom of each Vaccine Analysis Print, we will most likely never know the true incidence[cxciv].

The role of the placenta during SARS-CoV-2 infection has been studied and reviewed by several groups[cxcv],[cxcvi],[cxcvii]. The discovery of IgM antibodies in cord blood, directed against SARS-CoV-2, led to the conclusion that the foetus had been infected with the virus as IgMs are too large to cross the placental barrier[cxcviii]. Indeed, a systematic review and meta-analysis revealed that approximately 3% of neonates born to SARS-CoV-2 positive mothers also tested positive for the virus[cxcix]. However, the vast majority of fetuses did not experience direct exposure to the virus, and in some 50% cases, received IgG antibodies from the mother, via the placenta[cc]. In a more extreme case series, Parcial et al. investigated the placentae of SARS-CoV-2 infected women, who had stillborn babies[cci]. It was found that SARS-CoV-2 spike protein was detected in all these placentas, accompanied by a range of pathogenic changes in the ultrastructure and histology of the placentae. It has been shown that the LNP-mRNA complexes, spike protein and exosomes containing mRNA and spike protein can cross the blood-placental barrier. A Pfizer document, the Pregnancy and Lactation Cumulative review from April 2021[ccii] on human vaccine recipients, reviewed 458 reports of exposure to the vaccine

during pregnancy. These reports included events of spontaneous abortion, induced abortion, uterine contractions, premature rupture of membranes, and fetal death. Under the heading of "Exposure During Pregnancy" they list fetal growth restriction, maternal exposure during pregnancy, prematurity, and neonatal death. A case report by Sookaromdee and Wiwanitkit[cciii] links Covid-19 vaccination to preterm birth at 24- and 28-weeks' gestation.

xvi. cannot affect or combine with human DNA

Both mRNA from SARS-CoV-2 and modRNA from BNT162b2 may be reverse transcribed. Zhang et al. showed that segments of SARS-CoV-2 were integrated in human tissue following infection. One proposed mechanism was via long interspersed nuclear element-1 (LINE-1) activity. Overexpression of LINE-1 had the capacity to drive reverse transcription and integration in a human cell line[cciv]. The authors noted that other integrants did not contain consensus LINE-1 endonuclease sequences, so other mechanisms may also be at play. Compelling data for LINE-1-based activity came when Aldén et al. showed that human liver cells could readily take up BNT162b2, which led to the upregulation and increased expression of LINE-1 in those cells[ccv]. The upregulation of LINE-1 by Pfizer's BNT162b2 modRNA also carries risks of cancer incidence and to embryonic health. Increased levels of LINE-1 can be found in rapidly dividing cells such as cancer cells and embryonic cells. Following the roll out of the modRNA-based vaccines, a new discovery on an old gene was made. Polymerase θ was known for its role in DNA repair, but new data led to it also being ascribed the function of reverse transcriptase[ccvi]. Importantly, the reverse transcription function of Pol θ was comparable to the reverse transcriptase enzyme found in Human Immunodeficiency Virus (HIV) with respect to fidelity, speed, and stoichiometry. Thus, Pol θ represents an additional route through which reverse transcription and integration may occur. This new discovery foreshadows the importance of appropriate safety studies being carried out before the release of a new gene therapy product utilizing modRNA. Together, the studies by Aldén, Zhang and Chandramouly place the modRNA-LNP complex as an agent for the transfer of genetic material[201,202,203]. The risk of sequence integration was further heightened after the discovery of modDNA contamination in both the Pfizer and Moderna products[ccvii]. Sequencing of Comirnaty and Spikevax vials revealed significant amounts of modDNA of varying lengths, which far exceeded limits set by the EMA, FDA and TGA. Critically, the findings by McKernan et al. have been independently verified (though not published to date) by three independent laboratories in the field of genome sequencing: Dr Sin Hang Lee's laboratory at Milford Molecular Diagnostics in Connecticut[ccviii], Dr Brigitte Konig's laboratory in Madgeburg, Germany[ccix], and in South Carolina senate testimony and online communications by professor of molecular biology and genetics, Philip J Buckhaults[ccx,ccxi,ccxii], where Buckhaults correctly observes that prior DNA limits were set for naked DNA, and did not contemplate the Pfizer and Moderna products containing synthetic modDNA, being potentially protected by highly efficient LNP transfectants. Commercial production of modified mRNA for modRNA vaccines requires large vats of *E. coli* utilizing plasmid modDNA encoding for the

modRNA sequences required[ccxiii]. One of the alarming discoveries of the modDNA contamination within the Pfizer product, was that the plasmid contained an SV40 promoter, including the SV40 enhancer and the SV40 "origin of replication" sequence ("ori")[205]. This "Ori" makes the plasmid "viable" in a context where an individual is both injected with BNT162b2 while also harboring an SV40 infection. Depending on the demographic population, the prevalence of SV40 infection in humans has been estimated between 2% to 23%[ccxiv]. An additional concern for the partial sequence of SV40, incorporating the promoter and enhancer, is that it is sufficient to drive the modDNA into the nucleus of the cell, thereby exposing it to genomic DNA[ccxv]. The risk of genomic integration of these Pfizer and Moderna modRNA/modDNA products is an ongoing point of debate. The number of modRNA molecules in a 30 ug dose of Pfizer BNT162b2 is 1.3 x 1013 (13 trillion). It has been reported that the number of LNPs per shot is in the range of 10-50 billion[ccxvi]. For simplicity, in the case of 13 billion LNPs, this would equate to approximately 1,000 copies of modRNA molecules in each LNP. According to studies by McKernan et al., where the ratio of RNA:DNA in the Pfizer products could be as low as 9 to 68, using either Agilent Tape Station™ or Qubit™ fluorometry analysis, this equates to approximately 15-100 molecules of modDNA to 1,000 molecules of modRNA in each and every LNP[ccxvii]. Assuming an equal distribution of modDNA molecules amongst each LNP, this suggests that there are approximately 195 billion to 1.3 trillion molecules of modDNA in each bolus injection of BNT162b2. Several studies have attempted to measure rates of integration of DNA in living systems, such as adenoviral delivery in mouse[ccxviii] and transfection of modified DNA molecules in cultured HEK293 cells. Results from Wang et al. demonstrated one integration for every 20–33,000 cells, beginning with 100 billion virus particles in one injection[215]. In the case of Pfizer BNT162b2, 13 billion transfection-ready LNPs equates to 1/10th the number of adenoviral particles, so we could speculate that the rate of integration may be in the range of one integration event per 200–330,000 cells. For BNT162b2 injections, the presence of multiple copies of the modDNA in each LNP are likely to increase this risk of integration. The exact rate of integration is speculative at this stage; however, spike protein has been detected in individuals as long as 6 months after their last dose of Covid-19 vaccine[ccxix]. The issue of the creation of somatic mosaicism in the cells and tissues thus affected must be considered. It is not clear where the BNT162b2 or mRNA-1273 modDNA may integrate in the genome. Given the biodistribution of the LNPs to both ovaries and testes[ccxx,ccxxi], if integration were to occur within or adjacent to oncogenes, there is potential for cancers of the reproductive organs. This would likely compromise the fertility of the individual. To date, several case reports discuss close temporal relationships with Covid injections and blood and lymphoid cancers[ccxxii,ccxxiii,ccxxiv,ccxxv]. Unfortunately, reproductive cell changes can cause events that will not be seen until years later.

xvii. an examination of the designation of these genetic technology products as vaccines rather than genetic technology or gene therapies

The gene-based Covid-19 vaccines fall into a special class of therapeutic agents defined

by the FDA as "gene therapy products"[ccxxvi], such that recipient cells produce antigens for transmembrane expression, or to leave the cell and to secondarily invoke an immune response. By design, therefore, by employing virus-like invasion and hijacking of cellular transcription, both mRNA and adenovector DNA gene-based vaccines cause non-immune cells to become de facto antigen-presenting cells, in their mode of immunogenicity. Therefore, these novel vaccine platforms risk tissue damage secondary to cytopathic autoimmune responses, raised against cells expressing foreign spike antigens. Before the SARS-CoV-2 pandemic, the use of such technology was experimental and mostly restricted to making proteins for the therapy of metastatic cancer. No mRNA vaccines had ever been authorised for public usage prior to the Covid-19 pandemic[ccxxvii] and viral-vector DNA vaccines only had limited use for Ebola, Dengue, and Japanese encephalitis[ccxxviii]. A vaccine according to the definition prior to Covid-19, was a pathogen or part of a pathogen, given in defined amounts with the intention of producing an immune response to the injected substance. The very nature of the genetic mRNA vaccines makes it impossible to predict the amount of spike protein (the actual vaccine, provoking the immune reaction) produced, the number of cells producing it, the number of cells destroyed as a consequence of the immune reaction and the length of time this production will be going on.

An injection of a protective cover containing a nucleic acid that will release its content into any cell it makes contact with is the very definition of gene therapy using a synthetic virus. A nucleic acid carried by a synthetic virus/vector that when injected into a host cell will force said host cell to produce a foreign molecule is called gene therapy or cell transfection.

xviii. an examination of epidemiological and statistical findings by pharmacovigilance departments within Australian governments in relation to the safety of Covid-19 vaccines at the time public statements as to the safety of Covid-19 vaccines were being made

In Australia a similar survey to V-Safe occurred for the Covid-19 vaccines. The National Centre for Immunisation Research and Surveillance (NCIRS), funded by the Department of Health and Aged Care, collected Covid-19 vaccine adverse event data in the active prompted reporting AusVaxSafety database up to end of reporting on 23 January 2023[ccxxix,ccxxx,ccxxxi].

For the Covid-19 vaccines of AstraZeneca, Moderna, and Pfizer, AusVaxSafety received 2,861,538 reports involving at least one adverse event. Of the 6,377,586 adverse event surveys completed, an average of 15% of respondents (956,637) reported missing work, study or unable to perform daily routines post vaccination, and an average of 1.14 in 100 people required a doctor or emergency department attention post vaccination [93-95]. This equates to approximately 48,710 people requiring medical attention from a survey that received reports from 24% of the Australian population. Bardosh et al.[ccxxxii] relied on efficacy data from the Pfizer Covid-19 vaccination booster trial. They found that for

university aged students, to save one Covid-19 hospitalisation (not necessarily ICU or death), 22,000 to 30,000 would need Covid-19 vaccination. But to save one hospitalisation a rate of 18 "very serious" to 98 "serious" vaccine related adverse events would occur. To this day, Australian regulators recommend booster shots with mRNA vaccines, calling them safe and effective. Even in January 2021, after receiving the Pfizer Non-Clinical Evaluation Report, the TGA must have known they were neither. Sadly, it must be stated that there is likely further concerning reports in documents held by regulatory agencies. The TGA continues to withhold data (FOI 2565) or heavily redacts data (FOI 3093) or turns over data found wanting in methods (FOI 2389-06). In the absence of regulatory transparency, researchers must scrutinise any available data provided by the sponsors to regulators for meeting post marketing legal obligations.

Endnotes: For all answers
Index

Third Answer

A/Prof Peter Parry, Co-Author:

Much of the information provided here is from letters to my employer (Qld Health) that I provided on my final day at work (30 September 2021) and in my first 'show cause' as to why not be terminated letter (2 June 2022). The point I was making in these letters was that evidence of efficacy (Term of Reference (ToR) Y ii & v) and safety (ToR Z) was lacking and hence these gene-based Covid-19 vaccines failed to satisfy informed consent on medical ethical grounds of beneficence and non-maleficence. My PhD thesis and related papers covered the topics of overdiagnosis, overmedication, iatrogenic harms, pharmaceutical industry corruption of medical research and literature, and medical ethics. I would've liked to take a vaccine and kept my job, but ethically could not do so, knowing what I knew at the time – my informed declination of the vaccine was based on information of low efficacy and substantial harms. Evidence supporting that has only been confirmed to a far greater degree in the past two years.

Term of Reference Y parts (ii) & (v): Lack of protection against infection and transmission

By mid 2021, just months after the rollout of the Covid-19 vaccines there were published papers indicating the vaccine neither prevented infection nor stopped transmission. If they partially achieved this, it was insignificant in denting the spread of the Delta variant. The rationale of protecting others via mandates or vaccinating children to protect grandparents is obviated by these published papers and official data and reports.

By as early as May 2021 the media reported a clear trend of vaccine failure to stop transmission. As reported on Forbes.com "Some countries with the highest vaccination rates are facing a surge in Covid deaths and infections – experts say complacency is

partly to blame", because the article surmised one reason being the public had a "false sense of security" vaccination would protect them from infection.

The viral loads of SARS-CoV-2 are reported as similar in vaccinated as unvaccinated for the Delta and Omicron variants.

Dr Anthony Fauci, head of the National Institute of Allergy and Infectious Diseases (NIAID), stated publicly (reported on 1 August 2021 – well before mandate deadlines were enforced) that the viral load in the noses of fully vaccinated people was "almost identical" to that in the noses of unvaccinated people in the case of the Delta variant.

On 5 August 2021 Dr Rochelle Walensky, director of CDC, stated that the vaccines "continue to work well with 'Delta' with regard to severe illness and death, but what they can't do anymore is prevent transmission". See full transcript of the CNN interview.

Doctors Fauci and Walensky based their views partly on official CDC data from a Massachusetts Covid-19 outbreak where the majority were fully vaccinated in line with the rate of vaccinations in the area.

A Wisconsin, USA, study in June/July 2021 found no difference at all in viral load by PCR test cycle threshold (Ct) data between 310 fully vaccinated and 389 unvaccinated individuals: Testing found high viral load in 68% of the fully vaccinated and 63% of the unvaccinated. A smaller asymptomatic group were more likely to be carriers of high viral load if they were fully vaccinated (82%) versus unvaccinated (29%). This data suggests that vaccinated people are more likely to be asymptomatic spreaders of SARS-CoV-2. This study was first published as a preprint online on 31 July 2021, again well before mandate deadlines were enforced. It is now published in the respected journal *PLoS Pathogens*.

A study published in the prestigious journal *The Lancet* online as early as 29 September 2021 showed significant breakthrough Delta variant Covid-19 infections and thus failure to prevent infection and transmission from the AstraZeneca vaccine. It was conducted in the Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam, amongst staff who'd been fully vaccinated with the AstraZeneca vaccine two months earlier – and hence at peak vaccine-provided immunity – found staff had 251 times the viral load of Delta in their noses compared with data from earlier SARS-CoV-2 strains in 2020 when unvaccinated. There were no 2021 unvaccinated hospital staff to compare the Delta outbreak with, but the higher viral load could be hypothesised to be either a feature of the Delta variant compared with earlier variants, or enhanced carrier status from being vaccinated. All 69 hospital workers tested (who had rapidly contracted the virus from a patient) recovered, only one required oxygen, most were relatively asymptomatic.

On 14 July 2021 media reported that over 100 personnel of the fully vaccinated crew of the British Royal Navy flagship contracted Covid-19 . In Gibraltar there was a large

wave of Delta variant despite a 118% vaccination rate (99% residents plus day workers from Spain). The 18 November 2021 article was titled "Christmas celebrations cancelled in most vaccinated area in the world as cases spike".

A large study published in the high impact factor journal *European Journal of Epidemiology* examining patterns of vaccination and Covid-19 cases across 68 nations and 2,947 United States counties found *no relationship* between vaccination rate of the population and case numbers. There was a non-statistically significant trend for higher vaccination rates to correlate with higher infection rates. This study was published 30 September 2021, ironically coinciding with the enforcement of mandates in many places of employment in Australia.

A British study in the high ranking journal *Nature Medicine* published 14 October 2021 found some Pfizer and AstraZeneca vaccine efficacy for reducing transmission but it fell with Delta compared with Alpha variants, and was inferior for those without natural immunity from past infection. Natural immunity was superior. Vaccinated individuals had nasal viral loads similar to unvaccinated individuals. This article was critiqued for over-estimating vaccine efficacy.

Three papers in *The Lancet* summarised more data and studies that the Covid-19 vaccines do not prevent transmission of SARS-CoV-2, they were titled:

- "Covid-19: stigmatising the unvaccinated is not justified". on 20 November 2021. This paper reported that UK and German data showed a progressive loss of vaccine efficacy that moved into negative efficacy after some months.
- "Breakthrough infections with SARS-CoV-2 omicron despite mRNA vaccine booster dose" on 18 January 2022.
- "Transmissibility of SARS-CoV-2 among fully vaccinated individuals" in January 2022.

The above studies and reports were published early – all by January 2022, giving ample reasons to withdraw mandates, to acknowledge the superiority or at least equivalence of natural immunity. Since then, many more articles in the published medical literature confirmed the lack of protection from infection and transmission. A list of 71 articles is compiled on the Brownstone Institute website.

A further list (with some overlap) of 162 published peer-reviewed papers indicates the equivalence or superiority of natural immunity compared to vaccine immunity. A 28 October 2021 systematic review of the literature, without even considering adverse events of the vaccines, concluded natural immunity was equivalent. An article in the *BMJ* related *Journal of Medical Ethics* concluded that "vaccine mandates [are] not justified".

Therefore, health authorities' claims that vaccines prevent transmission are not supported

by the evidence. The claim that they reduced transmission applied to some extent for earlier variants such as the Alpha variant but no longer applied for the Delta variant dominant in the latter part of 2021, and the Omicron variant present in Australia since December 2021. The medical basis for mandates evaporated by mid 2021 and the rationale for vaccinating children to save grandparents was disproven before the early 2022 provisional authorisation for children. This is separate to the mandates being challenged on human rights and religious grounds.

Term of Reference Y part (iv): the Covid-19 vaccines stay at the injection site

They don't.

The Japanese drugs regulator (PMDA) asked Pfizer to do a rat biodistribution study. This showed the lipid nanoparticle (LNP) envelope that carries the mRNA transfected all organs in the rats' bodies, the ovaries were particularly affected. See page 6 & 7 of the linked document. That study was never formally published in a medical journal. It was discovered through a FOI request to the PMDA and made known publicly by virologist-vaccinologist A/Prof Byram Bridle of Guelph University, Canada on 28 May 2021. Note that this important information was early in the vaccine rollout. By June 2021 this study had been reported on the internet and increased the educated hesitancy to these novel genetic vaccines among people who understood the implications.

A later FOI request to the TGA indicates that the TGA was aware of this biodistribution study as it posted a table on page 45 of a January 2021 TGA document on the eve of the vaccine rollout. But this information was not released to clinicians or the public and hence informed consent on this critical issue was denied. We discussed this in section 6.2 in our peer-reviewed paper in a PubMed listed journal Biomedicines, titled: "'Spikeopathy': Covid-19 spike protein is pathogenic, from both virus and vaccine mRNA". We republish the table of the Pfizer rat biodistribution study that only lasted 48 hours and some organs were still seeing rising titres of LNP, as per Figure 5 in our paper, noting it is Table 4.2 on p. 45 in the TGA January 2021 document.

Table 4-2. Mean concentration of radioactivity (sexes combined) in tissue and blood following a single IM dose of 50 µg mRNA/rat

Sample	Total Lipid Concentration (µg lipid equiv/g (or mL))						
	0.25 min	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181
Adrenal glands	0.27	1.48	2.72	2.89	6.80	13.77	18.21
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687
Bone marrow (femur)	0.48	0.96	1.24	1.24	1.84	2.49	3.77
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112
Heart	0.28	1.03	1.40	0.99	0.79	0.45	0.55
Injection site	128.3	393.8	311.2	338.0	212.8	194.9	164.9
Kidneys	0.39	1.16	2.05	0.92	0.59	0.43	0.42
Large intestine	0.013	0.048	0.09	0.29	0.65	1.10	1.34
Liver	0.74	4.62	10.97	16.55	26.54	19.24	24.29
Lung	0.49	1.21	1.83	1.50	1.15	1.04	1.09
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.366
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.26
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253
Small intestine	0.030	0.221	0.476	0.879	1.279	1.302	1.472
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112
Spleen	0.33	2.47	7.73	10.30	22.09	20.08	23.35
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.000
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456
Whole blood	1.97	4.37	5.40	3.05	1.31	0.91	0.42
Plasma	3.96	8.13	8.90	6.50	2.36	1.78	0.81
Blood:plasma ratio	0.815	0.515	0.550	0.510	0.555	0.530	0.540

The full reference for the TGA document is:

> Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATY). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd. Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf

Novavax, although being a protein-based antigen vaccine as many traditional vaccines are, embeds a full-length (and thus pathogenic) SARS-CoV-2 spike protein in a LNP matrix. This LNP matrix might be leading to movement of the Novavax spike protein through the body and away from the injection site in the deltoid muscle. This could explain cases of myocarditis and other adverse events reported from the Novavax vaccine. In my research into what would be a safe vaccine I emailed Novavax in mid-2021 asking if they were going to do a biodistribution study given their use of LNP. They replied in correspondence dated 30 July 2021, stating:

- Information about biodistribution: A pharmacokinetic/pharmacodynamic study has not been performed on the Novavax Covid-19 vaccine. Please contact Novavax Medical Information after the vaccine is approved and/or authorized for use by the FDA or any countries' regulatory body.

The AstraZeneca and Johnson & Johnson adenovector DNA vaccines also appear to travel through the blood stream due possibly to their adenovirus shell and enter cells in the cardiovascular and nervous systems to produce spike proteins far from the deltoid muscle injection site, and hence the adverse events such as blood clots associated with them, for which they've been withdrawn from the market.

Endnotes: For all answers
Index

Reference: Z

Index

A systemic analysis of peer reviewed and published scientific studies (including preprints), including studies published by overseas health authorities in 2021, 2022, 2023, and 2024 suggestive of adverse health outcomes in recipients of Covid-19 vaccines, and where shown, a comparison with published scientific studies of adverse health outcomes for any other therapeutic treatments of prior historical concern.

Explanatory Memorandum

Index

An examination to confirm the extent of Covid-19 vaccine adverse event studies and case reports, when they first emerged and in what numbers and on what medical topics, and the extent to which such studies and reports were being considered by Australian health authorities and were being shared with the Australian public.

For example, what analysis did the TGA undertake and what considerations were made upon receiving advice from Norwegian Health authorities regarding deaths of elderly in nursing homes following vaccination with Pfizer vaccine.

And a review of the extent to which Australian governments and authorities communicated independent studies with the Australian public.

Question(s) on Notice

Index

In respect of **Reference Z**, please provide any further information concerning peer reviewed and published scientific studies (including preprints), including studies published by overseas health authorities in 2021, 2022, 2023, and 2024 suggestive of adverse health outcomes in recipients of Covid-19 vaccines, that were readily accessible to Australian health authorities.

Answer(s)

Index

First Answer

Dr Astrid Lefringhausen, Co-Author:

In respect of 2021, our September 2022 publication *Covid-19 vaccines – An Australian Review*[ccxxxiii] cites 94 publications from around the world, 70 of which are from 2021 or earlier and were therefore freely available, as well as a compilation from January 2022 by the "Save us now" organization in the UK covering 1,011 case studies reporting side effects after vaccination.

As reported on the Childrens Health Defence Europe website, the EU's European Medicines Agency (EMA) Periodic Safety Update Report (PSUR#1) covering the first 6 months of 2021 rollout of the Pfizer vaccine, showed:

- 327,827 case reports (individuals) containing 1,172,887 adverse events
- Three times more cases reported for women than for men
- Highest number of reported cases in the 31 – 50 age group
- 44% of case reports were classified with outcomes as either unknown or unresolved
- 84% of case reports had no history of comorbidities
- 5115 deaths occurred after vaccine was administered
- 46% of fatal outcome cases occurred in those without any comorbidities

All these reports and scientific studies were available on the internet.

By the end of 2022 there were well over 2,500 studies published worldwide, covering Serious Adverse Events (SAE) and deaths following Covid-19 vaccinations. Our August 2023 publication 'Spikeopathy': Covid-19 spike protein is pathogenic, from both virus and vaccine mRNA[ccxxxiv] cites 253 publications and scientific papers only 40 of which are from 2023.

The Covid-19 Mortality working group published their analysis of excess deaths in Australia in November 2022 showing over 17,900 excess deaths, only half of which can be connected to Covid-19 via the death certificate (which may indicate died with Covid-19 not of Covid-19). The volume of publications on SAEs has steadily increased since then.

The first Cleveland study of 51,017 working-aged Cleveland Clinic employees came out in late 2022 and showed the vaccines were ineffective when the XBB lineages were dominant[ccxxxv]. In 2023 a new study covering 48,344 working-aged Cleveland Clinic employees was published, showing those not "up-to-date" on Covid-19 vaccination had a lower risk of Covid-19 than those "up-to-date". They concluded that "the current CDC definition provides a meaningless classification of risk of Covid-19 in the adult population"[ccxxxvi].

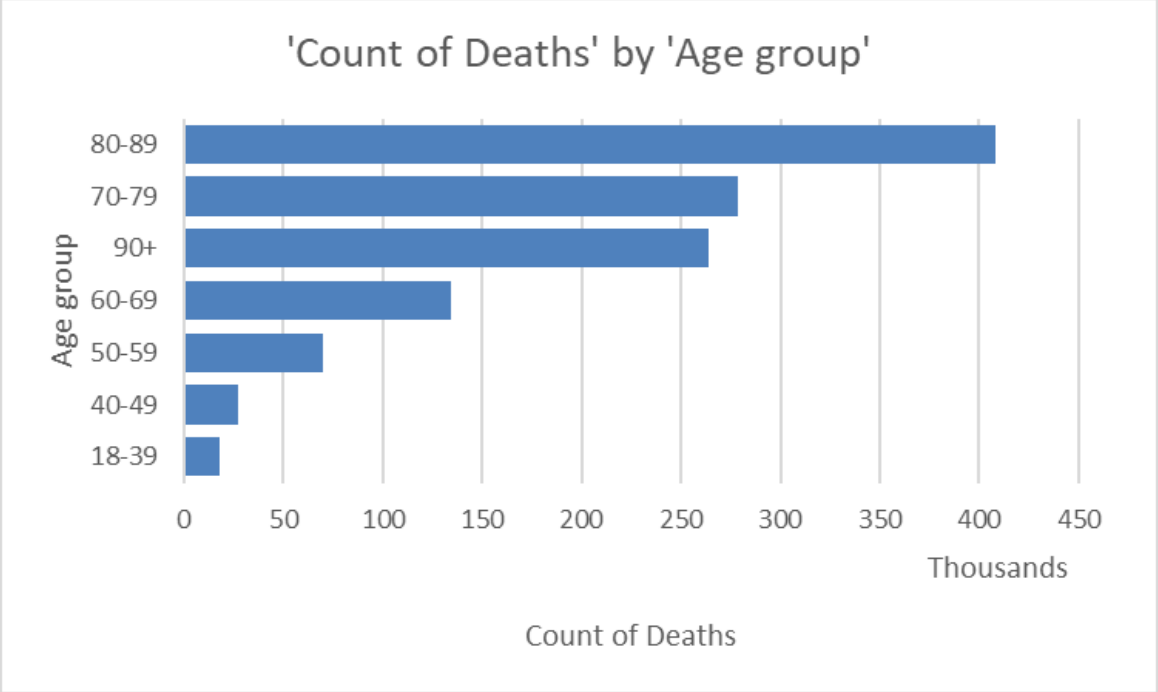
There are now well above 3500 publications worldwide regarding Covid-19 vaccination

related SAEs, many of them NIH sponsored.

The ONS, England's Office of National Statistics is one of the very few health agencies publishing deaths by vaccination status (Deaths by vaccination status, England - Office for National Statistics).

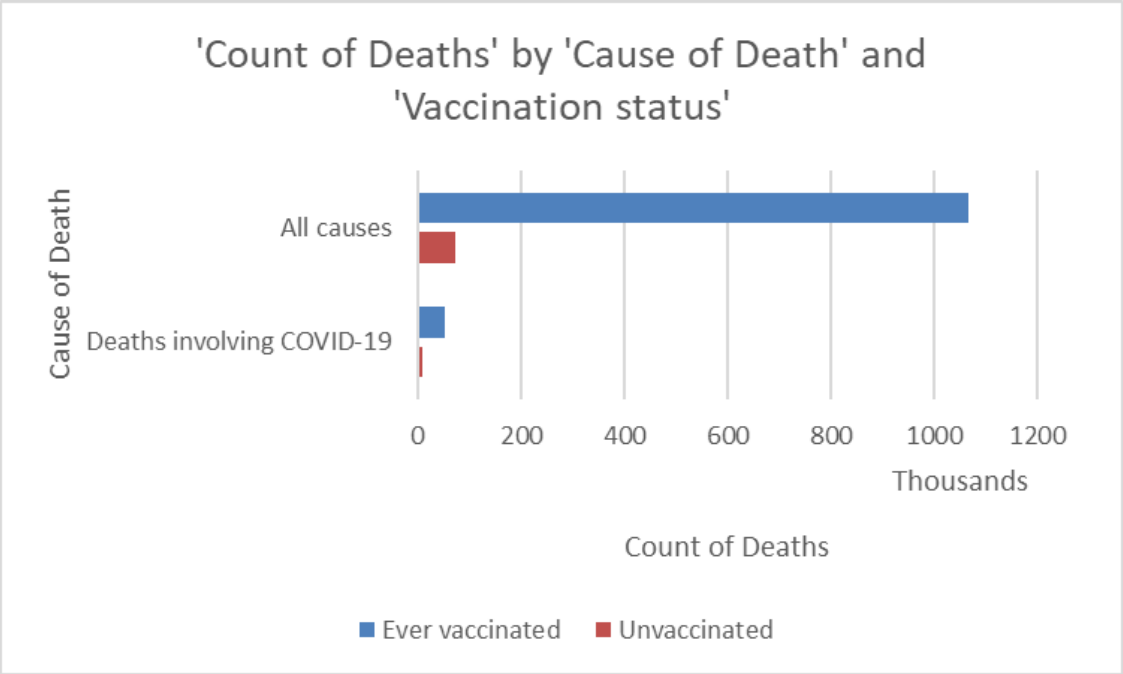
Currently data from 1 April 2021 up to 31 May 2023 is available in excel format. The latest excel file covering data for this entire period summarizes on table 5 deaths per month by age group, vaccination status and for all causes versus caused by Covid-19. Altogether 1.2 Mn people died in England during those 2 years of all causes, and as expected, almost 1 Mn or 80% of them were above 70.

Age group	Sum of Count of Deaths
80-89	408601
70-79	278325
90+	263849
60-69	134418
50-59	70073
40-49	27272
18-39	17775
Grand Total	**1200313**



Count of deaths by cause of death and vaccination status however paints a slightly different picture, it compares death by vaccination status and clearly shows there was a pandemic of the vaccinated.

Sum of Count of Deaths Cause of Death	Vaccination status Ever vaccinated	Unvaccinated	Grand Total
All causes	1065843	73659	1139502
Deaths involving COVID-19	51970	8841	60811
Grand Total	**1117813**	**82500**	**1200313**



The vaccinated make up 1,117,813 or 93% of the total 1,200,313 deaths in England over the 2-year period observed. Deaths involving Covid-19 are only 60,811 but 51,970 of them or 85% are in the vaccinated. Roughly 30% of the English population refused any Covid-19 vaccination, but the percentage of unvaccinated in the deaths overall is 15% for deaths involving Covid-19, 7% of total deaths. If the vaccines were safe and effective, the numbers would be reversed.

All this information cited above is freely available and easy to find. It is inconceivable that Australian health authorities are not aware of it.

Endnotes: For all answers
Index

Second Answer

A/Prof Peter Parry, Co-Author:

The controversy over the Covid-19 vaccines has much to do with their novel gene therapy technology mechanism of action. They involve the insertion into our cells of gene codes to produce the foreign protein, the spike protein of the SARS-CoV-2 virus.

The immunisation effect is secondary in that our cells that happen to be transfected by the gene codes produce spike proteins that are then extruded on the outer cell membrane where they attract our immune white blood cells (T and B lymphocytes) that form an immune response. This response would attack any of our cells making the spike protein. This is what happens when a virus enters our cells and replicates. It is also why it is not incorrect to refer to the mechanism of action as primarily a gene therapy.

Essentially these gene-based vaccines act as 'synthetic viruses' which is what we argued in our literature review paper: "'Spikeopathy': Covid-19 Spike Protein is Pathogenic, from Both Virus and Vaccine mRNA". Our review was published in August 2023 but among the 253 references we cited were many medical journal papers from much earlier in the pandemic that pointed to the risks of harms from these gene-based vaccines as well as the toxicity of the lipid-nanoparticles (LNP) for transporting mRNA across human cell membranes.

A similar literature review by Swiss/German authors published on 3 May 2023 with 448 references of which about 90 overlapped with our references, coined the term "Post Covid-19 Vaccine Syndrome" (PCVS) and many of the papers of the harms of the Covid-19 vaccines it cited were from 2022.

As early as 17 September 2022 an Italian review of the literature titled "Understanding the Pharmacology of Covid-19 mRNA Vaccines: Playing Dice with the Spike?" also outlined the risks of harms of these vaccines due to their mechanism of action.

All three of these review articles are in reputable PubMed listed journals.

Pfizer and Moderna Covid-19 vaccines use mRNA codes that directly produce spike proteins in our ribosomes within our cells. The mRNA has been modified with N1-methylpseudouridine replacing the natural nucleic acid uridine. This was to stop rapid degradation. The problem is as we review the literature in section 6.3 of our review – it works too well and there is evidence of modified mRNA producing spike proteins months after vaccination.

The lipid-nanoparticle carrier envelope encasing the mRNA is to get it to traverse the cell membrane of muscle cells in our deltoid muscle to produce the spike proteins. However, the LNP is like the N1-methylpseudouridine, too efficient. It passes through all membranes in the body and transports the mRNA to cells in all organs including the brain and can cross the placenta. See answer to Question on Notice for Reference Y iv.

The AstraZeneca and Janssen (Johnson & Johnson) vaccines use DNA codes for the SARS-CoV-2 spike protein and this means they enter cells, make mRNA which then goes to the ribosomes and makes spike proteins just like the Pfizer and Moderna vaccines. To get the DNA inside our cells it is protected and encased in the shell of an adenovirus. Once again, that delivery mechanism has been too efficient, taking the DNA

codes beyond the deltoid muscle into the blood stream and to cells around the body, notably causing blood clots for which most jurisdictions have now removed those two vaccines.

All four gene-based Covid-19 vaccines had their phase III randomised placebo controlled clinical trials published in the prestigious *The New England Journal of Medicine* just days to weeks before being emergency use authorised by the FDA in the USA and provisionally authorised by the TGA here in Australia and similar drugs regulatory agencies in other nations. The AstraZeneca study was published online on 16 December 2020, Pfizer study on 31 December, Moderna study 4 February 2021, Johnson & Johnson (Janssen) on 16 June 2021.

These were all interim reports on ongoing RCTs not due for completion for over a year, although they were effectively aborted by vaccinating the placebo participants after several months, 20 weeks in the case of the Pfizer vaccine. Further, the vast majority of authors of these studies declared conflicts of interest of financial income, payments or investments in the respective sponsoring pharmaceutical companies. It is common practice and highly probable they signed non-disclosure agreements with regard to non-published results and methodology.

However, since the scandals of hidden clinical trial data revealed in court cases involving $Billion fines against companies like Johnson & Johnson, Pfizer, GSK, Eli-Lilly, AstraZeneca et al. in the 2000s, there has been an obligation for researchers to post RCT data to the website clinicaltrials.gov. An independent group of researchers analysed the Pfizer and Moderna phase III clinical trial data hosted on clinicaltrials.gov and published in the high impact factor vaccinology journal *Vaccine* on 31 August 2022. This paper by Fraiman et al. is titled "Serious adverse events of special interest following mRNA Covid-19 vaccination in randomized trials in adults" and found – contrary to the impression conveyed by the papers published under the sponsoring pharmaceutical companies in *The New England Journal of Medicine* – that serious adverse events are relatively common. This is despite ostensibly using the same data. As of September 2022, it could be argued that the TGA and similar agencies around the world should've paused the vaccines while examining this paper's findings.

However, the phase III clinical trial data submitted by Pfizer, Moderna and AstraZeneca to the FDA and appearing in *The New England Journal of Medicine*, excluded four known subjects from the vaccine arms of the RCTs who suffered serious adverse events. They include Brianne Dressen who suffered Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in the AstraZeneca RCT; Augusto Roux who suffered myocarditis and neurological and hepatic injuries in the Pfizer RCT; Maddie de Garay who suffered 35 severe adverse events covering multiple organ systems and is paralysed in a wheel chair in the adolescent Pfizer RCT; and Olivia Tesinar who suffered shoulder inflammation warranting surgery, neurological injuries and subsequent lymphoma in the Moderna RCT. Dressen, Roux and Tesinar were totally excluded, and de Garay reported

as Functional Neurological Disorder implying anxiety as causation. Tesinar claims she knows another participant who had a stroke in the Moderna RCT was not reported to the FDA or in the data in *The New England Journal of Medicine* paper.

These cases are presented at the www.React19.org website, set up by Ms Dressen, other Covid-19 vaccine injured and medical professionals. See: https://react19.org/videos-and-podcasts/four-clinical-trial-participants-dearly-discarded-13 . Dressen and Roux's cases are discussed in a paper "The coverage of medical injuries in company trial informed consent forms" in the peer-reviewed *International Journal of Risk and Safety in Medicine* published 4 May 2023.

This indicates the RCT papers in *The New England Journal of Medicine,* from which the "safe and effective" messaging was derived, involved suppression of important adverse events/harms data. This implies fraud and is reminiscent of numerous past scandals involving sponsored clinical trials and medical journals. Past scandals in medical publishing indicate the named authors on these papers could be completely unaware of such suppression of data, which can occur at the level of clinical trial research companies hired by pharmaceutical companies to run RCTs. As reported, on 2 November 2021, in the *British Medical Journal (BMJ)*, in an article titled: "Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial", three whistleblowers gave information to the BMJ that practices occurred in one of the sites of the Pfizer RCT:

> "For researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson (video 1), emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio recordings, and emails."

A notable historical example with some striking parallels was Merck's anti-inflammatory analgesic drug Vioxx (rofecoxib) which is estimated to have caused 38,000 to 55,000 cardiac deaths in the USA for the five years it was on the market. A key publication leading to FDA approval in *The New England Journal of Medicine* had excluded three heart attacks in the Vioxx arm of the RCT. Vioxx was withdrawn after a publication in *The Lancet,* which the FDA tried unsuccessfully to prevent, based on the full RCT data showed it was unsafe due to increased cardiovascular risk. A timeline of the Vioxx scandal published by National Public Radio in the USA provides more detail.

A related issue is that the FDA's pharmacovigilance database recorded 6,636 reports of deaths associated with Vioxx by the time it was withdrawn from the market, yet the estimated real total was 5- to 9-fold greater than this, indicating an *under*-reporting factor for passive pharmacovigilance databases such as VAERS and the TGA's DAEN. This is explored further in Terms of Reference Y.

In terms of published articles on the risks of the Covid-19 vaccines, in terms of their novel genetic mechanism of action, as early as 1 June 2021 for online publication, a German author with genetics and virology expertise, published in *Virus Research*, a reputable Elsevier journal with an impact factor of 5, an article arguing that the possibility of gene code integration into human DNA could not be excluded. The article was titled "Adenoviral Vector DNA- and SARS-CoV-2 mRNA-based Covid-19 Vaccines: Possible Integration into the Human Genome – Are Adenoviral Genes Expressed in Vector-based Vaccines?". At the same time public health messaging and fact-checkers were vigorously discounting this possibility, yet here it was stated as not impossible in a reputable medical journal. The author did err on the side of benefits of vaccination outweighing risks of SARS-CoV-2, but that was while pre-Omicron variants were still prevalent, and his last sentence speaks to unknown future consequences of "possibly novel human ailments in vaccinated individuals".

Other aspects with potential for serious harms related to the novel gene-based technology have been published in recent months. A paper in the prestigious journal Nature, titled "N1-methylpseudouridylation of mRNA causes +1 ribosomal frameshifting", reports that because the N1-methylpseudouridine is a larger molecule than the natural uridine it replaces in the mRNA genetic code, it can lead to misprinting of amino acids in the ribosomes, so instead of perfectly copied spike proteins the ribosomes can produce nonsense proteins with unknown immunological and pathological potential.

A paper published 30 March 2023, "Batch-dependent safety of the BNT162b2 mRNA Covid-19 vaccine", based on all Danish Eudravigilance pharmacovigilance data for the Covid-19 vaccines reported to the European Medicines Agency, sorted the adverse events according to the batch numbers of the vials of Pfizer vaccines (the principal vaccine used in Denmark). The results show an extreme batch variability that suggests extreme deficits in quality control of the mass production of these mRNA vaccines. Just ~4% of batches (blue in graph) accounted for ~71% of adverse event reports, ~32% of batches (yellow) caused almost zero adverse events, the remaining two thirds of batches (green) were in the middle, see figure 1 which is Figure 1 from the paper.

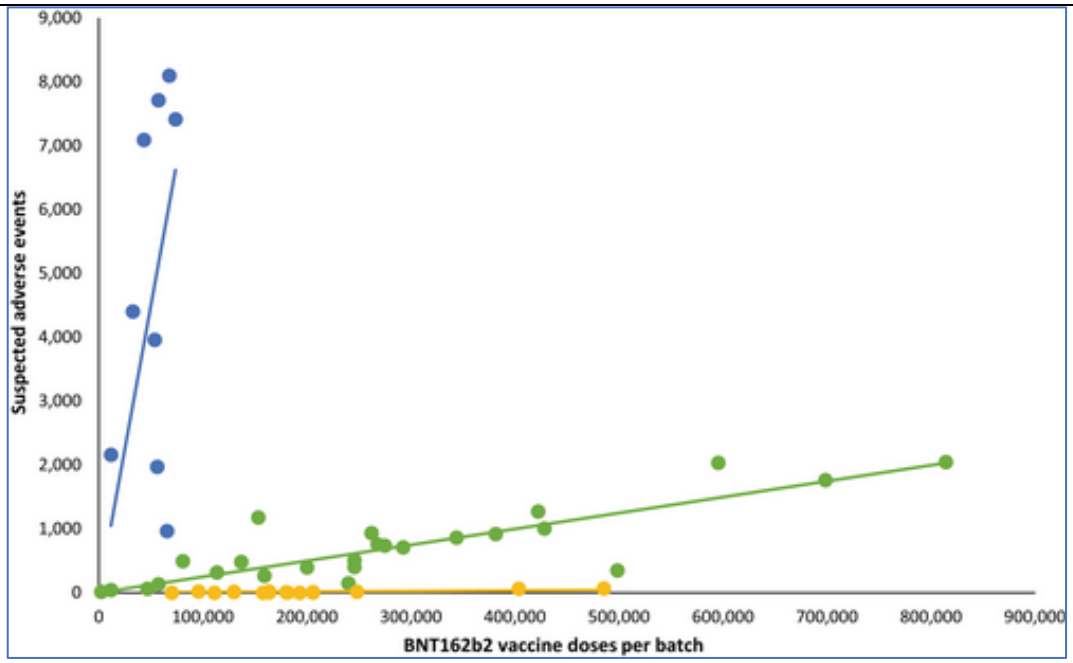


Figure 1: Figure 1 from Schmeling et al. https://onlinelibrary.wiley.com/doi/10.1111/eci.13998

It is now reported that the mRNA used in the RCTs was manufactured by a completely different means to that produced in mass quantities to provide billions of doses to the public. The clinical trials used PCR ('process 1') to accurately produce the mRNA gene code, but in mass production ('process 2') used plasmid DNA in E.coli bacteria in vats to make mRNA which then had to be distilled and decanted from the solution. This appears to have led to contamination of the vaccine vials with plasmid DNA that increases the risk of integration of the DNA gene codes for spike protein (or other proteins from shortened bits of plasmid DNA) into our own cellular DNA. A preprint paper by McKernan et al refers to this issue and is reference 3 in another literature review published 8 February 2024 in *Frontiers in Immunology* titled: "The mRNA-LNP vaccines – the good, the bad and the ugly?" . This review is another indication that as time passes the bigger journals are becoming more open to allowing papers quite critical of the Covid-19 vaccines.

This review by a group of immunologists provides a litany of problems with the mRNA vaccines: the replacement of uridine with N1-methypseudouridine and consequent frame-shifting, the batch variability poor quality control issue, integration of the spike protein gene code into human DNA risk, oncogenic (cancer) risk, they cite Fraiman et al (the independent analysis of the Pfizer and Moderna clinicaltrials.gov data discussed above) that the clinical trials themselves had data of high serious adverse events, they cite a *BMJ* article about European Medicines Agency leak of information about low levels of intact mRNA in Pfizer's vaccine, they refer to VAERS data showing an ~30-fold increase in death compared with traditional vaccines, no value in children citing Swedish data, and criticise the modelling data used to claim vaccines saved many lives. Despite these myriad downsides the tone of the paper softens the critique, which is perhaps why it got published – see more from Dr Kostoff's *TrialSite News* article below.

The review in *Frontiers in Immunology* has a section on "Tolerogenic responses". This is the phenomenon reported by several studies of increasing IgG4 with repeated booster doses of mRNA vaccines. This correlates with impaired immunity to SARS-CoV-2 and higher rates of infection and possibly of Long Covid. A large study of over 50,000 Cleveland Clinic healthworkers found the more boosters, the higher risk of Covid-19 viral infection although there was transient protection in terms of disease severity but not after a new mutation of Omicron appeared. Figure 2 from the article illustrates rising incidence of Covid-19 with doses of vaccine. Another study notes the increase in IgG4 phenomenon applies particularly to the mRNA vaccine technology and warrants more research.

A major narrative review of the peer-reviewed literature and other data sources by Mead et al. in *Cureus* titled "COVID-19 mRNA vaccines: lessons learned from the registrational trials and global vaccination campaign" was published 24 January 2024. The abstract states:

> Our understanding of COVID-19 vaccinations and their impact on health and mortality has evolved substantially since the first vaccine rollouts. Published reports from the original randomized phase 3 trials concluded that the COVID-19 mRNA vaccines could greatly reduce COVID-19 symptoms. In the interim, problems with the methods, execution, and reporting of these pivotal trials have emerged. Re-analysis of the Pfizer trial data identified statistically significant increases in serious adverse events (SAEs) in the vaccine group. Numerous SAEs were identified following the Emergency Use Authorization (EUA), including death, cancer, cardiac events, and various autoimmune, hematological, reproductive, and neurological disorders. Furthermore, these products never underwent adequate safety and toxicological testing in accordance with previously established scientific standards. Among the other major topics addressed in this narrative review are the published analyses of serious harms to humans, quality control issues and process-related impurities, mechanisms underlying adverse events (AEs), the immunologic basis for vaccine inefficacy, and concerning mortality trends based on the registrational trial data. The risk-benefit imbalance substantiated by the evidence to date contraindicates further booster injections and suggests that, at a minimum, the mRNA injections should be removed from the childhood immunization program until proper safety and toxicological studies are conducted. Federal agency approval of the COVID-19 mRNA vaccines on a blanket-coverage population-wide basis had no support from an honest assessment of all relevant registrational data and commensurate consideration of risks versus benefits. Given the extensive, well-documented SAEs and unacceptably high harm-to-reward ratio, we urge governments to endorse a global moratorium on the modified mRNA products until all relevant questions pertaining to causality, residual DNA, and aberrant protein production are answered.

In answering the Question on Notice for Reference Z, one can only provide a few examples a multitude of papers in the peer-reviewed medical literature. There are compilations of thousands of case reports, case series, and studies of Covid-19 vaccine injuries that have been published in medical journals. React19.org has a list of 3,580 such articles sorted into categories of vaccine injury and is easily perused at https://react19.org/science-and-research/published-science-database .

The anonymous clinical academic Dr John B. on Twitter/x.com has over 2,000 posts since June 2021, the majority are of published studies and case reports of Covid-19 vaccine injuries and of underlying pathophysiology of such injuries. This is perhaps the most instructive compilation for Members of Parliament and their staff to peruse as Dr John B. gives pithy quotes and synopses from this literature of hundreds of papers that portray the range and causes of serious adverse events from these gene-based Covid-19 vaccines. See: https://twitter.com/DrJohnB2 . In email communication with me (A/Prof Peter Parry) Dr John B. indicated he would lose his high profile clinical academic job at a US institution if he didn't remain anonymous.

A Dr Ronald Kostoff, who writes for trialsitenews.com performed a systematic literature review in mid-December 2023 using the PubMed search engine for articles on adverse events from the Covid-19 vaccines. He published this at *TrialSite News* titled: "Adverse effects following Covid-19 vaccinations as reported in the Pubmed/Medline literature". The search yielded *6,194* studies and case reports that were sortable into categories of Blood Clotting Disorders, Bleeding Disorders, Cardiovascular Disorders, Skin Disorder, Neurological Disorders, and Autoimmune Disorders.

As Dr Kostoff read through the Abstracts of all these papers, and further into the text if necessary, he noted a pattern of censorship and understating of the risks that contrasted with the actual reported findings of the studies/case reports. His article makes the following opinion on the medical literature which is of interest in considering 'The Science':

> The results obtained in this study should be viewed as the "floor" of the severity and magnitude of adverse events that occurred post-Covid-19 vaccinations, since they are based on a highly flawed and distorted literature. The Pubmed/Medline-based database is no better or more credible than the VAERS database for any Covid-19-related topic, or any other topic that has commercial, political, or military applications. The Medline literature is highly biased, and the extreme censorship of what gets entered into that database translates to strong under-representation of adverse events following Covid-19 vaccinations. The peer-reviewers, Editorial Boards of journals indexed by Medline/Pubmed, Editors, and Publishers of those journals have been fully compromised by what amounts to *bribery* from NIH (and other government) grants, Industry and Foundation grants and contracts, and other revenues from the Covid-19 vaccine promoters.
> We cannot quantify how distorted this literature is, since we do not know what

submissions 1) were rejected after peer-review or 2) never even considered by the journal Editors. These limitations should be kept in mind when reading the results and conclusions from the present study, and in fact from reading results and conclusions from any study based on the mislabeled "independent" peer-reviewed journal literature.

Based on my reading of thousands of Pubmed abstracts on Covid-19 topics over the past four years, there appear to be (unstated) requirements a submitted article needs to fulfill to have any chance of being published in the mainstream biomedical journals, and the severity of these requirements increases with increasing journal Impact Factor. Single adverse events dominate the literature retrieved for the present Op-ed, and the majority of the articles are Case Reports. This helps give the impression to the public that these adverse events are rare, which is strongly emphasized by the Covid-19 vaccine promotors. The submitted article needs to state that the adverse event reported is a rare event. Additionally, the submitted article needs to state that the vaccine is beneficial and has saved many lives and helped avoid many hospitalizations. Analyses showing that the adverse events are not rare are discouraged, and many of the retractions (and probably many if not most of the outright rejected submissions) have occurred when the truth of the severity and widespread adverse impacts are shown in the article.

Conversely, articles that show strong benefits from the vaccine can be published with minimal supporting evidence, while articles showing strong benefits from alternative therapies are routinely rejected. For example, the Lancet paper that halted trials of hydroxychloroquine for Covid-19 was later retracted because the accuracy of the data could not be confirmed. This is but one example of many where a journal allowed publication of a paper showing adverse effects from a known safe alternative to Covid-19 vaccinations based on the flimsiest of evidence. Such actions have occurred so frequently it is difficult to believe they are accidental.

In the PubMed listed Elsevier published journal *Pathology – Research and Practice,* Dr Peter Rhodes, former ICU director, and I summarised the problems of the gene-based Covid-19 vaccines in a wider context that considers bias in the medical literature. Our paper "Gene-based Covid-19 vaccines: Australian perspectives in a corporate and global context" was published 12 December 2023.

A very recent 12 February 2024 paper in the journal *Vaccine* presented disturbing adverse event data from the vaccines. It was titled "Covid-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals" . The study was funded with over $10 million USD of CDC funding, and the disturbing data was presented in unembroidered language. The paper compared observed rates from local hospital electronic records of 13 Adverse Events of Special Interest (AESIs) within the first six weeks of a vaccine dose consisting of serious neurological, haematological and cardiac diseases with

expected rates of those disorders given the number of vaccinated people and doses in areas from eight nations including Victoria and NSW from Australia.

Appendix A to this paper is the supplementary data document and can be downloaded. In the tables red highlighted data indicates an Observed over Expected (OE) ratio >1.5 and yellow highlighted data an OE ratio of >1.0<1.5. Both are where the 95% confidence intervals exceed 1.0. Where the lower 95% CI is <1.0 the result is coloured green even if the calculation is >1.0. A standout is the data from Victoria for myocarditis and pericarditis OE ratios, for example Table 9 shows an OE of 9.26 (myocarditis) and 5.28 (pericarditis) for the second Pfizer dose and 23.71(myocarditis) and 7.62 (pericarditis) for the second Moderna dose. In percentage terms these are increased risks of 926% and 528% (Pfizer), 2,371% and 762% (Moderna). If similar but generally lesser risks from first dose and subsequent booster doses is added, then myo/pericarditis can no longer be termed "rare" in this Victorian data. Variation in data and lesser rates in other jurisdictions may represent less accurate medical records keeping than in Victoria.

Supplementary Table 10. Pericarditis; Aggregated OE Ratios by last dose and site, period 0–42 days

		Overall		Australia:NSW		Australia:Victoria		Canada:BC		Canada:Ontario		Denmark	
Dose	Vaccine	OE_Ratio	CI	OE_Ratio	CI	OE_Ratio	CI	OE_Ratio	CI	OE_Ratio	CI	OE_Ratio	CI
1	ChAdOx1	1.29	(1.15,1.44)	1.01	(0.69,1.42)	3.43	(2.87,4.07)	0		1.80	(1.07,2.85)	2.41	(0.78,5
	BNT162b2	1.54	(1.47,1.62)	1.37	(0.99,1.85)	6.78	(6.15,7.47)	0.27	(0.13,0.50)	1.83	(1.54,2.15)	1.57	(1.24,1
	mRNA-1273	1.74	(1.54,1.97)	-		10.65	(7.61,14.51)	-		2.33	(1.71,3.10)	1.76	(0.96,2
2	ChAdOx1	1.27	(1.12,1.43)	1.11	(0.77,1.54)	3.24	(2.70,3.86)	-		-			
	BNT162b2	1.38	(1.32,1.45)	2.11	(1.63,2.70)	5.28	(4.80,5.78)	0.92	(0.63,1.30)	1.88	(1.58,2.22)	1.43	(1.16,1
	mRNA-1273	1.67	(1.50,1.85)	-		7.62	(5.34,10.55)	1.44	(0.91,2.19)	2.77	(2.26,3.35)	2.53	(1.70,3
3	ChAdOx1	6.91	(3.45,12.36)										
	BNT162b2	1.19	(1.10,1.28)	1.03	(0.47,1.96)	3.29	(2.88,3.74)	1.54	(1.00,2.27)	1.46	(1.14,1.84)	1.50	(1.20,1
	mRNA-1273	1.39	(1.20,1.59)	-		4.69	(3.68,5.90)	1.60	(1.10,2.26)	1.25	(0.91,1.69)		
4	BNT162b2	1.55	(1.30,1.83)			3.00	(2.28,3.89)	2.35	(1.13,4.33)	0.98	(0.61,1.50)	1.09	(0.77,1
	mRNA-1273	2.64	(2.05,3.35)			5.67	(3.82,8.09)	2.47	(1.38,4.07)	1.59	(0.93,2.55)		

Vaccines: Pfizer/BioNTech (BNT162b2), Moderna (mRNA-1273), and Oxford/Astra Zeneca/Serum Institute of

Figure 2: Supplementary table 10 (part thereof) from Faksova et al.
https://www.sciencedirect.com/science/article/pii/S0264410X24001270?via%3Dihub#s0120

The consistently higher adverse event OE for Moderna (100ug mRNA) over Pfizer (30ug mRNA) is consistent with a dose-response effect and fulfills one of the Bradford-Hill causality criteria.

Interestingly Table 13 shows very high OE ratios for Novavax for cardiovascular conditions, i.e. 20.18 dose 1, 39.26 dose 2 (myocarditis) plus 13.73 dose 1 and 33.99 dose 2 (pericarditis), well exceeding Pfizer and Moderna. This is suggestive that the full-length spike protein is conveyed to the heart by the LNP matrix that it is embedded in.

In summary, statements from health authorities and political leaders that 'the Science' says the Covid-19 vaccines 'are safe', or that there is 'no evidence' of widespread harms, are not borne out by a careful analysis of the full published scientific literature. Published data such as the very recent CDC sponsored study, and particularly the health records from Victoria, show a near 50-fold increased risk of myocarditis or pericarditis

by the second booster for Pfizer and ~68-fold risk by the second booster of Moderna. Danish data shows a batch variability problem which may relate to 'Process 2' mass production of mRNA from plasmid DNA in E.coli bacteria in vats, a process not used for the vast majority of vaccinees in the original clinical trials. Quality control failures like this would lead to product recalls if this were a vital engine part for automobiles or aeroplanes.

Product withdrawals are common among pharmaceutical drugs and vaccines. A 2016 study examined product withdrawals due to adverse event reports from 1953 to 2013. It was titled "Post-marketing withdrawal of 462 medicinal products because of adverse drug reactions: a systematic review of the world literature" in the reputable journal *BMC Medicine*. Over a decade ago the tally being 462 products shows withdrawals of such products are not rare, although the study found the regulators have been inconsistent in when they do so. This fact is worthy of consideration with regards to the current products under discussion here.

Index

Reference: AA

Index

A systemic analysis of Covid-19 vaccine adverse event reporting during 2020 to 2023 by:

i. Australian State and Territory governments;
ii. the Therapeutic Goods Administration (TGA) internal database, the Adverse Event Management System (AEMS), and public database, the Database of Adverse Event Notification (DAEN), including an overview of vaccine adverse event data prior to 2020;
iii. the National Centre for Immunisation Research and Surveillance (NCIRS) AusVaxSafety database and the "adverse event of special interest (AESI) long-term follow-up program" for thrombosis with thrombocytopenia syndrome and myocarditis;
iv. the United States Vaccine Adverse Event Reporting System (VAERS), including a brief overview of vaccine adverse event data prior to 2020;
v. the European Medicines Agency EudraVigilance database, including an overview of vaccine adverse event data prior to 2020;
vi. the Medical & Health products Regulatory Agency Yellow Card system, including a brief overview of vaccine adverse event data prior to 2020; and
vii. any studies or programs by Australian government agencies or medical institutes involving the administration to Australians of saline placebos misleadingly labelled as Covid-19 vaccines, with particular reference to records and knowledge of this possible activity held by the Burnet Institute.

Explanatory Memorandum

Index

An examination of local and international adverse event reporting systems in the context of Covid-19 vaccines, and whether the number (or volume) of reporting was historically significant, and the degree to which Australian authorities communicated any historically significant data trends for Covid-19 vaccines to the Australian public.

Question(s) on Notice

Index

In respect of that submission and in particular index **Reference AA**, can you please inform the committee whether adverse event reporting, in terms of side effects and deaths, increased significantly or not after the introduction of Covid-19 vaccines in this

country and around the world?

Answer(s)

Index

First Answer

Dr Jessica Rose, Co-Author:

In answer to Reference AA and the Question on Notice in respect of Reference AA, and in particular (iv) of Reference AA:

> Provide a system[at]ic analysis of Covid-19 vaccine adverse event reporting during 2020 to 2023 by the United States Vaccine Adverse Event Reporting System (VAERS), including a brief overview of vaccine adverse event data prior to 2020.

Brief overview of data in VAERS in context of all vaccines since 1990.

The numbers shown in Figure 1 represent the total numbers of adverse event reports successfully filed on a per-person basis per year for all vaccines combined from 1990-2024. 94% of all reports from 2021 were in the context of the Covid-19 injectable products (Pfizer/BioNTech/Moderna/Janssen).

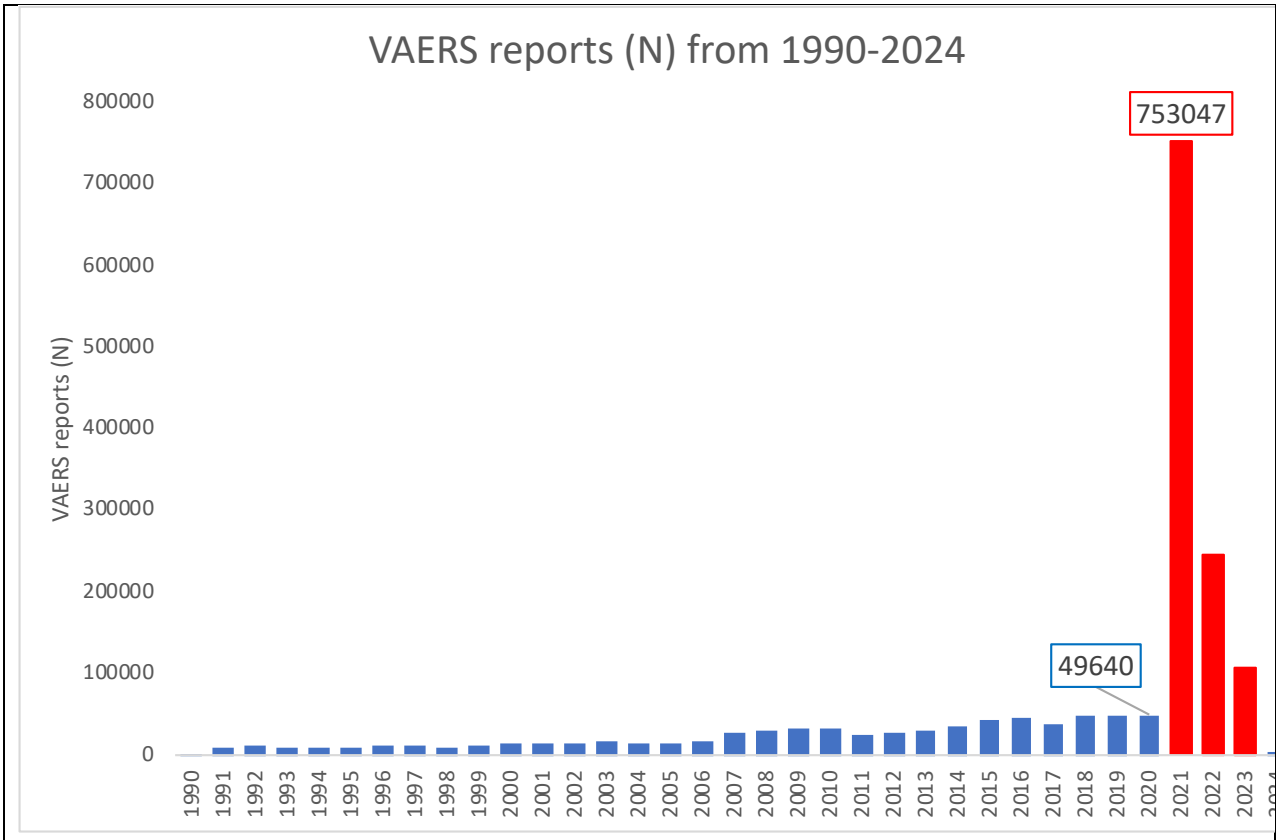
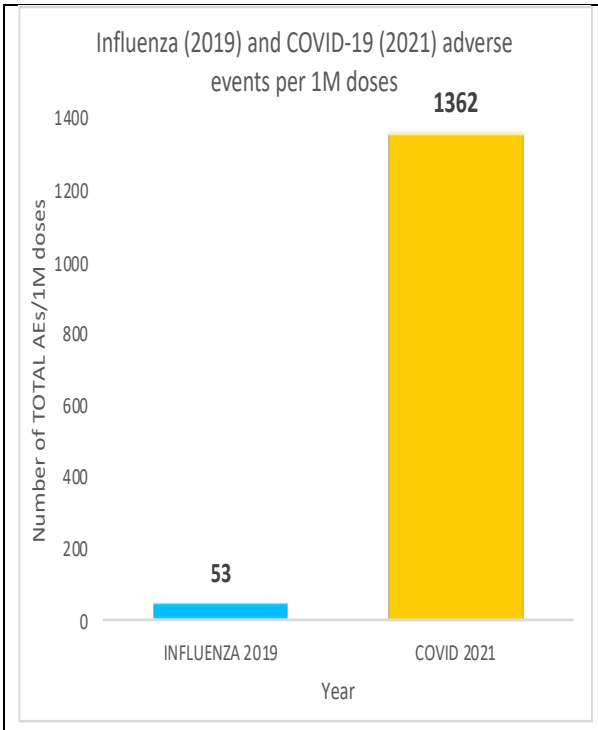


Figure 1: VAERS reports of adverse events for all vaccines combined from 1990 through to 2023.

There was a 1,417% increase in reporting between 2020 and 2021 which has yet to be explained by the CDC, FDA or HHS. This increase is NOT due to increase in the number of shots administered.

Figure 2 shows the number of adverse event reports successfully filed in the contexts of Influenza vaccines in 2019 and Covid-19 injectable products in 2021 normalized to shot number per million doses. It is evident and clear that the increase in the number of adverse events is not due to an increase in shot number. The Covid-19 shots are associated with a 26- (left) and a 100-fold (right) increase in total adverse events and deaths, respectively, when compared per million doses with Influenza vaccines in the same timeframe.



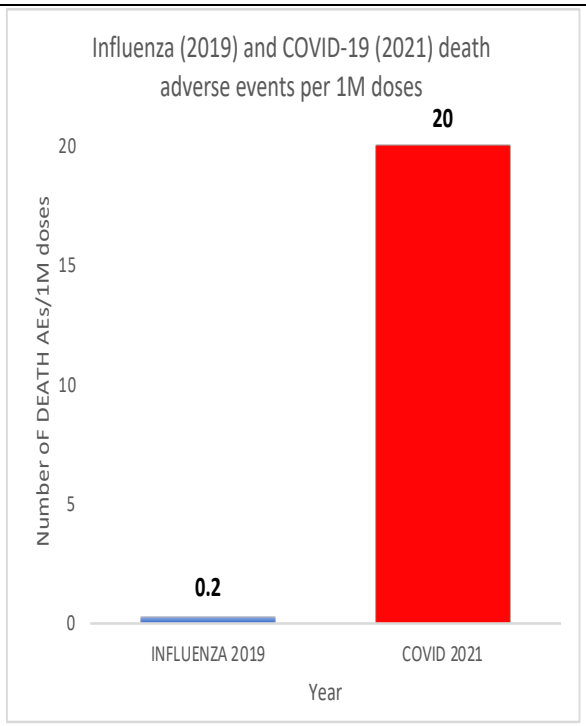


Figure 2: The total number of adverse events, and the total number of deaths filed to VAERS in 2019 in the context of Influenza vaccines and in 2021 in the context of the Covid-19 injectable products per million doses administered each year, respectively.

In addition to the number of adverse event reports filed being significantly higher in 2021, the range of MedDRA-coded adverse event types is also significantly higher. This corresponds well to the comprehensive injuries reported in clinical settings and is likely based on immunological dysfunction induced by the shots.

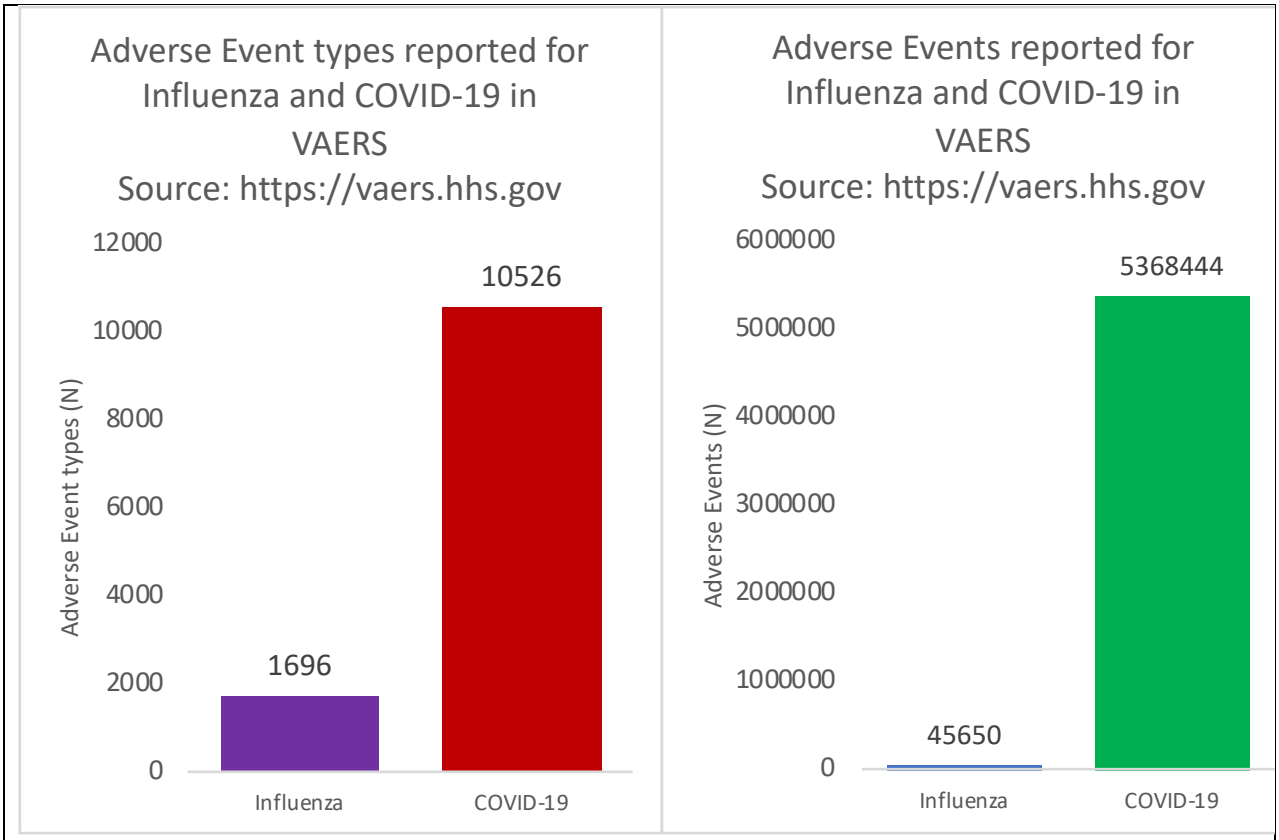


Figure 3: Total number of MedDRA-coded adverse event **types** (left) and total number of adverse events (right) reported to VAERS in the contexts of Influenza vaccine and Covid-19 injectable products from December 14, 2020 through March 25, 2022 (466 days).

As of March 25, 2022, according to the WONDER/CDC system, there were 1,696 different types of adverse events and 45,650 total adverse events reported to VAERS in the context of the 14 variations of flu vaccines. Also, according to the WONDER/CDC system, there were 10,526 different types of adverse events and 5,368,444 total adverse events reported to VAERS in the context of the 3 variations of the Covid-19 products used in the United States. N.B. These counts do not represent the individuals who experienced an adverse event but the total number of events that were reported. This has yet to be explained by the CDC, FDA or HHS.

Our World in Data data for new injections from the initial roll-out date to July 2023, superimposed with myocarditis reports from VAERS for the same dates shows a strong correlation (R=0.8) and a high covariance, as shown in Figure 4. This satisfies the Bradford-Hill Criteria (BHC) (for causality) *reversibility*: when a 'drug' is withdrawn, the 'side effects' disappear. Two more BHC are shown to be satisfied when examining dose data in myocarditis reports, as shown in Figure 5. Dose 2 is associated with a 4-fold increase in reporting of myocarditis in 15-year-old boys demonstrating *specificity* (with regard to age and gender), and this increased signal following dose 2 demonstrates *dose response* (with regard to an increase in signal upon second dosing). A recently published peer-reviewed paper shows that myocarditis is associated with hospitalization in 76% of

reports.[ccxxxvii] Thus myocarditis is NOT transient or mild.

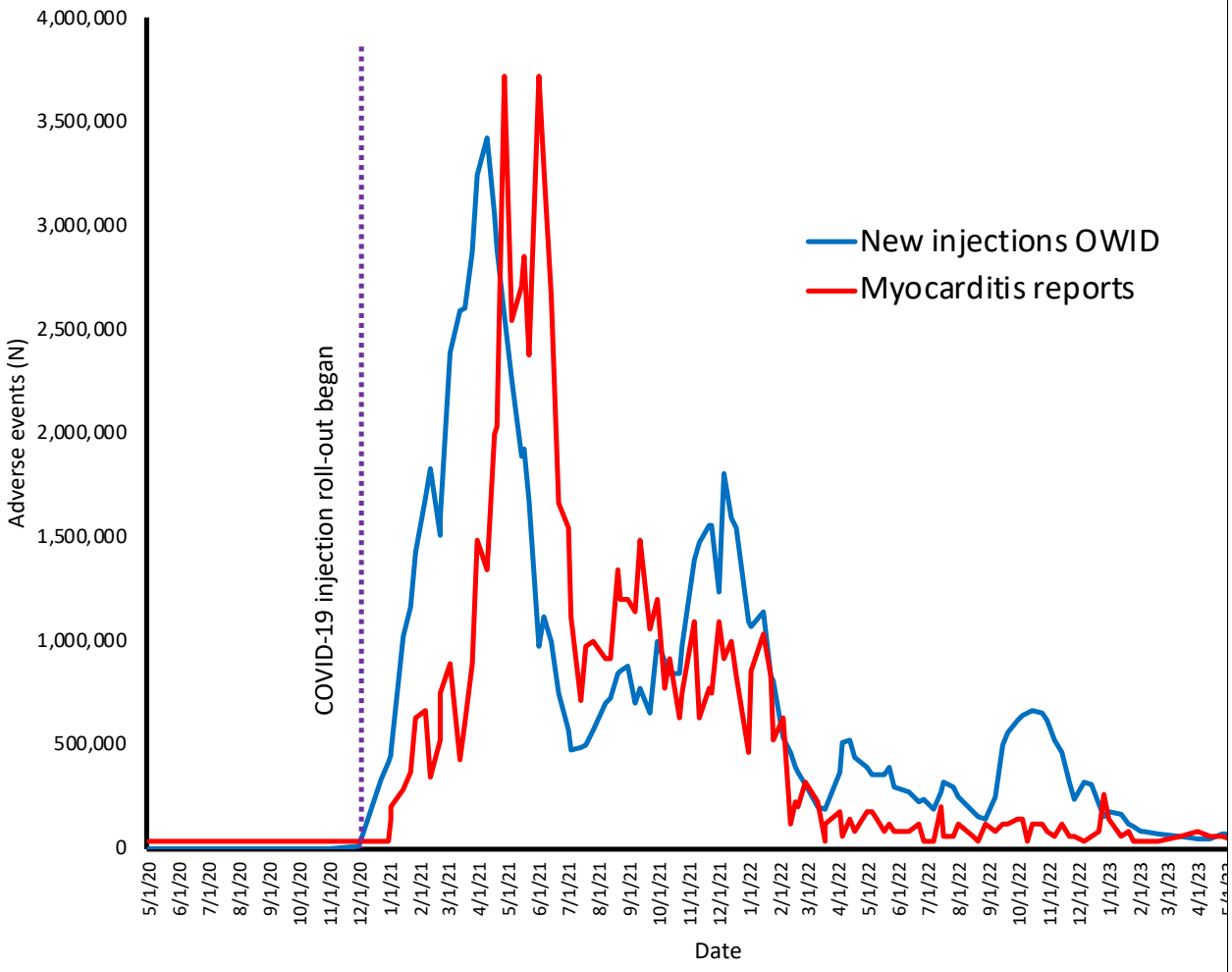


Figure 4: VAERS reports of myocarditis (red) superimposed with Our World in Data 'new vaccinations' (blue) from May 1, 2020 through to July 1, 2023.

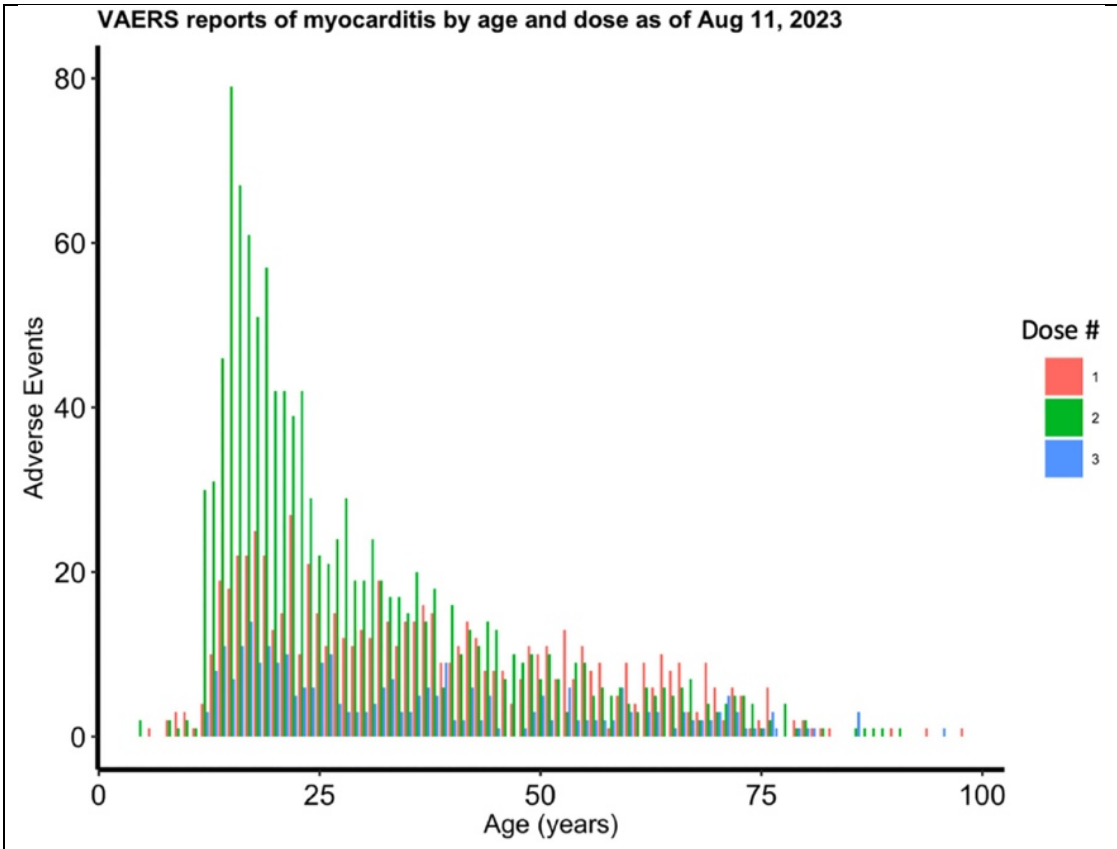


Figure 5: All myocarditis reports in VAERS Domestic Data as of 11 August 2023 are plotted according to age and dose [dose 1 (pink), dose 2 (green), and dose 3 (blue)].

Endnotes: For all answers
Index

Second Answer

Dr Suzanne Niblett, Co-Author:

Dr Jessica Rose has provided some of her findings regarding increases in adverse event reports made to the U.S. based Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The following response will provide an outline of the reports of adverse events made to (i) the Australian Therapeutic Goods Administration (TGA) Database of Adverse Event Notification (DAEN) – medicines system and, (ii) the National Centre for Immunisation Research and Surveillance (NCIRS) led AusVaxSafety system.

The VAERS is the United States early warning national vaccine safety system that monitors the safety of vaccines authorised or licenced for use by the U.S. Food and Drug Administration (FDA) (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html). It is co-managed by the CDC and the FDA.

The TGA DAEN – medicines is a national database that provides information about the adverse events reported in relation to medicines, vaccines and biological therapies used in Australia https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen-medicines. The DAEN-medicines specifically provides information about products "prescribed or dispensed by a health professional with a prescription" and products "purchased from a supermarket, pharmacy or another outlet without a prescription".

The AusVaxSafety system is a national vaccine safety surveillance system led by the National Centre for Immunisation Research and Surveillance. It is a collaboration between immunisation providers, private enterprise, research institutions, state and territory governments and the Australian Government Department of Health and Aged Care specifically set up to assist in the monitoring and detection of vaccine safety events (https://ausvaxsafety.org.au).

All three systems provide post-marketing safety monitoring.

Both the VAERS and the TGA DAEN are passive surveillance systems that rely on the spontaneous, voluntary report of adverse events by a reporter. An advantage of these systems is that anyone can submit a report to VAERS or to the TGA DAEN including health care professionals, vaccine manufacturers and the general public. The disadvantage is that the process of reporting is not always well understood and is time-consuming, factors that can act as barriers to reporting and that may contribute to the well-recognised under-reporting of drug reactions using spontaneous surveillance methods. In regards to the latter, it has been estimated that only 5% to 10% of adverse events are reported (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9635349/ ; https://www.tga.gov.au/news/media-releases/new-web-service-helps-consumer-reporting-side-effects). This may be a conservative figure, with some analyses indicating that the under-reporting factor (URF) may be substantially greater. What would be expected is that the URF is not consistent across a database and would vary depending on the type of adverse event. Despite these complexities, any interpretations of findings from a spontaneous reporting system should consider the impact of under-reporting.

The AusVaxSafety system is an active surveillance system. The AusVaxSafety program follows up people who have received a vaccine by sending them an SMS or email with a short survey asking specifically whether they have had an adverse event following their vaccination. If an adverse event is reported, the AusVaxSafety survey collects information about specific but general adverse events, about medical attendance in relation to the adverse event, and about how the adverse event impacted daily routines. These surveys are sent out on day 3, day 8 and day 42 following vaccination. The advantage of this system is that individuals are actively followed up regarding their post-vaccination experience. The disadvantage is that not all who are vaccinated are able to participate in these surveys. Invitations to participate are restricted to those receiving a

vaccine at state immunisation clinics or by a GP or other immunisation provider who is signed up to the AusVaxSafety active surveillance system (https://ausvaxsafety.org.au/Covid-19-vaccine-safety-surveillance/what-ausvaxsafety-doing). Those receiving vaccines via other sources will not be offered to participate.

Overview of TGA DAEN Data

The total number of adverse event reports (AERs) added to the Therapeutic Goods Administration Database of Adverse Event Notification (TGA DAEN) between 1 January 1971 (the inception of the DAEN – medicines) and 1 November 2023 is presented in Figure 1 for all medicines, vaccines and biological therapies ("all medicines"). Data for this graph was captured for 7 periods all commencing on 1 January 1971 and finishing on 31 December 1980, 31 December 1990, 31 December 2000, 31 December 2010, 31 December 2020, 31 December 2022 and 1 November 2023 respectively.

As shown in Figure 1, the number of AERs listed in the TGA DAEN has risen steadily from 1 January 1971 reaching 414,283 AERs by 31 December 2020. The rate of AERs then increased dramatically and significantly following the introduction of the four Covid-19 vaccines, with 196,152 additional AERs added from 1 January 2021 to 1 Nov 2023. Over 70% of these adverse events were in relation to Covid-19 vaccines and for 97% of those entries, the Covid-19 vaccine was listed as the single suspected medicine.

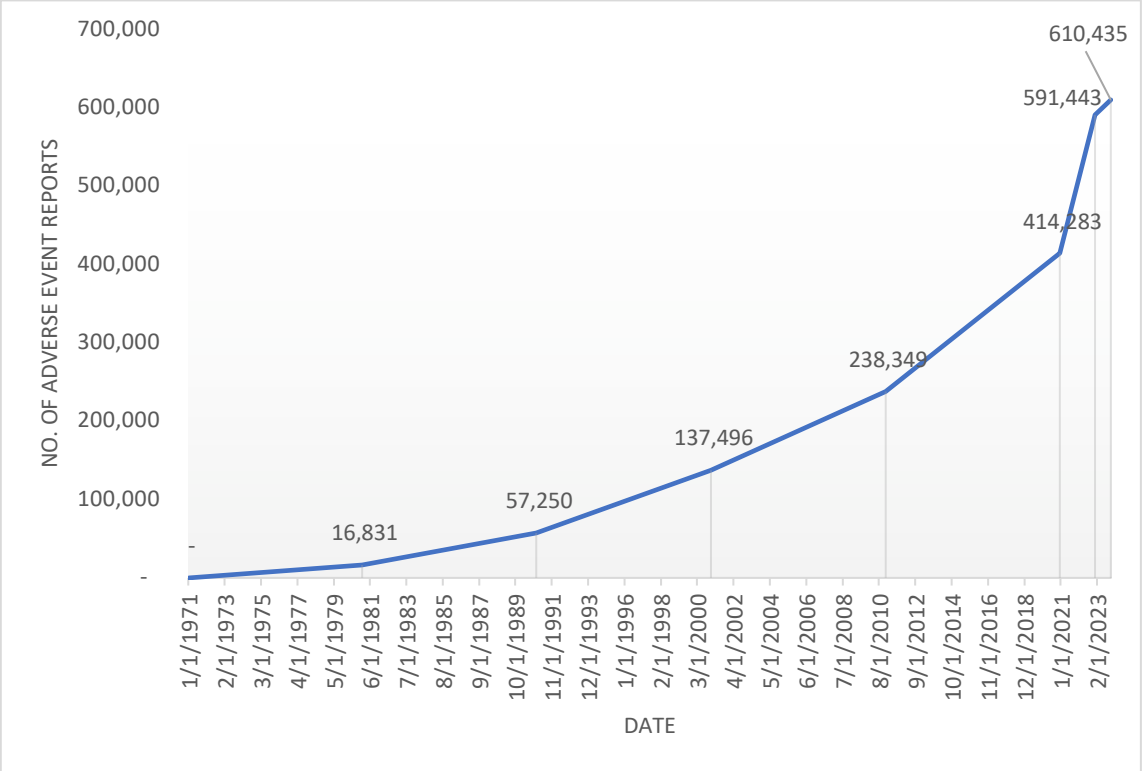


Figure 1: Number of adverse event reports (AER) submitted to the TGA DAEN between 1 January 1971 and 1 November 2023. *Source:* TGA DAEN extracted 15 November 2023.

Figure 2 presents the number of AERs submitted to TGA DAEN each year from 1 January 2009 to 31 December 2022. As shown in Figure 2, the number of AERs submitted in 2021 and 2022 were substantially higher than in previous years. In particular, 2021 annual report rate was approximately 5.7 to 6 times higher than the number of reports reported for 2018, 2019 and 2020. Approximately 83% of the 177,215 reports added during the 2021 to 2022 period listed one or more Covid-19 vaccines as the suspected medicine.

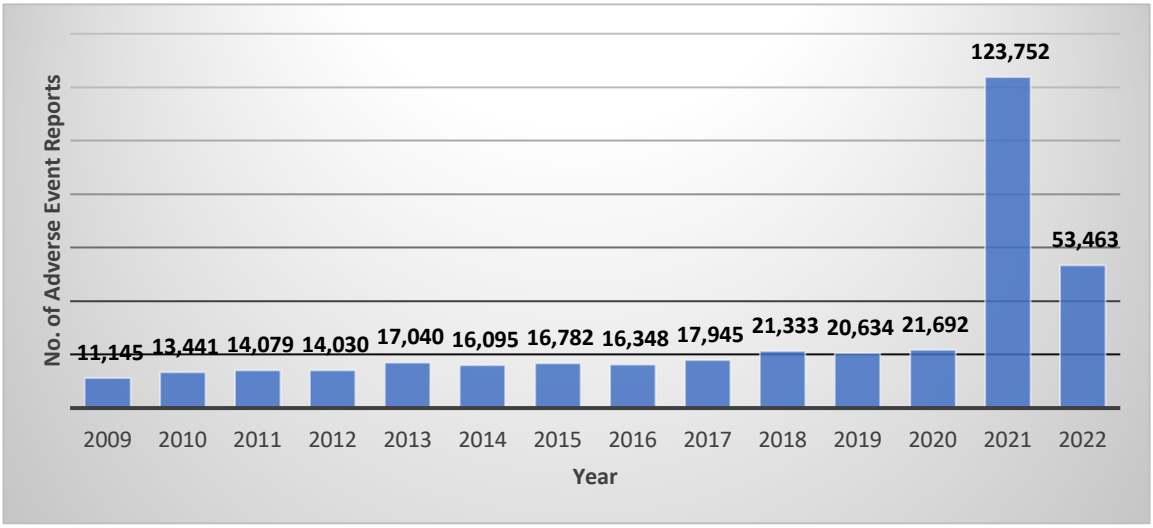


Figure 2: Number of adverse event reports submitted each year to the TGA DAEN from 1 January 2009 to 31 Dec 2022. *Source:* TGA DAEN extracted 13 July 2023.

Figure 3 presents the relationship between the number of AERs submitted to the TGA DAEN from 1 January 2020 to 31 June 2023 that were related to the Covid-19 vaccines compared to the overall number of AERs reported for all medicines, vaccines and therapies ("All medicines"). The graph clearly shows that the AERs related to Covid-19 vaccines constituted the majority of AERs across this period.

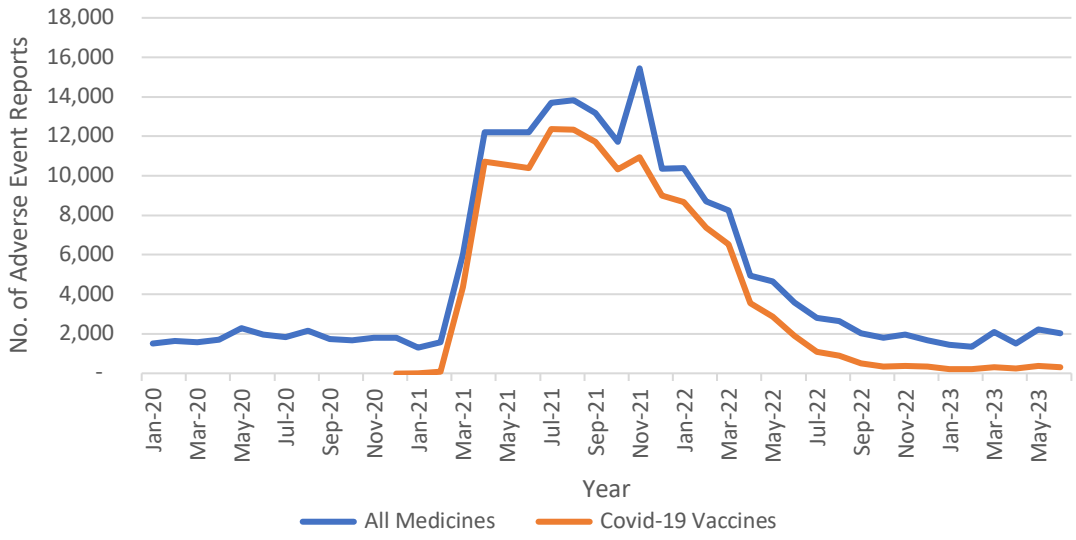


Figure 3: The number of adverse event reports (AER) submitted to the TGA DAEN monthly in relation to (a) one or more of the Covid-19 vaccines between 1 January 2020 to 31 June 2023 and (b) all medicines,

vaccines and therapies used in Australia ("All Medicines").

Figure 4 presents the number of adverse event reports (AER) with an outcome of death submitted to TGA DAEN between 1 January 1971 and 31 December 2022, annualised across 5-year increments from 1971 to 2020 and the 2-year increment for 2021 and 2022. As shown in Figure 4, the number of AERs that reported death as an outcome and that were added to the TGA DAEN in 2021 and 2022 was 61% higher than the average number of AERS associated with death reported annually from 2016 to 2020. In 2021, approximately 52% of the AERS with death as an outcome reported a Covid-19 vaccine as the suspected medicine. Approximately 35% of the deaths across the 2021 and 2022 period reported a Covid-19 vaccine as the suspected medicine.

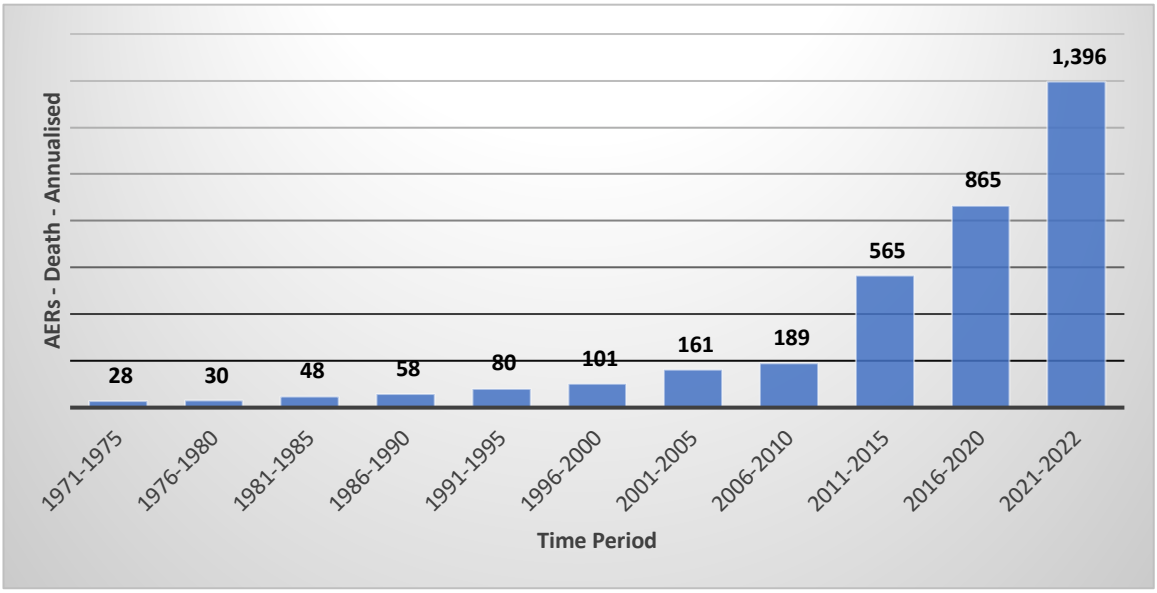


Figure 4: Number of adverse event reports (AER) with an outcome of death submitted to the TGA DAEN between 1 January 1971 and 31 Decembrer 2022. The AER data is annualised across 5-year increments from 1971 to 2020, and the 2 year increment for 2021 and 2022. *Source:* TGA DAEN extracted 15 November 2023.

Table 1 is taken from a larger analysis examining the number of AERs submitted to the DAEN overall, and specifically in relation to the Covid-19 vaccines and influenza vaccines between 1 January 1971 to 28 April 2023. As at the 28 April 2023, there had been a total of 597,936 AERs submitted to the TGA DAEN across the 52-year period with a total of 9,932 different medicine terms listed as suspected medicines. Of these, 138,228 (23.1%) were submitted across just 2.5 years in relation to the Covid-19 vaccines (11 medication terms) with over 97% of the Covid-19 vaccine AERs related to a single Covid medicine. This well exceeded the total number of AER submissions ever made to the DAEN in relation to influenza vaccines (27,135 across 52 years, 4.5% of all AER). The data in Table 1 also shows that Covid-19 vaccines accounted for 7.2% of all deaths ever reported across 52 years. This contrasted the 0.7% associated with the influenza vaccine.

Importantly, it should be noted that over 70% of these cases and deaths occurred prior to 18 December 2021 which is the point at which the rate of Covid-19 infection began to

rise in line with the omicron wave.

Table 1: Number of AERs made to TGA DAEN between 1 January 1971 to 28 April 2023 for all medicines and where influenza vaccines and Covid-19 vaccines were listed as suspected medicines.

	No. of cases	(% of all DAEN cases)	No. of cases where death was outcome	(% of all DAEN deaths)
All medicines *(9,932 medicine terms)*	597,936		13,759	
Covid-19 vaccines (*11 medicine terms)*	138,228	(23.1)	986	(7.2)
Pfizer	*81,275*	*(13.6)*	*437*	*(3.2)*
Moderna	*7,673*	*(1.3)*	*36*	*(0.3)*
AstraZeneca	*48,178*	*(8.1)*	*484*	*(3.5)*
Novavax	*994*	*(0.2)*	*3*	*(0.02)*
Type not specified	*718*	*(0.1)*	*28*	*(0.2)*
Influenza vaccines *(41 medicine terms)*	27,135*	(4.5)	94	(0.7)

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 12 May 2023. *258 of these cases reported both an influenza vaccine as a 'suspected' medicine and one or more Covid vaccines as a 'suspected' or 'not-suspected medicine.

While mass vaccination would be expected to contribute somewhat to the surge in adverse event reports noted, these longitudinal results cannot be substantially discounted based on the number of doses of Covid-19 vaccines administered. The DAEN provides information about adverse events reported in relation to all medicines, vaccines and therapies used in Australia over the last 50 or so years. The annual use of prescribed and over-the-counter medicines and therapies, as well as other vaccines, is significant in Australia. A report by the Australian Institute of Health and Welfare found that in 2020-2021, 314.8 million prescriptions were provided to 16.6 million patients (https://www.aihw.gov.au/reports-data/health-welfare-services/medicines/overview). In a separate national study on prescribed medicine use in Australia on a typical day, the authors reported to find that over a third of Australian use at least one PBS prescription on a typical day and extrapolated these findings to estimate that approximately 9 million people use over 27 million dispensed medicines (https://pubmed.ncbi.nlm.nih.gov/32779806/). Dosage numbers of 62 million across a three-year period with this kind of background use of medication, vaccine and therapies is not remarkable. The level of negative adverse responses to those dosages, however, is.

To further review the issue of dose, Table 2 presents the results of an analysis comparing the absolute risk of adverse events per 100,000 doses of Covid-19 vaccines against influenza vaccines. Consistent with the VAERS data, the rate of report standardised to dose was much higher in Covid-19 vaccines compared to influenza vaccines for AERs overall and for AERs with death as a reported outcome. As shown in Table 2, the absolute risk of an adverse event report was calculated as 189.5 per 100,000 doses of Covid-19 vaccine compared to 11.33 per 100,000 doses of influenza vaccines. This converts to a relative risk of 16.7 indicating that AERs were reported 16.7 times more

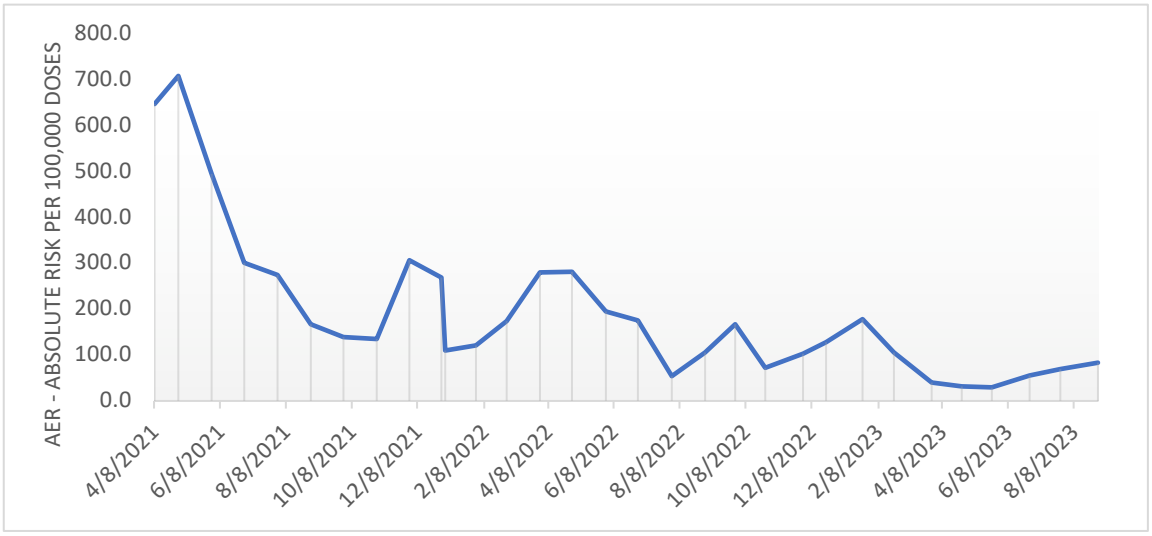
frequently following Covid vaccination than influenza vaccination across this period. This was compatible with the 136.2 and 5.3 figures per 100,000 observed in VAERS data presented above which gave a relative risk of 25.7. The number of AERs with an outcome of death through this period was 1.55 vs 0.09 per 100,000 doses for Covid-19 vaccines and influenza vaccines respectively, converting to a relative risk of death from a Covid vaccine of 16.9. Of note is that half of the 10 deaths listing influenza vaccine as a suspected medicine also listed the Covid-19 vaccine as a suspected medicine. Removal of these cases from both sides of the analysis resulted in a doubling of the relative risk to 32.4. The VAERS reported 2.0 vs 0.02 AERs with an outcome of death per 100,000 which gave a relative risk of 100. Differences in the relative risk values across the two databases possibly reflect differences in collection methodology, the collection period (relative to the commencement of the Covid-19 vaccination campaign) and the specific Covid-19 and influenza vaccines in use in each country. The VAERS analysis related to a 2021 period that followed shortly after the commencement of the broader vaccination program in the US, while the Australian analysis related to a 2022 that was 12 months after program commencement. Figure 5 shows the changes in the absolute risk of an AER following a Covid vaccination over time. Absolute risk of AERs calculated from the TGA DAEN data varied considerably over time with values as high as 646.6 and 708.5 per 100,000 doses evident across the March to April 2021 period (Figure 5(a)). Similarly, the absolute risk of AERs with an outcome of death also varied over time with values peaking in the first three months at 7.9 per 100,000 and then again after the role out of the boosters at 7.0 at the end of Feb 2023 (Figure 5(b)). Calculations of the relative risk of an AER with the outcome of death using this data, assuming no change to influenza vaccine risk, would have converted to relative risk values of 87.8 or 77.8 respectively.

Table 2: Reports of adverse events made to TGA DAEN from 1 March 2022 to 14 August 2022 where influenza vaccines and/or Covid-19 vaccines were listed as suspected medicines. The overall numbers of adverse event reports are presented together with the Absolute Risk (AR) per 100,000 doses and Relative Risk (to influenza vaccine; RR) values.

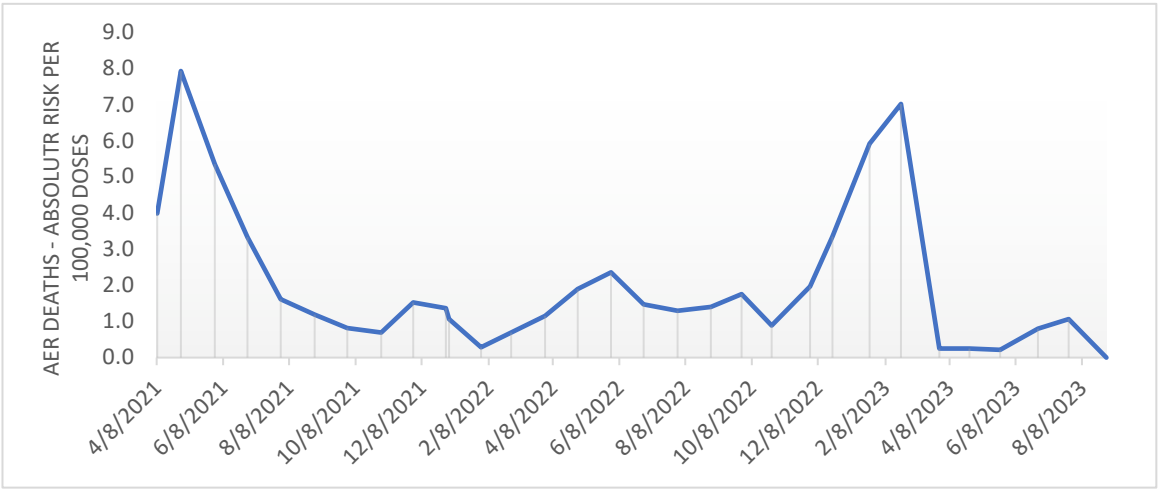
	Cases			Deaths		
	No. of cases	AR per 100,000 doses	RR (99% CI)	No. of cases - death	AR per 100,000 doses	RR (99% CI)
Covid-19 vaccines	16,473	189.53	16.73 (15.5-18.1)	135	1.55	16.85 (7.2-39.2)
Influenza vaccines	1,229*	11.33		10**	0.09	

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/), extracted 10 May 2023. Doses: Influenza vaccines 10,846,430 (https://www.health.gov.au/sites/default/files/documents/2022/08/influenza-flu-immunisation-data-1-march-2022-to-14-august-2022.pdf); Covid-19 vaccines 8,691,619 (https://www.health.gov.au/sites/default/files/documents/2022/03/Covid-19-vaccine-rollout-update-1-march-2022.pdf, https://www.health.gov.au/sites/default/files/documents/2022/08/Covid-19-vaccine-rollout-update-15-august-2022.pdf). *90 of these cases reported both an influenza vaccine and one or more Covid vaccines as a 'suspected' medicine. A further 5 cases reported a Covid vaccine being given but not suspected. **5 of the influenza deaths also reported a Covid-19 vaccine as a suspected medicine. Four of

these were verifiable to TGA FOI 3845.



(a)



(b)

Figure 5: Number of adverse event reports submitted to the TGA DAEN, where a Covid-19 vaccine was listed as a suspected medicine, overall (a) and with an outcome of death (b) for various time periods from 8 April 2021 to 30 August 2023 and converted to Absolute Risk per 100,000 doses.

In addition to the sheer number of reports submitted to the TGA DAEN in relation to Covid-19 vaccines was the broad spectrum of adverse events reported. Table 3 presents the number of different types of adverse events submitted to the TGA DAEN where Covid-19 vaccines were listed as suspected medicines compared to influenza vaccines. Consistent with the VAERS data, a substantially broader spectrum of events have been reported in association with 2.5 years of administration of Covid-19 vaccines than have been reported in association with influenza vaccines across 52 years. When corrected on dose for the period 1 March 2022 to August 24 2022, it was evident that approximately 5 times more different types of adverse events where reported. As mentioned above, this is consistent with the mobility of the components of these vaccines through the circulatory system and tissues.

Table 3: The number of different adverse event *terms* among AERs submitted to the TGA DAEN where influenza vaccines or Covid-19 vaccines were listed as suspected medicines: (a) from 1 January 1971 to 28 April 2023; and (b) from 1 March 2022 to 14 August 2022) expressed per 100,000 doses.

	(a) No. of adverse event terms reported to 28 April 2023	(b) No. of adverse event terms reported 1/3/2022 - 14/8/2022 per 100,000 doses
Covid-19 vaccines	3,862	2,276
Influenza vaccines	1,660	443

Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/), extracted 12 May 2023.

The AERs submitted to the TGA in association with Covid-19 vaccine included adverse event terms spanning all 27 of the MedDRA system organ classes classified by the TGA. For all 27 classes, AERs associated with Covid-19 vaccines represented a substantially higher proportion of cases than AERs associated with influenza vaccine, both overall across the 52 years and in the 6-month analyses. A thorough analyses of these data has been conducted and will be made available via publication or report shortly. Of note was the findings for the class "Cardiac disorders" which was particularly significant and will be presented briefly here.

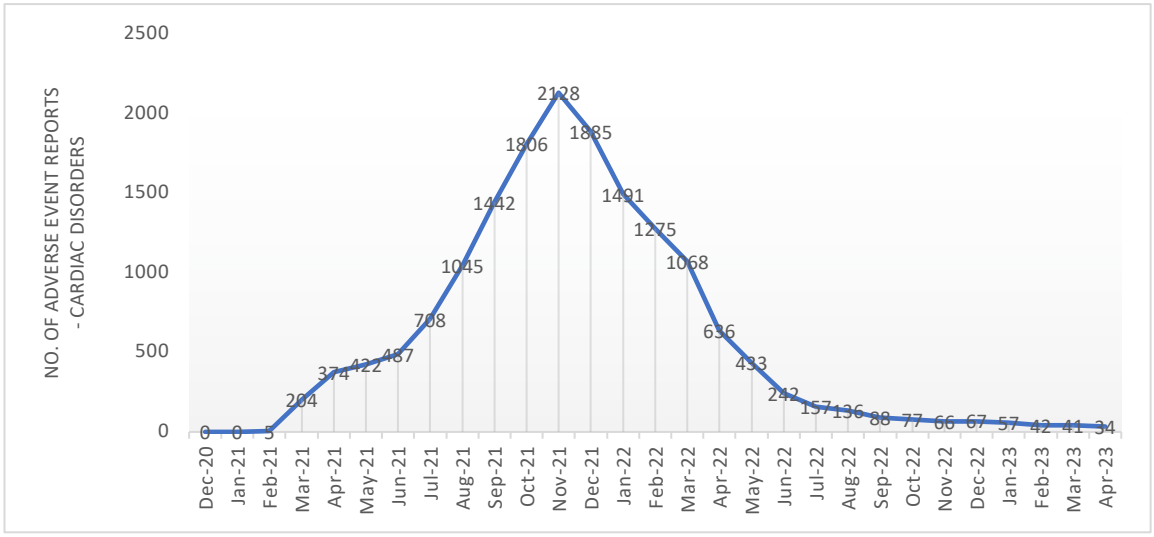
Table 4 presents an analysis of the number of AERs made to the TGA DAEN between 1 January 1971 and 28 April 2023 that included one or more adverse event classified as a "cardiac disorder" for all medicines, vaccines and therapies ("all medicines") and where Covid-19 or influenza vaccines where the suspected medicines.

Covid-19 vaccines were listed as suspected medicines for 16,408 **(38.0%)** of the 43,165 AERs ever submitted to the TGA DAEN across 52 years that included adverse event classified under the SOC "cardiac disorder". This is a large proportion of AERs reporting cardiac disorders as part of their symptoms being contributed in 2.5 short years. Covid-19 vaccines were also listed as suspected medicines for 289 (13.3%) of 2,171 AERs reporting a "cardiac disorder" where death was an outcome. Over 60% of these cases and deaths pre-dated 18 December 2021 when Covid-19 case numbers began to rise (Figure 6). The findings contrasted influenza vaccines which have only ever been associated 1.7% of the AERs reporting a cardiac disorder and 0.9% AERs reporting a cardiac disorder where the outcome was death.

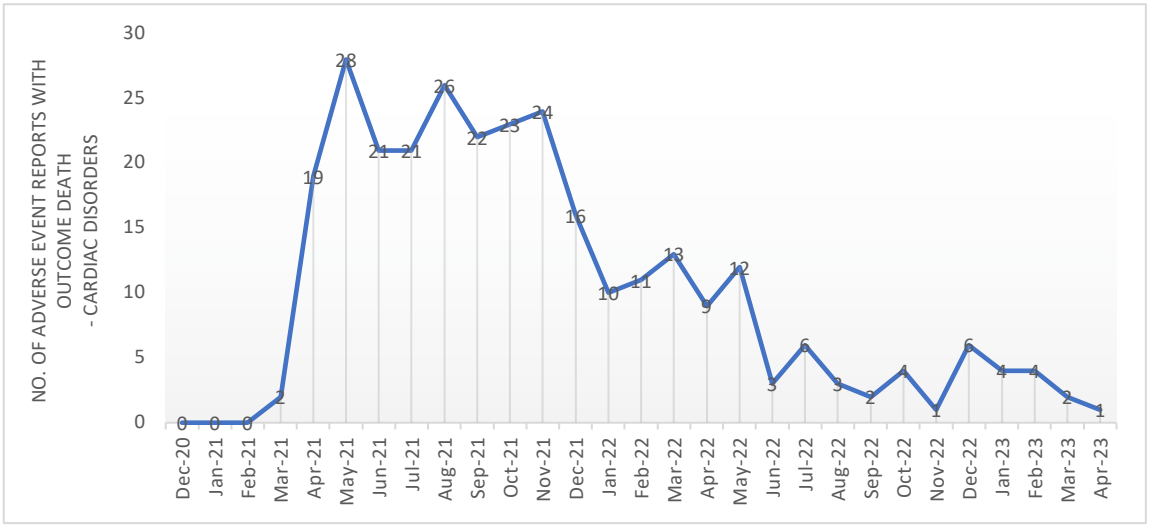
Table 4: Reports of adverse events made to TGA DAEN from 1 January 1971 to 28 April 2023 categorised as "cardiac disorders" by TGA for all medicines and where Covid-19 vaccines and influenza vaccines[1] were suspected medicines.

	No. of cases	(% All reporting cardiac disorder AEs – cases)	No. of cases where death was an outcome	(% All reporting cardiac disorder AEs – deaths)
All medicines	43,165		2,171	
Covid-19 vaccines	16,408	(38.0)	289	(13.3)
Influenza vaccines[1]	716	(1.7)	19	(0.9

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 12 May 2023. [1] 26 of these cases reported both an influenza vaccine and one or more Covid vaccines as a 'suspected' or 'not-suspected medicine.



(a)



(b)

Figure 6: Reports of adverse events made to TGA DAEN from 1 January 1971 to 28 April 2023 categorised as "cardiac disorders" by TGA where Covid-19 vaccines were listed as a suspected medicine

(a) and where death was an outcome (b). *Source:* TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 12 May 2023.

Table 5 presents the number of AERs reporting an adverse event classified as a "Cardiac disorder" during the period from 1 March 2022 to 14 August 2022, together with the absolute risk per 100,000 doses of Covid-19 vaccines and influenza vaccines, and the relative risk of a cardiac disorder adverse event following Covid-19 vaccination compared to influenza vaccination. As shown in Table 5 the absolute risk of reporting one or more adverse events classified as a cardiac disorder was calculated as 29.9 per 100,000 doses of Covid-19 vaccine compared to 0.6 per 100,000 doses of influenza vaccines. This converts to a relative risk of 47.7. The number of AERs reporting one or more adverse events classified as a cardiac disorder with an outcome of death through this period was 0.51 vs 0.02 per 100,000 doses for Covid-19 vaccines and influenza vaccines respectively, converting to a relative risk of death associated with a Covid vaccine and the report of a cardiac disorder of 27.5.

Table 5: Reports of adverse events made to TGA DAEN between 1 March 2022 to 14 August 2022 where Covid-19 vaccines and/or influenza vaccines were listed as a suspected medicine. The numbers of adverse event reports including an adverse event from the DAEN's MedDRA system organ class 'cardiac disorder' are presented together with the Absolute Risk (AR) per 100,000 doses and Relative Risk (to influenza vaccine; RR) values.

	Cases			Deaths		
	No. of cases reporting adverse events	AR per 100,000 doses	RR (99% CI)	No. of cases where death was outcome	AR per 100,000 doses	RR (99% CI)
Covid-19 vaccines	2,598	29.89	47.7 (34.7-65.5)	44	0.51	27.5 (4.3-177.3)
Influenza vaccines	68*	0.63		2	0.02	

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 10 May 2023. Doses: Influenza vaccines 10,846,430; Covid-19 vaccines 8,691,619. *5 of the 68 cases that reported an influenza vaccine as the suspected medicine also reported one or more Covid vaccines as a 'suspected' medicine.

Figure 7 shows the percentage of all adverse event reports made to TGA DAEN between 1 January 1971 to 28 April 2023 that included one or more adverse events classified as a "Cardiac disorder" for all medicine terms (100%) and where Covid-19 vaccines and influenza were listed as suspected medicines, *stratified on age group*. The substantial increase in AERs made to the TGA DAEN that include cardiac disorder adverse event terms since the introduction of the Covid-19 vaccines is particularly evident in the age groups 12 to 17 years old where AERs related to the Covid-19 vaccines contributed 60.6% of all of the AERs ever reported that included a term classified as a cardiac disorder. The contribution to cardiac disorder related AERs was also particularly high in the working age group of 18 to 64 years contributing almost half (47.6%) of the AERs associated with a cardiac disorder ever reported in the history of the DAEN in this age group.

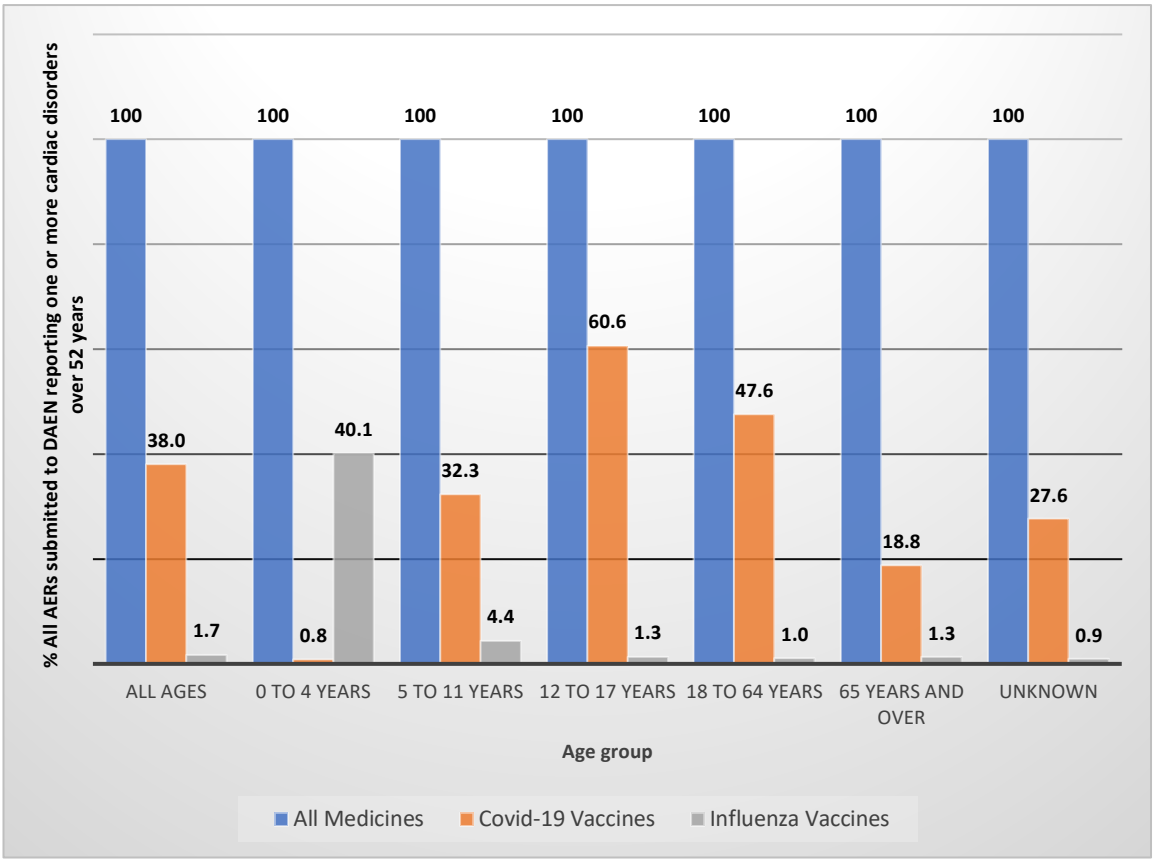


Figure 7: Percentage of all adverse event reports made to TGA DAEN between 1 January 1971 to 28 April 2023 that included one or more adverse events classified as a "cardiac disorder" - for all medicine terms (100%) and where Covid-19 vaccines and influenza were listed as suspected medicines, stratified on age group.

Table 6 presents the number of AERs submitted to the TGA DAEN between 1 January 1971 and 28 April 2023 that included one or more adverse event classified as a "carditis" term for all medicines, vaccines and therapies ("all medicines") and where Covid-19 and influenza vaccines where the suspected medicines. Included in this adverse event group were the terms *myocarditis, myopericarditis, immune-mediated myocarditis, autoimmune myocarditis, hypersensitivity myocarditis, eosinophilic myocarditis, giant cell myocarditis, pericarditis, pleuropericarditis, pericarditis constrictive, and carditis*.
Covid-19 vaccines were listed as suspected medicines for 5,480 **(67.0%)** of the 8,144 AERs ever submitted to the TGA DAEN across 52 years that included one or more of the carditis terms. Clozapine, a drug well-recognised for its cardiac impacts, accounted for the majority of the remaining AERs contributing to 27% of all AERs in this sub-group.

Table 6: Reports of adverse events made to TGA DAEN between 1 January 1971 to 28 April 2023 and categorised as 'carditis' terms[1] (not including terms specifically stated to have infectious association) for all medicines and where Covid-19 vaccines, influenza vaccines and clozapine were listed as a suspected medicine.

	No. of cases reporting adverse events	% All reporting AE sub-group - cases	No. of cases where death was a reported outcome	% All reporting AE sub-group - deaths
All medicines	8,144		105	
Covid-19 vaccines	5,480	(67.3)	26	(24.8)
Influenza vaccines	32*	(0.4)	1	(1.0)
Clozapine	2,260	(27.8)	49	(46.7)

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 1 Dec 2023. [1] Includes terms: *myocarditis, myopericarditis, immune-mediated myocarditis, autoimmune myocarditis, hypersensitivity myocarditis, eosinophilic myocarditis, giant cell myocarditis, pericarditis, pleuropericarditis, pericarditis constrictive, carditis.* *6 of these cases reported both an influenza vaccine and one or more Covid vaccines as a 'suspected' or 'not-suspected medicine.

Table 7 shows the breakdown of report for carditis adverse events associated with Covid-19 vaccination. Notable was that Covid-19 contributed 36.4 % of AER reports ever made to the DAEN that included myocarditis with all but 3% of the AERs listing either Covid-19 vaccines or clozapine as the suspected medicine. Also remarkable, Covid-19 vaccines were listed as the suspected medicine for 91% and 92.5% of cases of myopericarditis and pericarditis ever reported across 52 years, respectively.

Table 7: Reports of adverse events made to TGA DAEN between 1 January 1971 to 28 April 2023 that included medical terms categorised as 'carditis' terms and where Covid vaccines were a suspected medicine[1]. The number of adverse events for all medicines and where influenza vaccines and clozapine are also presented.

	No. of cases reporting adverse events						
MedDRA reaction term	All medicines	Covid-19 vaccines	*(% All)*	Influenza vaccines	*(% All)*	Clozapine	*(% All)*
Myocarditis	3,632	1,321	*(36.4)*	13	*(0.4)*	2162	*(59.5)*
Myopericarditis	515	468	*(90.9)*	3	*(0.6)*	26	*(5.0)*
Eosinophilic myocarditis	9	3	*(33.3)*	-	-	-	-
Giant cell myocarditis	2	1	*(50.0)*	-	-	-	-
Pericarditis	4,110	3,801	*(92.5)*	20	*(0.5)*	104	*(2.5)*
Pleuropericarditis	8	2	*(25.0)*	1	*(12.5)*	1	*(12.5)*
Pericarditis constrictive	4	1	*(25.0)*	-	-	-	-
Carditis	145	142	*(97.9)*	-	-	-	-

Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 12 May 2023. [1]For simplicity, only the medical terms that were reported in association with adverse events that were reported following Covid-19 vaccines have been presented. The data for the remaining medical terms can be provided on request.

Table 8 presents the number of AERs reporting an adverse event classified as a "carditis" term during the period from 1 March 2022 to 14 August 2022, together with the absolute risk per 100,000 doses of Covid-19 vaccines and influenza vaccines and the relative risk of reporting a 'carditis' event following Covid-19 vaccination compared to influenza vaccination. As shown, the absolute risk of reporting one or more carditis terms was calculated to be 9.0 per 100,000 doses of Covid-19 vaccine compared to 0.03 per 100,000 doses of influenza vaccines. This converts to a relative risk of reporting one of the carditis terms following Covid vaccination of **325.7** compared to influenza vaccines.

Table 8: Reports of adverse events made to TGA DAEN between 1 March 2022 to 14 August 2022 where Covid-19 vaccines and/or influenza vaccines were listed as a suspected medicine. The number of adverse event reports including an adverse event sub-categorised as "carditis"[1] are presented together with Absolute Risk (AR) per 100,000 doses and Relative Risk (to influenza vaccine; RR) values.

	Cases			Deaths		
	No. of cases	AR per 100,000 doses	RR (99% CI)	No. of cases death was outcome	AR per 100,000 doses	RR (99% CI)
Covid vaccines	783	9.01	325.7 (73-1449)	8	0.09	10.0 (1-154)[2]
Influenza vaccines	3*	0.03		0	0.00	

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 10 May 2023. Doses: Influenza vaccines 10,846,430; Covid-19 vaccines 8,691,619. [1] Includes terms: *myocarditis, myopericarditis, pericarditis, eosinophilic myocarditis, pleuropericarditis, carditis*. *2 of the 3 cases reported both an influenza vaccine and one or more Covid vaccines (Pfizer) as a 'suspected' medicine. [2] The reference group (influenza vaccine listed as a suspected medicine) recorded 0 adverse events. The RR ratio was estimated by moving one case from the no event group into the event group.

Figure 8 shows the percentage of all adverse event reports made to TGA DAEN between 1 January 1971 to 28 April 2023 that included one or more "carditis" adverse even terms disorder" for all medicine terms (100%) and where Covid-19 vaccines and influenza were listed as suspected medicines, stratified on age group. The findings are startling with 97.7%, 90.4% and 70.6% of all AERs that include one or more carditis terms that have ever been submitted to the TGA DAEN across 52 years for the 5 to 11 year, 12 to 17 year, and 18 to 45 year age groups, respectively, were associated with Covid-19 vaccines. Much of the balance of AERs reporting one or more 'carditis' terms being contributed by clozapine.

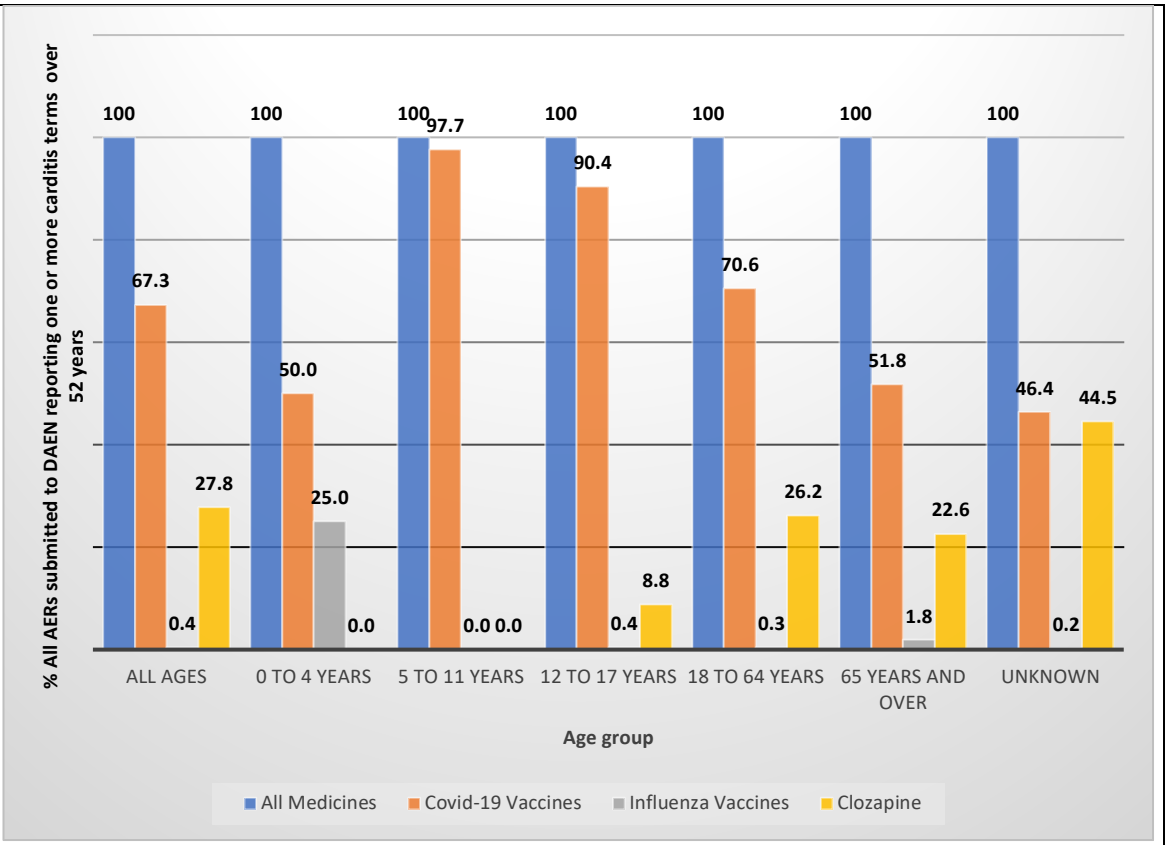


Figure 8: Percentage of all adverse event reports made to TGA DAEN from 1 January 1971 to 28 April 2023 where death was an outcome that included one or more adverse events classified as a carditis term - for all medicine terms (100%) and where Covid-19 vaccines, influenza vaccines and clozapine were listed as suspected medicines, stratified on age group.

As stated previously, the above findings have been taken from a larger analysis of the AERs associated with Covid-19 vaccines in the context of the history of the TGA DAEN and compared to those specifically related to influenza vaccines. The broader findings will be made available via publication or report shortly. What can be stated clearly from these analyses is that Covid-19 vaccines have contributed a disproportionate number of adverse events to the TGA DAEN and that questions need to be asked about how and why these clear safety signals have been dismissed.

Overview of Data Reported for the AusVaxSafety Program

AusvaxSafety collects data on days 3, 8 and 42 following vaccinations. However, NCIRS only publish a component of the day 3 data on their website. The day 8 and day 42 data has not been published to their webpage. The following tables and text present a summary of analyses of the publicly available AusVaxSafety data for Covid-19 vaccines, influenza vaccines and the National Immunisation Program vaccines. Data collected in response to surveys sent on day 3 following vaccination have been collected over time from the AusVaxSafety webpage (https://ausvaxsafety.org.au/safety-data). Screenshots of this data have been taken over the last two years and can be provided on request.

Historical results for the day 3 data were extracted from the AusVaxSafetySummary reports (https://www.health.gov.au/sites/default/files/documents/2020/11/vaccine-safety-in-australia-ausvaxsafety-summary-report-2019; https://www.health.gov.au/sites/default/files/documents/2021/10/vaccine-safety-in-australia-ausvaxsafety-summary-report-2020; https://www.health.gov.au/sites/default/files/documents/2022/09/ausvaxsafety-Covid-19-vaccine-surveillance-summary-report-2021; https://www.health.gov.au/resources/publications/vaccine-safety-in-australia-ausvaxsafety-summary-report-2021)

Table 9 provides a summary of the number of surveys returned for each of the various vaccines, together with the percentage of those surveys reporting one or more events, and where available the range of data reported across the subgroups based on dose, age, ethnicity, cancer and transplant status, and pregnancy status. This adverse event data is further summarised in Figure 9. Notable for this data is the high rate of report of adverse events reported 3 days following Covid-19 vaccination compared to that adverse event rates reported following the seasonal influenza vaccines and the national immunisation program (NIP) vaccines. Also notable is the increase in the rates of report of adverse events for the influenza vaccines and NIP vaccines following the roll-out of the Covid-19 vaccines. This may reflect the impacts of co-administration of the Covid-19 vaccines with these other vaccines with adverse event report rates for influenza vaccines being steady at around 6% across 2019 to 2021 but then tripling to 17.5 and 17.3% following the push to co-administer vaccines in early 2022. Similarly, the adverse event report rates for the NIP vaccines were steady at around 11% to March 2022 but then almost doubled to 18.4% and 20.7% in later reports. Due to the potentially confounding effects of the Covid vaccines on the adverse event rates reported for influenza and NIP vaccines, comparison of the adverse event rates for Covid-19 vaccines against these vaccines have excluded data the post-March 2022 findings. When the adverse event rates at day 3 following Covid-19 vaccination were compared to the rates reported for influenza vaccines and the NIP vaccines prior to March 2022, it was found that the rate of report of adverse events following Covid-19 vaccination was approximately **7 times higher** than the report rate for influenza vaccines and **4 times higher** than the report rates for NIP vaccines. This disparity was even more evident in a comparison of the ranges of adverse event rates across the various subgroups. The sub-group adverse event report rates for Covid 19 vaccines ranged from 23-75%, whereas the subgroup rates ranged from 4-10% and 5-19% for the influenza and NIP vaccines.

Comparison of the rates of report of adverse events following vaccination with the Covid-19 vaccines between the TGA DAEN and AusVaxSafety surveillance systems demonstrates that that the AusVaxSafety rate of report is approximately 207 times larger than the TGA DAEN per dose estimate of 0.212%. This was calculated as follows. The number of doses of Covid-19 vaccines as of 8 Feb 2023 was found to be 64,708,932 (https://www.health.gov.au/sites/default/files/2023-02/Covid-19-vaccine-rollout-update-10-february-2023.pdf). The number of adverse events published to the TGA DAEN as

of 8 Feb 2023 (extracted 22 Feb 2024) was 137,517 adverse events. This converts to a rate of report for the TGA of DAEN of 0.213%. The AusVaxSafety data for the period to 6 February 2023 indicates a report rate of 44.1% which is 207.5 times larger than the estimate from the DAEN. This comparison supports serious under-reporting of adverse events within the TGA. As discussed above, the disparity would be expected to be greatest for less severe symptoms that would not motivate someone to make a spontaneous report but that may be more readily provided in an active surveillance report. One would expect that the disparity maybe less for more severe reactions where motivation to report spontaneously may be higher. However, the counter-impact on the fact that the AusVaxSafety data is only the day 3 data must also be considered.

Table 9: Summary of the number of surveys returned for each of the various vaccines on day 3 following vaccination together with the percentage of those surveys reporting one or more adverse events, and where available the range of adverse event rates reported across the subgroups based on dose, age, ethnicity, cancer and transplant status, and pregnancy status.

Year	Number of surveys returned	No. of surveys returned	% reporting at least 1 adverse event	Range reported across sub-groups
Covid-19 Vaccines				
2021/2022	(as of 4 Apr 2022)	6,230,944	44.7	
2021/2022	(as of 30 May 2022)	6,378,761	44.4	23 - 75
2021/2023	(as of 6 Feb 2023)	6,611,017	44.1	24 - 75
Seasonal Influenza Vaccines				
2019	(Apr 2019 - Aug 2019)	237,124	6.0	NA
2020	(Apr 2020 - Aug 2020)	289,971	6.0	NA
2021	(29 Mar 2021 - 9 Sep 2021)	231,668	6.6	4 - 10
2022	(as of 30 May 2022)	83,873	17.5	16 - 23
2023	(13 Mar 2023 - 4 Sep 2023)	215,455	17.3	14 - 22
National Immunisation Program Vaccines				
2020		NA	NA	5 - 19
2021	(1 Jul 2021 - 31 Dec 2021)	60,063	11.0	NR
2021/2022	(1 Jul 2021 - 31 Mar 2022)	92,794	11.4	NR
2022/2023	(1 Jul 2022 - 10 Oct 2023)	149,904	18.4	NR
2022/2024	(1 Jul 2022 - 4 Jan 2024)	173,695	20.7	NR

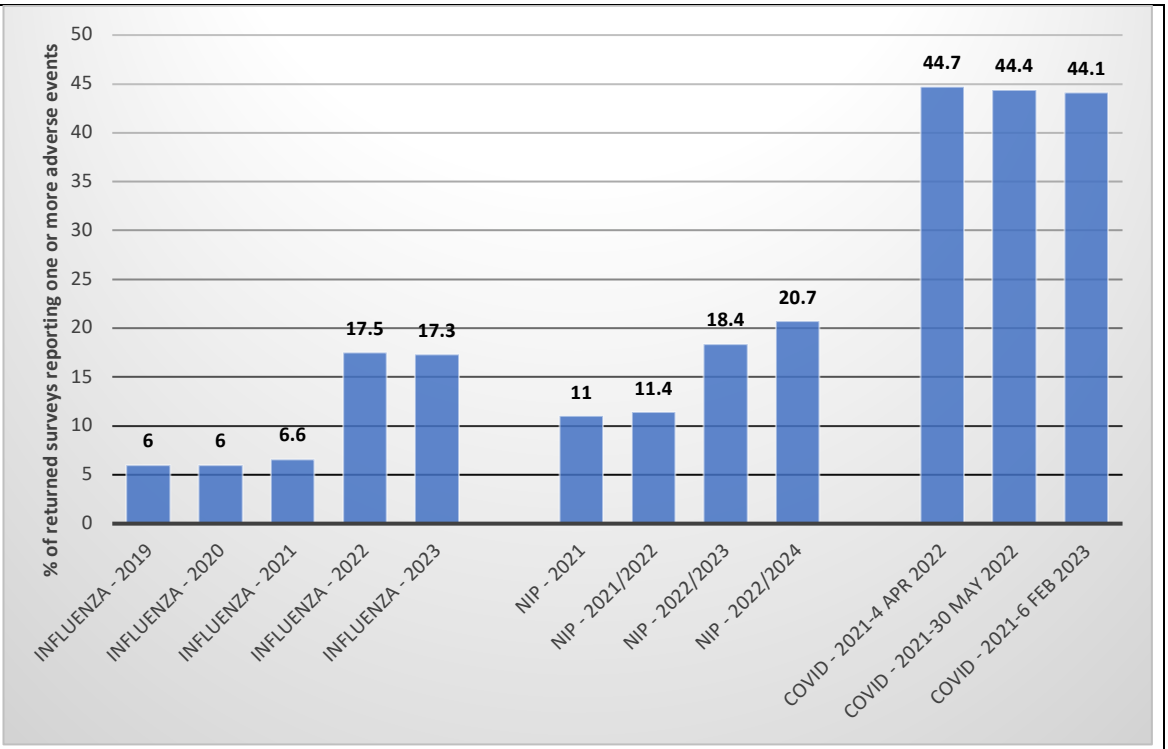


Figure 9: Summary of the percentage of surveys returned reporting one or more adverse events on day 3 following vaccination with Covid-19, influenza, the national immunisation program (NIP) vaccines.

Table 10 provides a summary of the rates of report (%) of attending a GP or emergency department by day 3 following vaccination, together with, where available, the range of the rates of report for attending a GP or emergency department by day 3 across the subgroups. The overall percentage of surveys submitted on day 3 following Covid-19 vaccination that reported they had visited a GP or emergency department in relation to an adverse event was 0.9% and 1.0% with a range of 0.3% to 3.4% across the various subgroups. This is more than double the rate of surveys reporting medical attendance within 3 days of an influenza vaccine. It is also higher than the rate reported for the NIP vaccines which was 0.7% and 0.8% with a range from 0.2% to 1.6%.

Table 10: Summary of the rates of report (%) of attending a GP or emergency department by day 3 following vaccination together with, where available, the range of the rates of report for attending a GP or emergency department by day 3 across the subgroups based on dose, age, ethnicity, cancer and transplant status, and pregnancy status.

Year	Number of surveys returned	% reported visiting a GP or ED	Range reported across sub-groups
Covid-19 Vaccines			
2021/2022	(as of 4 Apr 2022)	1.0	
2021/2022	(as of 30 May 2022)	1.0	
2021/2023	(as of 6 Feb 2023)	0.9	0.3 - 3.4
Seasonal Influenza Vaccines			
2019	(Apr 2019 - Aug 2019)	0.4	
2020	(Apr 2020 - Aug 2020)	0.3	
2021	(29 Mar 2021 - 9 Sep 2021)	0.3	0.3 - 0.7
2022	(as of 30 May 2022)	0.2	0.1 - 0.8
2023	(13 Mar 2023 - 4 Sep 2023)	0.3	0.1 - 1.1
National Immunisation Program Vaccines			
2020		NA	0.2 - 1.6
2021	(1 Jul 2021 to 31 Dec 2021)	0.8	
2021/2022	(1 Jul 2021 to 31 Mar 2022)	0.7	
2022/2023	(1 Jul 2022 to 10 Oct 2023)	0.7	
2022/2024	(1 Jul 2022 to 4 Jan 2024)	0.7	

Table 11 provides a summary of the ranges of report rates (%) across the various subgroups (grouped on dose, age, ethnicity, cancer and transplant status, and pregnancy status) for vaccination impact on daily routines and general symptoms, on day 3 following vaccination with Covid-19, influenza, and NIP vaccines. A substantially higher number of individuals reported being impacted by Covid-19 vaccination with a report range of 4% to 43% compared to 2%-4% and 2%-5% for the influenza and NIP vaccines respectively. The ranges of report rates for all six general symptoms (local reaction, fatigue, headache, muscle and joint pain, gastrointestinal symptoms and fever) were also substantially higher 3 days following Covid-19 vaccination compared to data collected 3 days following influenza or NIP vaccination. Between 4% and 63% of sub-groups receiving a Covid-19 vaccine reported these symptoms compared to only 2% to 3.6% of subgroups receiving influenza vaccines prior to 2022 and 1.0 to 8.7% of those receiving NIP vaccines in 2020.

Table 11: Summary of the ranges of report rates (%) across the various subgroups (grouped on dose, age, ethnicity, cancer and transplant status, and pregnancy status) for vaccination impact on daily routines, and general symptoms, on day 3 following vaccination with Covid-19, influenza and NIP vaccines.

Year	Impact on routine activity	Local Reaction	Fatigue	Headache	Muscle & Joint Pain	Gastro-intestinal symptom	Fever
Covid-19 Vaccines							
2021/2023	4-43	12-60	12-66	8-64	6-59	3-29	2-47
Seasonal Influenza Vaccines							
2021		0.9-2.8	1.3-2.3	0.3-1.8		0.1-0.7	0.6-3.6
2022	2-4	11-16	9-14	3-9	4-8	2-4	2-10
2023	2-5	10-17	8-13	2-9	4-9	2-5	2-11
National Immunisation Program Vaccines							
2020		1.0-8.7	1.4-4.4	0.8-2.1		1.7	0.4-6.0

These data collectively suggest a substantial increase in the rate of report of adverse events both overall and for specific general symptoms 3 days following vaccination with Covid-19 vaccines compared to influenza and NIP vaccines. These increased impacts are reflected in higher rates of GP and ED attendance and the higher report of impact on daily routines.

It must be emphasised at this point that these findings relate to the results of the day 3 surveys only. Data provided at the day 8 and day 42 surveys and in the text box responses of all three surveys have not been made publicly available. As a result, this data may be biased against the detection of serious adverse events that may not be diagnosed within this time frame. Access to day 8 and day 42 data, as well as the text box information detailing other adverse events experienced, is needed to more fully elucidate the adverse impacts of Covid-19 and other vaccines followed as part of the AusVaxSafety program.

It should also be emphasised that the increase in general symptoms following Covid-19 vaccination that is well evident in this data should not be disregarded on account of some view that these are just common or general symptoms. These symptoms often form part of symptom constellations associated with severe illness and death. In the context of Covid-19 vaccines, there are 47 AERs with an outcome of deaths that report 'headache', 34 that report 'fatigue' and 141 that report 'gastrointestinal disorders' (data extracted 22 Feb 2024).

Index

Third Answer

Dr Astrid Lefringhausen, Co-Author:

An FOI request for "age-stratified statistical breakdown of all presentations and admissions (to public hospitals in Victoria) for cardiac related symptoms ... for the period

1 January 2018 to 23 January 2023" to the Victorian Department of Health (DOH) (F23/0136) showed a correlation of increased cardiac presentations during 2021 and early 2022 with the primary series and booster dose rollouts of Covid-19 vaccines, across all age groups.

This correlation is quite tight, as seen for example in Figure 1 for the 20-29-year-old age group, which shows the FOI cardiac presentations data mapped against the vaccinations administered. This age group did not start receiving the Covid-19 vaccine until a couple of months after older groups, and so the correlation is even tighter than represented in the graph, which shows Covid-19 doses for all ages.

Employment and travel mandates came into effect mostly in October, timing with peak monthly cardiac emergency department presentations of 3,925 twenty-something-year-olds and 1,217 hospital discharges, which Figure 1 aggregates to 5,142 despite some likely overlap.

The data show an almost 3-fold increase in cardiac presentations in period as compared to 2020. There was a second smaller peak in March 2022 timing with the first booster dose that was also mandated in some workplaces.

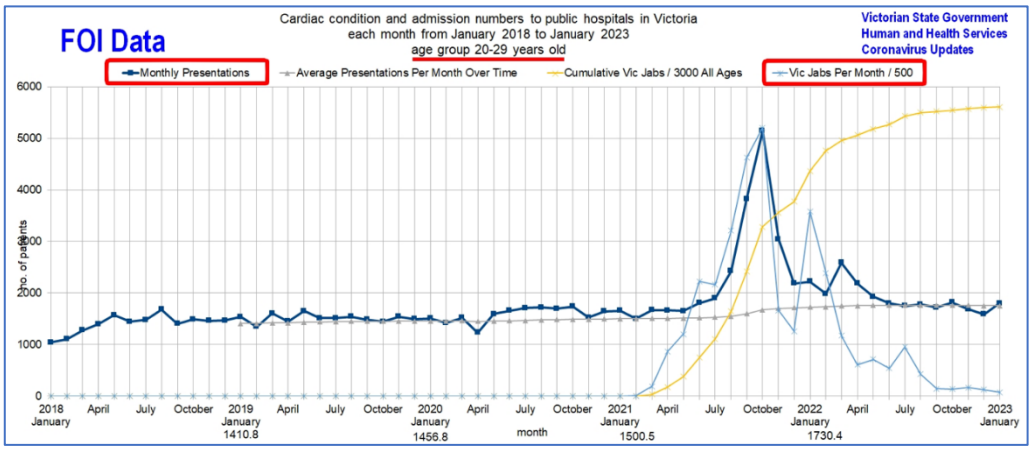


Figure 1: FOI derived Victorian public hospital cardiac admissions 20-29yo and C19 vaccinations.

Adverse events following immunisations in WA, Australia

The following information is from the Western Australia Vaccine Safety Surveillance (WAVSS) annual report 2021. WA is unique insofar that it is one of the few states in Australia where the vaccine side effects can be clearly differentiated from the Covid-19 infection effects. Due to their aggressive no-Covid-19 policy throughout 2021, there was no community transmission of SARS-CoV-2 in WA until early 2022, after almost four million doses of Covid-19 vaccinations had been administered in 2021.

The vaccination campaign began on 22 February 2021, and the increase in adverse events following immunisation (AEFIs) with the Covid-19 vaccines was reported at almost 24x the rate (per 100, 000 doses) of AEFIs for all other vaccines combined.

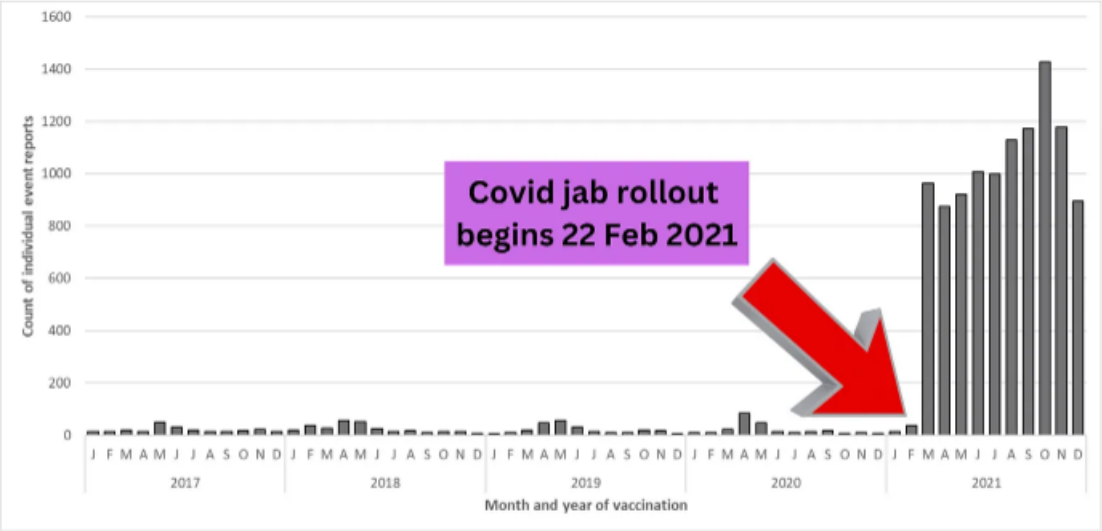


Figure 2: Adverse events following immunisation reported to WAVSS by month, 2017-2021, excluding active surveillance reports for routine vaccination adverse events.

Western Australian Vaccine Safety Surveillance – Annual Report 2021

Figure 2.

The report states, that:

> the number of adverse events following immunisation (AEFI) reported to Western Australia Vaccine Safety Surveillance (WAVSS) was significantly higher in 2021 than in previous years (10,726 compared with an average of 276 per year for the 2017-2020 period) due to the introduction of the Covid-19 vaccination program.

The peak month for adverse effects was October 2021, the same month when walk-in vaccinations for everybody over 18 became available, and vaccine mandates for the majority of WA workers were announced.

The background rate of both myocarditis and pericarditis in the WA population was higher in 2021 than the previous five-year average (Table 12).

Table 12: Background rates (WA) of myocarditis and pericarditis prior to (2016-2020) and after (2021) the introduction of COVID-19 vaccination. Rates calculated based on principal diagnosis for emergency departmer presentations and hospital inpatients.

Time period	Myocarditis rate (per 10,000 separations*)	Pericarditis rate (per 10,000 separations)
2016-2020	0.556	3.903
2021	0.749	4.892

*A separation refers to a patient being discharged from hospital

Figure 3.

Chest pain was the fifth most common reported AEFI and rates of myocarditis and pericarditis increased in 2021 by 35% and 25% respectively over the past 5 years (Figure 3). In total, 138 confirmed cases of myocarditis or myopericarditis were reported to WAVSS in 2021. Since had virtually no Covid-19 cases in 2021, these adverse event

reporting figures cannot be confounded by Covid-19 infections.

Excess All-Cause Mortality Data

Across many nations, all-cause mortality (ACM) increased during the Covid-19 pandemic. Deaths associated with Covid-19 were seen primarily in the elderly and/or those with co-morbidities in 2020.

However, from 2021 onwards, the excess death rate, compared with the pre-pandemic 5-year average, extended to working age adults and young people[ccxxxviii].

Across European nations a correlation between higher rates of vaccination and higher rates of excess ACM has been recorded[ccxxxix]. The authors state: Analyses of 31 countries ... show that all-cause mortality during the first nine months of 2022 increased the more the higher 2021 vaccination uptake; a one percentage point increase in 2021 vaccination uptake was associated with a monthly mortality increase in 2022 by 0.105 percent (95% CI, 0.075-0.134).
Australian Bureau of Statistics (ABS, 2023) data shows deaths during 2020 were within or below the 2015-2019 five-year average, apart from a brief rise coinciding with the first wave of Covid-19 in Australia (Figure 4).

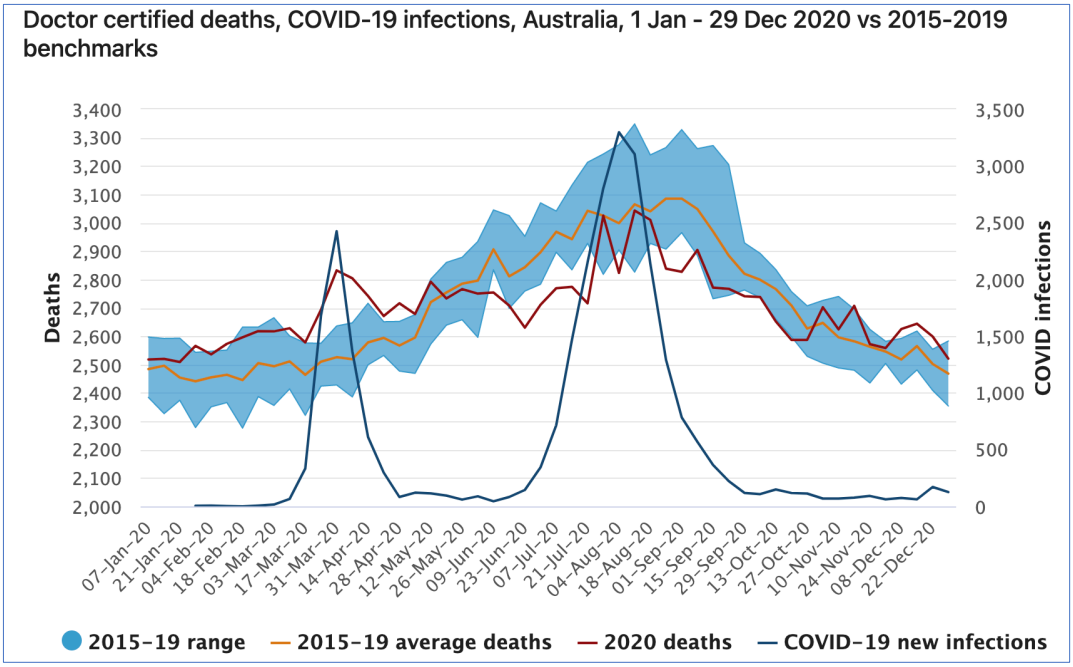


Figure 4: ABS mortality and Covid-19 data, 2020.

Deaths started to rise during 2021, months before the late arrival of a major Covid-19 infections wave in Australia, in December 2021. In 2021 there was a remarkably low rate of seasonal influenza during the southern hemisphere winter in Australia, during which deaths trended within the pre-pandemic range.

Similar patterns have been seen in other nations. In Germany, Kuhbandner and Reitzner (2023)[ccxl] used actuarial science based on life insurance and similar data to calculate the excess mortality in Germany for the pandemic years 2020, 2021, and 2022. They found there had been 4,000 excess deaths in 2020 during the early waves of Covid-19, accounted for mainly by those aged in their 70s.

In 2021 there were approximately 34,000 excess deaths, and in 2022 the number had risen to 66,000. Excess deaths in younger age cohorts began from April 2021. These findings by age cohort were depicted in figure 1 from their paper, here presented as Figure 9.

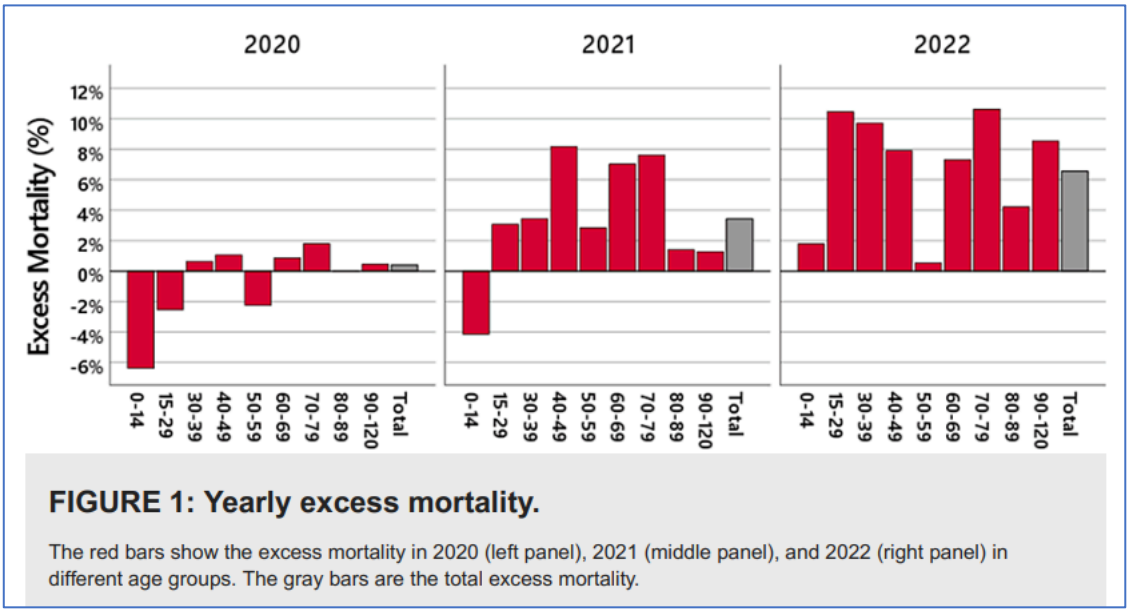


Figure 5: Excess mortality in Germany 2020-2022 from Kuhbandner & Reitzner (2023).

Scherb and Hayashi (2023)[ccxli], confirmed the German figures and found similar correlation of excess ACM with the Covid-19 vaccines in Japan. The authors calculated ACM trends from 2005 to 2022, noting variables that give rise to wide confidence intervals for population mortality trends. They found that in both Germany and Japan in 2020, the first year of the Covid-19 pandemic, there was only a small rise in ACM in Germany and a drop in Japan. However, in 2021 there was a further rise in both countries and a marked rise in 2022.

In Germany there was 1.89% or 18,274 (CI -9,855, 45,615) excess ACM in 2020, which was not statistically significant. In 2021 this rose to a statistically significant 4.99% or 48,617 (CI 19,895, 76,526) excess deaths, and 6.67% or 66,528 (CI 36,743, 95,459) excess deaths in 2022.

In Japan, ACM was -2.84%, i.e., below the trend, in 2020. There were 0.80% or 11,547 (CI -11,902, 34,625) excess deaths in 2021, and a startling 8.37% or 122,158 (CI 98,438, 145,504) excess deaths in 2022. This was more than double the rate of excess deaths in

2011 (4.03%), the year of the earthquake and tsunami.

Scherb and Hayashi concluded:

> The allegedly confirmed high death toll in 2020 from Covid-19 in high income countries [21,22] did not come true, neither in Japan nor in Germany. ... it should be investigated to what extent the ... highly significantly increased mortalities in Germany and Japan in 2021 and 2022 might be due to pandemic countermeasures, including the vaccinations.[243]

Adverse events following vaccination in Malta and Israel

A study by Cuschieri, et al. (2022)[ccxlii] assessing vaccination-induced changes in hospital activity in Malta from Q1 2020 to Q1 2021 found a significant drop in accident and emergency(A&E) attendances to hospital for ear-nose, and throat (ENT) A&E, obstetric (OBS) A&E, ophthalmic (Opthth) A&E, and paediatrics (Paed) A&E ($p < 0.01$) respectively. In contrast, attendances increased for psychiatric and dental services. The authors conclude that this was most likely due to patients fears of contracting Covid-19 while in hospital.

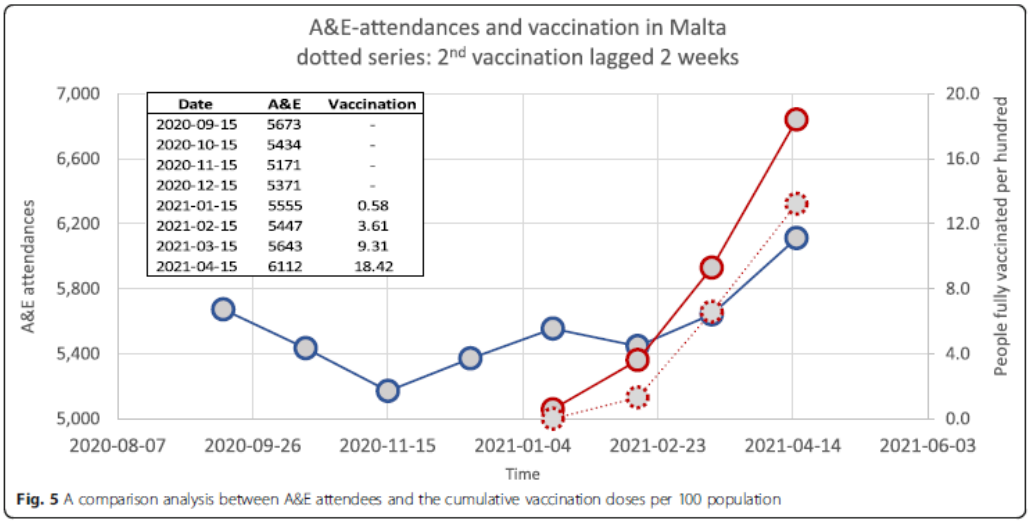


Fig. 5 A comparison analysis between A&E attendees and the cumulative vaccination doses per 100 population

Figure 6.

Covid-19 vaccination began in Malta at the end of December 2020. Figure 6 shows the comparison analysis of A&E attendances and cumulative vaccination doses per 100 population. The graph shows a significant relationship between A&E attendance and cumulative vaccination. With every 1% increase of vaccination, A&E attendance rises by 0.9%. When including a delay of two weeks after vaccination for stronger vaccination or side effects, this relationship became statistically even stronger.

Israel was regularly referred to as the Covid-19 laboratory of the world (and Pfizer), since they were ahead of almost all other nations in their vaccination rollout and

compliance. Sun, et al.[ccxliii] used a dataset from the Israel National Emergency Medical Services (EMS) from 2019 to 2021 for a retrospective, population-based study, to evaluate the possibility of association between the volume of cardiac arrest (CA) and acute coronary syndrome (ACS) EMS calls in the 16–39-year-old population and a range of potential factors like Covid-19 infection and vaccination rates.

They showed that both the CA and ACS call counts started increasing in early January 2021 and closely followed the second dose curve. No association between Covid-19 infection and the CA and ACS call counts was found.

The authors also observed a second increase in EMS calls around April 18th, which tracked closely the estimated number of single doses administered for individuals who recovered from Covid-19, starting on April 11th.

The Israel Ministry of Health approved the vaccination of individuals of age 16 and over after recovery from a Covid-19 infection with only one vaccine dose, as long as three months had elapsed from their recovery. Since the peak of the third wave of Covid-19 in Israel for people under 40 was around January 11, 2021, this could explain the peak of EMS calls following singe vaccinations 3 months later.

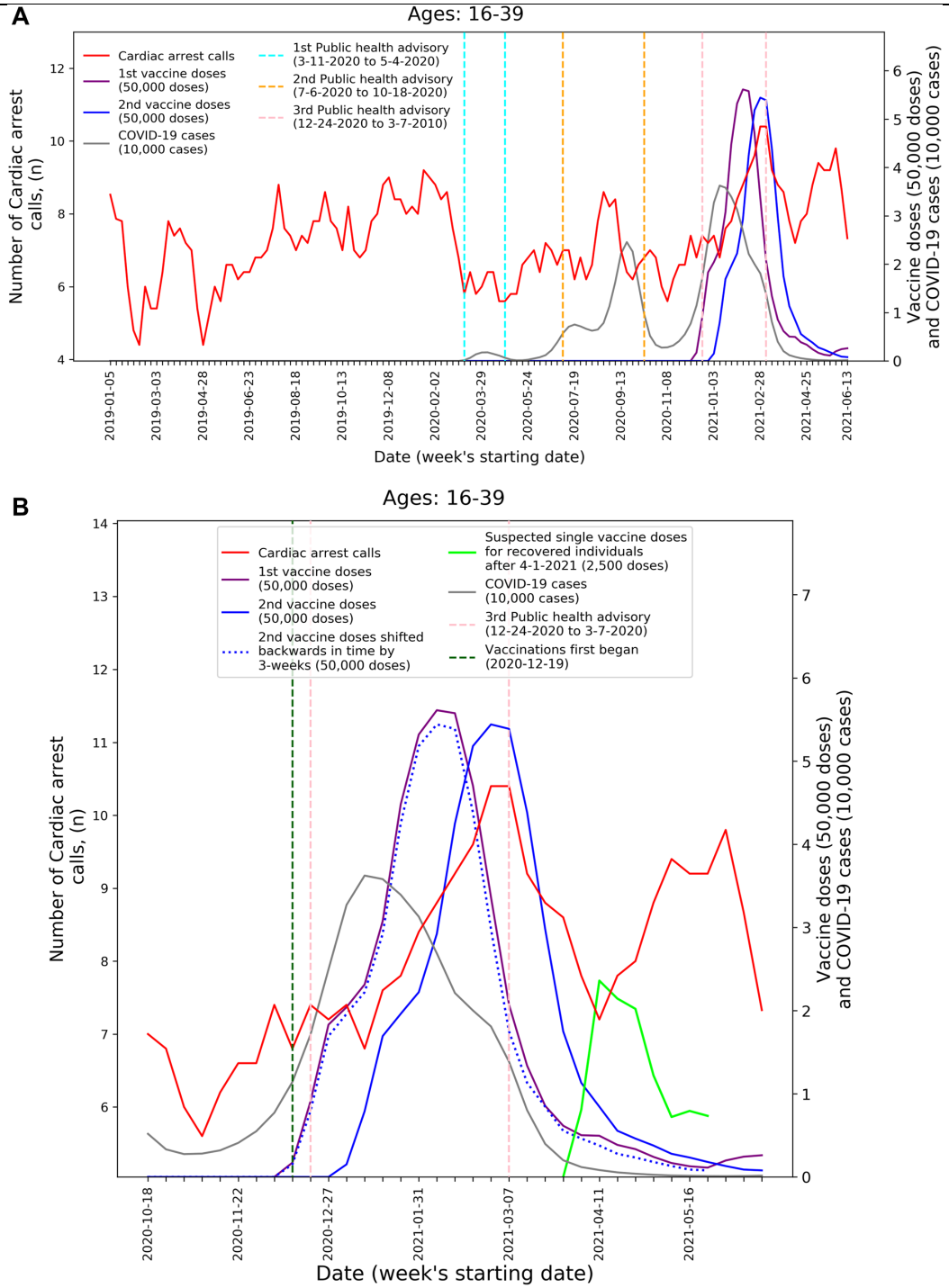


Figure 7. Weekly counts of cardiac arrest calls (five-week centered moving-average), Covid-19 cases (three-week centered moving-average), and vaccination doses (three-week centered moving-average) for those between 16 and 39 during: A) the study period (January 1st, 2019, to June 20th, 2021) and B) the third Covid-19 wave and vaccination distribution period (October 18th, 2020, to June 20th, 2021). *Covid-19* Coronavirus disease 2019.

In January 2022 the "Save us now" organisation put together a list of 1011 case studies reporting side effects after Covid-19 vaccination (Table 1, Turni, et al.[ccxliv]).

Most of these side effects had not been listed in any of the vaccine brochures or on the Australian Government websites. By the end of 2022, the number of papers on SAE of

Covid-19 vaccinations was well above 1500, and exceeding 3000 by late 2023. Prominent side effects are cardiac, autoimmune and immune disorders, infections, skin and neurological conditions as well as neurodegenerative effects but the list covers virtually all organ systems of the body.

In summary, the Covid-19 vaccines have caused an unprecedented increase in reported SAEs, not even considering the underreporting factor.

Endnotes: For all answers
Index

Fourth Answer

Dr Tess Lawrie, Proposed Witness:

In answer to Reference AA and the Question on Notice in respect of Reference AA, and in particular (v) and (vi) of Reference AA:

I am Dr Tess Lawrie, founder of World Council for Health, which launched in September 2021.
The World Council for Health is a broad, grassroots, expert-led initiative to work together to empower global and community health.
In 2021, our organisation noticed an explosion in adverse event reports in the United Kingdom's Yellow Card reporting system, which we raised and put before the Regulators, including with or through the following reports:

1. Urgent Preliminary Report of Yellow Card Data dated 9 August 2021;
2. WCH Covid-19 Vaccine Pharmacological Report dated June 2022;
3. Persus Report - A report on MHRA's Regulation of the Covid-19 vaccines dated April 2023;
4. WCH Vaccinating Against C19 During Pregnancy: It's Safer to Wait dated 5 April 2023.

I am aware that these same reports and information were also used by people in Australia.

Index

Fifth Answer

Rebekah Barnett BA (Comm), Proposed Witness:

In Western Australia (WA) in 2021, adverse events following immunisation (AEFIs) associated with the Covid-19 vaccines were reported at almost 24 times the rate (per 100,000 doses) of AEFIs for all other vaccines combined. The Western Australian

Vaccine Safety Surveillance (WAVSS) Report (2021) refers to this phenomenon as an "exponential increase."

WA is unique in that the 2021 vaccine safety surveillance data is unconfounded by Covid-19 infections, because there was almost zero community transmission of the virus during this time.

Key points from the WAVSS 2021 Report:

- Background rates of myocarditis and pericarditis increased by 35% and 25%, respectively.
- 57% of AEFIs were treated in the emergency department or were hospitalised.

The Premier, Mark McGowan, announced that WA hospitals were "under enormous pressure" on 31 October, the same month that AEFIs peaked at over 1,400. McGowan stated that he didn't know the cause of the hospital crisis but suggested it might be related to Covid-19. There were only 16 documented cases of Covid-19 in WA in October.

Index

Reference: BB

Index

A systemic analysis of the formal guidelines and procedures used during 2021, 2022, and 2023 by State and Territory governments, hospital administrators responsible for receiving and processing AEFI, and the TGA and NCIRS, to assess adverse event reports in respect of Covid-19 vaccines, including:

i. the criteria for assessing possible causal association (unrelated, possibly related, probably related, definitely related etc.) in respect of the Covid-19 vaccines;
ii. who was responsible for first receiving adverse event reports, performing initial assessments and the criteria used to perform assessments, the qualifications of those responsible for first receiving adverse event reports and for conducting the initial assessments, to whom they reported, and to whom they sent adverse events after assessment, and to which databases;
iii. what directions, guidelines, procedures, or policies were created or implemented for Covid-19 vaccine adverse event report assessments and which of these were specific to the assessment of Covid-19 vaccine adverse event reports;
iv. what directions, guidelines, procedures, or policies were created or implemented for the assessment of Covid-19 vaccine adverse events reporting death as an outcome after Covid-19 vaccination and which of these were specific to Covid-19 vaccine adverse event report assessments;
v. what directions, guidelines, procedures, or policies were created or implemented and provided to coroners specifically for investigating deaths following Covid-19 vaccination.

Explanatory Memorandum

Index

An examination of Australia's adverse event reporting system, the IT platforms used, their integration nationally, their public transparency, personnel qualifications, and agreed procedures and standards observed nationally.

Question(s) on Notice

Index

In respect of your joint submission and in particular index **References BB and JJ**, are you able to point the Committee to any formal guidelines and procedures that were put in place prior to or just after the rollout of Covid-19 vaccines Australia to specifically assess adverse events caused by the vaccines, by State and Territory governments and

the TGA, in case those experimental drugs proved to not be as safe and effective as the Australian people were told?

And the second part of my question here is:

Do we know who was responsible for first receiving adverse event reports, the criteria they used to perform assessments, what the qualifications were of those people responsible for first receiving adverse event reports
and for conducting the initial assessments, and who they reported to?

My issue here is we have been asking lots of questions here in the Senate about how Australia's adverse event reporting system works, and we only ever receive the same blanket reassurances from the TGA that everything is fine, and they treated the Covid-19 vaccine adverse events very specially, but we still have not seen any evidence about how they were doing that, and who was doing that?

Answer(s)

Index

Answer

Dr Phillip Altman, co-author:

As far as I am aware, the TGA has not issued any specific guidelines for the reporting of adverse drug reactions regarding the Covid-19 vaccines since the rollout of these products. Given that the normally expected comprehensive safety data supporting the Covid-19 was lacking before their release to the public and there was no evidence available regarding long term safety, it would have seemed prudent to implement special safety monitoring especially as it was recommended to use these products in very young children, pregnancy and for healthy people.

In the event that potentially conflicted individuals were involved in the subjective assessment of severity and causality related to the Covid-19 vaccines, it would also have been prudent to implement an independent safety audit system given the risks involved in the mRNA lipid-nanoparticle gene-based vaccines which had never before been used in medicine.

Index

Reference: CC

Index

A systemic analysis of epidemiological and statistical tools and information platforms used by Australian governments and overseas pharmacovigilance authorities for monitoring the safety of Covid-19 vaccines, with particular emphasis on:

i. adverse even reporting systems utilised by Australian Local Hospital Networks and Primary Health Networks;
ii. adverse event reporting systems utilised by Australian State and Territory government health departments;
iii. the NCIRS AusVaxSafety system implemented for Covid-19 vaccines;
iv. the TGA's AEMS and DAENS databases and the interaction of those databases with State and Territory government adverse event reporting systems.

Explanatory Memorandum

Index

An examination of the nationally and internationally agreed standards for the epidemiological and statistical modelling of Covid-19 vaccine safety signals, for example Proportional Reporting Ratio (PRR) and other established statistical tools.

An examination of the network structure, national standards, national procedures, and network coordination between State, Territory, and Federal government adverse event reporting systems, and the pharmacovigilance departments they each connect with.

Question(s) on Notice

Index

In respect of **References W and CC**, please provide any further information concerning Australian epidemiological data being compiled and published and relied upon by Commonwealth, State and Territory governments during the Covid-19 pandemic from early 2020 into 2023, the manner in which the data was being collected, the integrity of the data, the availability of the data to non-government health experts, and how that data was being used transparently to inform government policy on the need for Covid-19 vaccines to the exclusion of all other repurposed drugs, and for justifying Covid-19 mandates.

Answer(s)

Index

Answer

Dr Suzanne Niblett, Co-Author:

Refer also to the responses by Dr Suzanne Niblett at Questions on Notice for References V and W.

Consistent with the response at Reference W, it is difficult to evaluate the epidemiological and statistical tools, and information platforms used by the Australian government and overseas pharmacovigilance authorities to collect data for monitoring the safety of the Covid-19 vaccines due to a lack of transparency by the various government agencies.

While adverse event reporting systems do appear to be working at the Australian State and Territory Health Departments level, as indicated by the relatively high proportion of adverse events reported to the TGA coming from these sources (https://www.tga.gov.au/sites/default/files/half-yearly-performance-snapshot-july-december-2021.pdf), it is not possible to evaluate their performance relative to capacity and whether time constraints, or a culture of restricting the reporting of potential adverse events was operating to avoid conflicting with the AHPRA & National Boards position statement dated 9 March 2021 (https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx). The potential impact of the latter may have contributed to an observed drop in the adverse event reporting rate across the first 6-months following the vaccine rollout (refer to Figure 5(a) in Dr Suzanne Niblett's response at AA). It is also difficult to assess the degree of interaction between these systems and AusVaxSafety and the TGA owing to the lack of provision of any real information around these processes.

AusVaxSafety System

The AusVaxSafety system is a national vaccine safety surveillance system led by the National Centre for Immunisation Research and Surveillance (NCIRS) set up to assist the monitoring and detection of vaccine safety events (https://ausvaxsafety.org.au). It is an active surveillance system whereby the program follows up with people who have received a vaccine by sending them an SMS or email with a short survey asking whether they have had an adverse event following their vaccination. If an adverse event is reported, the AusVaxSafety survey collects information about specific but general adverse events, about medical attendance in relation to the adverse event, and about how the adverse event impacted their daily routines. These surveys are sent out on day 3, day 8 and day 42 following vaccination.

The advantage of the AusVaxSafety system is that individuals are actively followed up regarding their post-vaccination experience. The disadvantage is that not all who receive a vaccine are able to participate. Invitations to participate are restricted to those

receiving a vaccine at state immunisation clinics and by a GP or other immunisation provider who is signed up to the AusVaxSafety active surveillance system (https://ausvaxsafety.org.au/Covid-19-vaccine-safety-surveillance/what-ausvaxsafety-doing). Those receiving vaccines via other sources will not be offered to participate. While the operation of this active pharmacovigilance system is, in theory, a potentially very important and useful pharmacovigilance tool, there are numerous issues with the management of this program that impact the utility of the resulting data and its availability to the public.

Firstly, as mentioned above, the program is managed by NCIRS and, therefore, NCIRS manage the distribution of surveys, the collection, collation, analysis and storage of data, and the publication of findings. However, NCIRS are extremely difficult to correspond with making it difficult to access information that is not provided on their webpage. They no longer provide a contact telephone number and do not appear to respond to email contact nor to the messaging option provided on their contact page. Recent correspondence with the Freedom of Information team at the TGA also indicates that NCIRS falls outside the regulations of the Freedom of Information Act (1982).

Transparency is therefore a significant issue with the AusVaxSafety data. While a reasonable amount of information regarding the survey distribution methodology is provided on the AusVaxSafety webpage and in NCIRS reports, other information about methodology and analytical processes is not so readily available.

A major issue with the AusVaxSafety data is that only a portion of the data collected by the AusVaxSafety system is made available to the public. Despite NCIRS receiving funding from the Australian Government Department of Health and Aged Care to collect data from vaccinees on day 3, day 8 and day 42 following vaccination, only a portion of the day 3 data is published to its webpage. The published day 3 data includes:

> *the number of surveys returned; the percentage of surveys returned that report one or more adverse events; the percentage of surveys returned that reported experiencing a number of general or "common' symptoms (local reaction, fatigue, headache, muscle and joint pain, gastrointestinal symptoms and fever); the percentage of people seeking advice or care from a doctor or a health care professional and/or attending an emergency department as a result of the symptoms they experienced; the percentage of surveys reporting that the symptoms they reported caused them to miss work, study or normal daily activities*. What is not reported from the day 3 data is: *the breakdown of the type of medical advice/care that was sought; specific details collected around the 'common' symptoms including what type of gastrointestinal symptoms the vaccinee experienced; whether the survey participants experienced fainting/loss of consciousness or seizures; whether their symptoms had resolved; and how many days their routine activities were affected by their symptoms*.

A summary of any symptoms provided in the free text box, where survey respondents can provide additional information not captured elsewhere in the survey, is also not readily available. Importantly, the NCIRS do not publish any of the day 8 or day 42 on their website. Three days is a short time frame that does not allow for identification of adverse events that develop, or are formally diagnosed, after the three-day period. One publication provides some analysis of the day 8 data but the exclusion criteria for this paper were arguably unnecessarily restrictive and could have excluded a large number of valid day 8 responses (https://pubmed.ncbi.nlm.nih.gov/35781813/). This publication is also restricted to the Feb 2021 to August 2021 period. Another publication examines a sub-set of the 42 day data (https://www.mdpi.com/2076-393X/10/12/2017) but the sampling frame in this publication was restricted by both site (130 community pharmacies) and period (August 2021 to April 2022). Finally, the publication of the survey data on the AusVaxSafety webpage as separate infographics makes comparisons of findings across the various vaccines and demographic and clinical sub-groups difficult. The publications mentioned above did not conduct a formal comparison of the adverse event report rates following Covid-19 vaccination against the rates reported for other vaccines. The only reference made to other vaccines in the first paper was a statement that "the frequency rates of adverse events in our study were higher than for other vaccines used in Australia, perhaps because mRNA and viral vector vaccines more often elicit transient mild to moderate side effects than other vaccine types." No attempt was made to quantify these differences or interpret their significance from a clinical or pharmacovigilance perspective.

The AusVaxSafety data is a potentially rich resource of information regarding of adverse events following Covid-19 vaccination, with over six and a half million surveys having been returned in relation to the day 3 data alone. Greater transparency and access to this data is required to allow independent peer-review of the results and interpretations made about the safety of the Covid-19 vaccines.

Adverse Event Management by the TGA

The TGA Database of Adverse Event Notification (DAEN) is a national database that provides information about the adverse events reported in relation to medicines, vaccines and biological therapies used in Australia https://www.tga.gov.au/safety/safety/safety-monitoring-daen-database-adverse-event-notifications/database-adverse-event-notifications-daen-medicines. It is a passive surveillance system that rely on the spontaneous, voluntary report of adverse events by reporters.

The TGA Adverse Event Management System (AEMS) is the TGA's internal database that receive adverse event reports submitted from State and Territory Health Departments, pharmaceutical companies, health professionals, patients /consumers, and others. These reports are evaluated and, where the TGA decides that the report is not a duplicate or non-genuine report, are submitted to the DAEN. The information provided in the DAEN includes a unique identifier number or "case number", a "report entry

date", the "age (years)" and "gender" of the person experiencing the adverse event, the "medicines reported as being taken" marked as whether they are suspected and not-suspected medicines, and a list of adverse event terms or "MedDRA reaction terms".

The spontaneous adverse event data collected by the TGA is key to post-marketing pharmacovigilance in Australia and the findings emanating from the TGAs processes are used to inform policies and are given scientific credibility without independent peer-review. The TGA does not publicly release (unless in response to Freedom of Information requests) detailed information about the processes and protocols employed in the collection of the data, how their data is processed and analysed, how safety signals are identified and interpretated, and specifically what theoretical basis they have for disregarding identified safety signals. This "black-box" methodology and results analysis and interpretation is completely inappropriate given the significance of the outcomes of TGA pharmacovigilance processes on informing decisions and policy.

While a proportion of the adverse event reports (AERs/cases) submitted to the AEMS are provided on the DAEN, it should be noted that the TGA conducts its own analysis using the AEMS and not the DAEN – a fact that infers the limited utility of the DAEN for proper pharmacovigilance analysis. The AEMS contains all of the AERs (cases) and columns as the DAEN, as well as some additional AERs and columns. As mentioned above – some cases are withheld from the DAEN because they are identified to be duplicate reports from multiple reporters, others because they are considered invalid AERs, and some are kept in a holding bay for further analysis, as discovered recently and explained further below.

Regarding the data columns, both the AEMS and the DAEN have the same columns as listed in the above paragraph (albeit possibly with slightly different headings), however, the data in those columns is not identical across the two databases.

Firstly, for a sub-set of cases, the AEMS "medicines reported as being taken" column includes bracketed data behind the medication that identifies the number of days prior to the onset of the adverse event that the medication was taken. This is not provided in the DAEN and is an important omission that impacts the ability to conduct independent review. It is well recognized amongst scientific and clinical researchers internationally that the evaluation of information relating to onset time is core to the assessment of causality and the identification of safety signals. The TGA has itself recognized this by the inclusion of this at point 10 of the TGAs response to Senator Babets question on notice (Question 6) at the Senate Committee Supplementary Budget Estimates 2023-2024 (PDR Number: SQ23-002126). Here the TGA clearly states that:

> *Potential signals are reviewed and assessed by a team of clinical evaluators that consider several factors which may include, but are not limited to: ……assessment of the epidemiologic evidence of a causal relationship between the vaccine and adverse event. This considers factors such as the temporal*

relationship between vaccination and onset of an adverse event.

The requirement to assess temporal relationship is also one of the Austin Bradford-Hill criteria. The failure of the TGA to provide this data in the DAEN prevents this important analysis.

Secondly, for a sub-set of AERs, some adverse event terms such as death are withheld.

Thirdly, some ages available in the AEMS have not been published to the DAEN, or possibly not updated. Comparison of the combined AEMS age data provided in TGA FOIs 3785 and 3845 to approximately 900 adverse event reports in a current DAEN data extract identified discrepancies in the age data for approximate 10% of cases reviewed.

For 51 cases, the AEMS data released under the FOI had ages listed where no ages were listed in the DAEN:

> Case numbers: *521302, 521644, 527357, 527894, 539580, 547142, 550219, 551345, 553220, 559992, 562980, 563271, 563420, 563423, 563526, 564420, 566222, 569816, 569819, 572390, 572539, 575293, 583673, 583871, 589841, 592707, 595884, 596955, 601767, 609222, 610007, 613388, 613645, 615875, 619817, 620719, 625877, 626537, 632776, 634300, 647488, 648326, 654822, 659968, 666513, 686967, 687085, 688521, 688525, 688526, 736519*).
>
> For a further 38 cases the age data provided in FOI 3785 and/or 3845 differed to the currently listed DAEN data by between 1 and 10 years (case numbers: *528392, 534410, 536914, 538304, 541331, 542302, 542726, 543110, 543260, 543359, 546933, 547870, 547969, 549691, 552088, 553718, 555676, 557946, 583670, 586021, 587068, 615803, 643592, 649510, 666439, 677502, 685337, 687442, 698967, 711210, 713647, 717886, 718925, 720798, 734522, 736431, 740271, 742514*).

These differences were in both directions with approximately equal number having lower ages in the DAEN compared to the AEMS as had higher ages. As of today, there are 22,410 cases listed in the DAEN in relation to the Covid-19 vaccines where the age is listed as unknown. If the above analysis is extrapolated to this data, it suggests the AEMS may provide age information for a substantial number of cases where this information is currently undisclosed.

Regarding the integrity of the data held by the TGA, comment can only be made on evaluation of what has been published to the DAEN.

As highlighted above, the omission of certain cases from the DAEN, without full disclosure of the process of exclusion is inconsistent with the peer-reviewed scientific process. In a peer-reviewable scientific study, the researcher (here the TGA) would

present detail of the number of AERs/cases they have received, the specific number that were excluded from publication to the DAEN, and a breakdown of why they were excluded.

Regarding the omission of cases, several concerning processes have been identified. One is the holding of AERs in a "bay" for review before publishing to the DAEN. This is of great concern and came to the attention of researchers following the release of FOI 4769, which provided a list of 22,270 AERs that had been classified as serious by the reporter. When attempts were made to merge the serious case classification against a current list of the AERs in the DAEN that reported a Covid-19 vaccine as a suspected medicine, it became evident that 18 cases (case numbers: *524840, 525766, 532490, 533237, 535309, 542068, 543387, 553247, 561434, 642028, 646070, 647742, 647794, 647920, 648396, 648397*) were not listed in the current DAEN. Inquiries were made to the TGA who stated that these cases had been in a holding database. The TGA then then added 15 of the 18 cases to the DAEN (all excepting cases: *646070, 772053 and 788811*). This is a concern given that the report dates for these fifteen cases span between 22/3/2021 and 21/10/2021, which appears to be a long time for these to be held out of the public view. The question is how many other non-duplicate/invalid reports are not visible to the public and therefore inaccessible by independent researchers.

Another concerning trend has been the unexplained deletion of cases from the DAEN, with cases being added and then later deleted, with some also then later reappearing on the DAEN. An evaluation of 13 DAEN extracts taken at various intervals across the period from 19 December 2021 to 4 August 2023 conducted specifically to identify case deletions and deletions of 'carditis' cases found that 635 cases had been deleted across the various time points. 103 (19.7%) of these cases were aged between 0 and 17 years. This is a substantial over-representation of this age group given that only 4% of adverse event reports listed on the TGA DAEN extract dated 4 August 2023 were aged 0- 17 years. Similarly, 169 of the 635 deleted cases reported myocarditis, myopericarditis, pericarditis and/or carditis as an adverse event term. This report rate is approximately 6.6 times higher than the background report rate of 4% for these four terms in the 4 August 2023 extract and, again, indicates a disproportionate representation among the deleted cases. Guillain-Barre syndrome was also over-represented with 22 cases of in the deleted group (3.5%), giving a report rate 17 times higher than the background report rate of 0.2% in the DAEN as of 4 August 2023. The detailed analysis of these deleted cases is summarized in a word document and accompanying excel document and can be provided on request.

Another issue noted with the DAEN is where cases have been indicated to be deaths but are not registering as deaths, that is, adding to the death count, in the DAEN. Three cases (case numbers: 670258, 688523 and 688525) have been identified that are listed in FOI 3785 as cases with fatal outcomes but that are not adding to the death count on the DAEN. The symptom text provided in VAERS entries for cases 688523 and 688525 clearly indicate that both events had a fatal outcome

(https://medalerts.org/vaersdb/findfield.php?IDNUMBER=2059884&WAYBACKHISTORY=ON; https://medalerts.org/vaersdb/findfield.php?IDNUMBER=2059885&WAYBACKHISTORY=ON). TGA case 737775 is another AER that is currently not showing as a death on DAEN despite a VAERS entry for that case clearly indicating a fatal outcome (https://medalerts.org/vaersdb/findfield.php?IDNUMBER=2306771&WAYBACKHISTORY=ON).

The accuracy of the age and gender data itself is also a cause for concern and could be argued to render the DAEN data not 'fit for purpose' for age and/or gender stratified analyses.

Firstly, there are errors in the age data that, in a properly managed database through very basic data cleaning, should have been identified shortly after being added. An extraction of AERs from the DAEN, for cases where a Covid-19 vaccine is listed as a suspected medicine and conducted on 23 February 2024, identified five cases that reported ages above the maximum age expected in Australia. These cases were listed as 147 years old (case number: 679067, report date: 8/12/2021), 135 years old (741475, 18/6/2022), 121 years old (635725, 1/10/2021; 673307, 29/11/2021) and 117 years old (695464, 17/1/2022). The ages are likely to be mis entries but indicate poor data audit practices especially when one considers their existence in the database for 18 months to over two years. This raises the question of how many other errors exist in the DAEN age data? As discussed above, the comparison of cases listed in FOIs 3785 and 3845 to a current DAEN extract found inconsistencies in age data for approximately 10% of cases.

Secondly, is the issue of missing age and gender data. The extraction of AERs from the DAEN for cases associated with Covid-19 vaccines (23 February 2024) identified 140,018 AERs with 1,015 deaths overall. Of these, 22,410 AERs (16%) did not have any age details listed, 4,094 case reports (2.9%) did not have a gender listed, and 1,103 cases were missing both age and gender data. Overall, 25,401 AERs (18.1% of all AERs related to Covid-19 vaccines) were missing crucial demographic data for age and/or gender. A review of the AERs reporting death also revealed that 98 deaths associated with Covid-19 vaccines that had no age data, 18 that had no gender data, and 14 that had neither age nor gender data.

This is an unacceptably high proportion of missing data and the absence of this demographic data is a serious issue for the conduct and interpretation of analyses of adverse event reporting for populations sub-grouped on age and/or gender. For example, in the 23 February DAEN extract, there were 5,874 adverse event reports associated with Covid-19 vaccines aged 0 to 17yrs (0-4yrs - 103 cases, 0 deaths; 5-11yrs 1602 cases, 4 deaths; 12-17yrs - 4169 cases, 5 deaths). The allocation of any portion of the 22,410 cases, and their associated adverse event data including 98 deaths, to any of these age groups could make a dramatic impact on the age group adverse events profiles and any interpretations of safety made.

To further investigate this, a review was conducted of the types of adverse events, and the number of cases reporting those adverse events, for the 22,410 cases listed in the DAEN that are missing age data. Table 1 presents a comparison of these data to the number of cases reporting specific adverse events within the smaller younger age groups. This comparison was designed to consider the differences that reallocation of case data from the substantial pool of unknown age cases to the smaller age groups may have on their adverse event profiles and safety signals. As shown in Table 1, the unknown age group includes a substantial number of cases reporting myocardial infarction, myocarditis, myopericarditis, pericarditis, carditis, pulmonary embolisms, cerebrovascular accidents, anaphylactic reactions and seizures compared to the younger age groups. Allocation of even a portion of these could seriously change the safety profile of the younger age groups. For example, allocation of any amount of the 130 myocarditis cases from the unknown age group to the 5-11 year group could increase the number of cases of myocarditis for this age group from 3 to anywhere up to 133. Similarly, reallocation of the 434 pericarditis cases currently in the unknown age group to the 5 to 11 group gives a possible case count range for this group of 27 to 461. Reallocation of the 110 cerebrovascular accident cases from the unknown age group gives potential ranges of 0-110, 0-111 and 2-112 for the 0-4yr, 5-11yr, and 12-17yr age groups, respectively. Transfer of any proportion of the 98 cases where death was an outcome from the unknown age group to the smaller age groups leads to potential ranges for the number of deaths of 0-98, 4-102, and 5-103 for the 0-4yr, 5-11yr, and 12-17yr groups, respectively. This is an unacceptably high risk of error that renders the younger age group data, in its current form, unreliable and uninterpretable.

The accuracy and adequacy of the adverse event data itself also a cause for concern and could also be argued to render the DAEN data not 'fit for purpose'. In particular, the use of "adverse event following immunisation" (AEFI) as an adverse event term. This term has largely been used in association with AERs associated with the Covid-19 vaccines. An extraction of AERs from the DAEN for cases reporting this adverse event term (23 February 2024) identified 1,082 AERs that included this term, 215 where death was an outcome. Of these 1,045 (96.6%) cases and 208 (96.7%) of deaths listed a Covid-19 vaccine as a suspected medicine. For 924 (88.4%) of the 1045 Covid-19 vaccines cases reporting, no other adverse event data were provided. Cases reporting AEFI as their only adverse event cause the same issues to the database as do the unknown age data (Table 2). Allocation of these cases to the case counts for serious adverse events such as myocardial infarction, cardiac arrest, myocarditis, pulmonary embolism, cerebrovascular accident, and seizure may substantially alter the true case count numbers and significantly impact proportionality analyses and interpretation of safety signals.

Finally, is some consideration of the transparency and accuracy of statements made by the TGA regarding the number of deaths the TGA acknowledges as linked to a Covid-19 vaccine. To date, 1045 AERs have been submitted to the DAEN where an outcome of death was reported and counted. In the TGAs most recent report it claims that only 14 of

these deaths have been linked to the Covid-19 vaccines. What is unclear, however, is exactly what work has been done to examine causality in the remaining cases of deaths and what proportion of the remaining reports of death the TGA has definitely been able to rule out a causal role for the Covid-19 vaccines.

Table 1: Comparison of the number of TGA DAEN cases, where a Covid-19 vaccine is listed as a suspected medicine, reporting specific adverse events across age groups.

	Unknown ages	0-4 yrs	5-11 yrs	12-17 yrs
(a) Cases				
All terms	22,410	103	1,602	4169
Myocardial infarction	113	-	1	-
Acute myocardial infarction	10	-	-	1
Cardiac arrest	8	-	3	1
Myocarditis	130	2	8	182
Myopericarditis	12	-	6	86
Pericarditis	434	-	27	225
Carditis	55	-	1	1
Chest pain	1,908	3	227	864
Pulmonary embolism	173	-	-	5
Cerebrovascular accident	110	-	1	2
Anaphylactic reaction	75	-	6	25
Seizure	118	3	23	49
Febrile convulsion	3	-	1	4
Adverse event following immunisation	384	1	9	16
(b) Deaths				
All terms	98	-	4	5
Myocardial infarction	9	-	-	-
Cardiac arrest	1	-	3	1
Myocarditis	3	-	-	-
Pericarditis	1	-	-	-
Chest pain	2	-	-	-
Pulmonary embolism	8	-	-	-
Cerebrovascular accident	7	-	-	-
Adverse event following immunisation	27	-	1	1

Table 2: Comparison of the number of TGA DAEN cases, where a Covid-19 vaccine is the suspected medicine, reporting specific adverse events.

	Number of cases	Cases reporting death
Adverse event following immunisation	1,045	208
Myocardial infarction	391	47
Acute myocardial infarction	157	27
Cardiac arrest	164	102
Myocarditis	1,349	19
Myopericarditis	478	1
Pericarditis	3,844	6
Carditis	144	-
Pulmonary embolism	1,611	78
Cerebrovascular accident	549	70
Anaphylactic reaction	1,435	1
Seizure	845	10
Febrile convulsion	25	-

Index

Reference: DD

Index

A systemic analysis of epidemiological and statistical findings in relation to the safety and efficacy of Covid-19 vaccines by pharmacovigilance departments within Australian governments during 2021, 2022, and 2023.

Explanatory Memorandum

Index

An examination of the safety signal findings for the Covid-19 vaccines, which findings were and were not shared with the Australian public and what, if any, accepted analysis was not undertaken.

Question(s) on Notice

Index

In respect of **Reference DD**, please provide any further information concerning the epidemiological and statistical findings in relation to the safety and efficacy of Covid-19 vaccines by pharmacovigilance departments within Australian governments during 2021, 2022, and 2023, the manner in which the data was being collected, the integrity of the data, the availability of the data to non-government health experts, and how that data was being used publicly and transparently to inform government policy of the ongoing need for Covid-19 vaccines throughout 2021 into 2024.

Answer(s)

Index

Answer

Dr Suzanne Niblett, Co-Author:

Please refer to the response by Dr Suzanne Niblett at References V, W, AA and CC in relation to this response.

As referred in Reference CC the TGA is the principal authority responsible for assessing, approving, and regulating medicines and vaccines in Australia. In a response to a Question on Notice from Senator Babet (Senate Committee: Community Affairs Committee, Supplementary Budget Estimates 2023-2024, Outcome: 1- Health Policy, Access and Support; Question 12; PDR Number: SQ23-00000553), the TGA stated "*as*

the national therapeutic goods regulator, the TGA is responsible for ensuring that all COVID-19 vaccines approved for use in Australia meet the high standards for safety, quality and efficacy."

As is well recognised, all Covid-19 vaccines were granted provisional approval initially and retained this status for much of the vaccine roll-out. The provisional approval of a vaccine comes with both general and specific requirements for post-marketing pharmacovigilance.

Key components of pharmacovigilance analyses are evaluations of the medicine/vaccine efficacy and safety, and the use of these data to formulate risk-to-benefit ratios to inform regulatory and policy decisions. In the case of the covid-19 vaccines, however, there was clearly a lack of quality data from which to conduct these analyses, particularly relating to the Australian context.

Evaluation of the efficacy of a medication/vaccine requires first identifying the impact of the disease being treated by the medication/vaccine on the population and then determining the effectiveness of the medicine/vaccine in reducing those impacts. Impact has generally been measured by determining the number of infections and the severity of those infections, defined by the need to seek medical care, hospitalisations, ICU admissions and/or deaths. However, the validity and reliability of these data is questionable, a factor that seriously effects the ability to draw valid interpretations from these data and any analyses stemming from these, including risk-benefit ratios.

The responses to the Question on Notice at Reference V detail some of the concerns around these Covid-19 infection case counts and estimations of hospitalisation, ICU admission and deaths from Covid-19. These include the following:

a. a lack of standardisation and understanding of the limitations of the PCR test, the principal and touted 'gold standard' laboratory test used to identify covid-19 cases. This includes a lack of knowledge regarding false positive and false negative rates and how these are impacted by variable sample collection, sample transport and storage, laboratory conditions, operator training, instrumentation settings, and the symptomatic status of individuals being tested.

b. the use of ICD-10 codes, U07.1 and U07.2, that allow individuals with a positive test result but no clinical evidence of an active infection (no symptoms) to be classified as cases, together with individuals with a negative test result that present with 'covid-19' symptoms that overlap considerably with other common conditions such influenza and infectious pneumonia. Both factors could potentially inflate the number of cases, hospitalisations and deaths associated with the disease;
c. potentially unreliable or outdated information regarding vaccination status; and
d. the inclusion of people who have recently received vaccines in the 'control' group used to compare the rates of the outcome variables against vaccinated individuals,

when their inclusion potentially confounds each of the outcome variables in such a way as to bias to an interpretation of greater vaccine efficacy.

It is uncertain how the above factors have impacted the TGA's review of the efficacy or benefit of Covid-19 vaccines in the Australian context. This is because inadequate data have been provided to facilitate independent review of these processes.

Regarding the evaluation of vaccine safety, the TGA has described its processes in a response to a Question on Notice from Senator Babet (Senate Committee: Community Affairs Committee, Supplementary Budget Estimates 2023-2024, Outcome: 1- Health Policy, Access and Support; Question 5; PDR Number: SQ23-002126):

> The TGA uses a wide range of methods to identify potential safety signals including internal signal detection, information from overseas regulators, published literature, data from sponsors and also external stakeholders which includes adverse event reports from health professionals, state and territory health departments and those included in the WHO adverse event database. The TGA may also take safety investigations to the Advisory Committee on Vaccines for consideration and advice.

As part of its evaluation of safety, the TGA monitors reports of adverse events that are received through its spontaneous reporting system, via existing clinical networks (AEFI-CAN and SAFEVIC), and through the active reporting system AusVaxSafety, According to the TGA, all adverse events are evaluated to confirm they are a valid report, and where appropriate are then risk assessed and entered into their adverse event management database.

Analysis of the adverse events for safety signals include: evaluation of the rates of common adverse events compared to serious adverse events including deaths; and the conduct of disproportionality analyses (e.g. Proportional Reporting Ratios, PRRs) together with other statistical analyses of the adverse event data from the TGA's Adverse Event Management System (AEMS).

Owing to the provisional nature of the Covid-19 vaccines authorisation, specific pharmacovigilance protocols were put in place regarding the assessment of safety signals. These were incorporated into the "COVID-19 Vaccine Pharmacovigilance Plan" and were discussed at an advisory committee on Vaccines – Meeting 25 held on 29 September 2021. The minutes of this meeting were not made available to the public but have since been released in a heavily redacted document in response to a freedom of information (FOI) request, TGA FOI-4029 (https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-03.PDF). An excerpt of that document is presented in the below screenshot (Figure 1).

Overview of the Delegate of the Secretary of the Department of Health

Implementation of the COVID-19 Vaccine Pharmacovigilance Plan (the Plan) has included identification of AESI via use of a combination of weekly disproportionality analysis and comparison of observed AEFI reporting rates to background and expected rates.

The TGA has adopted the use of Proportional Reporting Ratio (PRR)[3] calculations for AEFI-vaccine pairs and revised the previous disproportionality analysis methods for COVID-19 vaccines to:

- increase the frequency of PRR analysis and reporting from bimonthly to weekly
- use PRR analysis by vaccine trade name rather than active ingredient
- use a lower threshold of a PRR >1 and case count ≥2 to identify vaccine-event pairs for assessment.

The current COVID-19 Vaccine Safety Monitoring Plan in Strategy 2.3 advises that the TGA will conduct enhanced cumulative data reviews for each COVID-19 vaccine to enable rapid analysis of AEFI rates to detect and confirm or disprove emerging COVID-19 safety signals. These methods include:

- access to Australian Immunisation Register (AIR) and vaccine distribution data for calculating COVID-19immunisation rates
- refined processes and statistical methods for analysing observed COVID-19 AEFI rates for detecting safety signals
- enhanced processes to determine if the frequency of particular AEFI are higher than expected

Figure 1: Screenshot taken from the minutes of an advisory committee on Vaccines – Meeting 25 held on 29 September 2021, released under TGA FOI 4029.

Notable from this screenshot of the COVID-19 Vaccine Pharmacovigilance Plan are the following: (1) the proposed increase in the frequency of PRR analyses and reporting from bimonthly to weekly; (2) the use of a lower PRR threshold of >1 and a case count of ≥2 as criteria for assessing a safety signal; and (3) the use of Australian Immunisation Registration data for the provision of COVID-19 immunisation data to estimate adverse event reporting rates.

While these enhanced pharmacovigilance processes were proposed, the results of these analyses have generally not been made available to the public, restricting the capacity for independent review. Minimal information has been provided around investigations into the rates of specific adverse events, such as myocarditis and/or pericarditis, but other adverse event reporting rates have remained largely undisclosed. No data regarding PRR values or other statistical findings have been made available to the public outside FOI requests or questions at Senate Estimates. This is despite the TGA frequently spruiking the conduct of thorough risk-benefit analysis and concluding that Covid-19 vaccines are "safe and effective".

The TGA response to the FOI request FOI 4032 did disclose detail relating the TGAs "*Proportionality Reporting Ratio analyses for the COVID-19 vaccines to 22 October*

2022". These were released as nine files, each file providing a list of the PRR values specific to a particular Disproportionality Analysis Report (DPAR) date. The link to each of these files is provided in Table 1. A summary of the PRR values presented across the nine DPAR dates, overall and separately, are summarised in Table 2.

Table 1: Disproportionality Analysis Report (DPAR) dates and links to files released under FOI request 4032.

DPAR Date	FOI 4032 document number and link
13-Mar-21	Document 1: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-01.pdf
19-Jul-21	Document 3: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-03.pdf
29-Sep-21	Document 2: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-02.pdf
29-Nov-21	Document 4: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-04.pdf
17-Jan-22	Document 5: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-05.pdf
24-Mar-22	Document 6: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-06.pdf
11-May-22	Document 7: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-07.pdf
15-Jul-22	Document 8: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-08.pdf
15-Sep-22	Document 9: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-09.pdf

Table 2: Summary of the number of adverse event terms identified with a proportional reporting rate (PRR) greater than 2.0, together with the mean, standard deviation and ranges of PRR values presented overall and for each DPAR date.

DPAR date	No of adverse event terms with PRR >2	Proportional Reporting Ratio (PRR)		
		Mean	± SD	Range
Total (1 Feb 2021 to 22 Oct 2022)	2528	6.6	± 5.5	2.1 - 118.4
13-Mar-21	10	15.0	± 10.9	4.7 - 36.9
19-Jul-21	267	7.2	± 5.5	2.1 - 32.3
29-Sep-21	342	6.7	± 4.8	2.1 - 36.5
29-Nov-21	339	7.4	± 5.7	2.2 - 51.5
17-Jan-22	350	7.9	± 9.0	2.3 - 118.4
24-Mar-22	370	6.4	± 4.7	2.2 - 39.5
11-May-22	351	5.7	± 3.9	2.1 - 45.0
15-Jul-22	300	5.5	± 3.2	2.1 - 31.3
15-Sep-22	199	5.3	± 2.6	2.3 - 19.1

The total number of adverse event terms with PRR values greater than 2.0 across the nine DPAR dates was 2,528 with PRR values ranging from 2.1 to as high as 118.4, and approximately 50% of all PRR values exceeding 5. The overall mean PRR value was 6.6, with mean PRR values calculated for each DPAR varying from 5.3 to 15.0 (Table 2). When duplicate adverse event terms were removed, 881 unique adverse events remained.

Noteworthy from the DPAR findings made available through FOI 4032 was the limitation of the DPAR data to nine dates that were bi-monthly, rather than weekly, and to PRR values >2, rather than >1. This is contrary to the enhanced pharmacovigilance proposed and discussed at an advisory committee on Vaccines – Meeting 25 held on 29 September 2021 (https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-03.PDF),

and which suggests that these items in the COVID-19 Vaccine Pharmacovigilance Plan (the Plan) were not implemented.

It is also unclear what comparison medicines/vaccines the TGA used for the calculation of the PRR values. Again, this lack of transparency of methods restricts independent review. The use of PRR values has limitations. Understanding the adverse event profiles of both the medicine/vaccine under review and the comparison group is important to understanding these limitations and how they may impact interpretation. With a lack of transparency, the TGA's methods, results and interpretation can again not be independently verified, or the veracity of their statements tested.

Excepting a small number of specific safety signals, such those relating to myocarditis, pericarditis, and thrombosis with thrombocytopenia syndrome (TTS), the TGA has generally not provided information about the safety signals they have investigated and/or the outcomes of those investigations. In response to a Question on Notice from Senator Babet (Senate Committee: Community Affairs Committee, Supplementary Budget Estimates 2023-2024, Outcome: 1- Health Policy, Access and Support; Question 2; PDR Number: SQ23- 002124) the details of some of the safety signals investigated and their outcomes were provided. In this document, the TGA states that they had "*completed more than 140 post-market COVID-19 vaccine safety investigations and evaluations resulting in more than 60 regulatory actions, including 43 updates to safety information in the Product Information documents.*" The TGA then provided a list of potential adverse events that had been investigated as of the end of October 2023, stratified on vaccine. The number of potential adverse events in this list are summarised in Table 3. The list included 97 "*potential adverse events investigated*" across the various vaccine groups. Eighteen of these had an outcome of "*product information updated*". These are listed in Table 4. Also notable was that multisystem inflammatory syndrome in children was listed as "*referral to external organisation for enhanced surveillance*", mastitis was "*under negotiation with sponsor*", and chest pain and type 1 diabetes mellitus were listed as "*second investigation going*".

Table 3: Summary of the number of potential adverse events investigated to the end of October 2023 as provided in response to a Question on Notice from Senator Babet (source details in text).

Vaccine group	Number of potential adverse events investigated
Total	97
Comirnaty	34
Spikevax	2
Comirnaty and Spikevax	2
Vaxzevria	20
Nuvaxovid	3
All covid-19 Vaccines	24
Comirnaty and Vaxzevria	12

Table 4: Summary of the potential adverse events investigated to the end of October 2023 that had an outcome of "product information change" provided in response to a Question on Notice from Senator Babet (source details in text).

Vaccine group	Product information change
Comirnaty	Parasthesia and hypoesthesia
Spikevax	Capillary leak syndrome
Comirnaty and Spikevax	Myocarditis/pericarditis
	Heavy menstrual bleeding
Vaxzevria	Acute disseminated encephalomyelitis/ encephalitis/ encephalopathy
	Thrombocytopenia and immune thrombocytopenia
	Capillary leak syndrome Guillain-Barre Syndrome
	Hearing disorders including deafness and tinnitus
	Traverse myelitis
	Venoous thromboembolism
Nuvaxovid	Parasthesia an hypoesthesia. Myocarditis/pericarditis. Tinnitus, hypoacusis and ear discomfort
All COVID-19 vaccines	vulvovaginal ulcerations (Lipschutz ulcers) in adolescent girls
Comirnaty and Vaxzevria	Erythema multiforme
	Menstrual bleeding disorder

Analysis of adverse event disproportionality using PRR values may, with limitation, identify differential reporting of potential adverse reactions, however, they do not necessarily provide an analysis of potential safety signals that may be indicated by differential occurrence. The TGA assesses the occurrence of adverse reports, and the rates of report, using the TGA's internal database, the AEMS together with AIR data. However, the public and independent researchers do not have access to this data and are only provided with access to the adverse event report data included in the Database of Adverse Event Notification (DAEN).

Extensive analyses of the adverse event reports listed in the DAEN associated with the Covid-19 vaccines has been conducted and revealed many potential safety signals. A small portion of these have been discussed in the response at Reference AA. The results presented in Reference AA are part of a substantially larger analysis that has identified many potential safety signals. These data will be released shortly via publications and/or reports and are available on request.

The findings outlined in Reference AA can be briefly summarised below:

a. Covid-19 vaccines were associated with 23.1% of adverse event reports ever submitted to the TGA across 52 years to 28 April 2023.
b. Covid-19 vaccines were associated with 7.2% of all deaths ever submitted to TGA across 52 years to 28 April 2023.
c. There were substantial increases in adverse event reports across all system organ classes.
d. When corrected for dose (1 Mar 2022 to 14 Aug 2022 analysis), the absolute risk of

submitting an adverse event report following a covid-19 vaccine was 16.7 times higher than for the influenza vaccine.

e. When corrected for dose (1 Mar 2022 to 14 Aug 2022 analysis), the absolute risk of an adverse event report with an outcome of death following a covid-19 vaccine was 16.9 times higher than for the influenza vaccine.
f. Covid vaccines were associated with 39% of all adverse event reports ever submitted to TGA across 52 years to 28 April 2023 where a cardiac disorder was reported.
g. Covid vaccines were associated with 13.3% of all adverse event reports ever submitted to TGA across 52 years to 28 April 2023 where a cardiac disorder was reported and death was an outcome.
h. The relative risk of developing a cardiac adverse event following a covid-19 vaccines compared to an influenza vaccine was 47.7 (1 Mar 2022 to 14 Aug 2022 analysis).
i. Greater evidence of the disproportionate occurrence of adverse events among individuals following Covid-19 vaccination were evident in analyses of myocarditis and/or pericarditis, particularly when data were stratified on age group.

The TGA often argues that the adverse events most frequently reported in association with Covid-19 vaccines are the 'common' adverse events such as headaches, fatigue, fever and myalgia, with an inference that these are innocuous symptoms. What the TGA fails to draw attention to is the uniquely high report of chest pain and dyspnoea among the Covid-19 vaccinees, and the exceptionally high frequency of report of common symptoms which are NOT always innocuous and can be present in association with serious disease and death (Table 5).

In an extraction of adverse event data related to covid-19 vaccines from the DAEN for the period from 1 December 2020 to 16 January 2024, it was found that chest pain reported in association with covid-19 vaccines contribute 15,480 (69.2%) of the overall 22,383 of adverse event reports of this adverse event (Table 5). Importantly, chest pain was the ***sixth*** most frequently reported adverse event associated with Covid-19 vaccines overall, the ***number one*** most frequently reported adverse event reported in association with covid-19 vaccines for the 5 to 11 years and the 12 to 17 years age groups, and the ***second*** most frequently reported adverse event for the 18 to 44 years age group in this analysis. Dyspnoea was reported in association with Covid-19 vaccines for 11,796 (44.6%) of all reports of this adverse event ever submitted to the DAEN (Table 5). Headache, fatigue, pyrexia, and myalgia associated with Covid-19 vaccines also represented between 43.0% and 71.7% of all reports of these adverse events ever submitted to the DAEN. The high report of these common symptoms, relative to the influenza and national immunisation program vaccines, was also noted for the AusVaxSafety data (refer to response at Reference AA).

Table 5: General MedDRA adverse event reaction terms among adverse event reports submitted to TGA DAEN from 1 January 1971 to 16 January 2024 where covid-19 vaccines and influenza medicines were listed as suspected medicine compared to all medicines.

MedDRA reaction term	All Medicines		Covid-19 Vaccines				Influenza Vaccines			
	No. of cases	No. of deaths	No. of cases *(% of All Medicines)*		No. of deaths *(% of All Medicines)*		No. of cases *(% of All Medicines)*		No. of deaths *(% of All Medicines)*	
Chest pain	22,383	158	15,480	*(69.2)*	50	*(31.6)*	248	*(1.1)*	4	*(2.5)*
Dyspnoea	26,427	414	11,796	*(44.6)*	89	*(21.5)*	773	*(2.9)*	4	*(1.0)*
Headache	52,181	126	33,313	*(63.8)*	46	*(36.5)*	2,030	*(3.9)*	0	*(0.0)*
Fatigue	26,905	177	16,232	*(60.3)*	34	*(19.2)*	958	*(3.6)*	2	*(1.1)*
Pyrexia	42,549	267	18,313	*(43.0)*	40	*(15.0)*	6,699	*(15.7)*	11	*(4.1)*
Myalgia	28,921	50	20,743	*(71.7)*	15	*(30.0)*	1,185	*(4.1)*	2	*(4.0)*

Cases = Reports of adverse events. Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 30 January 2024.

Finally, of note is the number of suspected serious adverse events in people who received a Covid-19 vaccine. A document released under FOI 4769 contains a list of TGA Case numbers for suspected serious adverse events in people who received a COVID-19 vaccine (https://www.tga.gov.au/sites/default/files/2023-11/FOI%204769.pdf). The document provides '*reports with a report date up to and including 19 October 2023*'. 22,271 cases of suspected serious events were listed. This represents 16% of all adverse events reported in association with Covid-19 vaccines to that date. This is a relatively high proportion of serious cases. It should be noted at this point that the TGA specifies that '*the assessment of seriousness reflects the view of the reporter. Inclusion in this category does not mean that the TGA has confirmed that the report meets the serious criteria*'.

In summary, there is a serious lack of transparency from the TGA in terms of detail about the methods, analysis and interpretation of the outcomes used to assess both the efficacy and safety of the Covid-19 vaccines, and thereby to calculate the risk-benefit ratio.

In general, there has been minimal to no data provided to the public regarding the detection and assessment of safety signals other than that released via FOI requests or Questions on Notice at senate estimates.

Where data on PRRs were made available through an FOI, it became apparent that not only were many PRR values detected that were well above the critical threshold for signal identification, but that the enhanced pharmacovigilance that the TGA assured the public would be conducted to justify the release of these provisionally approved vaccines was in fact not being implemented.

Where information regarding the safety signals that had been investigated were released in response to a Senate Committee Question on Notice, discrepancies were noted

between the number of safety signals that the TGA claimed to have addressed in their text response compared to their tabulated response. Furthermore, the numbers of signals evaluated where substantially smaller than the number of PRRs included in the DPAR documents with no explanation as to why so many adverse events with high PRRs were not being followed-up. Moreover, the outcomes listed in the response suggest numerous product information updates, but one has to ask, were the public and health professionals properly advised of these findings and do they impact the vaccine injury compensation claim criteria?

The provision of only a subset of the data the TGA used for its analysis has also been highlighted. The DAEN provides no information about onset periods and is impacted by large numbers of adverse event reports that are missing data for age, gender and specific detail about the adverse event. This is a critical issue, with the proportion of cases impacted by this missing data well exceeding the number of cases in important sub-group analyses. The allocation of even small amounts of data from the ill-defined cases to the smaller groups stratified on age, gender and/or adverse event could seriously impact sub-group adverse event profiles, a factor that could be argued to render the database as 'not fit for purpose' for these analyses. In addition to this, the missing data, particularly for serious cases and deaths indicated a lack of follow up and due diligence by the TGA. Furthermore, evidence of incorrect age data persisting for well over 12 months indicates poor data auditing and questionable data quality. Finally, the practice of adding and later deleting cases, with over-representation of young cases and cases of serious illness including myocarditis, pericarditis and Guillain-Barre Syndrome is highly concerning.

In short, the TGA makes many references to "following the science" without any evidence that they are in fact adhering to core scientific principles and practices. It is unscientific and highly inappropriate that the TGA operate with 'black box methodology' that is unavailable for public and peer-scrutiny. This is particularly concerning considering the influence of the TGA's opinions on decisions and policies, and their potentially conflicting relationship with pharmaceutical companies.

The powers afforded by a Royal Commission are required to provide access to all the documentation around the TGA's protocols, analyses, results and interpretations, and to all of the data required to the conduct of proper independent robust scientific evaluation of Covid-19 vaccine efficacy and safety.

Index

Reference: EE

Index

A systematic and independent analysis of all Covid-19 vaccine adverse event reports of deaths reported to the TGA through the DAEN system as reported by the TGA in its "vaccine safety report", and a further systematic and independent analysis of all deaths recorded on the AEMS system.

Explanatory Memorandum

Index

An independent review and analysis of all Covid-19 vaccine adverse event reports received by the TGA, to confirm whether the TGA provided reasonably accurate data transparency.

Question(s) on Notice

Index

Dr Madry, in respect of your joint submission and in particular index **References EE and FF**, are you able to confirm for the Committee whether the TGA has been transparent in providing reliable and timely access to data scientists like yourself, for researching and modelling purposes, the data contained in the TGA's DAEN and AEMS adverse event reporting systems, for being able to confirm timely and accurate reporting of Covid-19 vaccine adverse events, so scientists like yourself could perform independent research to confirm the Covid-19 vaccines are 'safe and effective'?

Answer(s)

Index

First Answer

Dr Andrew Madry, Co-Author:

The Therapeutic Goods Administration (TGA) is the agency I will refer to. In particular, the reporting of adverse events. Currently there are approximately 140,000 adverse event reports listed in the TGA's Database of Adverse Event Notifications (DAEN) where a Covid-19 vaccine was reported as a "suspected medicine". Among these are 1011 cases where death was a reported outcome. I emphasise that these are "reported deaths" where the person reporting suspected Covid-19 vaccination to be involved in the death and that

we know that the majority of these are reported by health professionals. All reports should be taken seriously.

The TGA accepts that ***only 14*** of these 1010 deaths are causally linked to Covid-19 vaccination. 13 are related to the AstraZeneca vaccine, and one is the death of a young lady following Moderna injection. How many of the remaining 997 deaths have been thoroughly assessed for causality is uncertain. The TGA has not been clear about this, and whether Covid-19 vaccines have been definitively ruled out as the causative agent for any of these.

The public facing reporting system is not fit for purpose, and consequently it has been up to the public and researchers to submit numerous Freedom of Information (FOI) requests in their attempts to understand and assess the impact of the Covid-19 vaccinations on the health of Australians.

For example, the public facing DAEN makes it impossible to unambiguously identify which cases are Deaths, as death is not a field supplied for these vaccines despite it being an adverse event term in the DAEN. Only a total count of deaths is provided.

Of course, if deaths were seen to be associated with young people this would cause great concern.

Members of the public have submitted numerous FOI requests to get information that should have been publicly available in the first place.

Where information has been provided, it is often rendered in such as way as to make analysis difficult, or impossible. For example, one FOI request asked for the ages of reported deaths. The FOI response from the TGA was provided as a pdf made from of an Excel spreadsheet with many columns, and with which came out as hundreds of pages mostly redacted, giving the appearance that there were tens of thousands of reported deaths.

I wanted to clear this up, and submitted my own FOI request to specifically obtain the TGA case numbers for the cases where death was an outcome, together with the age of death. At the time there were approximately 600 deaths reported. The deaths were skewed towards the elderly but there were many deaths in young people. This format unambiguously identified the actual number of reported deaths and facilitated merging with other data.

This lack of transparency and obfuscation, firstly in the DAEN, and then in the FOI responses is unacceptable.

In response to the TGA's poor transparency in the publishing of adverse event reporting data, a group of volunteers have created a website, OpenDAEN, which allows users to

view the adverse events data in an easily searchable format similar to the way that OpenVAERS provides a view of the US CDC's VAERS system.

For example, it allows one to see that the most commonly occurring adverse event for young people is chest pain. The risk of chest pain in young people (and more serious manifestations such as myocarditis, pericarditis) is not necessary when the risk from Covid-19 to healthy young people is negligible.

Had this dashboard been available earlier, it would have been easier for the public to view the increase in heart-related issues experienced by young people in association with the Covid-19 vaccinations.

Other important information, surfaced by Senator Rennick, is statistical data on the time lag from date of last vaccination to date of death. The TGA response to Senator Rennick showed that 60% of deaths, where the delay was known, occurred within two weeks of vaccination.

Senator, given that it is unlikely that people close to death are vaccinated for Covid-19, known as the "healthy vaccinee bias", this is a grave concern. The data that is needed is the vaccination status of all deaths since 2021 and date of last vaccination. This data can easily be deidentified, to protect privacy. We know how to analyse this data, and the public has a right to know this.

The public needs access to the relevant data in the AEMS which is the initial entry point of adverse events.

Index

Second Answer

A/Prof Peter Parry, Co-Author:

My PhD research into the overdiagnosis, overmedicating epidemic of 'paediatric bipolar disorder' in very young children mainly in the USA included analysing iatrogenic adverse effects of psychotropic medications prescribed. The research made me familiar with the FDA's Adverse Event Reporting System (FAERS) for pharmaceutical drugs. The FAERS also included vaccines until 1990 when that data was separated out and collated in the Vaccine Adverse Event Reporting System (VAERS) and responsibility handed from the FDA to the US Centres for Disease Control and Prevention (CDC) for managing VAERS data.

In the case of antipsychotic medications prescribed to young children for (often misdiagnosed) bipolar disorder diagnoses, investigative journalists from *USA Today* and the *New York Times* analysed FAERS data and found thousands of reports of paediatric

deaths from these drugs. This data was disputed by some child psychiatrists in the USA. However, a later paper, published in the *Journal of the American Medical Association (JAMA) Psychiatry* confirmed an increased risk of 3.5-fold of unexpected death, 4.29-fold for cardiac and metabolic causes – significantly correlated with high antipsychotic doses given for mania/bipolar disorder. Given the extent over time of the paediatric bipolar disorder overdiagnosis epidemic, the findings of the investigative journalists have face validity. I described this in pp. 137-140 of my thesis on the Flinders University Theses website. The former chief-editor of the *Canadian Journal of Psychiatry*, Prof Joel Paris, has said that "50 years from now, paediatric bipolar disorder will be seen as the greatest scandal to befall psychiatry". The time lag implies there is a cover-up, which is a common institutional response to scandal.

The relevance is that current passive pharmacovigilance databases such as VAERS and the TGA's DAEN need to be taken seriously.

Under-reporting factor is the norm for passive pharmacovigilance databases

Under-reporting factors for the true rate of adverse events are the norm in passive pharmacovigilance databases such as the TGA's Database of Adverse Events Notifications (DAEN), UK MHRA's YellowCard, US FDA's FAERS, US CDC's VAERS, European EMA's Eudravigilance, WHO's VigiAccess and other national databases.

Data and research showing underreporting factors with previous drugs/vaccines

A US government quality assurance analysis calculated that the CDC's VAERS under-reports by a factor of 10- to 100-fold; that only 1% to 10% of all serious vaccine injuries are reported.

A comparison of VAERS sensitivity to capture very serious adverse events well-known to be caused by vaccines, namely anaphylaxis and Guillain-Barré syndrome was published in the respected journal *Vaccine*. Reporting of these two adverse events ranged from 12% to 76% but mostly around 25% for several vaccines. In other words, an under-reporting factor of 4-fold for a life-threatening well-recognised vaccine adverse event.

A comparison of reports of anaphylaxis during the Pfizer C19 vaccine clinical trial with VAERS reports during the public rollout suggested a VAERS under-reporting factor of 31-fold.

In terms of prior examination of Australia's DAEN system, significant under-reporting to the Australian TGA of febrile convulsions in infants due to the influenza vaccine in Australia 2010 was estimated to have occurred with rate of febrile convulsion secondary to flu vaccine of 1 in 110 infants, but only 77 cases were ultimately reported to the

TGA's DAEN. This was reported in a letter to the *BMJ* . As also reported in the *BMJ,* this led to the suspension of the Australian flu vaccine for young children at the time and medical ethicists criticising Australian experts on flu for having been influenced by pharmaceutical industry lobbying.

The case of Vioxx (rofecoxib) is noteworthy as it was a drug that was eventually withdrawn from the market, albeit after a 5-year period wherein there was evidence of fraud in the original study that suppressed heart attack risk, and independent peer-reviewed publications that it caused an unacceptable cardiovascular risk. This is discussed in more detail under Terms of Reference U. Of note here is a graph on VAERSanalysis.info of drug/vaccine market recalls/withdrawals.

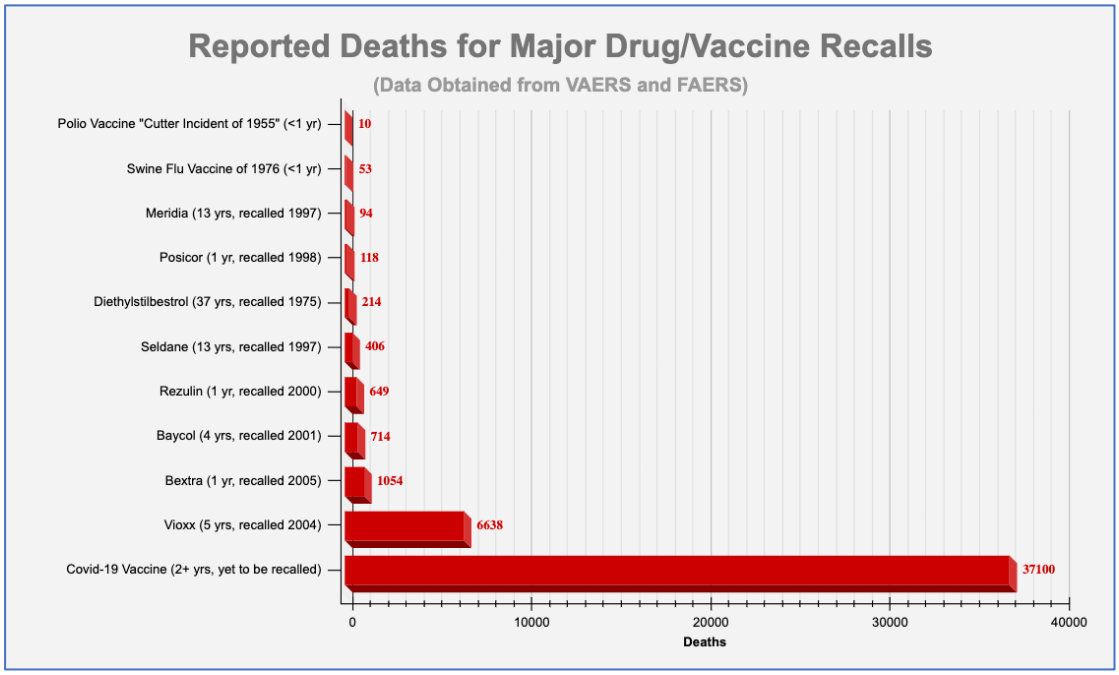


Figure 1: Reported deaths for major drug/vaccine recalls, from VAERSanalysis.info
https://vaersanalysis.info/2024/02/02/vaers-summary-for-Covid-19-vaccines-through-1-26-2024/

For Vioxx's five years on the US market there were 6,638 reported deaths to the FDA's drug adverse event reporting system, FAERS. Some of these may have come from other nations. An article in *The Lancet* estimated that of the 20 million Americans prescribed the drug and estimated 88,000 to 139,000 suffered myocardial infarctions. The author, FDA scientist Dr David Graham, in testimony to the US Congress estimated a 30% to 40% fatality rate, and hence 26,400 to 35,200 (if 88,000 heart attacks) to 41,700 to 55,600 (if 139,000 heart attacks) deaths. Given the FAERS deaths reports were only 6,638, the under-reporting factor is somewhere between 4-fold and 8.4-fold. If a portion of the reports were from outside the USA, then the under-reporting factor would increase.

Note also that the bar for market withdrawal of the polio vaccine in 1955 (10 death reports) and Swine Flu vaccine of 1976 (25 reports at time it was recalled, 53 in total reported) was much lower than for Vioxx and for the current Covid-19 vaccines. One

possible variable associated with this is the funding change to regulators from the taxpayer to the pharmaceutical industry, as reported in the *British Medical Journal* (*BMJ)* in a 29 June 2022 article titled "From FDA to MHRA: are drug regulators for hire?".

Active surveillance surveys

One way of detecting the under-reporting factor is by comparison with active pharmacovigilance surveys such as the AusVaxSafety survey of the National Centre for Immunisation Research and Surveillance (NCIRS) and in the USA with the "V-safe" survey of the CDC.

Up to 23 January 2023, AusVaxSafety received 6,377,586 completed surveys of which 2,861,538 reports included at least one adverse event. Across all doses of the three vaccines, Pfizer, Moderna, AstraZeneca, an average 15% of respondents (956,637) reported missing work, study or unable to perform daily routines post-vaccination, and an average of 1.14 in 100 people required a doctor or emergency department attention post vaccination. This equates to approximately 48,710 people requiring medical attention from a survey that received reports from 24% of the Australian population. The survey did not specifically ask about most serious adverse events beyond typical lethargy, headache, arthralgia reactogenicity effects and time off work and daily routines. The survey also was restricted to the days following vaccination rather than later adverse events.

Nonetheless, the results of the *active* AusVaxSafety survey indicate that the number of reports to the *passive* DAEN **under-report** the true rate.

Further, there was a higher rate of adverse events with the Moderna than with Pfizer mRNA vaccine, which is consistent with a dose-response effect as the Moderna vaccine (100µg) has more than three times the amount of mRNA as a dose of the Pfizer vaccine (30µg). Also, the higher rate of work absenteeism after the second dose and the timing interval from first dose and then to booster is consistent with a dose response effect. A high 35% missed work or duties after the second dose. This is a level unheard of with regards to vaccines made by normal non-genetic vaccine technologies, and without lipid-nanoparticle matrices that can slip through cellular membranes as is the case of the Novavax vaccine. A dose-response effect is a Bradford-Hill criterion for increased likelihood of causality.

The following figure shows the AusVaxSafety data for Moderna mRNA vaccine.

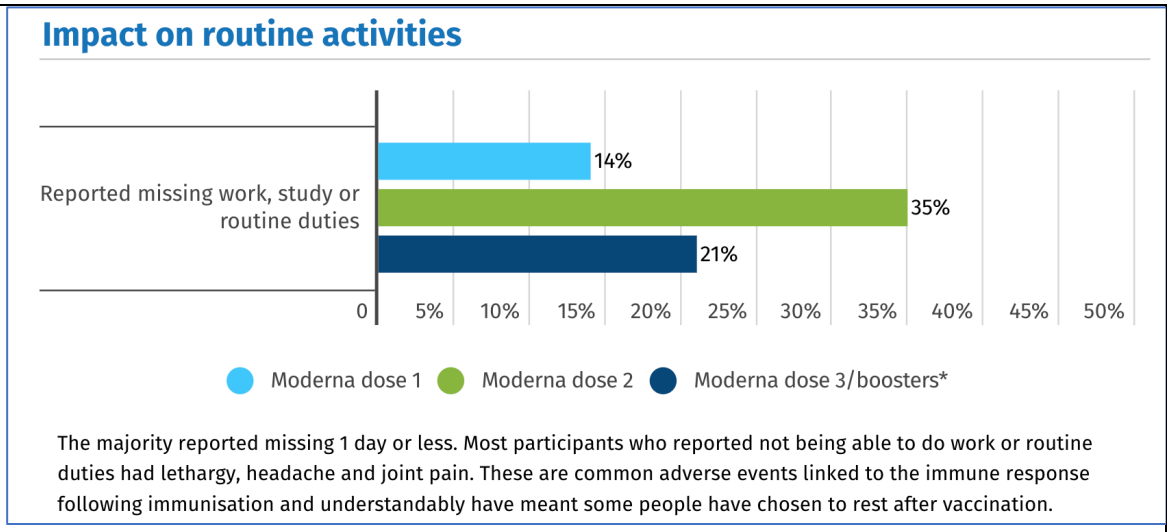


Figure 2: Impact on routine activities of Moderna doses 1, 2 & booster, AusVaxSafety data. See: https://ausvaxsafety.org.au/Covid-19-vaccines/moderna-bivalent-Covid-19-vaccine

By way of comparison, AusVaxSafety indicated medical care presentations of 1.14 per 100 for the Covid-19 vaccines of AstraZeneca, Pfizer and Moderna, the TGA's DAEN showed a reporting rate of 2.1 per 1,000 doses in its safety report of 22 January 2023. By 26 January 2023 the estimated total doses per 100 people was 243.22 (figure 2) consistent with the three doses data from the AusVaxSafety survey. Very roughly 1.14 versus 2.1 per 1000 doses suggests an under-reporting factor of about 5-fold. However, given the AusVaxSafety data was time-limited and the DAEN reports likely covered a longer timespan than the AusVaxSafety survey, the data indicates an under-reporting factor applying to the DAEN data is likely larger.

Index

Reference: FF

Index

A systematic and independent review of the data held by the TGA on the AEMS system and data published on the DAEN system in respect of adverse event reports for Covid-19 vaccines, including:

i. all national and international Covid-19 vaccine adverse event reports held by the Pharmacovigilance Special Access Branch (PSAB) during 2021, 2022, and 2023;
ii. all epidemiological and statistical modelling of Covid-19 vaccine safety signals conducted by the PSAB in respect of national and international adverse event reports during 2021, 2022, and 2023;
iii. all epidemiological and statistical modelling of Covid-19 vaccine safety signals received by the PSAB from equivalent Pharmacovigilance units located in the FDA, WHO, EMA, and MHRA, in respect of national and international adverse event reports during 2021, 2022, and 2023; and
iv. a comparison between DAEN reports and AusVaxSafety to assess under-reporting of Covid-19 vaccine adverse events.

Explanatory Memorandum

Index

An independent review and analysis of all Covid-19 vaccine adverse event reports received and analysed by the TGA to confirm whether the TGA provided reasonably accurate data transparency on Covid-19 vaccine safety to the Australian public.

Question(s) on Notice

Index

Dr Madry, in respect of your joint submission and in particular index **References EE and FF**, are you able to confirm for the Committee whether the TGA has been transparent in providing reliable and timely access to data scientists like yourself, for researching and modelling purposes, the data contained in the TGA's DAEN and AEMS adverse event reporting systems, for being able to confirm timely and accurate reporting of Covid-19 vaccine adverse events, so scientists like yourself could perform independent research to confirm the Covid-19 vaccines are 'safe and effective'?

Answer(s)

First Answer

Dr Andrew Madry, Co-Author:

I reproduce below my answer for the Question on Notice in respect of Term of Reference EE.

The Therapeutic Goods Administration (TGA) is the agency I will refer to. In particular, the reporting of adverse events. Currently there are approximately 140,000 adverse event reports listed in the TGA's Database of Adverse Event Notifications (DAEN) where a Covid-19 vaccine was reported as a "suspected medicine". Among these are 1011 cases where death was a reported outcome. I emphasise that these are "reported deaths" where the person reporting suspected Covid-19 vaccination to be involved in the death and that we know that the majority of these are reported by health professionals. All reports should be taken seriously.

The TGA accepts that ***only 14*** of these 1010 deaths are causally linked to Covid-19 vaccination. 13 are related to the AstraZeneca vaccine, and one is the death of a young lady following Moderna injection. How many of the remaining 997 deaths have been thoroughly assessed for causality is uncertain. The TGA has not been clear about this, and whether Covid-19 vaccines have been definitively ruled out as the causative agent for any of these.

The public facing reporting system is not fit for purpose, and consequently it has been up to the public and researchers to submit numerous Freedom of Information (FOI) requests in their attempts to understand and assess the impact of the Covid-19 vaccinations on the health of Australians.

For example, the public facing DAEN makes it impossible to unambiguously identify which cases are Deaths, as death is not a field supplied for these vaccines despite it being an adverse event term in the DAEN. Only a total count of deaths is provided.

Of course, if deaths were seen to be associated with young people this would cause great concern.

Members of the public have submitted numerous FOI requests to get information that should have been publicly available in the first place.

Where information has been provided, it is often rendered in such as way as to make analysis difficult, or impossible. For example, one FOI request asked for the ages of

reported deaths. The FOI response from the TGA was provided as a pdf made from of an Excel spreadsheet with many columns, and with which came out as hundreds of pages mostly redacted, giving the appearance that there were tens of thousands of deaths of reported deaths.

I wanted to clear this up, and submitted my own FOI request to specifically obtain the TGA case numbers for the cases where death was an outcome, together with the age of death. At the time there were approximately 600 deaths reported. The deaths were skewed towards the elderly but there were many deaths in young people. This format unambiguously identified the actual number of reported deaths and facilitated merging with other data.

This lack of transparency and obfuscation, firstly in the DAEN, and then in the FOI responses is unacceptable.

In response to the TGA's poor transparency in the publishing of adverse event reporting data, a group of volunteers have created a website, OpenDAEN, which allows users to view the adverse events data in an easily searchable format similar to the way that OpenVAERS provides a view of the US CDC's VAERS system.

For example, it allows one to see that the most commonly occurring adverse event for young people is chest pain. The risk of chest pain in young people (and more serious manifestations such as myocarditis, pericarditis) is not necessary when the risk from Covid-19 to healthy young people is negligible.

Had this dashboard been available earlier, it would have been easier for the public to view the increase in heart-related issues experienced by young people in association with the Covid-19 vaccinations.

Other important information, surfaced by Senator Rennick, is statistical data on the time lag from date of last vaccination to date of death. The TGA response to Senator Rennick showed that 60% of deaths, where the delay was known, occurred within two weeks of vaccination.

Senator, given that it is unlikely that people close to death are vaccinated for Covid-19, known as the "healthy vaccinee bias", this is a grave concern. The data that is needed is the vaccination status of all deaths since 2021 and date of last vaccination. This data can easily be deidentified, to protect privacy. We know how to analyse this data, and the public has a right to know this.

The public needs access to the relevant data in the AEMS which is the initial entry point of adverse events.

Index

Second Answer

A/Prof Peter Parry, Co-Author:

The following answer is the same I provided in respect of Term of Reference/Question on Notice EE.

My PhD research into the overdiagnosis, overmedicating epidemic of 'paediatric bipolar disorder' in very young children mainly in the USA included analysing iatrogenic adverse effects of psychotropic medications prescribed. The research made me familiar with the FDA's Adverse Event Reporting System (FAERS) for pharmaceutical drugs. The FAERS also included vaccines until 1990 when that data was separated out and collated in the Vaccine Adverse Event Reporting System (VAERS) and responsibility handed from the FDA to the US Centres for Disease Control and Prevention (CDC) for managing VAERS data.

In the case of antipsychotic medications prescribed to young children for (often misdiagnosed) bipolar disorder diagnoses, investigative journalists from *USA Today* and the *New York Times* analysed FAERS data and found thousands of reports of paediatric deaths from these drugs. This data was disputed by some child psychiatrists in the USA. However, a later paper, published in the *Journal of the American Medical Association (JAMA) Psychiatry* confirmed an increased risk of 3.5-fold of unexpected death, 4.29-fold for cardiac and metabolic causes – significantly correlated with high antipsychotic doses given for mania/bipolar disorder. Given the extent over time of the paediatric bipolar disorder overdiagnosis epidemic, the findings of the investigative journalists have face validity. I described this in pp. 137-140 of my thesis on the Flinders University Theses website. The former chief-editor of the *Canadian Journal of Psychiatry*, Prof Joel Paris, has said that "50 years from now, paediatric bipolar disorder will be seen as the greatest scandal to befall psychiatry". The time lag implies there is a cover-up, which is a common institutional response to scandal.

The relevance is that current passive pharmacovigilance databases such as VAERS and the TGA's DAEN need to be taken seriously.

Under-reporting factor is the norm for passive pharmacovigilance databases

Under-reporting factors for the true rate of adverse events are the norm in passive pharmacovigilance databases such as the TGA's Database of Adverse Events Notifications (DAEN), UK MHRA's YellowCard, US FDA's FAERS, US CDC's VAERS, European EMA's Eudravigilance, WHO's VigiAccess and other national databases.

Data and research showing underreporting factors with previous drugs/vaccines

A US government quality assurance analysis calculated that the CDC's VAERS under-reports by a factor of 10- to 100-fold; that only 1% to 10% of all serious vaccine injuries are reported.

A comparison of VAERS sensitivity to capture very serious adverse events well-known to be caused by vaccines, namely anaphylaxis and Guillain-Barré syndrome was published in the respected journal *Vaccine*. Reporting of these two adverse events ranged from 12% to 76% but mostly around 25% for several vaccines. In other words, an under-reporting factor of 4-fold for a life-threatening well-recognised vaccine adverse event.

A comparison of reports of anaphylaxis during the Pfizer C19 vaccine clinical trial with VAERS reports during the public rollout suggested a VAERS under-reporting factor of 31-fold.

In terms of prior examination of Australia's DAEN system, significant under-reporting to the Australian TGA of febrile convulsions in infants due to the influenza vaccine in Australia 2010 was estimated to have occurred with rate of febrile convulsion secondary to flu vaccine of 1 in 110 infants, but only 77 cases were ultimately reported to the TGA's DAEN. This was reported in a letter to the *BMJ* . As also reported in the *BMJ,* this led to the suspension of the Australian flu vaccine for young children at the time and medical ethicists criticising Australian experts on flu for having been influenced by pharmaceutical industry lobbying.

The case of Vioxx (rofecoxib) is noteworthy as it was a drug that was eventually withdrawn from the market, albeit after a 5-year period wherein there was evidence of fraud in the original study that suppressed heart attack risk, and independent peer-reviewed publications that it caused an unacceptable cardiovascular risk. This is discussed in more detail under Terms of Reference U. Of note here is a graph on VAERSanalysis.info of drug/vaccine market recalls/withdrawals.

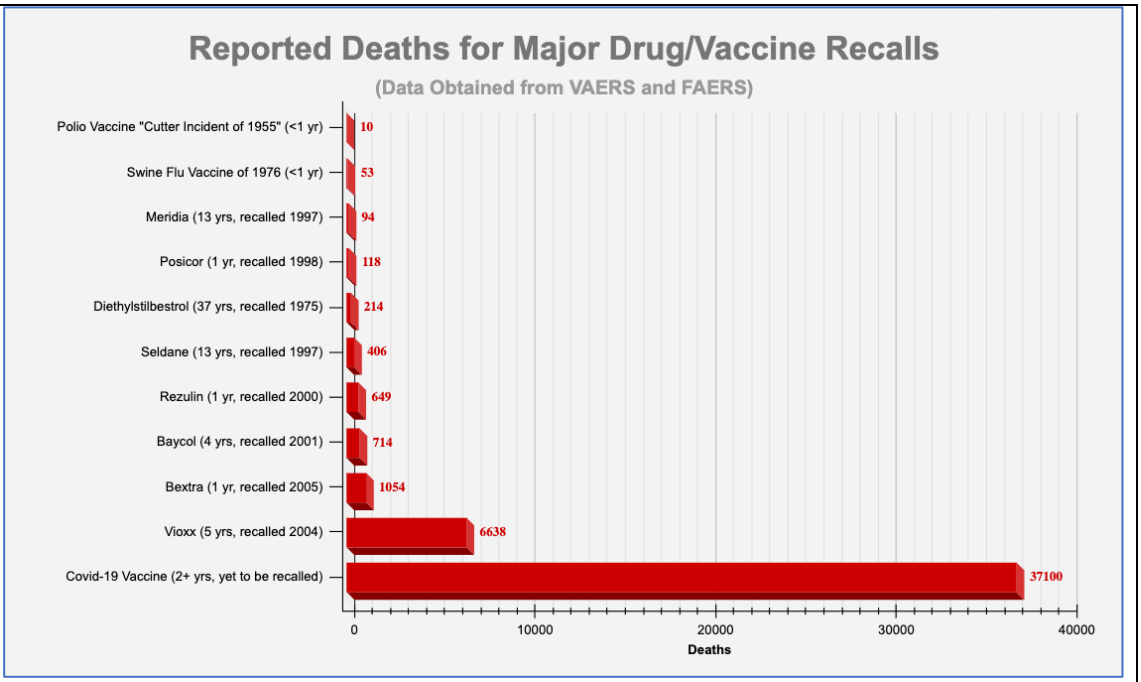


Figure 1: Reported deaths for major drug/vaccine recalls, from VAERSanalysis.info
https://vaersanalysis.info/2024/02/02/vaers-summary-for-Covid-19-vaccines-through-1-26-2024/

For Vioxx's five years on the US market there were 6,638 reported deaths to the FDA's drug adverse event reporting system, FAERS. Some of these may have come from other nations. An article in *The Lancet* estimated that of the 20 million Americans prescribed the drug and estimated 88,000 to 139,000 suffered myocardial infarctions. The author, FDA scientist Dr David Graham, in testimony to the US Congress estimated a 30% to 40% fatality rate, and hence 26,400 to 35,200 (if 88,000 heart attacks) to 41,700 to 55,600 (if 139,000 heart attacks) deaths. Given the FAERS deaths reports were only 6,638, the under-reporting factor is somewhere between 4-fold and 8.4-fold. If a portion of the reports were from outside the USA, then the under-reporting factor would increase.

Note also that the bar for market withdrawal of the polio vaccine in 1955 (10 death reports) and Swine Flu vaccine of 1976 (25 reports at time it was recalled, 53 in total reported) was much lower than for Vioxx and for the current Covid-19 vaccines. One possible variable associated with this is the funding change to regulators from the taxpayer to the pharmaceutical industry, as reported in the *British Medical Journal* (*BMJ)* in a 29 June 2022 article titled "From FDA to MHRA: are drug regulators for hire?".

Active surveillance surveys

One way of detecting the under-reporting factor is by comparison with active pharmacovigilance surveys such as the AusVaxSafety survey of the National Centre for Immunisation Research and Surveillance (NCIRS) and in the USA with the "V-safe" survey of the CDC.

Up to 23 January 2023, AusVaxSafety received 6,377,586 completed surveys of which 2,861,538 reports included at least one adverse event. Across all doses of the three vaccines, Pfizer, Moderna, AstraZeneca, an average 15% of respondents (956,637) reported missing work, study or unable to perform daily routines post-vaccination, and an average of 1.14 in 100 people required a doctor or emergency department attention post vaccination. This equates to approximately 48,710 people requiring medical attention from a survey that received reports from 24% of the Australian population. The survey did not specifically ask about most serious adverse events beyond typical lethargy, headache, arthralgia reactogenicity effects and time off work and daily routines. The survey also was restricted to the days following vaccination rather than later adverse events.

Nonetheless, the results of the *active* AusVaxSafety survey indicate that the number of reports to the *passive* DAEN **under-report** the true rate.

Further, there was a higher rate of adverse events with the Moderna than with Pfizer mRNA vaccine, which is consistent with a dose-response effect as the Moderna vaccine (100µg) has more than three times the amount of mRNA as a dose of the Pfizer vaccine (30µg). Also, the higher rate of work absenteeism after the second dose and the timing interval from first dose and then to booster is consistent with a dose response effect. A high 35% missed work or duties after the second dose. This is a level unheard of with regards to vaccines made by normal non-genetic vaccine technologies, and without lipid-nanoparticle matrices that can slip through cellular membranes as is the case of the Novavax vaccine. A dose-response effect is a Bradford-Hill criterion for increased likelihood of causality.

The following figure shows the AusVaxSafety data for Moderna mRNA vaccine.

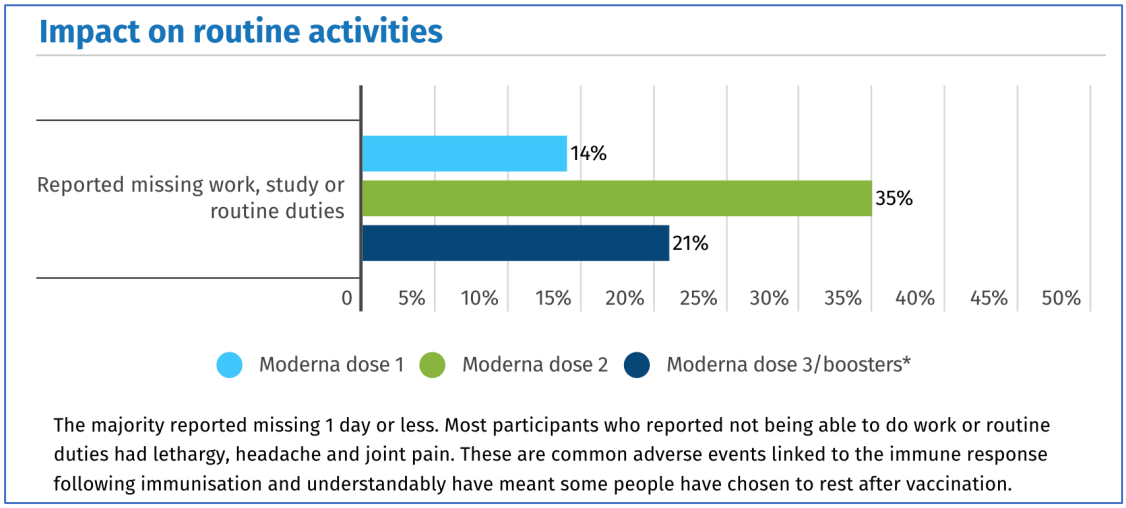


Figure 2: Impact on routine activities of Moderna doses 1, 2 & booster, AusVaxSafety data. See: https://ausvaxsafety.org.au/Covid-19-vaccines/moderna-bivalent-Covid-19-vaccine

By way of comparison, AusVaxSafety indicated medical care presentations of 1.14 per 100 for the Covid-19 vaccines of AstraZeneca, Pfizer and Moderna, the TGA's DAEN showed a reporting rate of 2.1 per 1,000 doses in its safety report of 22 January 2023. By 26 January 2023 the estimated total doses per 100 people was 243.22 (figure **) consistent with the three doses data from the AusVaxSafety survey. Very roughly 1.14 versus 2.1 per 1000 doses suggests an under-reporting factor of about 5-fold. However, given the AusVaxSafety data was time-limited and the DAEN reports likely covered a longer timespan than the AusVaxSafety survey, the data indicates an under-reporting factor applying to the DAEN data is likely larger.

Index

Reference: GG

Index

A review and analysis of the real-time safety systems used by Australian governments to inform and alert health practitioners of potential or actual side effects or contraindications in respect of treatments or the use of identified therapeutic goods, and the interaction of these safety systems with pharmacovigilance departments within Australian governments, and how those safety bulletin systems operated prior to 2021.

Explanatory Memorandum

Index

A review of pre-existing systems to inform health practitioners of any problems or potential problems with treatments or therapeutics.

Question(s) on Notice

Index

In respect of **References GG and HH**, please provide any further information concerning the real-time safety systems used by Australian State and Territory governments to inform and alert health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines, and how reliably from early 2021 those real-time safety systems were informing Australian health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines.

Answer(s)

Index

Answer

Dr Duncan Syme, Co-Author:

My name is Dr Duncan Syme I obtained my medical degree in 1987 at Monash University, then my specialist degree in General Practice in 1997. I have been in continuous medical practice for 34 years since then but was suspended in February 2022 by AHPRA and the Medical Board because they considered my writing of exemptions for patients a danger to the public. Their reasoning given was that my

views may cause the public to lose confidence in the medical profession, or the boards position, on Covid 19 vaccination.

During my time as a full-time medical practitioner in Australia I have always been aware of an operational real time drug safety system. This reporting system was capable of alerting medical practitioners to drugs that were being reported as having an association with adverse patient outcomes.

For the Committee I shall give a brief background history of the real time drug safety system in Australia which started with the Australian Adverse Drug Reaction Bulletin, first published in 1974.

This was commonly known as the ADRAC (Adverse drug reaction advisory committee) bulletin. In 1975 this bulletin was then issued with the Australian Prescriber magazine. This magazine which describes itself as "an independent peer-reviewed journal providing critical commentary on drugs and therapeutics for health professionals". The publication informed doctors about newly approved medications, and reviews of other medications or clinically practical drug related issues. In February 2010 ADRAC bulletin was effectively incorporated into the Australian Prescriber, which now contains a drug safety update section to provide practitioners with up-to-date information regarding adverse drug reactions. This magazine continues to this day but has been in digital form since 2016.

The Australian Prescriber magazine states in February 2024:

> *Medicines Safety Update* articles provide health professionals with practical advice on contemporary and emerging drug safety issues. By sharing the summaries, we hope these safety messages reach a wider audience of health professionals. We also hope this will encourage reporting of suspected adverse drug reactions to the TGA, which is critical to increasing our knowledge of drug safety and improving patient outcomes.

These summaries are linked to the original TGA articles.

The puzzling thing is that since the Covid 19 vaccines were rolled out in March 2021, there seems to be a a significant disconnect between the substantial adverse event reporting on the DAEN (Drug adverse event notification) system, which has had over a 1000 deaths and 135,000 adverse reactions reported to it, yet there has been absolutely nothing reported in the drug safety update section of the Australian Prescriber, in relation to any of the vaccines the Therapeutic Goods Administration had provisionally approved for Covid.

There have been very well reported safety concerns in the mainstream media in

relation the Pfizer BioNTech 162 b2 vaccine and its association with myocarditis in young adults, and the AstraZeneca ChAdOx1-S association with intra-cerebral thrombosis, yet nothing has appeared recording the very large number of associated adverse reactions post vaccination, in the real time drug safety reporting systems to formally inform Australian doctors of a safety concern. If you then compare this with reports on other drugs, for example drugs which cause hypo-natraemia, the TGA issued a safety update after only 135 reports of associated adverse reactions. One must then question, has there been a decision at a high level to obscure reports on adverse reactions to the Covid 19 vaccines from Australian doctors for political, commercial, or other unknown reasons.

Index

Reference: HH

Index

A review and analysis of the real-time safety systems used by Australian governments to inform and alert health practitioners of potential or actual side effects or contraindications reported in respect Covid-19 vaccines from 2021, and the interaction of these safety systems with pharmacovigilance departments within Australian governments receiving Covid-19 vaccine adverse event reports.

Explanatory Memorandum

Index

A review and analysis of all Covid-19 vaccine adverse event reports received and analysed by Australian government health departments, to confirm whether real-time safety systems provided reasonably accurate Covid-19 vaccine safety messaging to Australian health practitioners for the purpose of providing necessary information to patients for the purpose of ensuring valid Informed Consent was being obtained from Australian citizens.

An independent review to confirm whether State and Territory health department real-time safety bulletin systems to inform and alert health practitioners of any safety concerns with respect to Covid-19 vaccines was fully and accurately functioning throughout 2021, 2022, and 2023.

Question(s) on Notice

Index

In respect of **References GG and HH**, please provide any further information concerning the real-time safety systems used by Australian State and Territory governments to inform and alert health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines, and how reliably from early 2021 those real-time safety systems were informing Australian health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines.

Answer(s)

Index

Answer

Dr Duncan Syme, Co-Author:

The following answer is the same as I provided for the Question on Notice to Term of Reference GG.

My name is Dr Duncan Syme I obtained my medical degree in 1987 at Monash University, then my specialist degree in General Practice in 1997. I have been in continuous medical practice for 34 years since then but was suspended in February 2022 by AHPRA and the Medical Board because they considered my writing of exemptions for patients a danger to the public. Their reasoning given was that my views may cause the public to lose confidence in the medical profession, or the boards position, on Covid 19 vaccination.

During my time as a full-time medical practitioner in Australia I have always been aware of an operational real time drug safety system. This reporting system was capable of alerting medical practitioners to drugs that were being reported as having an association with adverse patient outcomes.

For the Committee I shall give a brief background history of the real time drug safety system in Australia which started with the Australian Adverse Drug Reaction Bulletin, first published in 1974.

This was commonly known as the ADRAC (Adverse drug reaction advisory committee) bulletin. In 1975 this bulletin was then issued with the Australian Prescriber magazine. This magazine which describes itself as "an independent peer-reviewed journal providing critical commentary on drugs and therapeutics for health professionals". The publication informed doctors about newly approved medications, and reviews of other medications or clinically practical drug related issues. In February 2010 ADRAC bulletin was effectively incorporated into the Australian Prescriber, which now contains a drug safety update section to provide practitioners with up-to-date information regarding adverse drug reactions. This magazine continues to this day but has been in digital form since 2016.

The Australian Prescriber magazine states in February 2024:

> *Medicines Safety Update* articles provide health professionals with practical advice on contemporary and emerging drug safety issues. By sharing the summaries, we hope these safety messages reach a wider audience of health professionals. We also hope this will encourage reporting of suspected adverse drug reactions to the TGA, which is critical to increasing our knowledge of drug safety and improving patient outcomes.

These summaries are linked to the original TGA articles.

The puzzling thing is that since the Covid 19 vaccines were rolled out in March 2021, there seems to be a a significant disconnect between the substantial adverse event reporting on the DAEN (Drug adverse event notification) system, which has had over a 1000 deaths and 135,000 adverse reactions reported to it, yet there has been absolutely nothing reported in the drug safety update section of the Australian Prescriber, in relation to any of the vaccines the Therapeutic Goods Administration had provisionally approved for Covid.

There have been very well reported safety concerns in the mainstream media in relation the Pfizer BioNTech 162 b2 vaccine and its association with myocarditis in young adults, and the AstraZeneca ChAdOx1-S association with intra-cerebral thrombosis, yet nothing has appeared recording the very large number of associated adverse reactions post vaccination, in the real time drug safety reporting systems to formally inform Australian doctors of a safety concern. If you then compare this with reports on other drugs, for example drugs which cause hypo-natraemia, the TGA issued a safety update after only 135 reports of associated adverse reactions. One must then question, has there been a decision at a high level to obscure reports on adverse reactions to the Covid 19 vaccines from Australian doctors for political, commercial, or other unknown reasons.

Index

Reference: II

Index

A review and analysis of the conduct of TGA pharmacovigilance following the rollout of the Covid vaccines and whether this met the standards set forth in the AusPAR provisional approvals for the vaccines, both for the general population and the pregnant population, including:

i. compliance by sponsors with TGA document *Pharmacovigilance responsibilities of medicine sponsors* (version 2.2, January 2021);
ii. all information received by the Secretary of Health falling under Section 23(d) of the Therapeutic Goods Act 1989, and the assessment of that information by the Secretary;
iii. all inspections of Covid-19 vaccine sponsors undertaken by the TGA in respect of the collection, collation, processing, timely and appropriate reporting and follow-up of adverse reaction reports performed by sponsors;
iv. all information concerning Covid-19 vaccine sponsors funding 'fact checker' organisations.

Explanatory Memorandum

Index

An independent review to confirm whether the TGA and sponsors fulfilled all pharmacovigilance obligations in respect of Covid-19 vaccines throughout 2021, 2022, and 2023.

An examination to confirm whether sponsors responsible for the collection of adverse event data and reports, were also funding 'fact checker' organisations that were and continue to deliberately neutralise media and social media reports of harms associated with Covid-19 vaccines, in circumstances where sponsors are obliged to approach all adverse reports in respect of their products as caused by their products, until proven otherwise.

Question(s) on Notice

Index

In respect of **Reference II**, please provide any further information concerning the conduct of TGA pharmacovigilance following the rollout of the Covid vaccines and whether this met the standards set forth in the AusPAR provisional approvals for the vaccines.

Answer

The People's Terms of Reference:

This is information held by the TGA which is inaccessible to the public.

There are no publications from the TGA in regard to monitoring of cancer diagnoses in real time (which is possible using SNOMED live coding by laboratories), miscarriage rates following vaccination, cardiac events or any other hospital episode or DRG statistics. Requests made of the Australian Institute of Health and Welfare for diagnosis-related groups (DRG) data cube data pertaining to these metrics was also refused. No live monitoring of any of these important medical statistics has been conducted by the TGA, if it has occurred, the TGA refuse to disclose this data.

Further, the TGA refused an FOI (TGA 2471, available on request) which specifically asked for the documents relating to the review of the first 14 deaths reported to the TGA in the under-65s.

Of the 1000 deaths reported to the TGA there are no review documents available to the public.

FOI 3643 showed that there was no implementation report on the key objectives listed in the Covid-19 vaccine safety monitoring plan described by the TGA. See Annexure 10 where the TGA confirms no such safety monitoring was implemented:

Dear [redacted]

FREEDOM OF INFORMATION REQUEST FOI 3643
Notice of Decision

1. I refer to your request dated 18 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following document:

> *"I request an implementation report on the Covid 19 Vaccine Safety Monitoring Plan as per the key objectives listed in the plan:*
>
> *1. timely collection and management of reports of COVID-19 vaccine adverse events following immunisation*
>
> *2. timely detection and investigation of COVID-19 vaccine safety signals*
>
> *3. timely action to address any COVID-19 vaccine safety concerns*
>
> *4. timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public confidence in vaccines*
>
> *5. close collaboration and coordination of effort with other vaccine safety stakeholder groups*
>
> *I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. I have interpreted your request as being for an evaluation report assessing whether the TGA has achieved the goals and objectives listed in the COVID-19 Vaccine Safety Monitoring Plan.
4. Unfortunately, I am unable to continue to process your request because the document you have requested does not exist. Therefore, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

All the deaths reported to the TGA and published via the Database of Adverse Event Notifications (the DAEN system) on the TGA website, as being of concern in relation to Covid-19 vaccines, need to be independently audited.

Further, and an examination of TGA internal deliberations and meetings focusing on the risks and presence of unique and novel and never-before-used genetic components associated within and found within the Covid-19 modRNA vaccines is required, as TGA FOI 3604 provides evidence of a complete failure to evaluate the risks to humans of never-before-injected genetic components (See Annexure 11):

FREEDOM OF INFORMATION REQUEST FOI 3604
Notice of Decision

1. I refer to your request dated 5 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

   "the following documents relating to the provisional approval of the Pfizer-BionTech BNT162b2 vaccine in January 2021:
   1. *"All documents relating to the TGA's assessment of the risk of and/or presence of **micro-RNA sequences (miRNA)** comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
   2. *All documents relating to the TGA's assessment of the risk of and/or presence of **Oncomirs** (oncogenic miRNA - microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
   3. *All documents relating to the TGA's assessment of the risk of and/or presence of **Stop Codon read-through** (suppression of stop codon activity) arising as a result of the use of pseudouridine in the Comirnaty miRNA active ingredient (mRNA genomic sequence).*
   4. *Any document showing that the TGA has assessed the composition of the **final protein product** (molecular weight and amino acid sequence) produced following injection of the Comirnaty mRNA product in human subjects.*
   5. *All documents relating to the TGA's assessment of the risk of the use of the **AES-mtRNR1 3' untranslated region** of the Comirnaty mRNA product in human subjects."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. Unfortunately, I am unable to continue to process your request because the documents you have requested do not exist.

The answer above has been limited due to time constraints.

Index

Reference: JJ

Index

A systematic analysis and review of processes and guidelines used to assess causality using appropriate analytical tools and sources of data relevant to an assessment of whether, prima facie, Covid-19 vaccines disproportionately caused harm or death to Australians as compared to any other registered or previously registered therapeutics in Australia, undertaken by Commonwealth, State, and Territory government pharmacovigilance units.

Explanatory Memorandum

Index

An examination to confirm what Australian pharmacovigilance units were seeing in real-time in respect of Covid-19 vaccines, in terms of accumulating causality assessments; and to confirm whether causality assessments were being performed rigorously and being reasonably accurately shared with the Australian public.

Question(s) on Notice

Index

Dr Sladden, in respect of your joint submission and in particular index **References BB and JJ**, are you able to point the Committee to any formal guidelines and procedures that were put in place prior to or just after the rollout of Covid-19 vaccines Australia to specifically assess adverse events caused by the vaccines, by State and Territory governments and the TGA, in case those experimental drugs proved to not be as safe and effective as the Australian people were told?

And the second part of my question here is:

Do we know who was responsible for first receiving adverse event reports, the criteria they used to perform assessments, what the qualifications were of those people responsible for first receiving adverse event reports
and for conducting the initial assessments, and who they reported to?

My issue here is we have been asking lots of questions here in the Senate about how Australia's adverse event reporting system works, and we only ever receive the same blanket reassurances from the TGA that everything is fine, and they treated the Covid-19 vaccine adverse events very specially, but we still have not seen any evidence about how they were doing that, and who was doing that?

Answer(s)

Index

Answer

The People's Terms of Reference:

Time constraints prevented a full and complete response to the above question which would have seen an extensive answer, had sufficient time been made available.

Term of Reference JJ continues to be advanced by The People's Terms of Reference.

Reference: KK

Index

In the event of a prima facie finding evidencing disproportionate harm and/or death associated with Covid-19 vaccines, a systemic analysis to determine when evidence of disproportionate adverse outcomes from the Covid-19 vaccines became apparent and discernible to relevant Australian government departments, including for each State and Territory:

i. the date upon which one or more type of adverse outcomes from one or more Covid-19 vaccines became statistically significant; and
ii. indicative of disproportionate harm or death to Australians as compared to any other registered or previously registered therapeutics in Australia; and
iii. where those findings were published, and to who those findings were reported; and
iv. an examination and comparison with re-purposed drugs used to treat Covid-19 in 2020 and any evidence of disproportionate harm or adverse events reports possibly caused by such re-purposed drugs.

Explanatory Memorandum

Index

An examination to confirm what Australian pharmacovigilance units were observing throughout 2021, 2022, and 2023, to confirm whether messaging by public officials of the 'safe and effective' nature of Covid-19 vaccines was accurate.

Question(s) on Notice

Index

In respect of **References KK**, please provide any further information concerning when evidence of disproportionate adverse outcomes from the Covid-19 vaccines became apparent and discernible to relevant Australian government departments, the dates upon which one or more type of adverse outcomes from one or more Covid-19 vaccines became statistically significant, and when any available data became available to Australian government departments indicative of disproportionate harm or death to Australians from Covid-19 vaccines, as compared to any other registered or previously registered therapeutics in Australia.

Answer(s)

Index

Answer

Dr Suzanne Niblett, Co-Author:

Evidence of disproportionate analyses relevant to this question on notice is provided in responses to Reference DD and AA.

By way of background, vaccines that have been withdrawn from the market for the following rates of serious AEFIs:

- The swine flu vaccine (1976) was withdrawn for a rate of one serious case of Guillain-Barré syndrome per 100, 000 doses.
- The rotavirus vaccine, Rotashield (1999), was withdrawn for a rate of one-to-two serious cases of intussusception per 10, 000 doses.
- The TGA withdrew Fluvax Junior (2010) for children aged 6 months to <5 after 25 reports of febrile convulsions following vaccination (16 of which were from WA) triggered an in-depth investigation, which determined a causal link between Fluvax Junior and increased risk of febrile convulsions (Investigation Into Febrile Reactions in Young Children Following 2010 Seasonal Trivalent Influenza Vaccination)

As has been highlighted in the previous references, both a large number of adverse event reports, and a broad spectrum of adverse events, have been submitted to the TGA since the roll-out of the Covid-19 vaccines. Figures 1 and 2 show the number of adverse event reports (AER) added to the DAEN over time. Figure 2 shows the proportion of these that were related to Covid-19 vaccines.

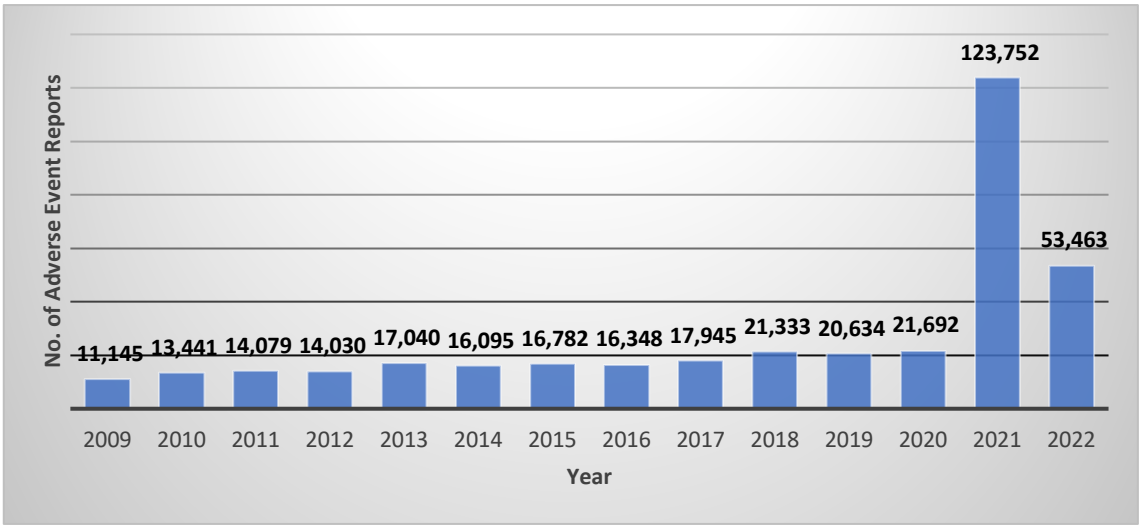


Figure 1: Number of adverse event reports submitted each year to the TGA DAEN from 1 January 2009 to 31 Dec 2022. *Source:* TGA DAEN extracted 13 July 2023.

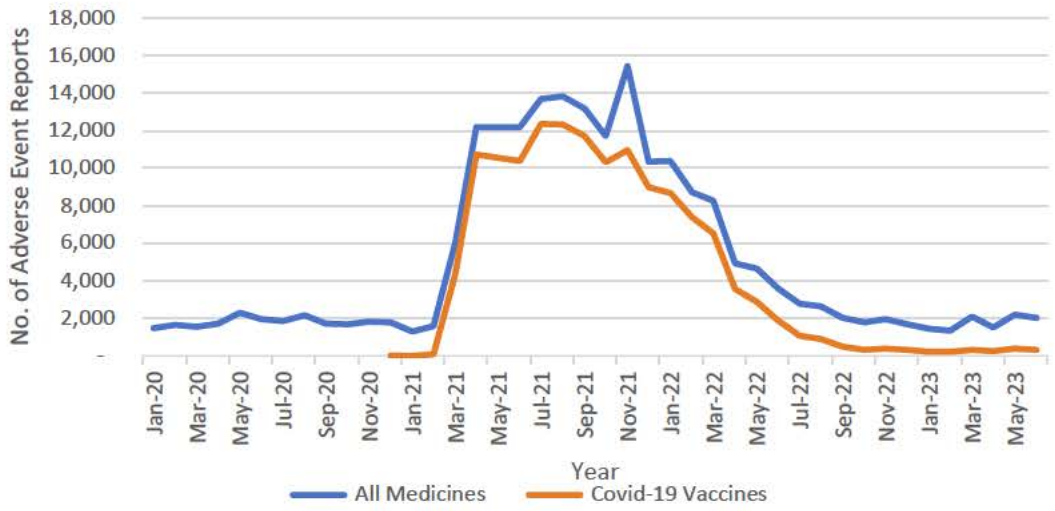
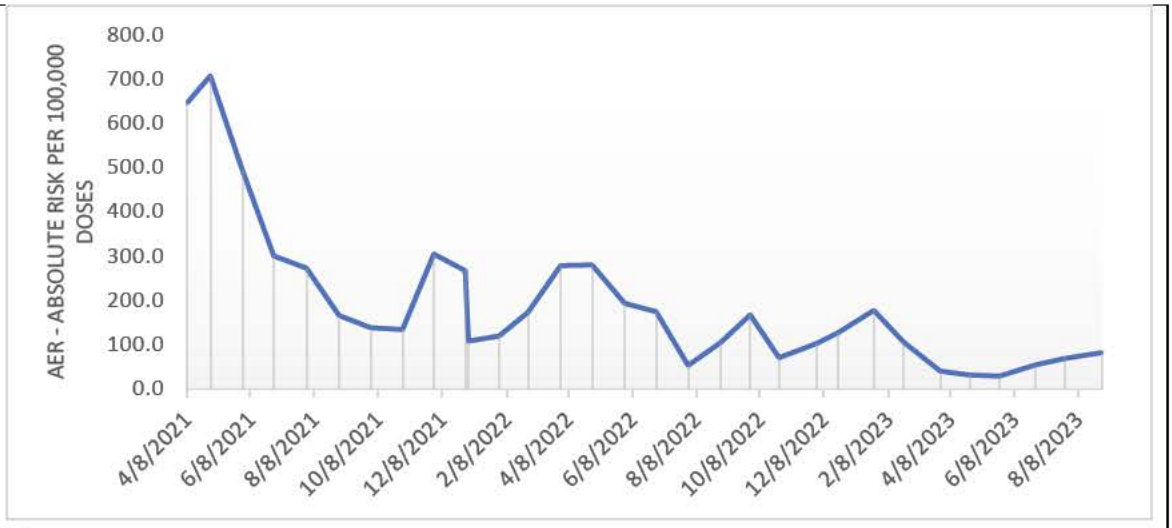


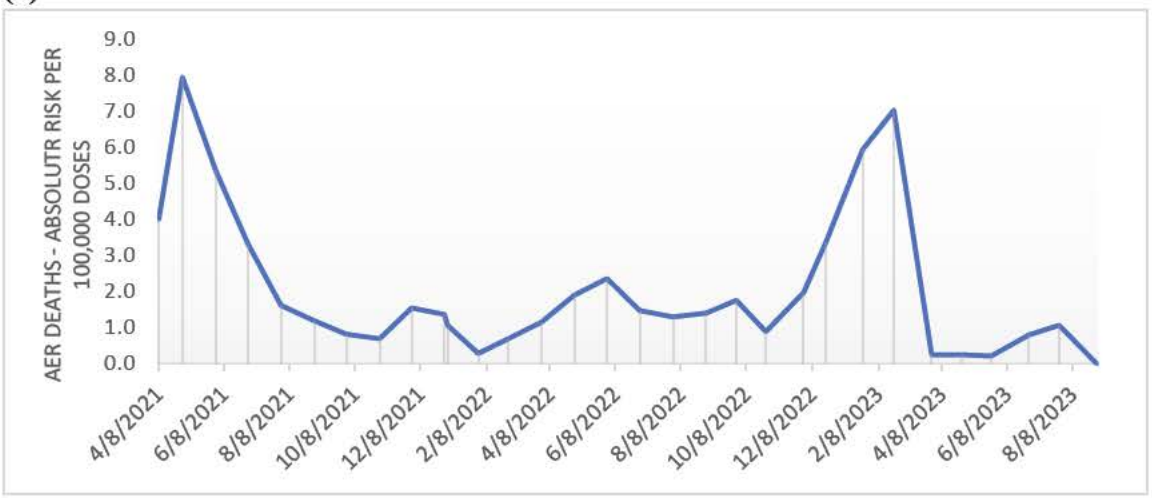
Figure 2: The number of adverse event reports (AER) submitted to the TGA DAEN monthly in relation to (a) one or more of the covid-19 vaccines between 1 January 2020 to 31 June 2023 and (b) all medicines, vaccines and therapies used in Australia ("All medicines").

Figure 3 shows the changes in the absolute risk of an AER following a covid vaccination over time. The absolute risk of AERs calculated from the TGA DAEN data varied considerably over time with values as high as 646.6 and 708.5 per 100,000 doses evident immediately following the rollout of the vaccines across the March to 30 April 2021 period (Figure 3(a)).

Similarly, the absolute risk of AERs with an outcome of death also varied over time with values peaking in the first three months at 7.9 per 100,000 and then again after the role out of the boosters at 7.0 at the end of Feb 2023 (Figure 3(b)).



(a)



(b)

Figure 3: Number of adverse event reports submitted to the TGA DAEN, where a covid-19 vaccine was listed as a suspected medicine, overall (a) and with an outcome of death (b) for various time periods from 8 April 2021 to 30 August 2023 and converted to Absolute Risk per 100,000 doses.

Evaluation of the adverse event reports provided in FOI 4769 (https://www.tga.gov.au/sites/default/files/2023-11/FOI%204769.pdf) indicated for the periods from vaccine release to the 8 of April 2021 the rate of report for serious cases was 79.4 per 100,000 doses of covid vaccine, respectively.

Evaluation of the individual data showed that for the period to 8 April 2021, there were 136 adverse reaction terms reported at rates between 1 and 292.4 cases per 100,000 doses of the Covid-19 vaccines. This included dyspnoea (23.2 per 100,000), tachycardia (18.7 per 100,000), chest pain (11.8 per 100,000), syncope (11.1 per 100,000), palpitations (8.2 per 100,000), anaphylactic reaction (8.0 per 100,000), pulmonary embolism (1.7 per 100,000), and deep vein thrombosis (1.6 per 100,000).

As discussed in Reference DD, the TGA have provided minimal information regarding the assessment of safety signals but the TGA response to FOI 4032 request did disclose detail relating the TGAs "Proportionality Reporting Ratio analyses for the COVID-19

vaccines to 22 October 2022". These were released as nine files, each file providing a list of the PRR values specific to a particular Disproportionality Analysis Report (DPAR) date. The link to each of these files is provided in Table 1. The PRR values presented across the nine DPAR dates, overall and separately, are summarised in Table 2.

Table 1: Disproportionality Analysis Report (DPAR) dates and links to files released under FOI request 4032.

DPAR Date	FOI 4032 document number and link
13-Mar-21	Document 1: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-01.pdf
19-Jul-21	Document 3: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-03.pdf
29-Sep-21	Document 2: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-02.pdf
29-Nov-21	Document 4: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-04.pdf
17-Jan-22	Document 5: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-05.pdf
24-Mar-22	Document 6: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-06.pdf
11-May-22	Document 7: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-07.pdf
15-Jul-22	Document 8: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-08.pdf
15-Sep-22	Document 9: https://www.tga.gov.au/sites/default/files/2022-12/foi-4032-09.pdf

Table 2: Summary of the number of adverse event terms identified with a proportional reporting rate (PRR) greater than 2.0, together with the mean, standard deviation, and ranges of PRR values presented overall and for each DPAR date.

DPAR date	No of adverse event terms with PRR >2	Proportional Reporting Ratio (PRR)		
		Mean	± SD	Range
Total (1 Feb 2021 to 22 Oct 2022)	2528	6.6	± 5.5	2.1 - 118.4
13-Mar-21	10	15.0	± 10.9	4.7 - 36.9
19-Jul-21	267	7.2	± 5.5	2.1 - 32.3
29-Sep-21	342	6.7	± 4.8	2.1 - 36.5
29-Nov-21	339	7.4	± 5.7	2.2 - 51.5
17-Jan-22	350	7.9	± 9.0	2.3 - 118.4
24-Mar-22	370	6.4	± 4.7	2.2 - 39.5
11-May-22	351	5.7	± 3.9	2.1 - 45.0
15-Jul-22	300	5.5	± 3.2	2.1 - 31.3
15-Sep-22	199	5.3	± 2.6	2.3 - 19.1

As shown in Table 2, there were 2,528 PRR values that were over 2 and that were reviewed across the nine DPAR dates. Of these 2,131 (84.3%) satisfied all 4 statistical criteria i.e. the PRR >2, number of cases in the vaccinated group >2, chi-squared value ≥4 and that the PRR lower confidence interval >1.

All 10 of the PRRs reviewed on DPAR date 13 March 2021 and 228 (85.4%) of the 267 PRRs reviewed on DPAR date 19 July 2021 satisfied all four of these criteria.

These data indicate that not only were many disproportionalities of occurrence and ratio evident but that these were evident very quickly after the roll-out and were associated with both high case numbers and statistical significance.

Index

Reference: LL

Index

A review of issues and themes and experiences among persons claiming to have been prima facie injured from one or more Covid-19 vaccine, including family members, spouses and partners who have lived experience with those they claim to have died as a prima facie consequence of receiving one or more Covid-19 vaccine, including systemic issues and any common themes:

i. relating to the Covid-19 Claims Scheme, including the Constitutional legality of the Scheme;
ii. relating to the recognition and treatment by Australian health practitioners of Covid-19 vaccine injuries and deaths.

Explanatory Memorandum

Index

To hear from Covid-19 vaccine victims.

Question(s) on Notice

Index

Dr Sladden, in respect of index **Reference LL**, as a medical doctor who has also been reporting extensively on Covid-19 in Australia and been in contact with many groups and organisations who have been critical of these experimental drugs, can you briefly tell us of those you understand to be Covid-19 vaccine victims:

How many Australian victims do you and your medical colleagues believe could have been affected?

Are their doctors speaking up about the likely cause of their injuries?

And how has the general medical community been treating them?

Answer(s)

Index

Answer

Dr Julie Sladden, Co-Author:

Estimates are that there may be over 250,000 severely injured, and possibly as many as 20,000 Australians died from complications caused by these injections. This estimation is based on the TGA's current number (approx. 140,000) of adverse event reports – of which a proportion were deemed serious - and applying an, assumed, conservative under reporting factor (10x).

Doctors are largely unaware, of the size of the problem due to a number of factors including lack of information from departments and institutions, or they are unaware of the extent of the Database of Adverse Event Notification reports and under reporting issues. Doctors are also not being given information regarding the range and extent of adverse event presentation that is now populating the peer reviewed literature. In reality many few doctors source the raw data and articles themselves, instead relying on information to be supplied directly to them by departments and professional institutions. When this information is not forthcoming, the doctors are left unawares.

Dr Rado Faletic co-director of Coverse says:

> 'If the doctor doesn't think (something) is caused by the vaccine they may not report it… By not reporting it, the government doesn't have the full picture so they don't put out safety notices and then doctors don't know that they should be looking out for it, so they don't report it."

A small but significant number who are aware, refuse to report due to fear this would be interpreted as speaking out against the program, and fear of professional consequences. This observation has been verified through a number of patient anecdotes attesting to the reluctance of doctors to report adverse events for fear of scrutiny by regulators.

We suggest that further work is needed to verify the true extent of the harms caused, requiring Australian government departments to be much more transparent with Covid-19 adverse event reporting data and actively report this to the doctors at the coalface.

In my correspondence with Dr Rado Faletic I received the following reply:

> The organisation, COVERSE's, has made various submissions to this inquiry and other inquiries, as well as our appearance before this inquiry. They have made it very clear that Australian doctors are hampered (either by AHPRA or by lack of insight/knowledge about our diseases), and the vicious circle that negatively downplays/ignores our vax injuries.
>
> Their various submissions can be found here: https://coverse.org.au/submissions/ including links to our submission to this inquiry and our video testimony from the first public hearing.

In my correspondence with independent journalist Rebekah Barnett, interviewer of Covid-19 vaccine injured persons of the group Jab Injuries Australia, I received the following reply:

> In my experience interviewing scores of Australians who sustained severe injuries following their Covid vaccinations, obtaining official acknowledgement, diagnosis, treatment and compensation has proved near impossible for most. Barriers include:
>
> - Unwillingness of medical professionals to appear to be critical of the vaccination rollout, and therefore refusal to even consider the vaccine as a potential causal factor. Where doctors or nurses verbally admit to patients that the vaccine is a likely cause, patients report that oftentimes they refuse to document it on the patient's records.
> - Additionally, injured Australians report that their vaccination nurses, GPs and specialists are woefully under educated about potential vaccine harms. Interviewees have recounted nurses googling symptoms which suddenly onset in the vaccination room – if the symptom is not listed on an officially recognised list, the patient has been told their sudden reaction is not from the vaccine. Similarly, patients report doctors googling their symptoms and ruling out the vaccine as a potential cause because they don't neatly fit a given side effect checklist.
> - Injured Australians report that their physical injuries are frequently misdiagnosed as anxiety. Many of my interviewees were prescribed anti-anxiety and anti-depressant medication, often numerous times, before their physical injuries (e.g.: myocarditis) were eventually identified. Patients generally have to visit multiple doctors over many, many months, to get the tests they need to identify the physical injury. It is therefore probably that a good number of Australians are currently taking anti-anxiety medication to treat their heart conditions.
> - The reticence or inability of medical professionals to diagnose, document and report injuries following vaccination makes it very difficult for injured Australians to obtain compensation, especially if their injury does not fall within the very narrow list of compensable conditions.
> - Injured Australians report difficulties with navigating the TGA's complex vaccine adverse events reporting system. Where a diagnosis is finally obtained months or even years after the initial injury, some patients report not knowing how to update their record. Some are too traumatised to deal with the bureaucratic framework. Of all the injured Australians I've interviewed, including families of people who died following vaccination, none have ever received a follow up contact from the TGA aside from an initial phone call to verify their identity. There appears to be no system in place for tracking the progress of the injured and updating their DAEN entries over the lengthy course of obtaining a diagnosis.

- All of this persists. Only this weekend I met a woman who became so ill after her vaccination that she has been told by her doctor that she only has a year to live. She reported that her doctor aggressively shut down her attempts to discuss vaccination as a causal factor, saying he's sick of hearing about people blaming the vaccines for their health problems. So the question is – if doctors won't explore all potential causes, how can patients get the right diagnosis and the treatment they so badly need?

Please also see my article below further detailing the problems faced by Covid-19 vaccine victims:

https://umbrellanews.com.au/featured/2022/12/no-help-no-support-censorship-of-australian-Covid-vaccine-injuries-despite-high-aefi-rates-nation-wide/

Index

Reference: MM

Index

A review and analysis of Australian Covid-19 pandemic modelling relied upon by Australian governments for making Covid-19 pandemic management decisions, policies, mandates, and laws, including:

i. Covid-19 modelling undertaken by the Doherty Institute;
ii. any other modelling relied upon;
iii. the extent to which reliance was placed upon modelling over real-time data.

Explanatory Memorandum

Index

An examination to confirm whether reasonable assumptions were used, the statistical modelling tools utilised, known and available real-time data that was incorporated or discounted, and conclusions reached in models to justify the reliance by Australian governments on commissioned models as a basis for actions implemented by Australian governments throughout 2021, 2022, and 2023, were entirely reasonable.

Question(s) on Notice

Index

In respect of **Reference MM**, please provide any further information concerning the veracity, accuracy, and scientific basis for pandemic modelling undertaken in Australia and relied upon by Australian governments for their various Covid-19 pandemic management decisions, policies, mandates, and laws.

Answer(s)

Index

Answer

Dr Andrew Madry, Co-Author:

The Doherty Institute provided the Australian government with modelling that informed the government on how to respond to the pandemic. The failures of this

modelling have been well documented in the mainstream media. For example *Lies, damn lies and modelling? Why Covid-19 forecasts haven't all come to pass* (Sydney Morning Herald November 2021 behind paywall)

From the article:

> *In March last year, federal government modelling said that in a worst-case scenario up to 150,000 Australians could die from Covid-19. Modelling also forecast nearly 3000 cases a day in Victoria during an October peak of the latest outbreak and hundreds of cases in ICU and hospital.*

Fortunately, the predictions turned out to be vast overestimates. In the article above the modellers say that one of the reasons was that vaccines were so effective:

> *New data has also played a role, specifically around the effectiveness of vaccines. In a huge positive, they have been far more effective at preventing hospitalisation and severe illness than originally thought, with all three vaccines currently being used in Australia performing better in real-world settings than they did in the original trials.*

Modellers look for answers why their models are wrong. The comment above is strange given the original trials were not powered to provided data on hospitalisation and death. In fact, more people died in the vaccine arm of the trial.

The failures of the Doherty Institute models included errors, for example showing numbers of ICU beds needed rather than general hospital beds. This is a significant error, given the resources required for ICU beds. The following article *Coronavirus Australia: Mistake in Covid modelling that informed lockdown* describes how a researcher from James Cook University spotted the problem.

In addition, much of the Doherty modelling was kept secret. In these situations, there needs to be open access to these models. Independent analysts can provide rapid peer review as well as pick up the mistakes.

A Royal Commission needs to review the process of development of these models and the interactions with government departments that sponsored it. Questions need to be asked such as did the organisation really have the capability to handle this type of modelling? Perhaps private institutions would have more pragmatic approach? Had they ever done it before with any success? Were the modellers being led to the results desired?

Government, cognisant of the economic harms caused by lockdowns, tried to use modelling to set targets for vaccination to show that once certain vaccination

coverage was achieved that society could begin opening up.

There was therefore tension created as people, fearful of opening up society too soon, assumed the outputs could be worse, i.e. more hospitalisations and deaths. For example, the following preprint, which includes authors from UNSW and QUT, *Six failures of the Doherty Modelling Report* points out many flaws in the Doherty modelling. These authors were fearful of worse outcomes than models predicted, in particular fearful of the effect of Covid-19 on children. We now know the fatality rate in healthy children is extremely low. For healthy children, in many countries, there have been zero Covid-19 fatalities. The perceived danger needed to be balanced by the harms caused to children by school closures. This is documented in other references in the Peoples Terms of Reference and has been highlighted in mainstream Australian media in recent weeks.

This article on pandemic modelling by an ANU researcher *Covid-19 showed modelling is broken. This needs urgent fixing* summarises the three factors to consider as:

- assumptions and values (i.e. the inputs to the model)
- maths and uncertainty (the model itself)
- the context

Regarding the context the article says:

> *A model is not only the representation of a situation, but also the product of many socio-political interactions. The problem with Covid-19 models was that they were generally detached from local knowledge and history, while being attached to a global narrative framing Covid-19 and potential responses.*

Modelling can be a dangerous tool when not understood. A Royal Commission needs to review governance over the use of modelling in guiding public decision making.

In correspondence on the above issues with modelling and simulation specialist engineer Jawahar Bhalla, Jawar returned to me the following salient considerations:

> Jawahar Bhalla BE:
>
> What is a model? A personal definition is that "a model is an abstraction of reality for a particular purpose". The suitability of a model's abstraction to its intended purpose is usually labelled its "fidelity", with a well-used definition of fidelity being "the degree to which a model or simulation

reproduces the state and behaviour of a real-world object or the perception of a real world object, feature, condition, or chosen standard in a measurable or perceivable manner; a measure of realism of a model or simulation faithfulness" (Gross, 1999),". A complete replication of the real-world is unachievable, as noted very eloquently by George Box in his much-quoted statement that "all models are wrong, but some are useful" (Box and Draper, 1919). The only definitively right model of a system is the system itself. A fundamental challenge for modellers is to abstract models with necessary detail commensurate with intended use, and by reference to objective data, to establish the right "fidelity" for a particular purpose. The methodology that enables this, builds on three fundamental concepts from systems engineering that underpin the integrity of any complex engineered system – verification, validation and accreditation.

Verification of a model focuses on determining that the "model is developed right" to meet its requirements (architecture, algorithm, methodology, implementation), while validation confirms that the "right model is developed" aligned with its intended purpose (through the conduct of objective tests against authorised reference data), while accreditation establishes suitability of operational use of the developed model for a particular set of use-cases based on the outcomes from the verification and validation activities. As an example, verification, validation and independent accreditation is foundational to the operational use of full flight simulators used to train civil aircraft pilots to fly fare-paying passengers. The Civil Aviation Safety Authority (CASA) in Australia (similar to the FAA in the US, and EASA in Europe), in its role of flight safety governance, identifies applicable flight simulation accreditation standards, and certifies independent accreditation authorities that then conduct initial and periodic fidelity checks (verification and validation) on all operational full flight simulators to ensure the integrity of the flying training that these high fidelity modelling and simulation devices deliver across a set of "accredited" flight training sequences.

However, there appears to have been a complete lack of formal and independent governance to ensure the fidelity and integrity of the modelling used through the Covid pandemic through formal verification, validation and accreditation such as:

- a defined set of scenarios as the basis for model abstraction
- a set of authorised reference data as a basis for verification and validation
- any independent oversight of the development process or of model certification
- a lack of objective evidence to ensure that the models were actually

used within the scope of their intended purposes.

In fact, the variance of the actual outcomes to that predicted by the models (for example a 10-fold over-prediction on the number of ICU beds needed in QLD recently for January 2022), is objective evidence in itself that the fidelity of the models were not suited to the use-cases in which they were applied.

"Governance encompasses the system by which an organisation is controlled and operates, and the mechanisms by which it, and its people, are held to account. Ethics, risk management, compliance and administration are all elements of governance" - The Governance Institute of Australia.

Given the significance of Modelling and Simulation to inform and support government policy on Covid-19, such as restrictions on society and even as far as mandates, the lack of objective frameworks applied by Government to establish and subsequently ensure the fidelity (suitability/integrity) of the models and data used is a huge cause for concern.

Index

A review and analysis of Covid-19 pandemic management decisions and policies, and particularly Covid-19 vaccine mandates compelling the receipt of Covid-19 vaccines as conditions of employment, implemented by Australian companies (private and public) and government departments that do not provide health services, including:

i. an examination of the review and consideration processes and risk-benefit assessments undertaken by Australian companies and (non-health) government departments into potential adverse impacts, side effects and potential harms from Covid-19 vaccines, including:
    a) an examination of risk assessments undertaken to consider the long-term safety of vaccine mandates, in the absence of any longitudinal safety data on Covid-19 vaccines at the time of vaccine mandates;
    b) an examination of health evidence relied upon to show benefit in vaccine mandates when the TGA's provisional approval decisions (AusPARs) noted Covid-19 vaccines had no data to show they prevented transmission;
ii. an examination of Australian companies and (non-health) government departments of assessments:
    a) undertaken to ascertain that officials and company officers responsible for vaccine mandates and policy held appropriate credentials, knowledge and subject-matter expertise to review and evaluate evidence regarding the safety and efficacy of Covid-19 vaccines including immunological, microbiological and nanotoxicological expertise;
    b) undertaken regarding the risks inherent in violating longstanding principles of patient-centred, individualised medical care, in favour of population-wide medical interventions irrespective of individual medical profiles;
    c) undertaken to evaluate the impact of prior vaccine mandates implemented in other nations earlier than Australia, with respect to key outcomes, particularly illness, hospitalisation and death;
    d) undertaken to ascertain whether vaccine mandates placed those responsible for implementation in violation of their obligations under their codes of ethics and conduct, their Occupational Health and Safety Regulations, privacy protections, and international human rights treaties and conventions.
iii. an examination of the review and consideration processes and risk-benefit assessments undertaken by Australian companies and (non-health)

government departments of the risks of serious illness or death to employees who chose to remain unvaccinated;

iv. an examination of the review and consideration processes and risk-benefit assessments undertaken by Australian companies and (non-health) government departments of the risks to Covid-19 vaccinated employees of serious illness or death from Covid-19 if exposed to unvaccinated employees;

v. the extent to which Australian companies and (non-health) government departments and their expert health advisors understood the difference between *absolute risk reduction* versus *relative risk reduction* in respect of Covid-19 vaccines;

vi. when Australian companies and (non-health) government departments first understood Covid-19 vaccines neither prevented infection or transmission;

vii. the legal basis upon which Australian companies and (non-health) government departments deemed discriminatory treatment based on vaccination status as legally justified when possessed of the knowledge that Covid-19 vaccines did not prevent transmission;

viii. the legal basis upon which Australian companies and (non-health) government departments deemed that compulsory Covid-19 vaccination as a condition of employment was legally justified when possessed of the knowledge that Covid-19 vaccines did not prevent transmission;

ix. an examination of any pressure placed on, or incentives provided to Australian companies to implement employment mandates by Australians governments.

Explanatory Memorandum

Index

An examination to confirm whether Covid-19 mandates (for non-public health government employees) and employment conditions imposed by Australian companies throughout 2020, 2021, 2022, and 2023 were reasonable and proportionate and consistent with the authorised use of the vaccines, noting that evidence of prevention of transmission was and remains absent from the Australian Public Assessment Reports (AusPARs), and with concerns about immunological benefit of injections into the body in provoking immunity in the upper airways to a
respiratory virus, real-time Covid-19 vaccine pharmacovigilance, epidemiological and pathology/serum data known by Australian governments and reasonably accessible by Australian companies.

The Work Health and Safety Act 2011 and Safe Work Australia code of practice for
managing work health and safety risks, alongside the Safe Work Australia

interpretive guideline for 'reasonably practicable' establishes the expectation that persons conducting a business or undertaking (PCBUs) should consult 'published scientific and technical literature' as part of their due diligence. This includes published pharmacovigilance reports and the AusPARs published by the TGA. It would also include literature describing the vaccines as new technology (mRNA and DNA) vaccinations, which required the Precautionary Principle to be stringently applied to risk assessments.

Question(s) on Notice

Index

In respect of **References NN**, please provide any further information concerning Covid-19 pandemic management decisions and policies and particularly Covid-19 vaccine mandates compelling the receipt of Covid-19 vaccines as conditions of employment, implemented by Australian companies, with especial attention to the guidance provided by Australian governments to Australian companies for undertaking risk-benefit assessments when considering implementing Covid-19 vaccine mandates, and what considerations and criteria Australian companies uniformly followed for observing all available scientific evidence, and which company personnel were designated best skilled to evaluate such medical and scientific considerations.

Answer(s)

Index

Answer

William Parry LLB, Proposed Witness:

The Question on Notice in The People's Terms of Reference marked NN contemplates whether a Royal Commission's terms of reference might better focus on the risk assessments undertaken by Australian companies, and how government policy may have affected these functions. My testimony explains why the committee authoring the terms of reference should understand that the behaviour of employers in not undertaking meaningful risk assessments was a manifest symptom of irregular governance by the incumbent Australian Government of the time.

About me

My name is William Parry, I hold Bachelors degrees in behavioural science (psychology), laws, and legal practice, and my relevant experience includes

advocating for workers through the Red Union Support network since 2022. I also hold a Diploma in business and experience and training in conducting risk analysis, as everyone should, but particularly during my volunteer service with the State Emergency Services as a first responder.

The Red Union Support network seeks to provide affordable industrial and support services to members in a professional, lawful, and efficient manner, particularly where members feel under-represented or abandoned by the established oligopolies of registered organisations.

Response to Question on Notice

The above Question on Notice contemplates that employers may have been deficient in undertaking risk assessments, which is true, but it does not appear to fully grasp why this might be the reality. My testimony is of course limited to my experience, but in my experience, employers, PCBUs, and duty-holders had their decision making co-opted by entities not contemplated in WHS or OH&S legislation, which was a downstream effect of improper governance.

The associations we serve do not discriminate on the basis of political belief or medical record or any other attributes, and we take each member with their unique perspective as worthy of work, participation in public life, freedom of association, representation, and the right to a fair hearing.

My work is not exclusive or limited to disputes resulting from Covid-19. However, these were the vast majority of my case load in 2022, and again recently, because I am tasked with being the senior advocate for over 1300 members who have lodged complaints with three Human Rights Commissions due to alleged Covid-related discrimination. This work involves attempting conciliation, corresponding and advocating with the Commissions towards conducting an investigation into systemic discrimination, representing or supporting members at tribunal hearings, and working with our legal consultants to identify the best route to arbitrate these complaints should a higher jurisdiction be required.

The stories of workers I have served are genuinely harrowing. Mandated members are distraught, defeated, and often clinically depressed. The work is draining. What is most distressing is that in many cases all a member is trying to achieve is re-employment back into the workforce of their area of expertise and experience. In nearly all cases this is prevented, in a manner where punishment for their inability to comply continues, sometimes due to cases of mask anxiety, but overwhelmingly relating to the various attributes that prevented a member's valid consent to receiving Covid-19 vaccinations. I of course have my own bias, having been on the front lines of advocating for those persecuted by medical record, but it

is my frank and thoughtful perspective that coercive methods of approaching Covid-19 vaccination were counterproductive and hazardous.

I of course expect rebukes from many Australians who dutifully or even eagerly lined up for their Covid-19 vaccinations. They may well say "but the consensus is that Covid-19 vaccination is safe and effective and is the best way to protect the community from the harmful effects of Covid-19. The benefits outweigh the harm."

This consensus bias should be removed from genuine enquiry. Should this consensus bias have been applied throughout the development of our Commonwealth, perhaps we would still expect the execution of academics as heretics for theorising that earth perhaps is not the apple of God's eye, or recommend thalidomide for morning sickness, or spray children with DDT as public health measure, or view robo-debt collection as a responsible and efficient fiscal policy, or use asbestos to build schools, or gossip hushed concern about any family where the mother works outside the home. We might still insist that subdermal lipid nanoparticles stay at the injection site, or that SARS-CoV-2 has an identified proximal zoonotic origin, or still be trusting the WHO when they declare that Covid-19 is definitely not airborne. Consensus bias should not taint any enquiry, nor its terms of reference.

Others might argue "Well I got my jab! Why don't they?"; or "I didn't want to get it, but I had to, so should they!"; or "such and such authority says they are safe and effective. Anti-vax concerns are misinformation!" These positions are misconceived, because medical treatment should not be coerced. Almost universally, federal authorities, agencies, and witnesses before senate committees have told us no one was forced to become vaccinated. We had the Coordinator General of the National Covid Vaccine Taskforce, Lieutenant General John Frewen, confirm that no one can receive medical treatment without valid consent and this is reflected throughout the national immunisations handbook, medical literature, common law, and human rights conventions.

The hollow arguments of "well why don't they just comply?" lack compassion and result in significant economic and psychosocial harm that has been mostly overlooked in the making of the mandatory medical treatment policies. There is a myriad of reasons why valid consent was not available. Perhaps those who rebuke with these questions should have asked the workers and engaged with their hesitations or objections in good faith?

Some very well did, but even on the rare occasion when meaningful consultation was attempted, it was superficial or a token gesture, because regulations and marketing slogans in furtherance of the Covid-19 National Immunisation Campaign prevented meaningful engagement around risk mitigation such that job

security, psychosocial hazards, economic wellbeing, workplace cohesion and culture, and real outcomes fell by the wayside.

My testimony from this point is broken into three parts. First I provide context for why WHS obligations were often not undertaken. Second, I express concern regarding Covid-era jurisprudence. Third, I explain the relevance of these Australian Governmental policies and actions.

1 – WHS and OH&S Duties and Protections were Eliminated

Broad and blunt mandates denied workers access to genuine consultation and prevented employers and managers any flexibility regarding reasonably practicable control measures that were might otherwise have been tailored to the hundreds of thousands of unique undertakings and workgroups in Australia.

Work Health and Safety, also known as Occupational Health and Safety, is a legislated duty and obligation by duty-holders and people conducting a business or undertaking ('PCBUs') in each state, but also federally. This legislation grants workers the right to genuine consultation in matters regarding their safety at the workplace.

The Covid-19 National Immunisation Campaign was a primary driver of mandatory-vaccination-to-work policies. These policies had the counterproductive effect of disabling W&OH&S functions from being performed by duty-holders through a blunt, one-size-fits-all approach, because the spirit of the Covid-19 Immunisation Campaign was enthusiastically followed by the States, which almost universally ploughed fertile ground for mandatory vaccination requirements for workplaces late in 2021.

All mandated PCBUs and duty-holders were entirely disabled from performing their function and obligations pursuant to WHS / OH&S requirements regarding Covid-19 mitigation in the following circumstances:

1. When a culture of dismissal and discrimination of vaccine-sceptical or vaccine-hesitant workers and their views existed; and
2. Wherever an authoritative Covid-19 vaccination mandate applied.

Alternatives such as testing or natural immunity we know were unable to be considered by duty-holders and PCBUs that followed governmental approaches.

Diligent and responsible PCBUs had their responsible decision-making powers and obligations regarding work and occupational health and safety and consultation entirely removed by a handful of federal bureaucrats and subordinate States – at least as far as Covid-19 mitigation strategies went. Worth noting is that

some governmental jurisdictions attempted risk assessments, but they seemed to be cart-before-the-horse justification exercises. Some others appeared to not even bother.

In other words, the Work and Occupational Health and Safety Legislation ceased to apply entirely, regarding Covid-19 mitigation in all mandated businesses, where the narrow decision-making of a few co-opted the broad and diverse decision making of tens of thousands of individual decision makers, who each knew their work group best.

As my evidence will underscore, coercion of medical treatment became both the virtuous and the diligent thing to do, while flexibility based on individual variations became dangerous and even impossible.

The informational landscape set by Federal broadcasters was one of fear-mongering for employers and PCBUs. See for example:

- Agribusiness owners concerned about liability for Covid-19 outbreaks if employees refuse vaccination, ABC News, 22 February 2021; and
- Unvaccinated workers could pose serious legal risks to businesses, lawyer warns, ABC News, 2 November 2021.

These stories appear to be published with the intention to persuade PCBUs to mandate Covid-19 vaccination, despite relying on a case of a worker's bacterial infection in an abattoir from unsanitary practices and absent vaccination options. There was no jurisprudence suggesting an employer would be liable for hosting a rapidly spreading respiratory disease, in the absence of making a medical treatment mandatory.

But even more relevant to the enquiry is why, in these stories, the experts consulted showed a clear bias, as they did not consider or warn against the risks of liability for worker injury resulting from the control measure itself, which was substantial, known, real, and is now evident – see for example:

- Secretary, Department of Education v Dawking [2024] NSWCA 4 (where a worker is entitled to compensation for psychological harm from the enforcement of a Covid-19 vaccination mandate, which was upheld on appeal); and
- Shepherd v The State of South Australia (in right of the Department for Child Protection) [2024] SAET 2 (15 January 2024) (where the employer is responsible for compensation for a cardiac inflammation vaccine injury).

In my experience, whenever the right to further consultation regarding injectable

control measures was raised, it was always already too late. Where a mandate existed, smaller or private employers almost universally believed that consultation was futile given the mandatory requirements.

Public and State employers would often say they had already consulted with "the workers", which was in fact consultation with a few senior delegates at often government-friendly registered organisations. The issue with such forms of consultation is that it is extremely unlikely that those being consulted would be losing their jobs or coerced into unwanted medical treatment as a result of the proposed control measure. There was almost always no direct consultation with those whom the policy would most affect.

Let me give two clear examples from my experience advocating for workers of these problems in practice.
First, when raising a WHS dispute with A/CEO of NALHN in June of 2023 regarding a need to review the mandatory vaccination policy based on emerging scientific evidence and our member's inability to practise her profession, the A/CEO simply replied, "As the Chief Executive Officer of the Northern Adelaide Local Health Network, I am required by SA Health to implement the mandatory SA Health Addressing Vaccine Preventable Disease: Occupational Assessment Screening and Vaccination Policy."
Our member no longer works in her profession in the public service, having been terminated, despite being completely healthy and having recovered from Covid while isolating, with no burden on any work resources or others within the workplace.
Second, absurd arguments were made by the State in Fischer v State of Queensland (Queensland Health) [2023] QIRC 318, a case I sketch below:

- Ms Fischer sought an exemption on religious belief but also while breastfeeding.
- Because her employer had not ever provided a copy of a risk assessment (despite over a thousand requests from herself and her fellow members), Ms Fischer provided her own risk assessment to support her exemption application based upon religious and exceptional circumstances in early 2023 – which was a highly cited scientific and medical essay (with reputable sources, including Pfizer's own clinical reporting.) Also, the majority of her role was educational and not patient-facing, she could enter through the back to avoid the lobby, and she had recovered immunity.
- She wrote in good faith and with health and safety in mind, in the hopes it would inform her employer of the risk compared to the benefit, and save her job.
- The employer denied the exemption on review, leading to the inevitable disgrace and punishment of Ms Fischer who could either choose to

appeal or resign. She chose to appeal her employer's decision to the relevant tribunal.

- When seeking arbitration, the tribunal asked Ms Fischer to argue, on the papers, why her case should even be heard. Ms Fischer argued that her employer had not conducted and could not evidence having conducted risk assessments for her role (or overall for the policy itself) and therefore could not be informed as to the demonstrable justification of limitation on her human rights or reasonable necessity for her discrimination given her relevant attributes.
- Also she argued that the employer should refer to her risk assessment, in the absence of their own.
- The State solicitor argued that the State did not need to provide a risk assessment because "There was also no lawful basis upon which she could request access to a risk assessment undertaken by the Department or MNH in relation to Covid-19 vaccines, or proof that she was at heightened risk of transmission."
- The State solicitor went on: "The Department was also not required to do its own risk assessment with respect to Covid-19 vaccines." Here the State solicitor cited Kathryn Roy-Chowdhury v The Ivanhoe Girls' Grammar School [2022] FWC 849 which involved a private school that was mandated by the Victorian Government, which is an absurd authority to appeal to in arguing that a State itself need not risk-assess its own enduring policy when faced with an employee's own risk assessment, particularly where discrimination is involved.
- Despite the worker's reply to this absurdity, the tribunal struck out the complaint because at [25] the Commissioner found "There is no doubt that Ms Fischer has prepared arguments that have the appearance of greater complexity. But when one strips back the veneer, what remains is the same arguments that have been run by many others, based in flawed science or vehemently held personal religious beliefs."
- No real evidence of risk assessment was brought by the employer, ever. The result was that this highly educated worker was forced to resign in disgrace and is unlikely to returned to her profession in the public sector.

Should an employer be terminating workers due to their medical hesitancy without providing a copy of empirical risk analyses?

It does not inspire trust or confidence that overwhelmingly, employers cannot show empirical evidence for coercive medical treatment policies.

Mandated companies and businesses lost reliable, healthy, and sometimes even otherwise serologically immune employees as they had no discretion.

What were some of the harms of coercive medication?

- The public overwhelmingly lost the services of discerning, ethical, and precautious professionals.
- Non-compliant employees lost their livelihoods and suffered extreme disgrace and anguish.
- Many who believe they were either jinxed or coerced into compliance remain quietly upset, even violated.
- Conversely, those who remain unequivocally in favour of mandatory vaccination are staunchly defensive of their perspective on the policies they supported, which may breed division and tribalism within workplace culture.

It never helps in situations of such hardship that, when PCBUs and duty-holders are asked to show their homework to justify the intense upheaval of many workers' lives and rights, they usually come up empty-handed. Often they will rely on infectious disease experts in testimony when defending themselves in industrial tribunals, such as A/Prof Paul Griffin who did not disclose conflicts of interest in several hearings until a hearing in mid-2023 in which it was revealed that he received funding from Pfizer, Moderna, and Novavax for research and his companies of which he was a director.

Employers' risk assessments were often superficial: they would simply say that Covid is dangerous and that the vaccines are effective, and then link to the Fair Work Commission or the Fair Work Ombudsman, Department of Health, or ATAGI. These sources did not reliably answer the health, ethical, or spiritual concerns of the worker – but merely suggest that vaccination is effective, and that other workers had failed to argue against mandatory vaccination policies. Linking to external sources was in essence an employer saying to a concerned worker "Look, I haven't done a risk assessment, but here see these federal authorities. Resistance is futile; you must comply or become unemployed."

There was already a distrust of these federal sources amongst Covid-19 vaccine-hesitant or objectors, given that to date the Federal Government has not provided copies of the contracts with the powerful multinationals to which our Commonwealth is now bound, and also because of the perceptions of bias which I explore below.

Perhaps this harm could have been avoided, had there been better assessment and flexibility for risk mitigation, including alternatives to vaccination, of which dozens were proposed throughout show-causes and proceedings. A strict and narrow mandate bluntly denies reasonable alternatives.

Unfortunately, sceptical and distrustful workers can no longer view Federal Government sources as impartial, and there is certainly sufficient historical

evidence that such distrust may not be a flaw or fault.

The denial or disablement of consultation is a critical failure that requires the wisdom of a protected Covid-19 royal commission to recognise and resolve.

2 - Failure of protective laws and right to fair hearing

Most industrial relations legislation, such as the *Fair Work Act 2009,* specifically state their objectives which generally include economic prosperity, trust and confidence, job security, and allowing a place to efficiently resolve disputes at low cost.

Unfortunately, those principles of Fair Work, but also human rights and anti-discrimination legislation, are currently strangled by suppressive Covid-era jurisprudence and arbitrary confirmation biases. Terms of reference should consider the three issues below.

First, judicial and tribunal decision makers often believe themselves bound by previous jurisprudence, which is unavoidably biased because:

- Employers (both private and governmental) have a significant resource advantage over workers groups – particularly as the large legacy union movements almost unilaterally acted as agents of the National Immunisation Campaign in their own right, commonly refusing to represent the hesitant, or objectors. Such imbalance produces jurisprudence unfavourable to the worker.
- Cases which were likely to lead to jurisprudence in favour of workers would usually settle, with full confidentiality provisions. I have experience resolving complaints of termination or discrimination for mandatory vaccination. Settlements at conciliation are never published.
- Because the strongest cases usually settle, the remaining cases that usually go to full hearing are those that are most avidly opposed, litigious, angry, outraged, or just extremely passionate about their rights – which does not set favourable precedent for workers.

The above naturally creates a feedback loop of increasingly hostile jurisprudence to hesitant or non-consenting workers.

Second, there is a question about whether Covid-era jurisprudence is heavily tainted by the aura of emergency, the media landscape, federally endorsed assumptions, and the undeniable culture of vilification for the unvaccinated that occurred in many social circles.

The objectives of industrial laws have been overwhelmingly underachieved during

Covid-era hearings, where decision-makers have opted to aid in the enforcement of the National Immunisation Campaign instead of achieving the objectives of the relevant industrial legislation or instrument. Decision-makers appear more interested in the intentions and proposed benefits of the mandating decision maker than the resultant negative outcomes of the enforcement of the mandate itself.

Third, terms of reference should consider whether decision-makers are unduly influenced by government campaigns overall.

I testify with confidence, from my experience, that there is clear loss of trust in the judiciary and arbitration tribunals which is likely due to unresolved perceptions of bias that almost absolutely favours government Covid policy. This loss of faith in our courts and tribunals is often hard to counter given the obstacles many now experience when attempting to return to work, all off the back of Covid-era judicial and tribunal decisions.

Perception of bias is understandable because some key justices in landmark vaccination mandate cases did not appear sufficiently impartial on the subject matter of hearings that carried exceptional weight for these people's human rights. For example:

- In July 2021, the now High Court Justice Beech-Jones endorsed a newly published paper by a Monash University Law Lecturer and Researcher (who commonly conducts research in regulating new genetic biotechnology, which is usually funded by university-industry partners such as Musculoskeletal Australia, who in turn are partnered with the manufacturers of the provisionally approved Covid-19 vaccines of the time).
- This academic paper was titled "Covid-19 Vaccine Mandates: A Coercive but Justified Public Health Necessity". Rudge's paper argued, amongst other critiques, that the *right to life* should be used as a justification for *coercive medical policies,* despite this justification being clearly inconsistent with Article 5 of the International Covenant on Civil and Political Rights.
    - "1. Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein or at their limitation to a greater extent than is provided for in the present Covenant."
    - The express limitation exists to stop a government from improperly wielding one human right to abrogate others, and is reflected in other human rights instruments, including ratified state human rights laws in Australia.
- Despite this oversight by the authors, Justice Beech-Jones praised the

article.

- Three months later Justice Beech-Jones decided the landmark case Kassam v Hazzard [2021] NSWSC 1320; 393 ALR 664 in favour of the State of NSW. Despite finding the policies coercive, the decision authorised the medical coercion, discipline, termination, and in some extreme cases, the destitution of tens of thousands of workers within Australia.

A second example of a critical perception of bias is the heavy-handed treatment and humiliation Deputy President Dean received by the then President of the Fair Work Commission, Justice Iain Ross and the media in late 2021. President Ross put Deputy Dean on restricted duties in October 2021, and DP Dean was further humiliated by the Australian Financial Review and President Ross, including accusations of misusing her office around December 2021, and she was ordered to undertake mandatory training before hearing further matters relating to mandatory vaccination. What did DP Dean do to merit this treatment? DP Dean received this disgraceful treatment for what many believed was a fairly principled, proper, and humane dissenting opinion in the case of Kimber v Sapphire Coast Community Aged Care Ltd [2021] FWCFB 6015; 310 IR 21 and also sharing a LinkedIn post suggesting that the most totalitarian National Immunisation Campaign elements were "medical apartheid", an apt and acceptable political belief.

DP Dean, in her dissenting opinion, focussed heavily on the human rights of the individual, including the self-determination of workers, bodily autonomy, and right to work over the promised transitory benefits of coercive medical treatment under the threat of termination.

The persecution of DP Dean for her opinion in late 2021 shares features with the persecution and raid by a State Department of Health and the AHPRA's ongoing suspension of Dr Mark Hobart in November 2021 for putting his patients' interests first by issuing exemptions to Covid-19 vaccinations. Both of these highly publicised stories sent a very clear message to Australians in similar roles about the consequences of standing up for individual human rights. It was perhaps, in essence, mass victimisation. It was a threat that, "if you speak up for others and their human rights or self-determination as a human being, you will be punished by the authorities."

These public punishments also emboldened those with hate and disgust against those who chose to argue that medical treatment should remain a choice, including in authoritative and judicial decision-making.

There is widespread consensus amongst those most affected by vaccination mandates that their employers, States, and authorities have no interest in debating them on their principled positions or objections. The experience is that these

organisations avoid arguing the merits of the policies or possible assumptions in good faith, and instead revert to other methods such as appeal to an infantile consensus, authority bias, or technical arguments that circumvent the primary issues – e.g., "is it really that unsafe for the worker to work in the circumstance?" Or "what were the medium- or long-term risks of the proposed control measure, and have they even been considered?" An employer would simply argue that the direction itself was reasonable, referring to jurisprudence from other matters, instead of engaging with the facts and the outcome.

What occurred was a cultural change which is not beneficial from an industrial-relations, public-good-governance, or even bio-security point of view.

Those who had a different perspective, who perceived the widespread derogation from human rights and the slippery slope towards an unfree society that demands receipt of novel medical products on short notice in order to participate in society, were intentionally vilified and victimised with enthusiasm.

To return to the main point, it is understandable that Covid-19 caused more of the public to become distrustful of the impartiality of not only the medical authorities, but also the legal authorities, in times of a National Campaign. The effect of widespread medical coercion has created probably the greatest resistance to public health messaging, and other more benign globalist policies, in modern history.

First of all, jurisprudence does not give an accurate representation to inform justice because it is biased towards those cases that do not settle, which does not set a balanced precedent. Secondly, responsible Judges have an apprehension of bias that set the scene for early jurisprudence, from which the rest would often follow. Thirdly, how are the public to expect a Fair Work arbitrator or doctor to be impartial when they could be severely defamed, reprimanded, suspended, or sacked for a reasonable political, judicial, or clinical belief or dissenting opinion?

These wounds to our societal fabric and trust-based system of government are likely only to ever be healed by a fully endowed Royal Commission which is prepared to give little weight to Covid-era jurisprudence, and investigate the source of perceptions of bias.

3 – Ad-hoc replacement of the Council of Australian Governments by the National Cabinet

Relevant to the Question on Notice in ToR NN, the aforementioned extinction of broad, considerate, and flexible WHS assessments by duty-holders of work groups, and the disablement and discouragement of good-faith informed PCBU participation in Covid-19 risk mitigation decision-making, was a downstream consequence of ad-hoc (or at least unlegislated) and unaccountable federal

government influence or directions via the so-called "National Cabinet".

The Covid-19 National Immunisation Campaign, and resultant removal of PCBU discretion and workers' rights to consult or decline medical treatment, was enabled by the so called "National Cabinet." The more harmful, and I would argue totalitarian, manifestations of the Covid-19 Immunisation Campaign, appear to have only been made possible by unaccountable and privileged pressure from the "National Cabinet". For example, the "National Cabinet" influenced AHPPC to change its advice which was originally against mandatory Covid-19 vaccination for aged care workers. See for example:

- This since-deleted media statement from 04 June 2021 in which "National Cabinet indicated an in-principle disposition to mandating aged care and disability workforce Covid vaccinations, and tasked AHPPC to provide advice on this matter as soon as possible." available on Web Archive; and
- Scott Morrison planned to use the National Cabinet to lobby state governments to go against health advice on Covid vaccinations (ABC News, 4 June 2021).

The above events resulted, within a week, in the changing of the AHPPC's advice, and so began the era of mandatory Covid-19 vaccinations for employment.

Although no one but the attendees knows exactly what happened at these "National Cabinets", the public is understandably suspicious about the manner in which highly lobbied lawyer politicians managed to influence a medical doctor to go potentially against his medical ethics, code, and oath and overturn his original position.

Notably, when the AHPPC advice was made, there was no risk assessment easily available with which to inform Australian Companies or their workers, just a broad sweeping statement.

Further, it is unlikely that this "National Cabinet" considered any cogent human rights assessments or a full diverse discussion of potential or ongoing harms of national medical coercion with novel medical products.

Following AHPPC's recommendation, it is fairly transparent that States reacted and implemented mandatory vaccination policies on short notice and in a rushed manner, where often law or legislation was probably misapplied, then contorted, and then amended in order to impose the policies. For example, the Pandemic Order amendments in Victoria on 15 December 2021 coincided with the ending of the state of emergency. The state of emergency declaration used by Victoria for mandatory vaccinations appeared by any interpretation a quarantine power by

authorised officers – not a broad power to coerce an entire economy to accept particular medical products in order to operate. The irregular reliance on a quarantine power to mandate vaccination for workers, and the subsequent rushed amendments for broader pandemic orders under Victoria's State Public Health and Wellbeing Act, appear to be a rushed attempt to comply with the National Cabinet and the seemingly subordinate AHPPC's recommendations.

As a metaphor, the tools available to the States were misused, then melted and warped, to fit the screws for the project ordered by the federal Government of Australia.

Summary

This culture of no oversight and tunnel-vision towards increasing vaccination at all costs, where any hesitation may result in disciplinary action, serious misconduct, termination, and disenfranchisement, appears to have been enabled by the "National Cabinet" and participating States.

The establishment of the "National Cabinet" and abolition of COAG transparently appeared as a means by a small group of federal Government ministers and bureaucrats and participating States to circumvent the good-governance safeguards and public protections offered by COAG.

The relevant employment mandates were unilaterally brought upon and introduced into our society nationwide by any governmental means necessary.

Therefore, to answer the question, PCBUs of Australian Companies overwhelmingly did not conduct adequate risk assessments or engage in good-faith and meaningful consultation.

PCBUs and duty-holders were often prevented, or discouraged, from complying with WHS and OH&S obligations. The way in which the federal Government utilised the "National Cabinet" enabled unilateral mandatory vaccination requirements nationwide.

The negative outcomes are significant. The consultation that could have occurred in a more Swedish-style approach to Covid-19 would have involved millions of interactions between employees, employers, their associations, and work groups, to ensure the most reasonably practicable way to protect health in the workplace is identified based on the circumstances and unique attributes of work groups.

Early jurisprudence appeared to be not fully impartial and laid the ground for repressive and anti-work policies, making employment inaccessible on the basis of medical choice, while excusing Australian companies from providing evidence of

necessity, benefit, or risk to justify the systemic discrimination.

Index

Reference: OO

Index

A review and analysis of Australian Excess Deaths in the years 2020, 2021, 2022, and 2023 including:

i. whether any Australian health departments specified:
   a) ongoing surveillance of Provisional Mortality Statistics (PMS) during and after the national Covid-19 vaccine campaign; and
   b) whether any such surveillance included plans of action should excess deaths become consistently apparent;
ii. an investigation into why no public investigations of the causes of excess deaths was undertaken in 2021, 2022 and 2023;
iii. an examination of the scientific basis the Australian Bureau of Statistics (ABS) switched from using a 'baseline' for predicted expected deaths based on the average of the five pre-pandemic years used for the PMS in 2020 and 2021, to a different and inferior baseline in 2022 and thereafter;
iv. an examination of the scientific basis the ABS switched to a new model for excess mortality in July 2023, and:
   a) any bias it may contain;
   b) why it was created retrospectively once large numbers of excess deaths were shown in the PMS;
v. an assessment utilising accepted causation criteria and any appropriate new or relevant epidemiological or statistical data tools and methods for determining whether Covid-19 vaccines contributed to Australian Excess Deaths in the years 2021, 2022, and 2023;
vi. whether and how the TGA's pharmacovigilance system was monitoring mortality statistics in real time as part of an early warning system (EWS);
vii. whether and how the TGA's pharmacovigilance system was monitoring cancer incidence and mortality statistics in real time as part of an EWS;
viii. whether and how the TGA's pharmacovigilance system was monitoring miscarriage, stillbirth, fetal anomaly and neonatal mortality rates in real time in vaccinated women as part of an EWS;
ix. whether and how in the absence of (ii) – (iv) the States were monitoring in real time those factors.

Explanatory Memorandum

Index

An examination to confirm whether excess deaths in Australia in and from 2020 were consistent with excess deaths to be expected from SARS-CoV-2 as a pandemic infectious disease, and were statistically significant to warrant the declaration of

Emergency issued under the Biosecurity Act.

An examination to confirm whether fluctuations in deaths in Australia in 2021 through 2023 were consistent with historical national averages, the measures taken to report this, and of the plans of action to be taken by Australian governments in the event that deaths were consistently in excess of pre-pandemic averages.

An examination to confirm whether excess deaths in Australia in 2021 through 2023 bore no scientific nor statistical nor causal relationship with the uptake of Covid-19 vaccines.

An examination to confirm whether excess deaths in Australia in 2021 through 2023 did not warrant any formal investigation by Australian governments.

Question(s) on Notice

Index

In respect of **Reference OO**, please provide any further information concerning Excess Deaths in Australia from 2020 through 2024.

Answer(s)

Index

Answer

Clare Pain BSc(Hon), MSc, Co-Author:

My credentials for writing about excess deaths are first, that I have a Masters degree in Operational Research from Lancaster University UK and worked as a statistician and economic forecaster in the UK from 1984 to 1996. Second, throughout 2023 and to date, I have been the research coordinator of the website www.excessdeathstats.com. The needs of this project have meant that I have spoken to researchers on the topic of excess deaths in several countries and have learned a great deal about how excess deaths can be calculated. Unfortunately, I have also come to understand that there is scope for the calculation to be done in a way that gives lower or higher numbers for excess deaths, as desired.

What has the ABS reported for excess deaths during the pandemic?

To get quickly to your point, in which you ask about data from 2020 to 2024. There are two statistical series produced by the Australian Bureau of Statistics (ABS) that are relevant to excess deaths. As we went through the pandemic in real time the

statistics available to the public and government were the monthly Provisional Mortality Statistics (PMS), which gave us a measure or 'indication' of excess mortality. These figures were released with a three-month lag, so, for example, a publication released in December 2021 reported on deaths to 30th September 2021.

These numbers provided the main guide as to levels of deaths to the public, the press and the government. They provided consistent evidence of excess mortality that were first seen in 2021 and then became entrenched in 2022 and for much of 2023, but they appear not to have been investigated. At the time of writing the most recent estimate of excess deaths from the ABS's Provisional Mortality Statistics covers 2023 up to 30th September. No data is available for 2024 as yet.

In July 2023, the ABS released a new, more complicated, model for calculating excess deaths. This model looks impressive and has good points, but I have concerns that it also has flaws, and these concerns are heightened because: unlike the PMS, the new model was developed *after the fact;* it halves the estimates of excess deaths; and rewrites important aspects of history of excess deaths in the pandemic. (More about that later). The new model (Measuring Australia's Excess Mortality during the Covid-19 Pandemic) now provides the 'official' estimates of pandemic excess mortality, according to the ABS, and it will be updated every six months. The first update was released on 18th December 2023, which covers data from 1st January 2020 to 31st August 2023.

The table below, which I have prepared, compares excess death numbers provided by the two approaches used by the ABS. For PMS numbers I have used the figures published by the ABS using the most recent download of monthly data available at the time of writing (PMS release 20th December 2023). Because deaths data can take months or even years to finalise, the numbers may differ from those in the first PMS releases that covered the years concerned[ccxlv]. For the new model 'Measuring Australia's Excess Mortality during the Covid-19 pandemic to August 2023', the data is taken from the table entitled, 'Excess Mortality by Year, Australia, 2020-2023'.

Excess deaths (number and %) as reported by ABS Provisional Mortality Statistics and Measuring Excess Mortality

Updated 1st February 2024 https:clarityonhealth.substack.com

	2020	2021	2022	2023 (part year)	Cumulative to end 2022	Cumulative to date	Cumulative from 2021
ABS Provisional Mortality Statistics (PMS) (Ref 1)							
Actual Deaths (Doctor certified and coroner)	162,666	172,039	190,775	137,048	525,480	662,528	499,862
Expected Deaths	161,065	161,065	165,172	124,671	487,302	611,973	450,908
Excess Deaths	1,601	10,974	25,603	12,377	38,178	50,555	48,954
% Excess Deaths	1.0%	6.8%	15.5%	9.9%	7.8%	8.3%	10.9%
ABS Measuring Australia's Excess Mortality (Ref 2)							
Actual Deaths	164,795	171,799	190,856	119,619	527,450	647,069	482,274
Expected Deaths	170,045	169,048	170,911	112,714	510,004	622,718	452,673
Excess Deaths	-5,250	2,751	19,945	6,905	17,446	24,351	29,601
% Excess Deaths	-3.1%	1.6%	11.7%	6.1%	3.4%	3.9%	6.5%
Difference in excess deaths 'Official Model - PMS'	-6,851	-8,223	-5,658	N/A	-20,732	-26,204	-19,353

Notes:

Data for 2023 is not consistent as it s reported to different time points. The Provisional Mortality Statistics are to September 30th. The Measuring Australia's Excess Mortality is to August 27th and 28th May for Northern Territory data

Numbers with a white background are given in ABS data downloads or reports Numbers with a beige background are calculated from data in ABS reports

https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release Ref 1

https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023 Ref 2

As you can see, according to the PMS, 50,555 more Australians have died than expected since January 1st 2020, while according to the new 'official' model, 24,351 more people have died than expected. Every year of the pandemic has thousands fewer unexpected deaths with the new model; 2020 become a year with a deficit of unexpected deaths; and 2021 (which was the year of the initial Covid-19 vaccine rollout when there was little Covid-19 in Australia until December) has its excess deaths figure markedly reduced, from 10,974 according to the PMS to 2,751 with the new model.

How can two measures produced by the ABS give such different results? Should we take the new model at face value without question, because it has been produced by our statistical experts, or should we request complete transparency about how it was chosen, bearing in mind that the new lower excess numbers are likely more convenient for members of the current and former governments who presided over the pandemic and may not want short-comings to be brought to light?

To answer these questions, we need to understand how excess deaths are calculated and the history of the ABS's reporting over the pandemic.

How are excess deaths are calculated?

Excess deaths are calculated by a simple equation:

Equation 1: *Excess deaths = Actual deaths – Expected deaths*

In most countries, including Australia, actual deaths are based on reliable data produced by the statistical office – in our case by the ABS. Expected deaths, in contrast, can be calculated as the statistical office sees fit as there is no prescribed way in which to measure them. In their paper examining excess death calculations worldwide for the first two years of the pandemic, Levitt et al say:

> *However, excess deaths calculations require modeling of the expected deaths that entails many assumptions and analytical choices. To obtain excess deaths estimates, one needs to define a control (reference) pre-pandemic period, use some model for extrapolating expected deaths in the pandemic period and compare them against observed deaths. There are many different possibilities on how to select the pre-pandemic reference period and on how to model data and extrapolations.*[ccxlvi]

Different countries have chosen different ways (known as methodologies or models) to calculate excess deaths during the pandemic and some countries, including Australia, have altered the way they calculate excess deaths several times during the pandemic.

The way chosen to calculate excess deaths should, one hopes, be logical, unbiassed and objective and there is also clearly less risk of bias if the method of calculation is chosen in advance rather than with the benefit of hindsight.

History of the ABS's reporting of excess deaths during the pandemic
Provisional Mortality Statistics (2020-2021)

Laudably, on 24th June 2020, the ABS put in place a system to report deaths more rapidly by setting up the Provisional Mortality Statistics (PMS) reports which were issued monthly until August 2023. (Prior to this I believe deaths were reported annually with deaths for a year being reported in September of the following year.)

In that first release of the PMS in June 2020, doctor-certified deaths for January to March 2020 were reported (there is usually a three-month delay as deaths data takes time to be reported, collated and analysed). There was also a section in the report entitled 'Measuring Excess Deaths'. Two quotes from this section are shown below.

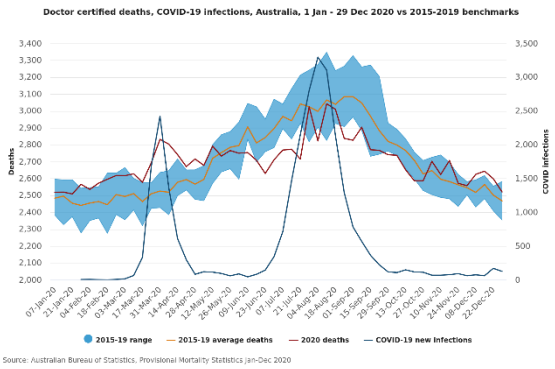
> *Excess mortality is an epidemiological concept typically defined as the difference between the observed number of deaths in a specified time period and the expected numbers of deaths in that same time period. Estimates of excess deaths can provide information about the burden of mortality potentially related to the Covid-19 pandemic, including deaths that are directly or indirectly attributed to Covid-19.*
>
> *Throughout this report, counts of deaths for 2020 are compared to an average number of deaths recorded over the past 5 years (2015-2019). These average or baseline counts serve as a proxy for the expected number of deaths, so comparisons against baseline counts can provide an indication of excess mortality. Minimum and maximum counts from 2015-19 are also included to provide an indication of the range of previous counts.*

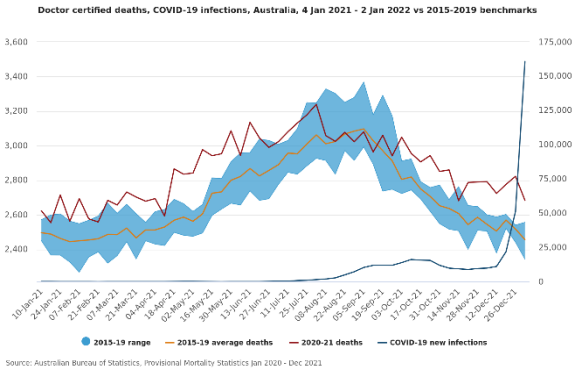
Thus, an expected number of deaths for each week of 2020 and 2021 was calculated by the ABS as the average of the number of deaths in the corresponding week for the five pre-pandemic years 2015-2019. Once an expected number of deaths had been predicted, excess deaths (or as the ABS put it, numbers above 'baseline') could be calculated as the actual deaths data came in, using the formula given in Equation 1 above.

This approach was logical and defensible. Other organisations such as the OECD and the UK's Office of National Statistics have used such a measure throughout the pandemic. Pros and cons of this model are listed in footnote[ccxlvii].

The 'indications of excess mortality' produced by the PMS reports for the whole of the years 2020[ccxlviii] and 2021[ccxlix] can be seen on the following two ABS graphs,

downloaded from the corresponding PMS reports.





In both graphs the blue range spans the maximum and minimum numbers of deaths seen in the corresponding week of the five pre-pandemic years 2015-2019. Technically there are excess deaths whenever the red line (actual deaths) is above the mustard line (expected deaths). The graph for 2020 (left) shows deaths were only in excess briefly at the start of the pandemic.

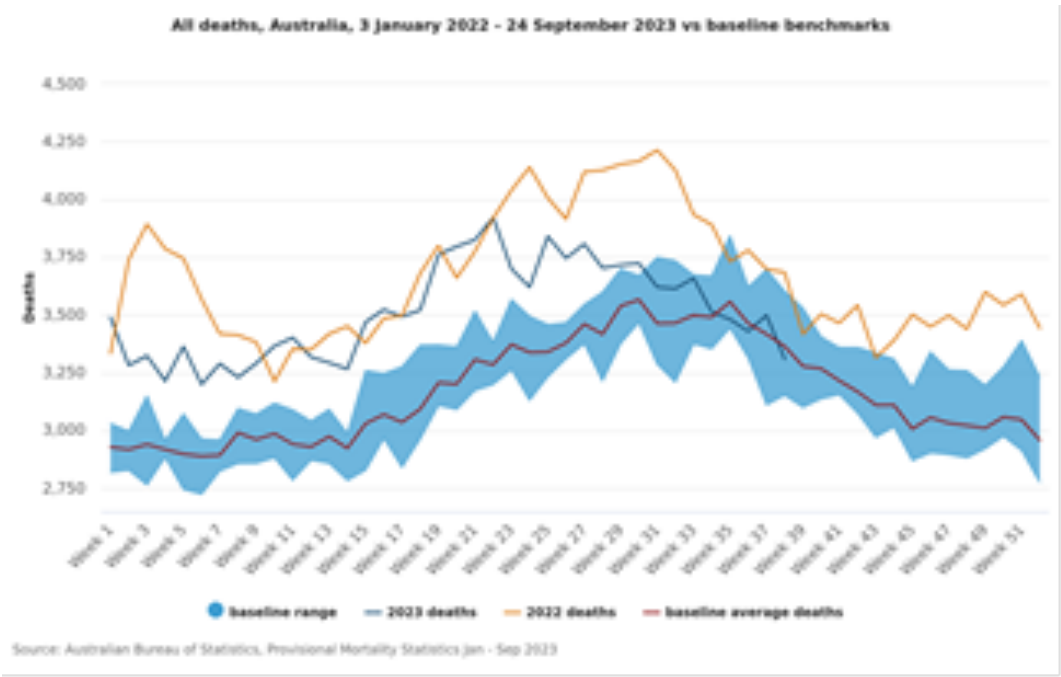
In the graph for 2021 (right), it is clear that there were excess deaths for much of the Autumn and Spring. Furthermore, actual deaths were above the maximum seen in the five pre-pandemic 'normal' years for many consecutive weeks in those seasons. This could (and I would argue, should) have been taken as a warning sign that something was awry. It's important to note that, although the ABS is now using a different retrospective 'official' measure of excess deaths during the pandemic, the PMS data was the key source of timely deaths information available to the government as we went through the pandemic. Clear indications of excess deaths were given in 2021 by the PMS, but it seems no investigation of the cause(s) of these deaths was carried out.

Provisional Mortality Statistics 2022 to date

The ABS decided to change the way they calculated expected deaths in the PMS for the years 2022 and 2023. A Royal Commission must ask why they made this change because it increased the average expected number of deaths and thus reduced the calculated excess deaths, which one imagines may have been politically expedient. For these years their baseline (ie weekly expected deaths) was calculated as the average of the number of deaths for each week in four years, 2017, 2018, 2019 and 2021. I (and many others) can see no good reason for adopting this new baseline, and criticisms of it are in a footnote[ccl].

Despite the move to a baseline that would reduce the number of excess deaths, for all of 2022 and the first half of 2023, actual deaths were above the baseline level as can be seen from the graph downloaded from the December 2023 PMS release, below. Hence, according to equation 1, the nation was not only experiencing excess deaths,

but at a level generally above the maximum levels seen in the four baseline years. (Note, in this graph the red line is expected deaths or baseline, the yellow line is actual deaths in 2022 and the blue line is actual deaths in 2023). At the time of writing the ABS has only published data to September 30th 2023 in its PMS. Despite this concerning graph, it appears there was no investigation into the causes of the excess deaths; rather it was assumed that they were all Covid-19 deaths. Attempts by Federal Senator Ralph Babet to get a Senate Committee Inquiry into excess deaths were voted against by the Senate, in March 2023 and February 2024, but passed on February 27, 2024.

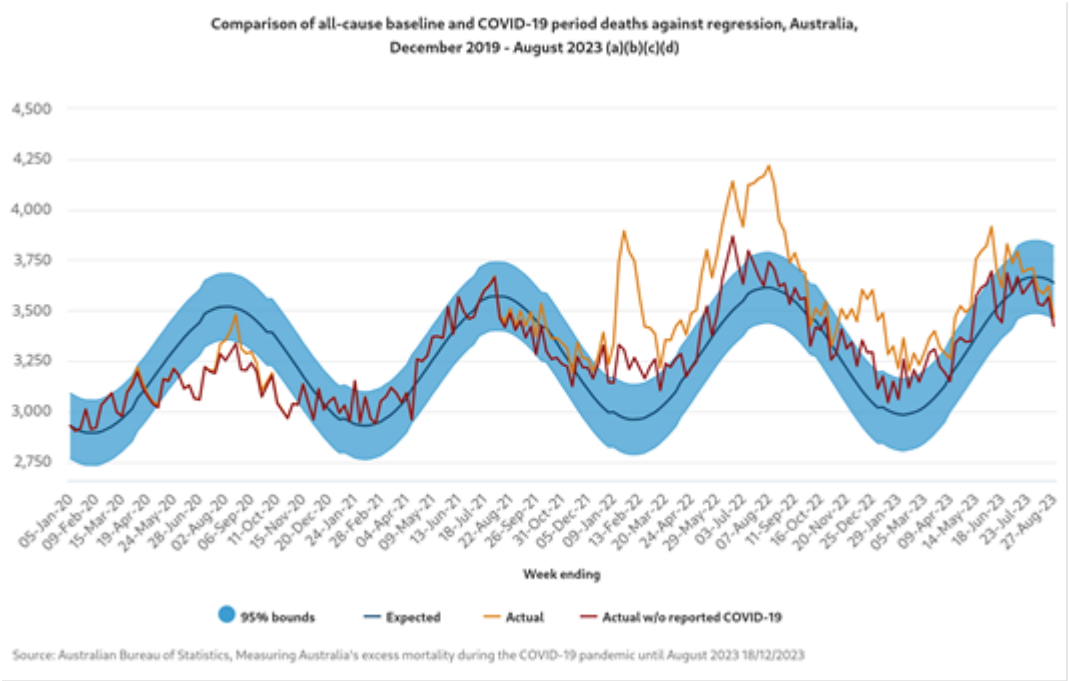


Measuring Australia's Excess Mortality during the Covid-19 pandemic: the ABS's new 'official' measure of excess deaths

On 19th July 2023 the ABS released a new model that has now become the 'official' estimate of excess deaths which will be updated every six months, with the first update published on 18th December 2023. As mentioned above, this new model predicts thousands more expected deaths for every year of the pandemic than was predicted using the PMS. The higher expected deaths gives lower numbers of excess deaths (see Equation 1 and the Table above, which compares excess death numbers calculated by the new model to those produced by the PMS).

The new model, in my opinion, rewrites the history of the pandemic. In particular, it shows a marked deficit of deaths in 2020 and few excess deaths in 2021 (see graph below and compare with graphs produced by the PMS for those years, above). Furthermore, in 2022 and 2023, when the graph does show prolonged periods of highly significant levels of excess deaths (above the upper 95% confidence interval) use of a red line showing 'actual deaths minus deaths 'from and with' Covid-19'

appears to tell the story that 'all the excess deaths are due to Covid-19 so we don't need to investigate more deeply'. Of course, it is completely wrong to include deaths 'with' Covid-19 (the underlying cause was something else); deaths from Covid-19 have been overstated (see answer to Question on Notice V); and it is not justified to assume every genuine death from Covid-19 was an excess death. With the median age of people dying from Covid-19 in 2022 being 85.8 years, while the median age of death was 82.2 years, half the people dying from Covid-19 were very old and frail and might have been expected to die that year anyway, so their deaths cannot be the unexpected, or excess, deaths.



A Royal Commission is needed to examine the new model

The new model has some points in its favour: it uses a long stretch of data from before the pandemic (2013-2019), and no data from during the pandemic; it models age-specific mortality rates and then converts to numbers of deaths using population estimates, which means that changes in population size and age-distribution are taken into account. In this respect it is superior to the PMS, especially the PMS with the baseline used in 2022 and 2023.

It also has some potential flaws: it is not obvious that a model used by NSW Health to predict influenza epidemics is the best approach to a model for Covid-19, which has not shown the same seasonal pattern as flu; the trend in the model puts in place higher expected deaths in 2020 and 2021, yet this trend was presumably driven by immigration which was at a standstill for most of these years with international borders closed. Furthermore, it is unclear how an imposed harmonic (sine and cosine) pattern of seasonality can be superior to a model which uses the actual pattern of seasonality seen in the past (as was the case with the PMS).

The main reason this model needs to be examined is that we need to be sure that it was not selected for the answers it produced – namely a halving of the excess deaths numbers and a major reduction in excess deaths in 2021, which is an important year to examine to test whether Covid-19 vaccines have contributed to excess mortality. We must remember that this model has been put in place retrospectively – looking back over the pandemic, knowing that the PMS has produced clear warnings of excess deaths, which have not been acted upon.

There are concerning signs that selecting the 'correct' answers may indeed have been important. In the methodology for the model we are told that two models examined (one for Australia and one for Western Australia) were rejected because they "resulted in a very low number of expected deaths for 2022 and 2023". So they were not rejected on principles and logic, but because they gave 'the wrong answer'.

While all may be above board with this new model and I have no doubt that the staff at the ABS are professionals of high integrity, it does provide a convenient picture for the government and makes a huge change to numbers of excess deaths after the event. Because of this, a Royal Commission must investigate to ensure that it was developed and selected for the right reasons.

Endnotes: For all answers
Index

Reference: PP

Index

An examination of Australian government transparency and accountability in the context of the handling of freedom of information requests (Federal and State equivalents) in relation to SARS-CoV-2 and the Covid-19 vaccine rollout, with particular reference to (but not limited to) the following:

i. the TGA;
ii. Sydney University;
iii. New South Wales Health.

Explanatory Memorandum

Index

An examination to confirm whether certain refusals by agencies and institutions to provide requested documents were reasonable and according to law, and to confirm whether redactions made to certain documents received pursuant to FOI requests were reasonable and according to law.

Australian governments make claims to value transparency, however throughout 2020 through 2023 there appears to have been a tendency to prioritise concealment when faced with challenges. This approach undermines the principles of accountability and openness that are essential for a healthy democratic system.

A series of examples involving the TGA in the context of reproductive health:

a) Failure of the TGA to require accessible organ histology reports in pre-clinical studies for Covid-19 vaccines. Pre-clinical histology reports are particularly relevant to reproductive organs as clinical trials did not include reproductive health parameters;

b) Failure of the TGA to extract ovary and testis histology reports when requested by a reproductive health clinician under FOI 2565;

c) Failure of the OAIC to provide a result to a requested review of the TGA rejection of FOI 2565 in over two years since the original request for review was made;

d) The TGA agreement to withhold studies (or parts thereof) containing the ovary and testis histology reports from the general public in accord with 'active steps' taken by pharmaceutical companies 'to ensure the

information contained within the documents is not disclosed to the general public' (TGA Internal Review Decision of 27 September 2021);

e) Failure of the TGA to query the effect of rising nanoparticle concentration in mammalian ovaries, which doubled from 24 to 48 hours post single 50mcg injection (after which measurements ceased). In the context of ovarian accumulation of nanoparticles, the TGA failed to consider prior research identifying rat ovarian and uterine toxicity known caused by a nanoparticle constituent in Covid-19 vaccines which mimics diethylstilboestrol effects in rat ovary and uterus.

Question(s) on Notice

Index

Dr Madry, in respect of index **Reference PP**, is it true to say the TGA and State governments provided a high degree of transparency and accountability in the context of the handling of freedom of information requests in relation to SARS-CoV-2 and the Covid-19 vaccines, for data scientists like yourself to undertake research and modelling of Covid-19 adverse events, cases, hospitalisations, and deaths independently and accurately, for confirming from such public data the Covid-19 vaccines are 'safe and effective'?

Answer(s)

Index

First Answer

Dr Andrew Madry, Co-Author:

Unfortunately, transparency has been sorely lacking. This has been partly explained by the TGA claiming to "not wanting to cause hesitancy".

North Queensland General Practitioner Dr Melissa McCann made inquiries to the TGA regarding known deaths of young people following Covid-19 vaccination. She initially requested causality assessments for all the deaths reported in the DAEN. This was rejected. Eventually she received redacted versions of the assessments for 10 young people (FOI-3727).

One of those was for the one of the 14 deaths, accepted by the TGA as causally related to Covid-19 vaccination, the sad death of a young lady following a Moderna Booster.

Review of these causality assessments, which are redacted, indicate that there was a causal link in several other of the cases. These include deaths of a 7- and 9-year-old who had heart attacks following Covid-19 vaccination.

The TGA response to questions on why these deaths are not included in the 14 accepted deaths is that in some cases the word "causal" is part of a template in the form and should not be interpreted as such. That the word *causal* is template text is difficult to understand when it appears in various forms for different reports, as seen in Fig. 1 below, which shows the various ways in which causality was indicated (or not) in documents 1-10, FOI-3727.

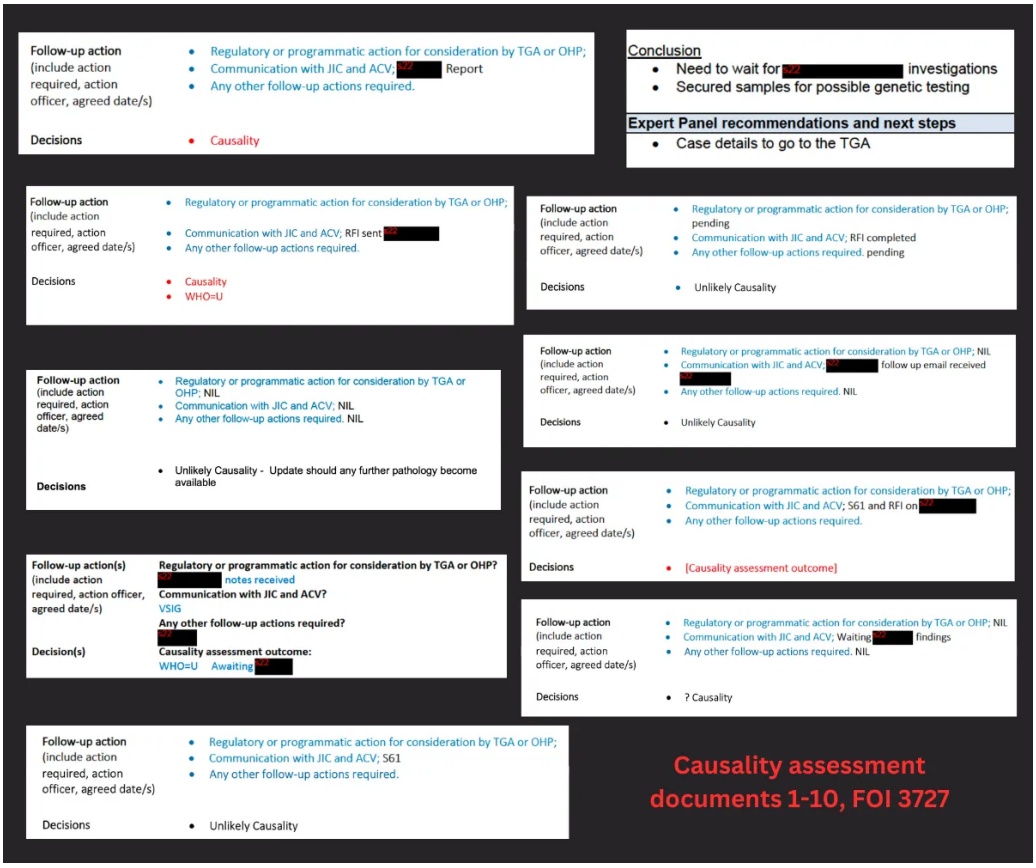


Figure 1: Causality assessment fields, FOI-3272, Documents 1-10.

I note the reports provided under FOI-3727 to Dr McCann were not originally uploaded to the Public Disclosure Log. However, they were eventually uploaded following pressure from the public.

We have no idea of the processes followed in these assessments. Perhaps they were only performed for a small sample, perhaps only for young people?

There are 1011 deaths reported in the DAEN. In the majority of cases, the report is made by a medical practitioner. We know of cases that have been reported to the AEMS and that have not appeared in the DAEN. Not all of these are duplicates or erroneous reports. Recently, our group reviewed an FOI that provided the case

numbers of adverse event reports where the reporter had classified the case as serious. We identified a number of the serious Adverse Event Reports (AER) that had not been added to the DAEN. When followed up, the TGA added the majority of these AER's to the DAEN. How many other AERs sit somewhere in a "holding bay" out of public view?

We also know of cases that have been uploaded to the DAEN and later removed. And where cases listing adverse events of special interest have been edited and the adverse event of special interest has been removed with no explanation.

There needs to be transparency of the process to assess the safety of these medicines.

We know the parents of these young people are looking for answers and they report they have not even been contacted by the TGA. The bereaved families and injured vaccine recipients have launched a class action which is currently before the courts.

Independent analysts can assist with the task. Another of the areas is the assessment of adverse events against batch numbers. Batch numbers are only available for a small percentage of cases. This is also not acceptable.

Index

Second Answer

Nancy Osmanagic, Proposed Witness:

My name is Nancy Osmanagic. I am a concerned citizen, not associated with any entity. This testimony summarises my experience with various government departments, particularly the TGA, where I have lodged Freedom of Information (FOI) requests regarding the Covid-19 era and how the departments did not act in accordance or comply with the objects of the Act and violated my right of access.

My experience highlights the need to include an examination of the Australian Government transparency and accountability in the context of the of handling freedom of information requests in relation to SARS-CoV-2 and the Covid-19 vaccine roll out in the terms of reference of a Royal Commission.

Initiative

Early in 2020, I grew increasingly concerned about anomalies in the government response to the announced health emergency.

Of my own initiative, I began submitting FOI requests to a range of official entities, primarily with the Department of Health and TGA, but also with the Treasury.

The results of these have been referenced and valued by medical experts, politicians, and the public. Unfortunately, there is much more data still withheld, with no apparent reasonably acceptable justification.

The statistics

Since July 2020, I have submitted 22 FOI requests. The focus areas range through:

- Scientific evidence of the Virus including the severity.
- Statistical information of confirmed cases and deaths.
- Evidence of the safety and efficacy of masks.
- The use of the RT-PCR test, CT Values and the collation of case numbers.
- The original communication internationally and nationally regarding the pandemic.
- Genetic sequencing.
- Identity of the internal and external advisers and vaccine candidates receiving indemnity, including the terms and conditions of the indemnity deed or agreement.
- Information outlining the budgeted or foreseen budgeted monetary amount to cover the indemnities including the assessment of likelihood or impact of events covered by the indemnity occurring and financial arrangements and capabilities in relation to meeting indemnity obligations.
- Quantity of Covid-19 vaccines ordered, received, administered and disposed of.
- Contaminant detection assays, DNA testing, total DNA content and total impurity content of particular batches.
- Information around the decision to exempt the vaccines from the Therapeutic Goods (poisons standard) labelling.
- Clinical overview, Toxicology overview/Nonclinical review, Risk Management Plan of all Covid-19 vaccines.
- The latest version of the ASA & RMP for Conformity and PSUR document for the Comirnaty Pfizer vaccine.
- All pharmacovigilance and risk minimisation activities for all Covid-19 vaccines.
- Evaluations of deaths and the de-identified medical information with the evaluation of cause of death and/or link assessment related to the Covid-19 vaccines for the reported deaths via DAEN for individuals under 40.

I can provide this hearing with a full list of the FOI tracking numbers and targeted

data, including a timeline of my submissions, interactions, and their results.

As of now, only 3 of the 22 requests have been fulfilled.

The challenges in getting results have included:

- delayed responses from the FOI'd departments;
- continual requests for extensions from the FOI'd departments;
- (FOI 2248 regarding the Pfizer Australia - COMIRNATY BNT162b2 (mRNA) vaccine with the Department of Health requested a 7-month extension after a 30 day had already been granted);
- template answers that did not address the specifics in my requests or questions;
- making actions dependent on payment of fees applied to FOI searches.

The process

The process was far from streamlined. The gatekeepers did not demonstrate a willingness to deliver transparency and accountability to the public. In my experience, they seem to have done everything in their power to make the process as difficult as possible. Even if not intended, their strategy seemed designed to wear me down and discourage me from pursuing my request. Indeed, it has been demanding on my time, energy and emotions, imposing high levels of stress.

I work full-time and am a devoted parent. In undertaking these FOI requests, I cannot calculate the invested hours required to:

- research, review, consult with others knowledgeable in pertinent legislation and healthcare, and historical pandemic comparisons;
- establish the most effective communication with the departments for the benefit of public awareness and accountability of our official entities and individuals.

On average, it took 6 months to negotiate the release of documents related to an FOI request. This involved an exchange of up to 50-100 emails per FOI submission. Documents I then received were highly redacted. For FOI 2389, It took an additional 16 months, with internal and OAIC reviews including formal complaints, to negotiate less redacted versions that would at least partially fulfil the FOI data requested.

Most replies either stated that a practical refusal existed, that the requested documents do not exist – or – are not held by these departments, noting that such information is managed by the States, such as FOI 1834, 1835, 1836 which focused on:

- the scientific evidence of the Virus including the severity;
- statistical information of confirmed cases and deaths;
- evidence of the safety and efficacy of masks;
- the use of the RT-PCR test, CT Values;
- the collation of case numbers;
- the original communication internationally and nationally regarding the pandemic and genetic sequencing.

As per the Australian Law Reform Commission inquiry ALRC 77 Open government: a review of the federal Freedom of Information Act 1982 8.24 - Concerns about the 'statutory lie'. “If a statutory lie is used, the applicant never knows that the document exists and, consequently, cannot appeal against the decision to refuse access”. The review states that a number of submissions consider that it is problematic and contrary to the spirit of the FOI Act and there are dangers associated with allowing agencies to pretend a document does not exist as the provision is open to abuse because the 'lie' is not, and cannot be, subject to review.

Some requests were rejected on grounds that the documents were exempt and not in the public interest such as FOI 2875 and 2920 regarding the indemnities and FOI 4382 regarding the DNA and Impurity testing.

Given what has now been confirmed about the injection contamination by Dr McKernan, and other independent laboratories elsewhere in the world, not the least, speedier disclosure could have saved lives. Instead, the process has been shockingly slow and drawn-out.

In addition, I have submitted 12 Information Commissioner review requests, starting in September 2020. With one exception, all requests have yet to be allocated to a review adviser.

Fees

The fees attached to each FOI submission averaged $700 per request. For FOI 2389, the decision-maker advised the estimated cost would $16,700. Yet, this fee was eventually reduced to just $62, after I lodged a request for an internal review and another to OAIC to waive the charges. The discrepancy between the two sums raises further questions about the department’s integrity, efficiency, priorities, and decision-making process.

Suspension of searches, pending fee payment has also impacted the ability to receive information in a timely manner. Depending on cost, I have had to reach out to persons of interest, asking for assistance to pay the fees (i.e. FOI 4382 cost

$796.47), this done, the data processing could continue. This particular fee was just recently waived due to a review with OAIC. The decision maker subsequently submitted a revised decision under section 55G of Act stating they have decided to set aside the reconsideration decision and substitute it with a decision to not impose charges associated with processing FOI 4382. This to-and-fro treatment raises even more questions about the department's process and integrity.

Vital knowledge

In February 2021, I submitted FOI 2248 which was then transferred to FOI 2389. This sought information about the approval process for the Pfizer vaccine. This FOI disclosed the Non-Clinical Evaluation Report BNT162b2 [mRNA] Covid-19 vaccine (COMIRNATY™) among others.

The resulting material has been extensively used by Australian federal senators in their own research including senate estimates and has been discussed and referenced by medical professionals worldwide.

In April 2023, I submitted FOI 4382, requesting data on 17 batches of the Covid-19 injections regarding the:

- contaminant detection assays
- DNA testing
- total DNA content
- total impurity content

I submitted a list of questions relating to the decision makers decision to gain clarity around how the exemptions would impact the specific information I requested and justification for these exemptions. The decision makers responses were vague and irrelevant to the points I raised. When I requested further clarity, I was advised by the TGA that:

> "a decision maker is not required under the Freedom of Information Act to respond to questions".

To further shut down my enquiry, the TGA decision-maker advised there is not currently a concern regarding DNA contamination. Yet, I have amassed a significant archive of reports that highlight safety concerns, including an open letter from a former professor of medicinal microbiology, discussing DNA testing and the risk of contamination, yet the decision maker ignored this evidence.

FOI Act Guidelines state:

> it is the decision maker's obligation to provide a statement of reasons as

per the checklist which highlights the key elements in preparing a statement of reasons under s 26 of the Freedom of Information Act 1982 (FOI Act)

Furthermore, on the release of documents, the decision maker also failed to clarify upon request that the documents released were in fact as per the schedule and refused to acknowledge or rectify this, even after numerous emails over a two month period. A complaint was subsequently submitted to the decision maker's superior and OAIC around the decision-makers conduct, also seeking a review of the decision. The outcome of the internal investigation of the decision makers conduct and review of decision once again demonstrated a lack of respect to the democratic underpinnings of Freedom of Information, the objects of the Act and Spirit of the Act. I can provide the correspondence and documents to support this claim to the hearing.

Throughout my experience with all FOI Departments, I have not been met with the "Principles of good decision making" under the Act nor have they demonstrated full compliance with the general principles under the Act.
Implicit to my FOI requests, there was both a public interest and benefit, related to:

- the health of the public
- the public's right to informed and valid consent
- Government transparency of their roles, responsibilities, and statutory obligations

The departments have made no attempt at any time to exercise or conduct a Public Interest Test nor did they provide any justification as to why they refuted my nominated public interest factors in favour of disclosure.

Agencies are not obliged to withhold exempt documents and have the discretion to release a document even if it technically falls within an exemption due to public interest. The availability of government information should be determined by the public interest as what most distinguishes the approach to disclosure of government information in the FOI Act from approaches taken prior to its enactment is its focus on the public interest. Before the FOI Act, the disclosure of government-held information outside legal proceedings was entirely at the discretion of the government. Yet on several requests, I was met with this roadblock on disclosure.

It is important that agencies understand and exercise this discretion as it is a means by which they can give practical effect to the spirit of the FOI Act.

Furthermore, their responses and decisions seem to breach the Public Service Act

1999, Section 10 which requires the Australian Public Service Values (that is: APS) to fulfil the following qualities:

- Committed to service – working efficiently and collaboratively to achieve results for the Australian community and Government;
- Ethical – in leadership, trust and acts with integrity;
- Respectful – of all people, including their rights and heritage;
- Accountable – to the Australian community under law and with the framework of the Ministerial responsibility;
- Impartial – apolitical, providing the Government with advice that is frank, honest, timely and based on the best available evidence.

Summary

In summary, for over three and a half years, I have endeavoured to assist in public awareness, transparency and expert analysis by requesting the TGA and other departments fulfil their duty of care to the people, on whose dollars they are funded. Unfortunately, the apparent outcome of this undertaking has included:

- obfuscation of data, rather than transparency and accountability;
- undermining the process through belaboured bureaucratic musical chairs;
- inability or unwillingness to confirm the data and its sources on which decisions and policies were made;
- placing third party commercial interests above the public duties of safe-guarding people's health.

The key slogans throughout the pandemic from government and associated departments were:

- "Follow the Science"
- "Trust the Experts"
- "Safe & Effective"

Yet they have been unable to provide evidence to support their claim of "Safe & Effective" by proving they are efficiently monitoring the safety, efficacy and conformity of the "approved vaccines", or deliver a single document demonstrating "the science" to justify the actions, response and measures from the so called experts of a supposed one-in-a-hundred year pandemic that affected and impacted the lives of all, and changed the world and society as we knew it.

Either – the departments are in possession of information and evidence that affirms their decisions:

- the consequences of which imposed overreaching, harmful measures upon all and sundry, regardless of impact;
- and – these impositions were absent of any flexibility or contingency plans to accommodate extant variables;

Or – the departments are not in possession of such, and therefore cannot justify their decision-making and infliction of society-destroying demands.

What is already clear from the Act but not always acknowledged – that, prima facie, the applicant has a right to obtain a requested document.

Below are some excerpts of the Department Of Health and Aged Care FOI Operational manual 2021-2025 which refers to the "Spirit of the Act".

I have yet to experience any department portray or align with the attributes described below:

> When interpreting or applying the provisions of the FOI Act, staff must seek to uphold the philosophy behind the FOI Act and promote its objectives as set out in section 3. The objects are focused on promoting a pro disclosure culture across government and a strong foundation for openness in government. This focus is aimed at providing the Australian community with a comprehensive right of access to government documents under the FOI Act, that is limited only where there is a stronger public interest in withholding access to documents.
>
> The Parliament intended the FOI Act to contribute to an increase in public participation in government processes, with a view to promoting better informed decision making and increasing scrutiny, discussion, comment and review of government activities. It also intended to facilitate and promote public access to information promptly and at the lowest reasonable cost where possible.
>
> The FOI Act promotes government accountability and transparency by providing a legal framework for individuals to request access to government documents. This includes documents about policy making, administrative decision making and government service delivery. Individuals can also request that ministers or agencies amend or annotate any information held about them. The applicant does not have to provide a reason for making a FOI request as the reason does not affect the applicant's right of access to documents.

Index

Third Answer

Dr Deirdre Therese Little, Co-Author:

The TGA Rejection of FOI 2565

Introduction

In 2022 the regulatory European Medicines Agency (EMA) added 'heavy menstrual bleeding' to mRNA Covid-19 vaccine Product Information.[ccli] This followed tens of thousands of menstrual adverse event notifications to regulatory agencies worldwide. The cause of this abnormal bleeding in both menstruating and in non-menstruating women remains unknown.

Reports of abnormal bleeding and cycles have followed the mRNA Covid-19 vaccines (Pfizer BNT162b2) as well as the Astra Zeneca viral vector vaccine. This would suggest the possibility of a common causative factor. In addition, the simultaneously arising pre- and post- menopausal bleeding reports suggest a possible oestrogenic factor.

No clinical trials for any of these vaccines studied reproductive health parameters in men or women. Health care providers, general practitioners and reproductive health clinicians are therefore reliant upon the pre-clinical rat studies for data of reproductive health outcomes following Covid-19vaccination. Informed consent to Covid-19 vaccination for reproductive aged women is therefore also significantly reliant on pre-clinical tested rat data.

In the usual process of development of new pharmaceutical products, pre-clinical animal study findings and outcomes inform the design and conduct of the subsequent human clinical studies. In the current context of Covid-19vaccines, clinicians therefore require both:

1) access to pre-clinical microscopy reports of tested animal reproductive organs;
2) confidence that pre-clinical animal organ data adequately informed the design and process of subsequent clinical trials omitting reproductive health parameter observation.

Research and History of FOI request 2565

As a reproductive health clinician of 40 years experience I, Dr Deirdre Therese Little MBBS DRANZCOG FACRRM sought microscopy reports of rat ovaries, testes and uterus in a Freedom of Information Request [FOI 2565], since these reports were not available in the public domain. Specific reason as outlined below were given to the TGA.

Research

Only one listed chemical ingredient is common to both mRNA vaccines and Astra Zeneca vaccines. This chemical is polysorbate 80. Published research[cclii] (*Gajdova et al*. see reference 4 below) had previously found this chemical (also known as 'Tween 80', polyoxyethylene sorbitan monooleate), induced ovarian cystic changes, decreased ovarian weight, abnormal cellular changes of the uterine lining and glands, prolonged oestrous cycle and persistent vaginal oestrous, when injected into young rats. Ovarian changes had occurred at all doses of polysorbate 80 tested over a tenfold dose range. Documented cellular changes closely resembled those observed in rats that had been injected with diethylstilboestrol (DES) in the same study. Polysorbate 80 had mimicked the DES effect of ovary damage and damage to the lining of the uterus when injected into rats. It was perhaps relevant that this chemical was present in Astra Zeneca vaccine and, in a slightly modified form, as polyethylene glycol in mRNA Pfizer vaccine nanoparticles. Polyethylene glycol is polysorbate 80 minus the oleate component. Hence, as a clinician, I sought to review Covid vaccine tested rat ovary and uterus microscopic findings, known as histology reports. Since Polysorbate 80 mimics the potent oestrogen diethylstilboestrol, rat testis microscopy was also relevant.

In addition, the Australian Government Department of Health TGA Nonclinical Evaluation Report January 2021 (FOI Disclosure log: FOI 2389)[ccliii] contained biological distribution results of the Covid-19 mRNA vaccine (Pfizer), showing high levels of nanoparticles containing this ingredient concentrating in the ovaries. Levels in the rat ovary were high, at ten times that of most other organs. The concentration in ovaries was also rapidly increasing over time, with the level in the ovary doubling between 24 and 48 hours following injection, according to the TGA document. No further measurements of concentration are recorded, so it is not known if concentrations kept increasing or perhaps plateaued.

New onset menstrual abnormalities, post-menopausal bleeding and bleeding in women who do not normally menstruate have been reviewed in medical literature[ccliv] and reported to medical regulators. [cclv] The cause of this signal remains unknown to RANZCOG and to the Royal College of Obstetricians and Gynaecologists (RCOG), since no clinical trials recorded or observed reproductive health markers or parameters.

My research presented hereto has been peer-reviewed and published in the Journal of Clinical Toxicology in 2022[cclvi] and its summary was presented as e-poster at the most recent RANZCOG Sydney Symposium on July 25th 2023[cclvii].

History of FOI 2565 Request

Summary: My Freedom of Information Request 2565 for reproductive organ microscopy reports was rejected on the grounds it was 'too voluminous'. After reducing the scope of the FOI request, it was again rejected, and was rejected on Internal Review. An added reason given by the Internal Reviewer was that the pharmaceutical companies had taken 'active steps' to 'ensure the information contained within the documents is not disclosed to the general public.'

Documented course of continued FOI 2565 rejection is detailed below, with appropriate references and attachments:

a. Adverse reproductive health events necessitate review of pre-clinical Covid-19 reproductive organ histology - specifically of rat ovary and uterus microscopy - to further future research, to establish safety, and to facilitate public vaccine confidence in women of reproductive age. Reproductive organ histology (microscopy) reports in Covid-19 vaccine pre-clinical studies cannot be accessed by reproductive health clinicians. They are also allegedly not presented in readily identifiable, accessible format to the TGA. As stated in the TGA Internal Review Decision of 27 September 2021, 'the histopathology in relation to reproductive tissues…is dispersed throughout each of the studies', requiring review of 3,667 pages (para 28).

b. On 29th July 2021 I made an FOI request for reproductive organ histology reports from Covid-19 vaccines' Developmental and Reproductive Toxicity Studies (FOI 2565). As a reproductive health clinician, this was a reasonable and relevant request.

c. On 21st August 2021 this FOI request was reduced, as I was asked to do, to:

> *histopathology/microscopic evaluation of gonads (ovaries/testis) of vaccinated animals in relation to Pfizer and AstraZeneca Covid-19 vaccines.*

d. On 26th August 2021 FOI 2565 request was rejected on grounds the ovary and testis organ microscopy reports were 'too voluminous'. I was provided with numerous references to other research papers which did not present the histology reports required.

e. On 4th September 2021, I requested an Internal Review of the decision in relation to FOI 2565. On 16th September I was asked to reduce my FOI application to exclude raw data, annexures and appendices. This I declined to do as the histology reports were most likely therein. Indeed, a later FOI request (FOI 3093) by another applicant on terms excluding raw data, annexures and appendices failed to yield histology reports.

f. On 27th September 2021 FOI 2565 with its reduced scope was rejected at Internal Review. Reasons provided for this rejection included:

- the rat ovary and testis microscopy reports after vaccination likely 'contain information that is commercially sensitive' (para 30).
- both pharmaceutical companies 'have taken active steps to ensure the information contained within the documents is not disclosed to the general public'.

g. The rejected FOI 2565 was then submitted for review to the OAIC (OAIC Reference: MR21/01138).

h. On 26th October 2021 receipt was acknowledged by the Intake and Early Resolution Team.

i. On 9th May 2022 the OAIC notified the TGA of my application for Information Commissioner review. My submission supporting this application was forwarded as requested and received 27th July 2022. I also replied to the TGA submission. Despite two subsequent enquiries, including a letter to the Minister for Home Affairs Clare O'Neil requesting a response I have had no result in over two years since my original request for OAIC review was made.

j. The TGA has acknowledged agreed arrangements whereby pharmaceutical companies may 'take active steps' to ensure pre-clinical study data (including data relevant to women's health requested in FOI 2565) 'not be disclosed to the general public' (para 31 of the 27th September 2021 Internal Review Decision). This is an obstruction to women's health. It hampers reproductive health research of unexpected safety signals and undermines public vaccine confidence. Such arrangements require further investigation and clarification.

k. Disregarding the documented high and rising concentration of nanoparticles in the mammalian ovary, doubling in the 24 hours preceding measurement discontinuation, raises questions about the competency of the TGA to recognize anomalies. The TGA did not subsequently require coherent gonad organ microscopy reports, permitting reproductive organ microscopy descriptions to be dispersed across 3,000 pages, rendering the time required to extract them excessive, expensive, and not feasible. The TGA further failed to appreciate the need for coherent reproductive organ histology review even after the appearance of unexpected safety signals in both pre- and postmenopausal women suggestive of oestrogenic effects. Vaccines' nanoparticle constituents (polyoxyethylene sorbitan monooleate in AstraZeneca vaccine and closely related polyethylene glycol in mRNA vaccines) injected into rats cause decreased ovarian weights, ovarian cystic

cavities, prolonged oestrous cycle, persistent vaginal oestrous, and plano cellular metaplasia in uterine endothelium and endometrial glands mimicking effects of diethylstilboestrol.

Summary of Key Issues

A. Failure of the TGA to require accessible organ histology reports in pre-clinical studies for Covid-19 vaccines. Pre-clinical histology reports are particularly relevant to reproductive organs as clinical trials did not include reproductive health parameters;

B. Failure of the TGA to extract ovary and testis histology reports when requested by a reproductive health clinician under FOI 2565;
C. Failure of the Office of the Australian Information Commissioner (OAIC) to provide a result to a requested review of the TGA rejection of FOI 2565 in over two years since the original request for review was made;

D. The TGA agreement to withhold studies (or parts thereof) containing the ovary and testis histology reports from the general public in accord with 'active steps' taken by pharmaceutical companies 'to ensure the information contained within the documents is not disclosed to the general public' (see TGA Internal Review Decision of 27 September 2021);

E. Failure of the TGA to query the effect of rising nanoparticle concentration in mammalian ovaries, which doubled between 24 and 48 hours after a single 50mcg intramuscular injection after which measurements ceased). In the context of ovarian accumulation of nanoparticles, the TGA failed to consider the known rat ovarian and uterine toxicity caused by a nanoparticle constituent. Since this component in Covid-19 vaccines mimics the toxic diethylstilboestrol effects in rat ovary and uterus, microscopy of these organs should not be withheld from reproductive health clinicians or indeed from the public who have funded these often-mandated vaccines.

Conclusion

The TGA has thus far failed to meet the expectations of the Freedom of Information Act of 1982. This compounds a failure of the TGA to comply with a reasonable request from a health care provider. The TGA were informed of the reasons for this FOI request. These highlight other significant systemic failures of the TGA relating to scientific and clinical competency, arrangements with pharmaceutical companies, and the lack of safety data transparency of taxpayer funded vaccines.

Endnotes: For all answers
Index

Reference: QQ

Index

A review and analysis of all procurement contracts between government bodies and the pharmaceutical corporations approved for the Covid-19 vaccination program, including between the Commonwealth government and its nominated representatives and:

i. Pfizer;
ii. Moderna;
iii. AstraZeneca;
iv. Novavax; and
v. An examination of assessments undertaken and reasons provided for not making available conventional inactivated, attenuated, or subunit vaccines.

Explanatory Memorandum

Index

An exercise in full transparency to examine and confirm whether the purchasing terms, price paid, and indemnities afforded suppliers and manufacturers were reasonable and proportionate as compared any other reasonable alternative treatments or protocols available as a prophylaxis or treatment for Covid-19.

Question(s) on Notice

Index

In respect of **References QQ**, please provide any further information concerning procurement contracts details between the Australian government and Pfizer, Moderna, AstraZeneca, and Novavax for the Covid-19 vaccines.

Answer(s)

Index

Answer

The People's Terms of Reference:

This information is held by the government.

The procurement contracts were refused under FOI (available upon request from lawyer Tony Nikolic) and in relation to a request during the *Kassam vs Hazzard* [2021] NSWSC 1320 trial.

The individual procurement contracts for Covid-19 vaccines each concern novel technology platforms containing *new biological entities* and for AstraZeneca, Pfizer, and Moderna, GMOs under the Australian *Gene Technology Act* 2000 (See: answer to Question on Notice S).

Critical issues involving valid Informed Consent being possible in the circumstances of the Covid-19 vaccines require disclosure of the procurement contracts for appreciating what additional information and knowledge was known to Australian governments about these new biologics which was not shared publicly with the Australian People.

The answer above has been limited due to time constraints.

Index

Reference: RR

Index

A full audit and itemised review of the total budget expended in relation to the Covid pandemic including all payments made by the Commonwealth to State and Territory treasuries, and payments to all other government and non-government recipients designated as part of the Covid response, including:

i. all contracts for Covid-19 advertising, reporting, and commentary placed by Australian governments and entered into with Australian news and media companies and outlets, inclusive of the terms and conditions of those contracts.

Explanatory Memorandum

Index

An exercise in full transparency to examine and confirm whether the Covid-19 expenditure by the Commonwealth government was reasonably necessary, on reasonable terms, for reasonable prices, involved reasonable auditing to ensure fulfillment of contractual terms, did not involve unreasonable or unnecessary indemnities, and was generally reasonable and proportionate and necessary when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference RR**, please provide any further information concerning he total budget expended in relation to the Covid pandemic including all payments made by the Commonwealth to State and Territory treasuries, and payments to all other government and non-government recipients designated as part of the Covid response. Where budgetary data is unavailable or not accessible, please also detail any failures in Covid-19 budgetary transparency.

Answer(s)

Index

Answer

Prof Gigi Foster, Co-Author:

Perhaps surprisingly, many sources of information about how much has been spent during the Covid era by different levels of Australian government is quite accessible on a quick Google search. This is probably because those in charge are not yet aware that the vast majority of this spending delivered no net benefit for the Australian people, and has instead held the country back enormously.

Some illustrative links are provided below:

> The Australian Institute of Health and Welfare's November 2023 report
> The Parliament of Australia's 2021 paper on the Public Health Response to Covid
> The Australian National Audit Office's report on the cost of the Covid vaccine rollout
> The Commonwealth's 2020-2021 Budget (including stimulus payments, like JobKeeper)
> The Treasury's May 2020 report on the Covid-19 stimulus packages

Many different line items are tallied in the reports above, and some estimates may include expenses that are also counted elsewhere. We also cannot know for certain what would have been spent on Covid if those in authority, instead of locking down whole healthy populations and taking other extreme actions, had simply followed the pre-2020 pandemic management plans that had been generated for just such an eventuality as Covid. In my view, there is no one incontrovertibly correct figure to report as the "total amount spent on Covid".

Nonetheless, I am confident in estimating that somewhere north of $500 billion was spent by Australia's Commonwealth and state governments from 2020 through 2023 that would otherwise, in a world free of Covid panic, have not been spent – on everything from JobKeeper to vaccines to PPE to the extra layers of bureaucracy required to keep the whole response effort going. The Institute for Public Affairs puts the total cost of Australia's response even higher, at $938 billion, where their estimate also includes foregone GDP and the pain of the inflation created by ploughing stimulus into an intentionally stalled economy.

As an economist, my first response to these sorts of figures is to ask what Australia received in return for these payments. In the case of Covid, sadly, what we achieved was little more than treading water, as I detail in my published cost-benefit analysis of Australia's Covid response, *Do Lockdowns and Border Closures Serve the 'Greater Good'?*. What was lost because of these policies, by contrast, goes far beyond the policies' direct costs, as detailed in the book linked to above and elsewhere in my and others' written evidence. In essence hence, we

paid handsomely for the privilege of inflicting huge damage on ourselves.

My second response is to ask what else, rather than this damage, we could have had instead for the level of expenditure that financed our Covid policy response. This is the age-old economists' question about opportunity cost: what potential things that could have been bought did we give up, in order to instead use our money to buy what we chose to buy?

The answer to this question is perhaps even more traumatising. Imagine what $500 billion could have bought in terms of helping people out of poverty, bringing health care, clean water, and education to our rural communities, lifting the achievement of our most disadvantaged students, or helping displaced youth and stressed families in their times of need. That we instead spent this eye-watering sum, and likely more, on policies that have hurt us all badly – particularly our least advantaged citizens – and will keep hurting us for at least another generation is horrible to contemplate.

Index

Reference: SS

Index

A review of all Covid-19 pandemic-related court cases that were denied to applicants on the basis of mootness or judicial notice, or in which judicial notice was taken in regard to evidence and advices from bodies including:

i. the Australian Technical Advisory Group on Immunisation (ATAGI);
ii. the National Centre for Immunisation Research and Surveillance (NCIRS);
iii. the National Health and Medical Research Council (NHMRC);
iv. the TGA Advisory Committee on Vaccines (ACV);
v. the TGA;
vi. The Peter Doherty Institute for Infection and Immunity.

Explanatory Memorandum

Index

To examine and confirm the extent to which Australian courts and tribunals received previously published information from certain bodies as evidence received 'on notice', thereby denying applicants any opportunity to test such evidence including denying applicants any opportunity to require authors of such evidence to appear and undergo cross-examination to further test such evidence.

To examine and confirm the extent to which Australian courts and tribunals ordered the discontinuation of proceedings based upon rulings of 'mootness', as a consequence of Australian governments (as defendants/respondents) reversing or changing or annulling Covid-19 mandate laws or policies originally the subject of proceedings and challenge by applicants, with the consequence being that applicants were denied court declarations in respect of the challenged Covid-19 mandate laws or policies.

Question(s) on Notice

Index

In respect of **Reference SS**, please provide any further information concerning Covid-19 related court cases that were denied to applicants on the basis of mootness or judicial notice, or in which judicial notice was taken in regard to evidence and advices from bodies including ATAGI, NCIRS, ACV, the TGA, and the Peter Doherty Institute for Infection and Immunity.

Answer(s)

Index

Answer

The People's Terms of Reference:

Time constraints prevented a full and complete response to the above question which would have seen an extensive answer, had sufficient time been made available.

Term of Reference SS continues to be advanced by The People's Terms of Reference.

Reference: TT

Index

A systematic review of Australian Whistle-Blower legislation to determine whether any such legislation failed to protect doctors, scientists, government officials, medical administrators, or hospital staff who attempted to raise safety concerns in the public interest with respect to Covid-19 vaccines and Covid-19 lockdown measures and mandates.

Explanatory Memorandum

Index

An examination to confirm whether Australia has adequate Whistle-Blower legislation for protecting employees and experts when seeking to legitimately challenge government messaging or share information on government activity or data, particularly in the context of a proclaimed emergency when Australian governments introduce extraordinary measures and invoke extraordinary legislation.

Question(s) on Notice

Index

In respect of **References TT**, please provide any further information concerning Australian Whistle-Blower legislation to determine whether any such legislation failed to protect doctors, scientists, government officials, medical administrators, or hospital staff who attempted to raise safety concerns in the public interest with respect to Covid-19 vaccines and Covid-19 lockdown measures and mandates.

Answer(s)

Index

First Answer

Julian Gillespie LLB, BJuris, Co-Author:

Time constraints prevent a full and complete response to the above question which with more time would have seen an extensive response. However…

Below the Committee will read the personal accounts of Australian doctors

persecuted by the Australian Health Practitioner Regulation Agency, commonly called AHPRA.

In each instance of typically an anonymous complaint being first filed and received by AHPRA against them, the common theme is one of providing information to the general community, often using social media, usually to raise or discuss safety concerns surrounding the Covid-19 drugs, being professional concerns that differed to the official narrative pushed by Australian governments from 2021.

As the answers to the Question on Notice for Reference L further detail, AHPRA issued a joint statement on 9 March of 2021 that effectively forbade health practitioners from speaking out publicly with any manner of information or discussion that could be construed as conflicting with Australian government messaging in respect of the national Covid-19 vaccine rollout.

Soon after AHPRA began to receive anonymous complaints about health practitioners and particularly doctors who were expressing their professional concerns about what was an unknown form of new drug said to act as a vaccine against Covid-19, for which there was acknowledged limited short-term safety data, and no medium or long-term safety data.

These reasonable concerns were not tolerated by AHPRA, and still are not to this day, and were used by AHPRA to allege that these doctors posed a risk to the health and safety of the Australian community, which often resulted in immediate suspensions pending further investigations and professional hearings for determining charges of *unprofessional conduct*, depending on the State or Territory responsible.

In brief, AHPRA has always conducted itself in relation to such Covid-19 information complaints, by assuming and invoking a presumption of guilt, not innocence, towards health practitioners in the matter of Covid-19 related complaints.

As the legal opinion discussed by lawyer Peter Fam in answer to Reference L further details, in every instance every doctor persecuted by AHPRA has properly and correctly invoked their responsibility to up-hold first and foremost their Medical Code of Conduct, which places the safety of their patients above and before all else.

The Medical Code of Conduct is discussed at paragraph 34 of the legal opinion shown at Annexure 8 in the following terms:

> In light of the fact that Codes of Conduct are admissible as evidence of

> what constitutes appropriate professional conduct or practice for the health profession, Codes of Conduct must necessarily be deemed to be **statutory rules**, in so far as they prescribe minimum levels of conduct and practice to be observed by a health practitioner, in order to be legally deemed an 'appropriately professional' practitioner. (emphasis added)

Yes, Codes of Conduct are ***Statutory Rules***.

The essential point being made here is that all health practitioners, whether Doctors or Nurses or Chiropractors, are required by law to observe their Codes of Conduct first, not the wishes and designs of Australian governments, including those seeking to coerce or lead the Australian People to receive new and largely unknown gene therapies.

Further, and the Codes of Conduct must be construed in and of themselves as *de facto* Whistle-Blower laws for the protection of health practitioners when raising their professional concerns publicly, when seeking to protect the health and welfare of their patients and persons in the Australian community.

To this end a Covid-19 Royal Commission must investigate the conduct of AHPRA, and confirm the duty of AHPRA to be:

> **The support and protection of health practitioners who invoke their expertise when seeking to uphold, as they are required to do by law, their Codes of Conduct.**

AHPRA must be subjected to a Covid-19 Royal Commission to investigate and confirm AHPRA:

> To have been operating with a presumption of guilt towards health practitioners who spoke up during the Covid era, and
>
> To have then undertaken wrongful investigations instead of asserting their Codes of Conduct afforded them *prima facie* protection from spurious complaints that at base sought to assert (wrongly) the primacy of Australian government Covid-19 messaging, and
>
> To have instead improperly ensured that these health practitioners were made the subjects of professional misconduct hearings that should have never taken place, let alone contemplated.

Lastly, a Covid-19 Royal Commission must confirm or recommend further judicial confirmation that the Codes of Conduct operate as statutory rules, that serve to protect health practitioners from frivolous and vexatious complaints and

stand as shields against persecution from government authorities.

In other words, a Covid-19 Royal Commission should seek to deem the Codes of Conduct effective Whistle-Blower laws for the protection of Australian health practitioners when suitably and appropriately invoked for the protection of their professional views and conduct, for the protection of the lives and health of the Australian community.

Index

Second Answer

Dr Duncan Syme, Co-Author:

My name is Dr Duncan Syme, I have been in full time clinical practice for over 34 years, from 1988 until mid-February 2022. I have never had any interactions with the Medical Board, other than renewing my registration. I graduated from Monash University Medical School in 1987, where I obtained my MBBS. I obtained my general practice fellowship, FRACGP, in 1997. I have had, what would be described as, a portfolio career in General Practice, fulfilling many different roles within the scope of general practice. Within my working career, I had also worked for a period in the pharmacovigilance section of a pharmaceutical company. I have also set up and been the principal investigator for a randomised control trial, for a wound healing device. I am familiar with trial ethics and drug safety issues. During the last 10 years of my employment, I had been working at Monash Health in their Hospital in the Home program. This was a job that I really enjoyed. I was the only full time Consultant in the largest Hospital In The Home program in Australia, I combined this with regular weekend accident and emergency work.

From the outset of the Covid pandemic I was extremely interested in both the disease and the highly unusual public health response to it. Given my previous work in the drug safety section of a pharmaceutical company, I was very interested in the rapid development of the novel Covid 19 vaccinations. My research led me to conclude there were significant safety issues with the product, and I was not prepared to subject myself to this experimental product. As a result of the State Government mandates imposed on employers requiring Covid 19 injections to maintain my employment, I was forced to resign from my job, I chose to do this rather than be sacked. My resignation took place in late October 2021.

Prior to the lead up to this decision, I had been pressured take the Covid injection by senior colleagues. I was also instructed, in a threatening manner, by a senior medical administrator not to speak about my concerns regarding the Covid 19 injections. There had also been warnings at work that the Head Nurse of the

Hospital in the Home Program would report anybody to AHPRA if she heard any "anti-vaccination" talk.

The Medical Board of Australia suspended my medical registration on February 17th, 2022, under section 156 of the National Law, as it applies in Victoria. I am still currently suspended, the date now being February 23, 2023.

This followed a complaint in October 2021, which was sent to the HCCC (Healthcare complaints commission) from a person unknown to me. The complainant was the owner and manager of a wedding venue reception center. She was upset about the exemption /support letters I had written for a young healthy couple who were at low risk of getting severe illness or dying from Covid. She made the incorrect assumption that the letters contained information that was anti-vax. The information was taken from the TGA website, from the applications of both Pfizer and Astra Zeneca.

I had provided support letters, for the patient's employers, to support their choice to not have a Covid vaccine as they did not wish to have their bodily autonomy violated by being injected with the Covid 19 injections to retain their jobs. These were letters of support; they were not exemptions as these individuals failed to meet the guidelines for exemption laid down by the Government. These patients demonstrated extreme psychological distress, resulting from the fact they were being coerced into a medical treatment that they considered could potentially harm them. They had already seen a close family relative suffer a severe reaction, to their first Pfizer injection, necessitating a hospital admission. This reaction later turned out to be myocarditis. They were also in the process of starting a family having just had a child and were planning another. They were extremely concerned about the impact these injections could have on conception.

AHPRA made great issue that psychological distress did not fit the ATAGI guidelines for exemptions, and this combined with the fact I had issued 87 other exemptions required investigation and immediate suspension. The reason given for my suspension was that they deemed my conduct being dangerous, because it could result in a public loss of confidence in the Medical Profession and the Medical Boards position on Covid 19 vaccination. They did not believe I had the right to exercise my professional judgement, based on years of experience, as to what was the most appropriate course of action for these patients. There was no refutation of what I said in the letter as being incorrect. As I mentioned above, this investigation has been going on for more than two years, AHPRA have committed numerous regulatory failures during this process. They have failed to keep me updated with the progress of their investigations and have not responded to many of my queries in a timely manner.

We asked the Medical Board for a review of my suspension in November 2022.

We made mention of the major financial hardship this was causing. This was rejected in January 2023. I have had one interview with investigators in March 2023. AHPRA commissioned a report written by a General Practitioner, who said I had paid a high price for my views on the management of the Covid pandemic, and her view was that I should be allowed back to work in July 2023. Despite my legal team writing several letters to AHPRA, we did not hear back from them until early February 2024, close to 7months later.

The financial implications of this process have been huge for both me and my family. I have three children, two of whom still live at home and are dependent upon me. My youngest child has significant educational disabilities and is schooled and cared for, in a full-time capacity, by my wife. I would estimate I have lost somewhere in the vicinity of 800,000 to 900,000 dollars over the last 2 years, as a result of not being able to work as doctor. I have been forced to access my superannuation early, which has resulted in a tax penalty. I did this in order to save my family home and keep my family financially afloat over this 2-year period. The profound uncertainty as to the future of my professional career and the financial security of my family is clearly hugely stressful. This has resulted in many sleepless nights for both me and my wife. We have had to rely on financial support from both our families. When you add reputational damage and professional isolation to this cocktail, it enables one to understand the reasons why many health professionals in this situation contemplate suicide. Fortunately, I have had very strong family support, and have no doubts about how I have acted professionally throughout the whole process. I strongly believe I have followed my Code of Conduct and the World Medical Association's Declaration of Geneva pledge.

AHPRA, through the position statement and attacks on ethical doctors, have caused a profound censorship of medical and scientific debate in this country. This is to the great detriment of the profession, and the patients whom we serve. The misuse of the National law in attacking ethical doctors who have opposed the government narrative and who have attempted to speak openly and honestly about data and science, has resulted in a major loss of confidence and fear within members of the medical profession. This fear now inhibits proper informed consent and fearless discussion with patients. From the public's perspective, doctors are now seen as serving the government's priorities first, rather than those of the patient. The doctor patient relationship has been severely compromised.

This treatment of me and several other colleagues, I know to be an abuse of the suspension power of the board, which is an interim, temporary measure and should be used in a manner which ensures least harm to the practitioner. This view is confirmed by case law in 3 States, Western Australia (Bernadt in WASCA), Victoria (Kozanoglu v VSCA) and Northern Territory (Nitschke NT supreme court). I have no doubt it has been done deliberately, to intimidate other doctors

and health practitioners into going against their code of conduct, and the Australian Immunisation Handbook legal requirements for consent for vaccination, for fear of losing their jobs and possibly their careers. This action by AHPRA and the Board has completely undermined informed consent, and thus millions of Australians have been unable to provide properly legal voluntary informed consent.

I would suggest AHPRA and the Board have made a position statement that had no legal authority or weight, and have used this unlawfully to attack doctors like myself, who have been following their Code of Conduct. This threat of disciplinary action, through a statement that had no legal force, has resulted in doctors failing to give their patients all the information necessary for proper informed consent to occur in the context of Covid-19 injectables.

In section 4.5 of the Medical Professionals Code of Conduct, it states that a patient's informed consent must be voluntary. Many health professionals know that their patients were not voluntarily consenting to this medical treatment. I have heard many patients and colleagues say that they submitted to the injection in order to keep their job, and they stated this at the time their doctor or nurse was administering the injection. This does not constitute legal consent, in fact the practitioners who proceeded to inject, and were aware of this, were committing physical assault.

The importance of voluntary consent, not being made under undue pressure, is also highlighted in the Australian Immunisation Handbook:

> Criteria for valid consent
>
> Point 2: It must be given voluntarily in the absence of undue pressure, coercion or manipulation.
>
> Point 4: It can only be given after the potential risks and benefits of the relevant vaccine, the risks of not having it, and any alternative options have been explained to the person.

Every doctor and nurse who is administering vaccinations needs to know this, otherwise they are breeching their Code of Conduct.

The position statement made by the Boards and AHPRA, along with the government mandates, are not compatible with the lawful administration of the Covid-19 injectables. There was coercion on doctors to not give proper risk-benefit and alternate treatment information for informed consent to be properly given by patients. If doctors did state potential risks e.g the lack of animal testing, the fact there was no long term safety data or omitted that the risk of severe illness

from Covid for most was low, they were then at risk of disciplinary action by AHPRA and the Medical Board.

Clearly, there has been major coercion and manipulation from media and government, applied to the citizens of Australia to get the Covid 19 injections.

The legal standard of consent has been set by Rogers v Whitaker in the High Court decision of 1992, and this now means it is a doctor's duty to warn patients of a material risk inherent in a proposed treatment. The position statement issued by AHPRA created a major dilemma for doctors providing necessary information to patients for informed consent to occur, as it is incompatible with the legal requirements of fully informed consent.

Furthermore, the doctor-patient relationship is a contract. A contract is not legally valid if one or both parties are being coerced. This statement has undoubtedly created a great conflict in many doctors, who knew that it was ethically wrong and legally incompatible with proper informed consent. The fact that exemptions were required by healthy individuals, not to have an experimental product in everything but name, is a complete inversion of bioethical principles.

The Declaration of Geneva created in 1948 by the World Medical Association (version 2006) is the basis upon which our medical Code of Conduct was developed. The second last sentence says:

> I will not use my medical knowledge to violate human rights or civil liberties even under threat.

The fact that the Medical Board of Australia supports and was involved in creating a statement that directly and indirectly supports the violations of human rights, places them in an untenable position, as the safe keepers of our profession.

Much is made of the ATAGI guidelines in relation to vaccine exemptions, these guidelines for exemptions were highly restrictive. Guidelines are not legally binding, they are intended to persuade, not enforce. So, commencing disciplinary action by stating someone did not follow the guidelines, where no patient injury occurred, could be considered an abuse of power by a regulatory authority.

Finally, there is the Australian Constitution section 51 (xxiiiA) which states that doctors cannot be forced into civil conscription by their government. The Federal Government attempted to circumvent this part of the Constitution by working with the State governments, via the unconstitutional National cabinet, and encouraged them to issue State mandates.
This completely contravenes the legal doctrine related to the limitation of government powers, based upon the Latin maxim *Quando aliquid prohibetur ex*

directo, prohibetur et per obliquum:

What cannot be done directly, should also not be done indirectly.

The actions of AHPRA and the Medical Board of Australia during this period leave me deeply concerned and disturbed, as to the ethical, moral and legal direction our regulatory authorities appear to be pursuing.

The above matters require urgent examination by a Covid-19 Royal Commission.

Index

Third Answer

Dr Mark Hobart, Co-Author:

I am a suspended GP of 38 years standing, suspended under the Board's immediate action power which is supposed to be interim and temporary with as minimal damage to the practitioner as possible; this is according to case law in 3 states, Western Australia (Bernadt in WASCA), Victoria (Kozanoglu v VSCA)and Northern Territory (Nitschke NT supreme court) . This was for allegations namely "Covid misinformation" and allegations I was issuing vaccine exemptions that did not meet the "requisite criteria". This was in November 2021. I still not have had a trial after over 2 years and there are several other doctors in the same boat, all because they tried to protect their patients and fulfil their duty according to the first law of medicine "primum non nocere" i.e. first do no harm.

I have been fighting the Medical Board in the courts since. I finally was heard in the Victorian Supreme Court in July 2022. This was a judicial appeal not a merits-based appeal as the medical board will not bring me to trial giving the excuse they were still investigating me. When they finally gave me the decision at the end of November 2022, 5 months after the trial, 12 months since I was suspended, they said the medical board needed further time continue their investigation! In other words, no decision was made. I then appealed to the Victorian Supreme Court appeal and on May 26, 2023, I served the papers on the Medical Board. The Medical Board referred me to VCAT for a hearing 7 hours later, what a coincidence! The Supreme Court heard me on November 3 and gave me their decision on November 10, 2023; they said in effect we're not hearing your appeal in the interests of avoiding "undue delay and efficiency" because the medical board had referred me to the tribunal! So, they also made no decision. On December 7 the VCAT gave me orders that it won't be until perhaps the end of September 2024 to hear my matter. I then applied for a summary dismissal of my case and on January 31 the tribunal said they'll hear that case on 11 July 2024. By which stage my period of suspension will be approaching three years without any

trial.

I should mention that in in July, August and Sept 2020 I attended a nursing home and looked after the residents during a Covid outbreak there. I was the only GP to do so, the other GPs did not attend and relied on nurses from the hospital to do so (the usual nurses from the nursing home did not attend either apart from one or two notable examples). Occasionally a doctor from the hospital would come. 54 out of 58 residents tested +ve on PCR. Very few were sick, in fact none had evidence of a respiratory illness. 11 were said to have died from Covid on the government statistics but I witnessed 5 which did not have any evidence of symptomatic Covid to have been from other causes, for example, I witnessed several cases of denial of care (notably one lady with a subdural haematoma who was denied transfer to hospital and died), as well as several cases of inappropriate palliative care, i.e. morphine and midazolam via syringe driver; one case I ceased the protocol and she made a miraculous recovery after being diagnosed as "dying" by the hospital doctors who had visited her. My opinion is that most of the 800 deaths in Victorian nursing homes in July, August and September 2020 would have been from inappropriate care rather than Covid.

I prescribed a lot of Ivermectin until it as banned here on 10 September 2021 and was involved in a trial, so I knew firsthand it was firstly a very safe drug even in the higher doses used for Covid and the data we collected indicated it was effective. It was banned at the same time as the Vaccine mandates were issued of course. I have no doubt this was politically motivated as Ivermectin is a safer drug than paracetamol or aspirin which are of course available at the supermarket.

I did many vaccine exemptions prior to suspension. 50% of the patients had suicidal ideation when I had the opportunity to ask. They had the choice of having the vaccine or losing their livelihood. I become angry and sick in my stomach when I reflect on this. I hope justice is one day served. This is a human tragedy on a vast scale.

Index

Fourth Answer

Ros Nealon-Cook BPsychSc, Co-Author:

I have outlined in previous answers, the sequence of events in 2021 that led to the suspension of my psychology licence and with it, the destruction of my career, reputation and livelihood. My crime? Attempting to raise safety concerns in the public interest, firstly with regards to child safety and secondly regarding the lockstep media censorship of qualified Australian health professionals who were similarly trying to protect the public from dangerous government policy.

When I registered with AHPRA in 2010 and adopted the APS Psychological Code of Ethics, I understood that freedom of speech, informed consent, and non-coercive practices were the cornerstone of ethical psychological practice. I had no hesitation in adopting these ethical principles, since they represent values that I hold as extremely important on a personal level.

AHPRA's March 2021 Position Statement (the "Gag Orders") starkly conflicted with these principles, imposing restrictions that felt antithetical to the values I stood for. These directives essentially prohibited free speech and informed consent, disgracefully crafted by bureaucrats who were either missing critical safety data (negligent), or deliberately withholding it (malfeasance). Any Australian mental health professional who has undertaken the mandatory (and substantial) ethics training requirement of our profession would be immediately aware that the "Gag Orders" were not only highly coercive but had the potential to impact millions of lives. In the video which led to my suspension, **my request was simply that government and media allow relevant medical experts to openly debate this critically important information** ... *surely* not an unreasonable request with so many lives at stake?

Choosing to speak out, driven by a duty to protect and advocate for the vulnerable, especially in light of my mandatory reporting obligations, resulted in severe personal and professional repercussions. You will be aware that I was not alone in being 'disciplined' for speaking out, and no doubt, you are familiar with my fellow 'heretics'. Are you also aware of the large numbers of Australian health practitioners who voluntarily left their professions (deregistration and early retirement) after witnessing the campaign of bullying and persecution to which my colleagues and I were subjected? Good, honourable medical experts were terrorised into ending their careers before they could be similarly 'punished'. As the 'suspended psychologist', many of these fine professionals sought my support, all suffering significant distress. I have certainly spoken to more than a hundred health practitioners who left the profession due to fears of persecution from AHPRA – including two veteran medical doctors who were experiencing severe suicidal ideation. Courtesy of the governments stazi-esque 'gag orders'. Writing and remembering these experiences makes me utterly sick to the stomach.

I've been asked to provide a detailed account of what I experienced at the hands of the various government tentacles for doing no more than fulfilling my statutory obligation to protect my clients and the children of Australia. However revisiting those experiences has proved too traumatic these last few days and this time, I'm putting myself first. Summary points were that I was suspended, repeatedly threatened with criminal offences, stalked on social media and required to attend a psychiatric assessment. A psychiatric assessment because the government didn't like what I was saying – it would be brilliant Orwellian farce if it hadn't been so

personally injurious.

Many of my suspended colleagues have been (or still are) involved with protracted legal battles with AHPRA in efforts to have their suspensions reverse. I've had countless requests to join class actions/fights against AHPRA however as a mother, for the sake of my own mental health and that of my family, I'm not willing to get involved in a game where I have zero faith that the hand is not entirely stacked against me. Remarkably, before facing the 2021 tribunal which stripped me of my license, I was counselled by two solicitors and a barrister, all independently advising against my even showing up. Their unanimous verdict? It would be an exercise in futility, a sham or in the words of one "a kangaroo court". That advice only cements my conviction that the current system is designed to fail us, to deny us a fair hearing. Sadly, my faith in receiving just treatment within this system remains utterly shattered.

I withdrew and wrote to AHPRA, HCCC explaining why. Of note:

> As a practitioner, I cannot ethically operate in an environment that promotes non-evidence-based government health policy above fundamental democratic freedoms and unalienable human rights. Similarly, I cannot ethically work in a system beholden to boards and bureaucracies that must either be ignorant of the existence of opposing information (indicative of incompetence) or complicit in suppressing that information (or possibly some combination of both).
>
> Although the addressees of this letter may find ways to avoid ethical imperatives whilst hiding behind corporate and political agendas, this does not obliviate any of you of your own professional ethical responsibilities – or your personal moral responsibilities. Have you not considered the *mens rea* piece here? *Why* would thousands of health professionals around the world, such as myself, have risked everything to raise awareness of these issues? Whether as mental health professionals, or a body that purports to 'represent' or 'regulate' our profession, it is critical to consider this.

Against this backdrop, I extend a heartfelt appeal to you, Senator Paul Scarr, inspired by my great-grandfather, Sir Joseph Cook, and my grandfather, Justice Richard Cecil Cook. Both served our country as embodiments of truth and integrity during a time when Australia was guided by stronger principles. I take pride in my heritage and urge you to embrace these values in your work, ensuring a legacy that your descendants can equally be proud of. This shared legacy highlights the paramount importance of unwaveringly committing to what is right, even in the face of adversity and professional risk.

Index

Fifth Answer

Dr Paul Oosterhuis, Co-Author:

The fallout from the attacks by the regulators on me has been substantial, both reputationally, financially, and psychologically.

After 32 years of practice in medicine, a lifetime of study, and service to the community as a doctor who specialised in anaesthesia and care of the critically ill, I found myself in conflict between my Hippocratic Oath and ethical responsibilities as a physician and the deeply unethical edicts of those in control of maintaining the register of medical practitioners.

The attacks were based solely upon my communications in the social media and had nothing to do with my lifetime of patient care, where I had reached the position of senior specialist in anaesthesia within the Australian health system.

Re: Evidence to the Australian Royal Commission.

Clearly I have much to say which is pertinent, including my most recent response to an anonymous complaint in 2023 which dealt directly with the Code of Conduct, and how I believed that my posts on Twitter/X and Substack, far from breaching these Code of Conduct, were actually all in robust support and compliance with the Code of Conduct.

Thankfully, my experiences at the hands of the regulators, the nature of my purported transgressions, and my responses have nearly all been documented on my Substack, and the Legal and Constitutional Affairs Committee is welcome to use these materials as my responses to the various Terms of Reference and Questions on Notice.

I would be happy to testify to this evidence if requested.

My social media 'transgressions' against the AHPRA gag order of March 2021 (as sent to me by the Medical Council of NSW in August 2021) used to justify the use of s150 immediate action powers for "public protection" and immediate suspension of my licence:

https://pauloosterhuis.substack.com/p/facebook-posts-the-medical-board

The support from the public and the international medical and scientific community that was presented to the Medical Council of NSW at the hearing:

https://doctors4covidethics.org/supporting-dr-oosterhuis/

My Testimony to the Medical Council at the s150 hearing where my licence was suspended:

https://pauloosterhuis.substack.com/p/my-testimony-to-the-medical-council

My response to the suspension in the Supreme Court of NSW in 2022, leading to the dropping of the suspension:

https://pauloosterhuis.substack.com/p/its-process-as-punishment

The renewed attack upon my licence in April 2023, again by an anonymous complainant:

https://pauloosterhuis.substack.com/p/the-right-of-physicians-to-communicate

My response to the Health Care Complaints Commission (HCCC, NSW) in respect of the April 2023 anonymous complaint, prepared by counsel William Parry of the Australian Medical Professionals Society (AMPS). In essence, me having to respond to another frivolous complaint: Annexure 12. The HCCC needed to be asked again to consider whether their robust investigation of frivolous and anonymous complaints is overreach and causing harm to health practitioners. See paragraph 23 of Annexure 12:

> Please consider the psychosocial hazards of notifications that curb Freedom of Speech, political expression, and proper evidence-based reasoned discussion and debate that is compliant with the Code and National Law; prior to notices or regulatory actions where there is no need established.

Index

Reference: UU

Index

A systematic review of all foreign funding to any Australian individual, institution, agency or department of any Australian government that were relied on by Australians for medical or scientific advice in regard to the Covid pandemic, and the contractual terms contingent on receipt of any such funding, in the generation of treatment protocols and/or Covid policy, including but not limited to:

i. the US National Institutes of Health;
ii. the US Department of Defense;
iii. the US Defense Advanced Research Projects Agency;
iv. any agencies of the European Union or European Council;
v. the World Bank;
vi. the WHO;
vii. the Bank of International Settlements;
viii. Bill Gates and any organisations with significant financial ties to Bill Gates or the Bill and Melinda Gates Foundation;
ix. GAVI (formerly the Global Alliance for Vaccines and Immunization);
x. Pfizer, Moderna, Janseen, Sanofi, Astra Zeneca.

Explanatory Memorandum

Index

An examination to confirm whether foreign funding played a substantive or significant role in shaping the approach to the Covid-19 pandemic by Australian institutions, and whether any such financial were reasonable and proportionate and necessary when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments and shared with or accessible by Australian institutions, and whether the terms contingent in the provision of any such funding were reasonable and proportionate when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 adverse event reports;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments

Question(s) on Notice

Index

In respect of **References UU**, please provide any further information concerning any foreign funding to any Australian individual, institution, agency or department of any Australian government that were relied on by Australians for medical or scientific advice in regard to the Covid pandemic, and the contractual terms contingent on receipt of any such funding, in the generation of treatment protocols and/or Covid policy.

Answer(s)

Index

Answer

The People's Terms of Reference:

This is information that is not available to the public.

However an example of overseas financial interference in Australian universities is the funding of REPLICATS at the University of Melbourne by the US agency DARPA, which also funded EcoHealth Alliance, believed to have been responsible for the release of SARS-CoV-2 (See: answer to Question on Notice R).

The answer above has been limited due to time constraints.

Reference: VV

Index

A systematic review and analysis of any suppression of clinical services that may have highlighted safety concerns associated with the Covid-19 vaccines, or better confirmed Covid-19 infection, including:

i. State or Territory coronial services;
ii. State or Territory pathology services that could reasonably have been expected to test pathology samples for the presence of proteins that would identify plausible evidence supporting Covid infection or Covid vaccines as a cause of death or injury;
iii. State or Territory pathology services that could reasonably have distinguished death 'from' Covid versus death 'with' Covid;
iv. State or Territory radiology services that could reasonably have assessed cardiac injury from Covid vaccines.

Explanatory Memorandum

Index

An examination to confirm whether any suppression of clinical services was organised by Australian governments and if so, an examination of the nature of those services and the risks or benefits associated with any identified services, and whether any such suppression was reasonable and proportionate and necessary when measured against the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments and shared with or accessible by Australian institutions, and whether the terms contingent in the provision of any such funding were reasonable and proportionate when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 vaccine adverse event reports;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference VV**, please provide any further information concerning any suppression of clinical services that may have highlighted safety concerns associated with the Covid-19 vaccines, or better confirmed Covid-19 infection.

Answer(s)

Index

Answer

The People's Terms of Reference:

This is information not available to the public.

There are currently no facilities in Australia to test pathology specimens for spike protein to establish whether a person died or was injured as a direct result of the COVID mRNA vaccines.

We have examples of inadequately conducted investigations by coroners officers and downplaying of post-vaccine deaths - the Raelene Gotzsche case; Dr Melissa McCann's series on the TGA intentionally not reporting Covid-19 vaccine deaths in children; the Adriana Takara case; the Tom van Dijk case; and DAEN case number 616124 - with no facilities in Australia to establish whether these deaths were due to vaccine injury as there are no pathology labs that are willing to test for spike protein presence by immunohistochemistry or spike RNA presence by PCR or RNA-ISH techniques.

The answer above has been limited due to time constraints.

Reference: WW

Index

A review and analysis of the use of any artificial intelligence, without public declarations of such, in the management of the Covid-19 pandemic including but not limited to:

i. the generation or authorship of medical treatment protocols;
ii. the generation or authorship of medical journal papers;
iii. the use of AI generated video to address the public (such as ProxyTwin) masquerading as qualified medical personnel.

Explanatory Memorandum

Index

An examination to confirm whether any artificial intelligence was organised or utilised or authorised by Australian governments in the management of the Covid-19 pandemic, an examination of the nature of the artificial intelligence resources employed and the risks or benefits associated with those resources, and whether employing or utilising or authorising AI resources was reasonable and proportionate and free of any form of deception on the Australian public, when measured against the true threat posed by SARS-CoV-2 to those vulnerable in the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments and shared with or accessible by Australian institutions, and whether the terms contingent in the provision of any such funding were reasonable and proportionate when measured against:

i. Peer reviewed literature and studies that became publicly available in respect of Covid-19 vaccination side effects;
ii. Analysis and studies and data that became publicly available in respect of Covid-19 vaccine adverse event reports;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **References WW**, please provide any further information concerning the use of any artificial intelligence, without public declarations of such, in the management of the Covid-19 pandemic.

Answer(s)

Index

Answer

The People's Terms of Reference:

Time constraints prevented a full and complete response to the above question which would have seen an extensive answer, had sufficient time been made available.

Term of Reference WW continues to be advanced by The People's Terms of Reference.

Reference: XX

Index

A systematic review and analysis of the health and economic impacts and costs forecast and consequent to Covid-19 mandates and lockdowns variously implemented by Australian governments on, and including:

i. families;
ii. small businesses;
iii. the national economy;
iv. individual sectors within the national economy;
v. health services;
vi. the cost of Covid-19 mandate measures including wealth transfers; and
vii. technical cost-benefit questions and issues concerning:
    a) the damage caused by hospital closures and procedural adjustments to in vitro pregnancies;
    b) the general damage to health from lost screening and lost procedures;
    c) the accumulated mental health damage of school closures and loneliness caused by lockdowns; and
    d) the future cost to health, life, and wellbeing from reduced government services locked in as a consequence of the approximately 400 billion dollars of government debt created by Australian governments in response to Covid-19.

Explanatory Memorandum

Index

An examination to confirm whether Australian governments properly and adequately assessed all reasonable options for protecting those who were vulnerable, and reasonably assessed all possible and likely adverse economic impacts from implementing mandates; what the actual realised extent of those impacts became and/or continue to be subsequent to the implementation of Covid-19 mandates, and whether the implementation of Covid-19 mandates was reasonable and proportionate and necessary compared with other options when measured against the true threat posed by SARS-CoV-2 to the Australian community generally, and to those vulnerable to SARS-CoV-2, as understood from epidemiological and statistical data and pathology/serum data known prior to implementing mandates, and known during the enforcement of mandate measures, as continually updated by Australian governments, and whether mandates were reasonable and proportionate and necessary when measured against:

i. Peer reviewed literature and studies in existence prior to the implementation of mandates;
ii. Economic advices received or submitted to Australian governments prior to mandates and during mandates;
iii. the true threat posed by SARS-CoV-2 to the Australian community, as understood from epidemiological and statistical data and pathology/serum data known and continually updated by Australian governments.

Question(s) on Notice

Index

In respect of **Reference XX**, please provide any further information concerning the Covid-19 pandemic modelling relied upon by Australian governments for making Covid-19 pandemic management decisions, policies, mandates, and laws.

Answer(s)

Index

Answer

Prof. Gigi Foster, Co-Author:

To my knowledge, Australian government references to "pandemic modelling" during the Covid era referred exclusively to epidemiological modelling – particularly of the Susceptible, Infected, Recovered (SIR) variety – which were simulation-based rather than data-based, and omitted any consideration of the effects of the government's Covid policies (allegedly intended to slow or stop the spread of Covid) on aspects of human life and society apart from who was infected with, recovered from, or died from Covid.

The tunnel vision that this produced in government authority figures was spectacular to witness. As their policies destroyed lives and livelihoods all around them, politicians and bureaucrats in charge during this era would point to their "modelling" (often also referred to as "science") to rationalise why the policies they were pursuing were the only viable option if Australia wished to avoid catastrophic levels of deaths and suffering due to Covid. This reasoning was the product of essentially religious belief in these epidemiological models and the simulations they contained. "Science" had absolutely nothing to do with it: the word was used as a fig leaf for lack of thought, coupled with deference to a flawed and incomplete method that nonetheless sounded smart to the layperson and hence could pass for a "scientific" justification for the government's policies. Most Australians could not decipher an SIR model paper, and were moreover

encouraged not to try to understand the modelling anyway since they were not "experts".

Instead of this unscientific and woefully incomplete approach to determining whether lockdowns were necessary, what should have happened was what happens in normal times when a new government policy is suggested: a thorough evaluation of the expected costs and benefits of that policy to all Australians, in all spheres touched by the policy. Lockdowns obviously created economic hardship and social distress, so an assessment of lockdown policies by a government that actually cared for its people's welfare would have included such costs. Instead, those of us who pointed out the costs of the government's Covid response (loudly, publicly, and repeatedly) were denigrated and accused of wanting people to die.

After years of waiting for any Australian government to properly assess its Covid policy response, I produced *Do Lockdowns and Border Closures Serve the 'Greater Good'?: A cost-benefit analysis of Australia's reaction to Covid-19* (Connor Court 2022, with Sanjeev Sabhlok). In this book we lay out the normal approach to policy evaluation and then proceed to apply that approach to the evaluation of Australia's Covid-era policies of lockdowns and border closures, using estimates based on actual data rather than simulations, and including costs and benefits in all categories and to all subgroups of people these policies plausibly affected. Using estimates generous to lockdowns and without quantifying many obvious intangible losses that lockdowns creates, our conclusion is that the costs of lockdowns were worth, at a minimum, 68 times the value of the benefits they could possibly have delivered in terms of human wellbeing.

The assessment that lockdowns were bad policy was something I proclaimed loudly on many broadcast and print media outlets in 2020 and 2021, and also something I directly communicated to the Victorian Parliament in August 2020, to no avail.

Index

Reference: YY

Index

An examination of Australian media companies and outlets and any involvement in the BBC instigated Trusted News Initiative (TNI), including:

i. the details of TNI partnership agreements;
ii. the details of TNI policies and practices implemented in Australia;
iii. the review and consideration processes and risk-benefit assessments undertaken by Australian media companies and outlets before and during implementation of TNI policies and practices;
iv. the legal assessments undertaken by Australian media companies and outlets to ensure implementation of TNI policies and practices would not and did not unreasonably interfere with opinions and criticisms shared publicly by Australian health practitioners and professionals concerning Covid-19 vaccines;
v. the legal assessments undertaken by Australian media companies and outlets to ensure implementation of TNI policies and practices would not and did not unreasonably interfere with the ability of Australian citizens to receive publicly available opinions and criticisms shared by Australian health practitioners and professionals, being information relevant to personal risk-benefit assessments by Australian citizens for the purpose of providing valid Informed Consent for Covid-19 vaccines.

Question(s) on Notice

Index

In respect of **References YY**, please provide any further information concerning Australian media companies and outlets and any involvement in the BBC instigated Trusted News Initiative (TNI) during the Covid years 2020 through 2024.

Answer(s)

Index

Answer

Julian Gillespie LLB, BJuris, Co-Author:

By their own admission, members of the "Trusted News Initiative" ("TNI") have agreed to work together, and have in fact worked together, to exclude from the

world's dominant Internet platforms rival news publishers who engage in reporting that challenges and competes with TNI members' reporting on certain issues relating to Covid-19.

Some of the partners within the TNI are the BBC, Facebook, Google/YouTube, Twitter, Microsoft, AFP, Reuters, European Broadcasting Union (EBU), Financial Times, The Wall Street Journal, The Hindu, CBC/Radio-Canada, First Draft, Reuters Institute for the Study of Journalism.

TNI members not only suppressed competition in the online news market but deprived the public of important information on matters of the highest public concern, especially independent sources of information on Covid-19.

For example, TNI members deemed the following to be "misinformation" that could not be published on the world's dominant Internet platforms: (A) reporting that Covid may have originated in a laboratory in Wuhan, China, yet so strong is the evidence of this likelihood there is a continuing US Congressional hearing into the matter; (B) reporting that the Covid vaccines do not prevent infection, despite the TGA and CDC subsequently making admissions to the effect that they do not prevent infection from Covid-19; (C) reporting that vaccinated persons can transmit SARS-CoV-2 to others, despite the TGA and CDC subsequently making admissions to the effect that Covid-19 vaccinated persons can and do continue to transmit SARS-CoV-2.

The TNI's very early commitment and ongoing commitment to be the guardians of Covid-19 information, through censorship, and to assist government's with their Covid-19 messaging was openly shared with the world:

27 March 2020: Trusted News Initiative announces plans to tackle harmful Coronavirus disinformation

10 December 2020: Trusted News Initiative (TNI) to combat spread of harmful vaccine disinformation and announces major research project

The most powerful "platform gatekeepers" are TNI members Facebook and Google, but the other TNI Big Tech Members - Twitter and Microsoft - play major platform gatekeeping roles as well.

The Department of Home Affairs has gone on record in Senate committee session admitting to sending members of the TNI 'take down' requests for the censoring of Australians and their views and opinions in respect of Covid-19, Covid-19 vaccines, and the management of Covid-19 by Australian governments.

This writer was also subjected to censorship by Google where after sharing factual

information on Covid-19 vaccines in the comments sections to YouTube videos, my account was suspended indefinitely with no particular reason provided by Google/YouTube.

The depth of interference and censorship on all matters related to Covid-19 where any content was not created by TNI members, or provided by government departments as part of their Covid-19 media and messaging, affected 100s of thousands of social media users globally. Examples include:

'Trusted News Initiative' Antitrust Litigation

CHD Files New Action Against Legacy Media Organizations For Antitrust and Free Speech Violations

The impacts of the TNI on Australian speech across the internet, and particularly on the views and opinions sought to be expressed by Australian health practitioners in relation to Covid and Covid-19 vaccines, requires a full examination by a Covid019 Royal Commission.

Index

Further Questions on Notice

Question on Notice

Index

Senator Antic to Dr Julie Sladden

I'm interested in some of the commentary that's been placed around the period known as Covid and what it did to public confidence in the institutions, in the medical industry and in the pharmaceutical industry as well. The perception that I hear when I speak to people and that I see reported is that the Covid period and the manner in which it was approached by some of those bodies has perhaps—and hopefully not—in the short term damaged beyond repair the perception and the trust that people have in those institutions and whether or not they think that a royal commission would go a long way to repairing some of the trust that has been lost and damaged during that period by the response.

Answer

Dr Julie Sladden answer – verbal part:

In one summarised statement, trust has been certainly eroded significantly in the medical profession and also various industries and systems associated with that. I think this is in part due to the breaches of informed consent and human rights and free speech, as I outlined in my opening statement, and also there has been definite clarity. The nefarious relationships that seemed to exist both in front of the scenes and also behind the scenes, and a lack of transparency over some of the decisions that were made. For example, the contracts with the pharmaceutical companies are still not available to the people. Taxpayers' dollars were used to purchase these injections. I think the Australian people have a right to know under what circumstances they were purchased. The most significant erosion of trust in my opinion happened in the consultation room of individual doctors and individual patients. Basically, there was an insertion of bureaucracy and a direction that had never been seen before in that sacred space between a doctor and a patient. There was a breach of informed consent. The answer I'd like to provide is quite detailed. I know we're short on time. I would really like to provide the rest of the answer on notice, if possible, please?

Rest of Answer on Notice:

Dr Julie Sladden – written part:

The public confidence and trust in institutions was significantly damaged during the pandemic response.
There were a number of key factors that contributed to this loss of public confidence, but by far the most serious breach of trust occurred in the doctors' consultation room.

Initially as the pandemic response started, the institutions seemed to be operating in their usual capacity providing messaging that informed stakeholders and the public. However, as time progressed this messaging changed, and dissenting voices were silenced. For example, when it was first publicly suggested, in late 2020, that vaccinations might become mandatory, several doctors publicly spoke in the media and suggested that mandatory vaccinations were not a good idea, and indicated the issue of informed consent. However, as time progressed, and with the issuing of the 6 March 2021 position statement by AHPRA and the Medical Boards, these voices became silent. Suddenly, the advocates for informed consent disappeared.

The true impact of that statement was not fully revealed until the mandates began to roll out, and mandated workers visited their GPs to discuss the vaccination in the hope of obtaining a 'medical exemption.' I have been told countless stories of people with valid health concerns and reasons for not wanting the injection, who were flatly refused even a temporary exemption. Without exception these stories are traumatic for the person involved, who went to their doctor for help and discovered that not only were they unable to get help but were sometimes treated dismissively by the doctor. The worst experiences involved people being berated by a medical professional, and sometimes a doctor seemed to simply be afraid.

This collective traumatic experience has been shared extensively through communities around Australia, both in private and in public. Historically, patients go to their doctor as a place of safety in times of medical need. But the position statement and the mandates combined to remove the doctors' consultation room as a place of safety for patients. Because of this I believe there has been a significant loss of trust in the medical profession as a whole.

A Royal Commission would go a long way to repairing some of the lost trust by highlighting the contributing factors, providing space for evidence to be heard, and indicating the changes that need to be made to restore this trust.

Question on Notice

Index

Senator Shoebridge to Dr Madry

Perhaps one of the first comprehensive studies was published in the *Lancet* in June 2022. It looked at excess deaths and preventable deaths and found that Covid-19 vaccinations had at that point or at least by the end of 2021 prevented some 14.4 million deaths as a result of comprehensive vaccinations across the globe, and it crunched the data in some detail. Is it your evidence that's just a mistake or is it your evidence that somehow that study and the other studies like it are mendacious in some way?

It's the *Global impact of the first year of Covid-19 vaccination: a mathematical modelling study* published in the *Lancet*.

Answer

Answer

Dr Andrew Madry – verbal part:

It's a very relevant question. I'm not specifically familiar with that paper. There was a paper published in the *Lancet* Western Pacific edition by Australian authors last year which found similar benefits. There has only been one set of randomised control trials, which are the gold standard, and they were the original manufacturer trials from Pfizer and Moderna. Those trials weren't powered to detect improvements in benefits from death or hospitalisation; they only dealt with infection. They didn't prove that. That one was modelling. That's a different thing altogether. Observational studies are confounded because they don't match up the patients, and the way it turns out is people who take more vaccinations tend to be different from those who don't in terms of their health outcomes. The Australian study by Liu and colleagues in the *Lancet* last year found benefits of hospitalisation and death from Covid vaccination and more boosters. However, that study also showed mortality benefits. The people who took more Covid vaccines somehow lived longer. It also showed a benefit against cancer. That was clearly ridiculous, if you look at the broader scope. It's a common thing that happens in observational studies, because the people who take more vaccinations have a different health profile from those who don't. So, 80-year-olds who don't take vaccination could be close to death, and so many of these studies are confounded.

We'd be very happy to provide a detailed analysis of papers such as that and others to show this. The only studies that have been done in randomised control trials are the original manufacturers trials, which as Mr Gillespie just said had a very short period of follow-up. It's a very good question.

Rest of Answer on Notice

Dr Andrew Madry – written part:

Dear Senator Shoebridge

I undertook to respond, on notice, to a question you posed, as to whether papers such as the one your referenced from the Lancet, claiming that Covid-19 vaccines saved 14.4 million lives, are "mendacious", in other words deliberately perverting the truth.

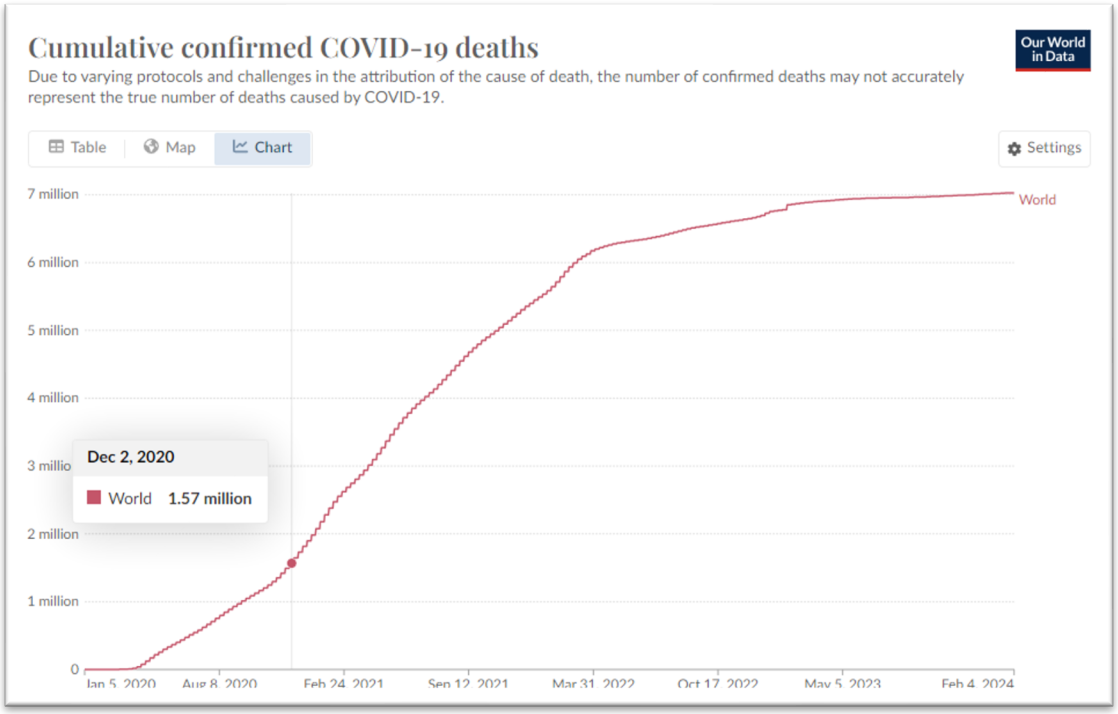
There are many reviews of this paper and rather than perform my own analysis I refer to that of respected scientists who show that this paper is flawed, at best basically useless, and at worst possibly harmful.

It is clear that many wealthy countries fared poorly during the pandemic. For example, the United States and UK, with relatively high rates of vaccination, fared amongst the worst. Exceptions are countries like Australia and New Zealand. We also have high rates of vaccination and have fared well relative to other wealthy countries. But this is largely because of geography and the ability to close island borders and quarantine incoming visitors for the first two years of the pandemic. Once the borders opened in late 2021, with a highly vaccinated population, Australia had one of the highest rates of infection in the world, with consequent deaths in the >95% vaccinated elderly population.

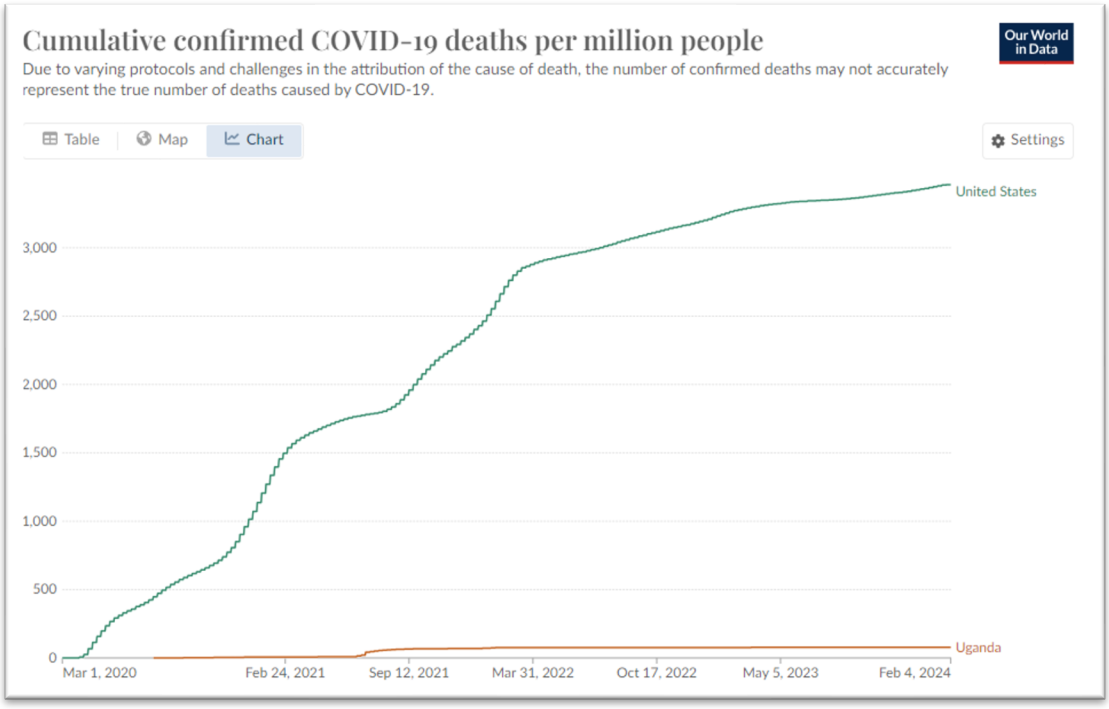
Some lower income countries, including those in Africa, fared much better in terms of Covid-19 fatalities. Of course, these poorer countries have a younger age profile. The biggest harms to those countries have been caused by economic impacts. These countries also had low vaccine uptake. The COVAX program, to provide global vaccine equity, is a well-documented failure.

With all the complexities in the global populations it is reasonable to ask can any model have a useful predictive value?

A quick look at the Our World in Data cumulative number of Covid-19 deaths is shown below (screenshot taken on 22 Feb 2024). I place the marker in December 2020 when the first authorisation of Covid-19 vaccines was granted. It is hard to see that vaccines did anything to slow down Covid-19 deaths. We also know that as time progressed the virus fatality rate became lower so we would expect the rate of deaths to slow down.

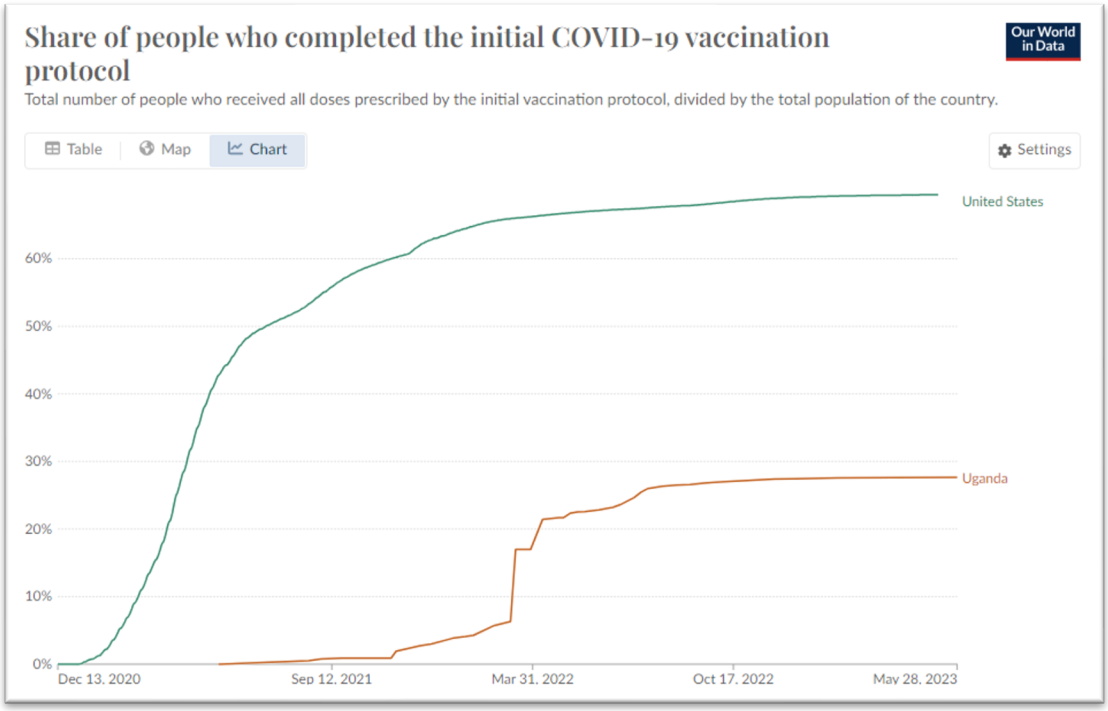


Comparing Covid deaths in a high income country (USA) and a low income country (Uganda) is shown below (y axis is shown relative to population).



United States (green) v. Uganda (red)

Population vaccination percentages are shown below for the same two countries.



United States (green) v. Uganda (red)

So, from this top-level view one has to question the bold claim made by the modelling paper of millions of lives saved.

Review of the Lancet paper highlights the question of using modelling to inform decisions in the context of complex scenarios such as the pandemic. In the pandemic just about everything was unknown and just about every assumed variable used as inputs to models was wrong.

This is not to say that modelling cannot be effective in any complex systems. Consider the development of an aeroplane. Just about every aspect of an aeroplane is modelled and air transport is a safe prospect in this century. The models are iteratively improved based on known data. However, we know the recent example of the 737 Max where a sensor was providing incorrect measurements, the aeroplane control systems responded by titling the aircraft towards the ground. There were two tragic fatal crashes. Bad data can be catastrophic.

In the pandemic the true underlying models (or behaviour) were unknown and the inputs to those models were falsely assumed to be known.

There needs to be careful governance of the application of models in the decision-making process

This governance needs to be overseen by practitioners with expertise in systems engineering and systems thinking.

The modelling exercise can still be useful. Included in any modelling exercise should be an evaluation of sensitivity. This is an analysis of the change in outputs in response to differing inputs.

It is now known that estimates of vaccine effectiveness promoted by manufacturers were wildly exaggerated. In fact, studies over the last year have shown negative effectiveness in certain situations, where those vaccinated are more likely to be infected. The Covid-19 vaccines provided no protection of transmission of the virus, as was claimed early on in the rollout. We later learnt there was no testing of transmission by manufacturers. We know also there is a huge gradient in fatality rate as a function of age.

To this end, I refer to the following articles that provide a review of the Lancet modelling paper:

- Professor Harald Walach: *Without Vaccination 18 Million More Deaths Worldwide? – Really?*

- *The Watson et al. "modeling study": did "Covid vaccinations" really prevent 14 million deaths?*

These articles go through various limitations and mistakes in the Lancet paper.

Well known statistician from Stanford, Professor John Ioannidis, wrote the following editorial in March 2020 on the exaggerated claims being made early on in the pandemic: *Coronavirus disease 2019: The harms of exaggerated information and non-evidence-based measures*

In a paper from 2022 titled *Forecasting for Covid-19 has failed* Professor Ioannidis writes in the abstract:

> Epidemic forecasting has a dubious track-record, and its failures became more prominent with Covid-19. Poor data input, wrong modeling assumptions, high sensitivity of estimates, lack of incorporation of epidemiological features, poor past evidence on effects of available interventions, lack of transparency, errors, lack of determinacy, consideration of only one or a few dimensions of the problem at hand, lack of expertise in crucial disciplines, groupthink and bandwagon effects, and selective reporting are some of the causes of these failures.

I also refer to my response to a question on notice at Reference MM, which also refers to modelling in Australia which similarly turned out to be highly inaccurate and potentially harmful based on the measures imposed as a consequence.

In Senator Shoebridge's question mistake and mendacity were mentioned as possible sources of error. From my understanding, errors may arise from research bias, and it is almost impossible to conduct a study without some degree of such bias.

For this reason, most researchers are educated in awareness of well-known biases including Information bias, Interviewer bias, Publication bias, Researcher bias, Response bias, Selection bias, Cognitive bias, and others. It is seldom necessary to resort to mendacity as a source of error.

Nevertheless, mistakes are made and some may even survive peer review, which is why many experienced scientists consider studies in the light of a well-honed scepticism. One mistake of note, you may recall, was an article published in *The Lancet* in 2020, an apparently fraudulent study discrediting the use of hydroxychloroquine in the management of Covid-19, which was later retracted[cclviii].

A. Observations on the Study that You raise

In the study by Watson et al, published in *The Lancet Infectious Diseases* in June 2022, *Global impact of the first year of Covid-19 vaccination: a mathematical modelling study,* all six authors were from the MRC Centre for Global Infectious Disease Analysis, Imperial College London, London, UK.

I ask you Senator Shoebridge to consider the following observations:

1. As the authors state, funding sources include the WHO, Gavi, The Vaccine Alliance, and the Bill & Melinda Gates Foundation, all of whom have reported interests in vaccination. This opens the authors to a potential conflict of interest, and a risk of many of the biases listed.

2. The 2022 study is not an observational study or trial that can be used to produce empirical 'findings' in relation to the vaccines. Rather, it is a comparison between a mathematical projection of what might have happened without vaccination, and what actually happened. Since mathematical modelling relies on simplified assumptions, any conclusions reached carry lower weight than those from empirical studies.

3. The mathematical projection was made using the same Imperial College model that has given grossly exaggerated predictions of deaths. For example, a projection was made that if Sweden did not lock down, the number of deaths would be more than ten times higher than the number that occurred. In their appendix file to Imperial College's Report #12, the team predicted between 66,393 and 90,157 deaths if the spread was unmitigated[cclix]. However, it turned out that Sweden suffered approximately 6,000 deaths[cclx] in the first wave with no lockdown.

4. The underlying assumption for the model used in this paper can be paraphrased as 'the vaccines save lives'. Therefore, the conclusion of the study, that vaccines saved an estimated number of lives, must be seen as a restatement of the assumption. This circular argument cannot prove, or find, that lives were saved.

5. If the conclusions of this study are derived from its assumptions, a search for truth must lead to an examination of those assumptions. Unfortunately, the assumptions adopted for this study are vulnerable to criticism, and we argue that they are unreasonable, as outlined below.

B. Stated and Unstated Assumptions are Unreasonable

Assumption 1

Covid viruses were dangerous, being the underlying cause of all deaths that comprised the estimated excess (i.e., 'unexpected') all-cause mortality during the period between the onsets of Covid and vaccination.

Criticism 1

Remembering that 2020 and 2021 was a period of global economic and social lockdowns, many excess deaths may have been caused by factors other than the Covid virus. According to a UN report[cclxi] published in 2022, the number of people affected by hunger rose to "*828 million in 2021, an increase of about 46 million since 2020 and 150 million since the outbreak of the Covid-19 pandemic*".

Also, in richer economies, there have been reports of significant differences in number of deaths between some neighbouring jurisdictions, indicating that factors other than air-borne viruses, which would not have stopped at the boundary, may have been at play[cclxii].

Even if Covid was the underlying cause of death, many of those deaths would have been in the frail and would have been expected in the same year. Hence, the proportion of deaths due to Covid that can be considered *unexpected,* or excess, is likely to have been low.

Therefore, the attribution of all excess deaths to the Covid virus is likely to give an exaggerated prediction of number of lives saved.

I consider this assumption to be unreasonable.

Assumption 2

Covid vaccine-induced immunity is effective against infection, transmission, and severe

disease and is more robust and longer lasting than immunity that would have prevailed in the absence of vaccination. Watson et al state:

> Vaccination was assumed to confer protection against SARS-CoV-2 infection and the development of severe disease requiring hospital admission ... and to reduce transmission from vaccine breakthrough infections (i.e., we assumed vaccinated individuals who develop infection would be less infectious than unvaccinated individuals) ....
>
> Immune evasion for infection-derived immunity occurs for 27% of the previously infected population.

Criticism 2 - Immunity

The Covid vaccines indirectly introduced an antigen[cclxiii] to prompt the same biological immune processes as those prompted by natural infection. This means that the upper limit to robustness and duration of immunity is set by those biological processes, and not by the antigen itself. So, immunity prompted by this type of vaccine[cclxiv] can only, at best, reach the standard of immunity prompted by infection. In this case, however, the Covid vaccines could not even have reached that standard, because the vaccine antigen was only a part of the virus.

In the supplementary study information Wang et al stated their assumption that natural immunity from infection was leaky, which they term 'immune evasion', leading to as many as 27% of the recovered population being vulnerable to reinfection. However[cclxv], that assumption does not accurately reflect the evidence presented in the article they cite[cclxvi], which, on the contrary, showed that antibody concentration rose sharply upon reinfection, indicating that immune response was effective:

> Among 91 previously infected subjects with serial measurements at three time points, including phase III (T3), 25 (27.5%; 95% CI, 18.4 to 37.5%) had a pattern of declining antibody concentration between T1 and T2, followed by a sharp rise at T3, indicative of reinfection (Fig. 2C).

Therefore, it is unreasonable to assume immunity prompted by vaccines of this type is superior than that which would have prevailed in the absence of vaccination.

Criticism 2.1 - Transmission

The antigen was injected into the main compartment of the body, thus bypassing the immune system of the protective mucosal membranes of the upper airways. Thus, the vaccines induced IgG type antibodies in the blood, rather than IgA type antibodies in the mucosal membranes. As evidenced in Mettelman et al (2022)[cclxvii] it was known that injections into the body are not effective at provoking a mucosal immune response

against respiratory viruses:

> ... designing effective vaccines that stimulate robust and protective immune responses in the respiratory mucosa has been an ongoing challenge. As a result, the majority of vaccines licensed for influenza and SARS-CoV-2, with the exception of the LAIVs [Live Attenuated Influenza Vaccine, in the form of a nasal spray], are delivered distally and rely on systemic innate and adaptive immunity, which may not be sufficient for protection at mucosal sites.

Indeed, the TGA stated in its Australian Public Assessment Reports that the Covid vaccines were not designed or tested for preventing transmission. (Nor, indeed, did the TGA approve the vaccines for the use of preventing transmission).

Therefore, it is unreasonable to assume that people with vaccine-induced immunity are less contagious than those with infection-induced immunity.

C. Observed Death Rates due to Covid were not affected by introduction of vaccines

As mentioned by Professor Fenton, if it were reasonable to assume that vaccinations reduced Covid deaths, then we should expect to observe countries with the least vaccinations suffering higher levels of deaths due to Covid. But this has not been the case. In his brief review[cclxviii] of Watson et al's paper, Prof Fenton states:

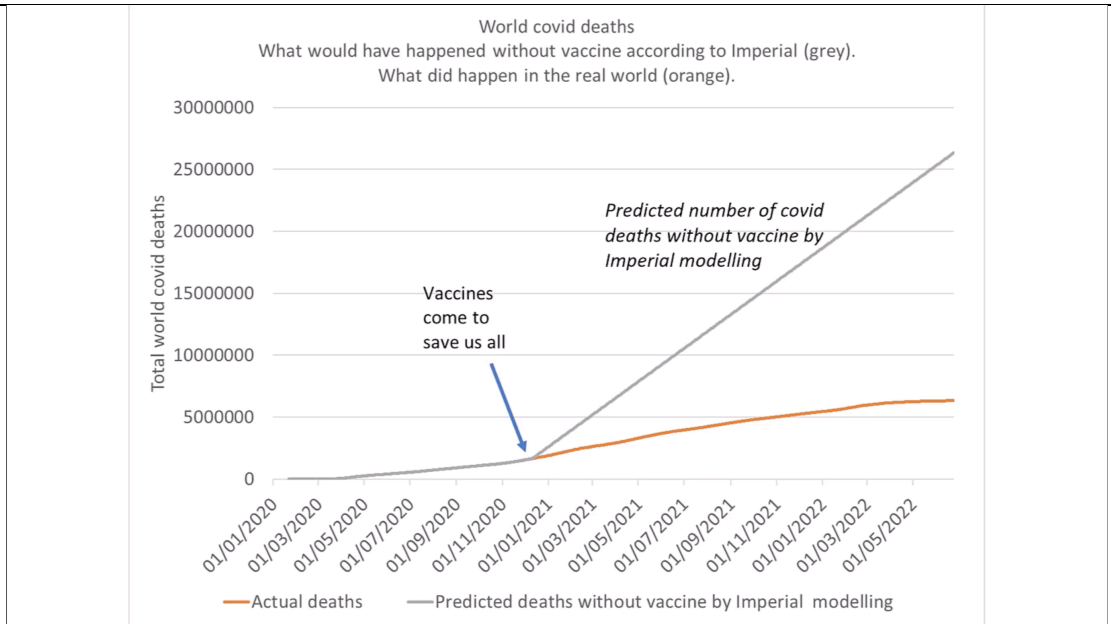
> Of course, the least-vaccinated countries didn't suffer a surge of Covid deaths, which shows an obvious flaw in their assumptions

Therefore, the assumption that the vaccine saved lives was unreasonable in light of the evidence that least-vaccinated countries suffered lower Covid deaths.

In the same brief review, Professor Fenton brought into relief the assumption that lives were saved in a graph figuratively depicting:

i) a predicted discontinuity kinking the number of Covid deaths *upwards* following the introductions of the vaccines; and

ii) *no* observed discontinuity kinking the progress of actual Covid deaths downwards after the introduction of the vaccines.



It was unreasonable to assume a discontinuous *increase* in Covid deaths at the onset of the vaccines if vaccines were expected to be lifesaving.

The absence of a discontinuous *decrease* in actual Covid deaths following vaccines shows retrospectively that it was unreasonable to assume that the vaccine saved lives.

D. The Conclusions are Not Consistent with Accepted Data on Vaccine Efficacy

As pointed out by Kenyon and Verduyn[cclxix] following official data on vaccine efficacy, even if the entire population of the world were over 70, and every single one of those were vaccinated, then only 3.2 million severe hospitalisations could possibly have been prevented. Only a proportion of those would have been deaths:

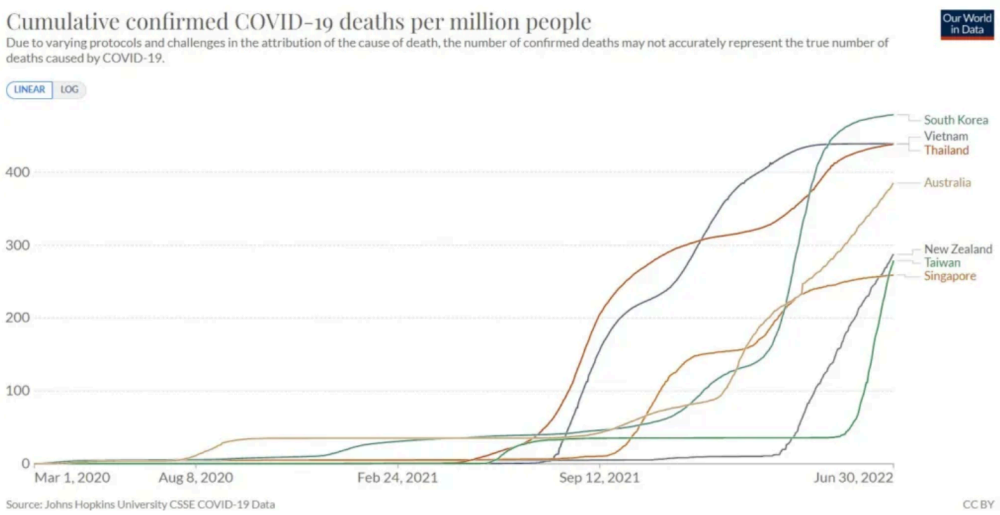
> ... on Jan 25, 2023, the UK Health Security Agency (UKHSA) published a report that estimated the number of people who needed to be vaccinated to prevent a Covid-19 hospitalisation. In Table 4 of Appendix 1, it is claimed that 2,500 people over 70 must be vaccinated to prevent one severe hospitalisation in that age group b. ... This is the lowest NNV (numbers needed to vaccinate) figure in the table. If we apply this number to the entire world population, and assume both that this entire population is over 70 years of age, and that every last soul was vaccinated, according to the UKHSA data, only 3.2 million severe hospitalisations would be prevented. Therefore, it is clearly impossible for the vaccines to have prevented 14.4 million deaths.

Therefore, the study conclusion that as many as 14.4 million deaths were prevented is inconsistent with official data on vaccine efficacy.

E. The Conclusions are Not Consistent with Real-World Data on Covid Deaths

As Dr Clare Craig has pointed out[cclxx], heavily vaccinated countries have suffered high mortality:

> South East Asia also tells an important story. These countries are heavily vaccinated and yet with the latest Omicron wave they have experienced mortality amounting to 300, 400 or even more per million. This is the same order of magnitude as Europe experienced in Spring 2020, with the original variant and before vaccination. The claim that vaccinations prevent 80%+ of Covid deaths does not fit with what is happening in the real world.



Therefore, the study's conclusion that vaccines saved lives is not consistent with real-world data.

F. Adverse Effects of the Vaccines May Reduce the Projected number of Lives Saved

No therapeutic compound is entirely safe. For evidence of adverse events see the answer to the Question on Notice for section AA.

The Covid vaccines carry known risks to the injected person such as due to:

i) possible pathogenicity of the antigens, their vectors, adjuvants, or impurities;
ii) genotoxicity of the synthetic DNA or modified RNA;
iii) the distribution of genetic material producing foreign proteins throughout the body including in cells in the brain, bone marrow, and gametes; and
iv) the lack of control of the amount of antigen produced by cells.

There is also a known risk of vaccine-enhanced advanced respiratory disease due to

repeated injections.

For the population, there may be risks due to administering non-sterilising immunity during a pandemic.

Further, the quantity of reports to adverse event registers such as VAERS, the MHRA Yellow Card reporting site, and DAEN has been high for the Covid vaccines relative to that for other administered compounds.

Yet, curiously for a scientific study, there is no acknowledgement that any deaths due to the vaccine itself would have a countervailing effect on the projected lives saved by the vaccine.

In summary

This review of the Watson et al study reveals serious flaws:

1) As the authors report, their study was partially funded by organisations known to benefit from advocating vaccines.
2) The study conclusions are derived by circular argument that simply extrapolates the following assumptions, which we believe are not reasonable:

   i) that Covid caused all of the excess deaths before the vaccine roll out; and

   ii) that vaccine-induced immunity had a greater capacity to reduce the spread and severity of disease than immunity that would have been prompted against a contagious virus in the absence of vaccination.

3) The study conclusions are consistent neither with accepted data on vaccine efficacy nor with real-world data on Covid deaths.
4) Nor does the study contain an acknowledgement of any countervailing effect of deaths due to the vaccine itself.

I feel that these flaws are so serious that the study should not be relied upon and instead should be retracted.

Endnotes: For all answers
Index

Question on Notice

Index

Senator Scarr to Julian Gillespie

People's Terms of Reference: can you take on notice whether or not it would be possible to abbreviate some of your proposed terms of reference? I'm not seeking an answer now. There is voluminous information and paragraphs you have in your proposed terms of reference. One of the things this committee needs to do is to work out, if it is so minded to propose actual terms of reference, how some of those points might be summarised.

Answer

Answer

Julian Gillespie LLB, BJuris, Co-Author:

Senator Scarr, as the Committee can observe above, many answers to Questions on Notice were not possible due to the limited time afforded to respond.

Throughout the process of receiving, collating, and organising answers provided, I have remained mindful of your request above for possibly:

Abbreviating some of our proposed Terms of Reference; or

Summarising our Terms of Reference.

First, those Questions on Notice we were unable to respond to, where the Term of Reference contains no helpful prior content in the Explanatory Memorandum sections, are Terms of Reference the Committee without more would appear to be unable to recommend in its final report. This reduces the number of our proposed Terms of Reference, a process of natural selection as it were.

Second, where Co-Authors and Proposed Witnesses have responded to Questions on Notice, now the Committee has further information for better placing our proposed Terms of Reference in a clearer light and context.

We hope then this will assist the Committee in not only recommending the Terms of Reference associated with those Questions on Notice, but should the Senate adopt your report and in turn seek to draw up draft Letters Patent with reference to our proposed Terms of Reference, then we feel the better course is to leave the task of abbreviating or summarising our Terms of Reference into appropriate Terms of Reference suitable for

Letters Patent, to the Office of Parliamentary Counsel (OPC). The OPC would we believe benefit from reviewing all original versions and attached information for better drafting Terms of Reference that suitably capture subject matter and issues meant to become the work of a Covid-19 Royal Commission.

Index

Annexure A

Index

QUESTIONS ON NOTICE FROM SENATOR MALCOLM ROBERTS

Questions on Notice for Professor Brighthope

Legal and Constitutional Affairs Reference Committee | 1 Feb 2024

Q.1

Professor Brighthope, in respect of your joint submission and in particular index **Reference B**, all Australian governments in August 2019 jointly published the Australian Health Management Plan for Pandemic Influenza, within which **Attachment E** details the scientific evidence for masking, personal protective equipment, border controls, stopping international spread, vaccine passports at borders, the use of thermal scanners at borders, isolating asymptomatic inbound passengers, quarantining people in contact with ill people, State border closures, school closures, workplace closures, working from home, cancelling of mass gatherings ...

In nearly every instance the Plan for Pandemic Influenza advised these measures had moderate but mostly minor beneficial effects, that is, less than a 10% possible benefit, and were mostly Not Recommended due to the greater detrimental effects and impacts upon health and the economy.

Professor Brighthope, did the science change suddenly 6 months later to warrant Australian governments accepting recommendations from the WHO to justify doing the exact opposite to what Australia's own Health Management Plan for Pandemic Influenza when SARS-CoV-2 arrived?

Q.2

In respect of index **References O & Q**, there has existed great controversy since 2020 about the use of repurposed drugs for the prevention of Covid-19 illness, and if ill, for treating patients with repurposed drugs, some of which like Vitamin D and intravenous Vitamin C have been used safely for nearly 100 years, and others like Ivermectin and Hydroxychloroquine, which have proven to be wonderfully safe and effective for treating prior coronaviruses.

Professor Brighthope:

1. Did Australians only need to receive these amazingly safe repurposed drugs to protect against getting sick with Covid-19, and if they got sick, would they have quickly got Australians feeling well again, without any side-effects?

2. If these long established and well-known repurposed drugs had been used from the beginning, would there have been any need for the experimental Covid-19 gene therapy drugs containing GMOs to be administered to Australians, with all the massive side effects and deaths they have caused?

Q.3

In respect of **Reference P**, please provide any further information concerning the evidence basis for any decision by Australian government health departments suspending or restricting access to repurposed drugs in the prevention of Covid-19 illness, and the treatment of Covid-19 illness, including any changes to guidelines or recommendations in respect of the use of antibiotics for treating Covid-19 illness.

Q.4

In respect of **Reference Z**, please provide any further information concerning peer reviewed and published scientific studies (including preprints), including studies published by overseas health authorities in 2021, 2022, 2023, and 2024 suggestive of adverse health outcomes in recipients of Covid-19 vaccines, that were readily accessible to Australian health authorities.

Q.5

In respect of **References Y**, please provide any further information concerning the veracity, accuracy, and scientific basis for the many medical statements made by Australian politicians and health bureaucrats and agencies concerning Covid-19 vaccines.

Q.6

In respect of **References W and CC**, please provide any further information concerning Australian epidemiological data being compiled and published and relied upon by Commonwealth, State and Territory governments during the Covid-19 pandemic from early 2020 into 2023, the manner in which the data was being collected, the integrity of the data, the availability of the data to non-government health experts, and how that data was being used transparently to inform government policy on the need for Covid-19 vaccines to the exclusion of all other repurposed drugs, and for justifying Covid-19 mandates.

Q.7

In respect of **Reference DD**, please provide any further information concerning the epidemiological and statistical findings in relation to the safety and efficacy of Covid-19 vaccines by pharmacovigilance departments within Australian governments during 2021, 2022, and 2023, the manner in which the data was being collected, the integrity of the data, the availability of the data to non-government health experts, and how that data was being used publicly and transparently to inform government policy of the ongoing need for Covid-19 vaccines throughout 2021 into 2024.

Q.8

In respect of **References GG and HH**, please provide any further information concerning the real-time safety systems used by Australian State and Territory governments to inform and alert health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines, and how reliably from early 2021 those real-time safety systems were informing Australian health practitioners of potential or actual side effects or contraindications in respect of Covid-19 vaccines.

Q.9

In respect of **Reference OO**, please provide any further information concerning Excess Deaths in Australia from 2020 through 2024.

Questions on Notice for Mr Peter Fam

Legal and Constitutional Affairs Reference Committee | 1 Feb 2024

Q.1

In respect of your joint submission and in particular index **Reference L**, concerning the 9 March 2021 joint statement issued by AHPRA which effectively gagged Australian doctors from sharing their concerns about Covid-19 vaccines with their patients, is there any legal basis to say that statement by AHPRA was illegal and was made illegally by AHPRA, where the consequence of AHPRA's statement was to cause all doctors who censored themselves with their patients, to breach their Codes of Conduct, thereby causing them to commit offenses under the National Law, possibly creating a basis for medical negligence lawsuits?

Q.2

In respect of index **Reference M** in your joint submission, and to your knowledge, in respect of Covid-19 vaccines, do you believe Australians were prevented from providing legally valid Informed Consent, due to information about Covid-19 vaccines that Australian governments failed to share with Australian citizens?

Q.3

In respect of **Reference E**, what details were made public about the involvement of the Department of Home Affairs (DHA) throughout 2020 to 2023, and what if any possible shortcomings may have arisen and should be investigated and examined when a department of national security was made responsible for directing Australia's whole-of-government public health response to Covid-19?

Q.4

In respect of **References B and F**, what was the explanation provided by the AHPPC for completely ignoring the Australian Health Management Plan for Pandemic Influenza which had been reaffirmed by all Australian governments in late 2019?

Q.5

In respect of **References F**, what was the scientific evidenced provided by the WHO when issuing Covid-19 recommendations pursuant to the International Health Regulations, which the AHPPC considered as sufficiently good to abandon the Australian Health Management Plan for Pandemic Influenza? Did the AHPPC share this scientific evidence with Australians or Australian scientists?

Q.6

In respect of **Reference B**, please provide any further information concerning Event 201 and any involvement by Australian organisations, agencies, or persons.

Q.7

In respect of **Reference H**, please provide any further information concerning the role and function of the National Health Emergency Media Response Network during Covid-19.

Q.8

In respect of **Reference I**, please provide any further information concerning Australian government "nudge" units and social media "disinformation" units.

Q.9

In respect of **Reference J**, please provide any further information concerning the functioning of Federal, State, and Territory government media liaison departments and activities during 2020, 2021, and 2022, in the context of Covid-19 public messaging.

Q.10

In respect of **Reference K**, please provide any further information concerning funding from Australian governments to any bodies or companies for media collaboration and advertising in regard to Covid-19, and particularly in respect of how any such funding could have or did in fact affect critical journalism in Australia during the same period, in respect of Covid-19.

Q.11

In respect of **Reference N**, please provide any further information concerning the roles performed by the Australian Defence Force (ADF) and Australian military personnel in response to Covid-19 throughout 2020, 2021, and 2022.

Q.12

In respect of **Reference R**, please provide any further information concerning any involvement of Australian scientists in the origins of the SARS-Cov-2 virus and any involvement of Australian scientists in the field of gain of function viral and bacterial research in the decade prior to the pandemic.

Q.13

In respect of **Reference S**, please provide any further information concerning the legal criteria required to be fulfilled or satisfied for the provisional approval and registration of Covid-19 vaccines in Australia.

Q.14

In respect of **Reference T**, please provide any further information concerning the application materials submitted by sponsors, including the clinical safety and efficacy data and references submitted by Covid-19 vaccine manufacturers and relied upon by the Therapeutic Goods Administration for the provisional approval of the Covid-19 vaccines.

Q.15

In respect of **Reference U**, please provide any further information concerning safety studies completed by the manufacturers, and any safety studies not performed or completed by the manufacturers, or the TGA, at the time of provisional approval of Covid-19 vaccines.

Questions on Notice for Dr Sladden

Legal and Constitutional Affairs Reference Committee | 1 Feb 2024

Q.1

In respect of your joint submission and in particular index **References BB and JJ**, are you able to point the Committee to any formal guidelines and procedures that were put in place prior to or just after the rollout of Covid-19 vaccines Australia to specifically assess adverse events caused by the vaccines, by State and Territory governments and the TGA, in case those experimental drugs proved to not be as safe and effective as the Australian people were told?

And, do we know who was responsible for first receiving adverse event reports, the criteria they used to perform assessments, what the qualifications were of those people responsible for first receiving adverse event reports and for conducting the initial assessments, and who they reported to?

The issue here is we have been asking lots of questions in the Senate about how Australia's adverse event reporting system works and we only ever receive the same blanket reassurances from the TGA that everything is fine, and they treated the Covid-19 vaccine adverse events very specially, but we still have not seen any evidence about how they were doing that, and who was doing that?

Q.2

In respect of index **Reference LL**, as a medical doctor who has also been reporting extensively on Covid-19 in Australia and been in contact with many groups and organisations who have been critical of these experimental drugs, can you briefly tell us of those you understand to be Covid-19 vaccine victims:

i. How many Australian victims do you and your medical colleagues believe could have been affected?

ii. Are their doctors speaking up about the likely cause of their injuries?

iii. And how has the general medical community been treating them?

Q.3

In respect of **Reference C**, please provide any further information concerning the Covid-19 pandemic management decisions, laws, policies, and the review and consideration processes and cost-benefit analyses undertaken by State and Territory governments into potential adverse impacts and mental harm from lockdown measures and mandates, with particular focus on children and infants.

Q.4

In respect of **Reference XX**, please provide any further information concerning the Covid-19 pandemic modelling relied upon by Australian governments for making Covid-19 pandemic management decisions, policies, mandates, and laws.

Q.5

In respect of **Reference MM**, please provide any further information concerning the veracity, accuracy, and scientific basis for the many medical statements made by Australian politicians and health bureaucrats and agencies concerning Covid-19 vaccines.

Q.6

In respect of **References NN**, please provide any further information concerning Covid-19 pandemic management decisions and policies and particularly Covid-19 vaccine mandates compelling the receipt of Covid-19 vaccines as conditions of employment, implemented by Australian companies, with especial attention to the guidance provided by Australian governments to Australian companies for undertaking risk-benefit assessments when considering implementing Covid-19 vaccine mandates, and what considerations and criteria Australian companies uniformly followed for observing all available scientific evidence, and which company personnel were designated best skilled to evaluate such medical and scientific considerations.

Q.7

In respect of **Reference RR**, please provide any further information concerning he total budget expended in relation to the Covid pandemic including all payments made by the Commonwealth to State and Territory treasuries, and payments to all other government and non-government recipients designated as part of the Covid response. Where budgetary data is unavailable or not accessible, please also detail any failures in Covid-19 budgetary transparency.

Q.8

In respect of **References KK**, please provide any further information concerning when evidence of disproportionate adverse outcomes from the Covid-19 vaccines became apparent and discernible to relevant Australian government departments, the dates upon which one or more type of adverse outcomes from one or more Covid-19 vaccines became statistically significant, and when any available data became available to Australian government departments indicative of disproportionate harm or death to Australians from Covid-19 vaccines, as compared to any other registered or previously registered therapeutics in Australia.

Questions on Notice for Dr Madry

Legal and Constitutional Affairs Reference Committee | 1 Feb 2024

Q.1

In respect of your joint submission and in particular index **References EE and FF**, are you able to confirm for the Committee whether the TGA has been transparent in providing reliable and timely access to data scientists like yourself, for researching and modelling purposes, the data contained in the TGA's DAEN and AEMS adverse event reporting systems, for being able to confirm timely and accurate reporting of Covid-19 vaccine adverse events, so scientists like yourself could perform independent research to confirm the Covid-19 vaccines are 'safe and effective'?

Q.2

In respect of index **Reference PP**, is it true to say the TGA and State governments provided a high degree of transparency and accountability in the context of the handling of freedom of information requests in relation to SARS-CoV-2 and the Covid-19 vaccines, for data scientists like yourself to undertake research and modelling of Covid-19 adverse events, cases, hospitalisations, and deaths independently and accurately, for confirming from such public data the Covid-19 vaccines are 'safe and effective'?

Q.3

In respect of **Reference II**, please provide any further information concerning the conduct of TGA pharmacovigilance following the rollout of the Covid vaccines and whether this met the standards set forth in the AusPAR provisional approvals for the vaccines.

Q.4

In respect of **References Y**, please provide any further information concerning the veracity, accuracy, and scientific basis for the many medical statements made by Australian politicians and health bureaucrats and agencies concerning Covid-19 vaccines.

Q.5

In respect of **Reference VV**, please provide any further information concerning any suppression of clinical services that may have highlighted safety concerns associated with the Covid-19 vaccines, or better confirmed Covid-19 infection.

Q.6

In respect of **Reference X**, please provide any further information concerning the use of social media including celebrities by Australian governments and health authorities to transmit information to the public regarding Covid-19 vaccines and Covid-19 cases, and the science and data sources relied upon for all incidences of such social media and celebrity messaging.

Q.7

In respect of **References QQ**, please provide any further information concerning procurement contracts details between the Australian government and Pfizer, Moderna, AstraZeneca, and Novavax for the Covid-19 vaccines.

Q.8

In respect of **Reference SS**, please provide any further information concerning Covid-19 related court cases that were denied to applicants on the basis of mootness or judicial notice, or in which judicial notice was taken in regard to evidence and advices from bodies including ATAGI, NCIRS, ACV, the TGA, and the Peter Doherty Institute for Infection and Immunity.

Q.9

In respect of **References TT**, please provide any further information concerning Australian Whistle-Blower legislation to determine whether any such legislation failed to protect doctors, scientists, government officials, medical administrators, or hospital staff who attempted to raise safety concerns in the public interest with respect to Covid-19 vaccines and Covid-19 lockdown measures and mandates.

Q.10

In respect of **References UU**, please provide any further information concerning any foreign funding to any Australian individual, institution, agency or department of any Australian government that were relied on by Australians for medical or scientific advice in regard to the Covid pandemic, and the contractual terms contingent on receipt of any such funding, in the generation of treatment protocols and/or Covid policy.

Q.11

In respect of **References WW**, please provide any further information concerning the use of any artificial intelligence, without public declarations of such, in the management of the Covid-19 pandemic.

Q.12

In respect of **References YY**, please provide any further information concerning Australian media companies and outlets and any involvement in the BBC instigated Trusted News Initiative (TNI) during the Covid years 2020 through 2024.

Annexure 1

MANDATORY REPORT OF RISK OF SIGNIFICANT HARM TO CHILD/REN

ROS NEALON-COOK
TO
THE ATTORNEY-GENERALS OF AUSTRALIA

27 AUGUST 2021

Ros Nealon-Cook (L1)

Subject: FW: URGENT: Mandatory Report of Risk of Significant Harm to Child/ren

Importance: High

From: Ros Nealon-Cook
Sent: Friday, August 27, 2021 7:37 AM
To: cronulla@parliament.nsw.gov.au; Mark.speakman@parliament.nsw.gov.au; jaclyn.symes@parliament.vic.gov.au; AttorneyGeneral@sa.gov.au; VickieAnn.chapman@parliament.sa.gov.au; attorney@ministerial.qld.gov.au; Waterford@parliament.qld.gov.au; Minister.Quigley@dpc.wa.gov.au; minister.uibo@nt.gov.au; electorate.arnhem@nt.gov.au; elise.archer@dpac.tas.gov.au; shane.rattenbury@act.gov.au
Subject: URGENT: Mandatory Report of Risk of Significant Harm to Child/ren
Importance: High

TO THE ATTORNEY-GENERALS OF AUSTRALIA

The link below directs you all, to a video containing material evidence regarding a mandatory report I am lodging, as required by law, in my position as an Australian psychologist. This report concerns risk of serious harm to Australian child/ren on all eight forms of harm:

1. Physical abuse
2. Neglect
3. Sexual abuse
4. Psychological harm
5. Danger to self and others
6. Relinquishing care
7. Carer concern
8. Unborn child

This video will also be released to the police, education authorities as well as the general public. The link follows:

https://rumble.com/vlq0js-australian-psych-perspective.html

I ask you all to URGENTLY engage with this material. Each additional day that this serious harm to children takes place, puts more lives at risk in the most grievous ways.

Kind regards,

Ros Nealon-Cook

Integrated Kids

Ros Nealon-Cook Assoc MAPS, FMCHC
PBA Registered Psychologist PSY0001410196
IFM Accredited Functional Medicine Health Coach

Restore Healthcare Clinic: 69 Megalong Street, Katoomba NSW 2780
PO Box 7137, Leura NSW 2780
T: +61 (02) 4742 0078
www.integratedkids.com.au

Annexure 2

RE: NSW COVID-19 UPDATE 29 JULY

ROS NEALON-COOK

TO

AUSTRALIAN ASSOCIATION OF PSYCHOLOGISTS INC (AAPI)

30 JULY 2021

Ros Nealon-Cook (L1)

From:
Date: Friday, 30 July 2021 at 11:20 am
To: Australian Association of Psychologists Inc <admin@aapi.org.au>
Subject: RE: NSW COVID-19 Update 29 July

Dear AAPI,

I want to raise a serious concern regarding impact on community mental health from lengthy lockdowns, and seemingly lack of concern re the long-term consequences for our country.

As a psychologist working primarily with children and families and residing in a tourist community, I've been beyond concerned about MH outcomes since the beginning and frankly, am at a loss as to WHY there hasn't been more discussion. This area (and much of coastal NSW) was devastated during summer 2020/21 by bushfires + subsequent flooding rains, landslides etc. Many families of course lost their homes, but much more concerningly, was the evaporation of international tourism, which is our, and many other Australian communities' bread and butter. By early 2020, many businesses were lost, families had broken up and all the other impacts on mental health the APS know well. We still hadn't washed the ash off our windows (this is not hyperbole) when this thing called "COVID" rolled into town.

Fast-forward to mid-2021 and the situation is extremely dire. The borders remain closed, so for the last 18 months, local businesses have worked their utmost to build appeal to Australian tourists within the confines of COVID rules - not an easy feat, but desperation certainly drives ingenuity. The streets and businesses prior to each school holidays are pristine, brimming with energy and hope, since those school holidays are the only thing that can keep them afloat. Yet by excruciating coincidence, lockdowns have commenced immediately prior to or within each major holiday period. Xmas 2020 with Northern Beaches, Easter 2021 and finally the July school holidays which, for so many, has been the final straw. Many clients have shared it's like living in a horror movie; yet as I try to work the impossible to support them, silently I agree.

We now have a group of Year 1s, that we refer to as the "Covid Kindies" who are the most stressed and anxious cohort of 6-year-olds I've come across. These are the children whose 2020 entry into formal school was severely compromised as it commenced immediately post the 6-month fire season and just as a worldwide pandemic began. Most already had higher anxiety than normal due to extremely stressed parents, then to add salt to the wound, were not allowed the usual and very important transition with parents on campus etc due to COVID restrictions. Soon after, they were thrown into a period of home-schooling with teachers whose stress-levels were also skyrocketing. You must have seen this 20-fold in Melbourne with your extended lockdowns.

What's finally got me writing is that last week, the only physical piece of mail I received was a fridge magnet and flyer (with balloons and streamers) from the local bottle shop, reassuring folk not to worry because they would deliver during lockdown. We're seeing sky-high rates of active addiction (new and returning) around the world, increases in suicide, self-harm, DV, PTSD in small kids, not to mention the huge increase in PND, which we know is one of primary factors in poor long term mental health outcomes. Yet nobody is talking about this much at all .. and people should be screaming by now. Sure, the government are putting a few extra $$ into Medicare for MH, but 6+4 (even with the "bonus" COVID 10) is not going to scratch the surface. We're talking decades and decades (and decades) of long-term negative mental health outcomes, in fact potentially way beyond that according to the Intergenerational Transfer of Trauma folk as well as via DNA according to Jablonka et al.

Yes, COVID is an emergency situation with a terribly contagious virus and, from the reading I've done (which is a lot), Delta is even more contagious. YET … there are many noted medical professionals around the world explaining that while COVID is deadly threat for a portion of the population (the elderly / immune compromised, obese etc) it poses almost no threat to children or healthy working aged folk. There will always be the rare outliers when we're dealing with population level stats (e.g., a 25 yr old who tragically contracts COVID and dies.. but let's not forget the 25year-old who tragically gets the vaccine and dies VAERs). What I would like to see openly and publicly debated

very loudly is how many are dying in this country from COVID compared to how many have and will die from the horrific effects of lockdowns. Surely we can isolate and protect those vulnerable, without creating a tsunami of mental health crisis? It actually seems absurd – likely a "can't see the wood for the trees" scenario.

This is an incredibly important conversation which I'm yet to see taken up with the seriousness it deserves. If I've missed one please send me links / papers immediately. From what I've seen, anyone speaking out is either thrown in with the "conspiracy theorists" or "antivaxxers" and immediately ridiculed. Please can you start an open, public discussion on this.

With hope, yours sincerely,

Ros Nealon-Cook

Annexure 3

RE: COVID-19 NSW | MASK REQUIREMENTS FOR EIGHT SYDNEY LGAS

ROS NEALON-COOK

TO

AUSTRALIAN PSYCHOLOGICAL SOCIETY (APS)

30 JULY 2021

From: Ros Nealon-Cook
Sent: Friday, 30 July 2021 11:17 AM
To: APS Communications <Communications@psychology.org.au>; membership renewal <membershiprenewal@psychology.org.au>
Cc: Reception <Recept@psychology.org.au>; Referral <Referral@psychology.org.au> Subject: RE: COVID-19 NSW | Mask requirements for eight Sydney LGAs Importance: High

Dear APS,

I want to raise a serious concern regarding impact on community mental health from lengthy lockdowns, and seemingly lack of concern re the long-term consequences for our country.

As a psychologist working primarily with children and families and residing in a tourist community, I've been beyond concerned about MH outcomes since the beginning and frankly, am at a loss as to WHY there hasn't been more discussion. This area (and much of coastal NSW) was devastated during summer 2020/21 by bushfires + subsequent flooding rains, landslides etc. Many families of course lost their homes, but much more concerningly, was the evaporation of international tourism, which is our, and many other Australian communities' bread and butter. By early 2020, many businesses were lost, families had broken up and all the other impacts on mental health the APS know well. We still hadn't washed the ash off our windows (this is not hyperbole) when this thing called "COVID" rolled into town.

Fast-forward to mid-2021 and the situation is extremely dire. The borders remain closed, so for the last 18 months, local businesses have worked their utmost to build appeal to Australian tourists within the confines of COVID rules - not an easy feat, but desperation certainly drives ingenuity. The streets and businesses prior to each school holidays are pristine, brimming with energy and hope, since those school holidays are the only thing that can keep them afloat. Yet by excruciating coincidence, lockdowns have commenced immediately prior to or within each major holiday period. Xmas 2020 with Northern Beaches, Easter 2021 and finally the July school holidays which, for so many, has been the final straw. Many clients have shared it's like living in a horror movie; yet as I try to work the impossible to support them, silently I agree.

We now have a group of Year 1s, that we refer to as the "Covid Kindies" who are the most stressed and anxious cohort of 6-year-olds I've come across. These are the children whose 2020 entry into formal school was severely compromised as it commenced immediately post the 6-month fire season and just as a worldwide pandemic began. Most already had higher anxiety than normal due to extremely stressed parents, then to add salt to the wound, were not allowed the usual and very important transition with parents on campus etc due to COVID restrictions. Soon after, they were thrown into a period of home-schooling with teachers whose stress-levels were also skyrocketing. You must have seen this 20-fold in Melbourne with your extended lockdowns.

What's finally got me writing is that last week, the only physical piece of mail I received was a fridge magnet and flyer (with balloons and streamers) from the local bottle shop, reassuring folk not to worry because they would deliver during lockdown. We're seeing sky-high rates of active addiction (new and returning) around the world, increases in suicide, self-harm, DV, PTSD in small kids, not to mention the huge increase in PND, which we know is one of primary factors in poor long term mental health outcomes. Yet nobody is talking about this much at all .. and people should be screaming by now. Sure, the government are putting a few extra $$ into Medicare for MH, but 6+4 (even with the "bonus" COVID 10) is not going to scratch the surface. We're talking decades and decades (and decades) of long-term negative mental health outcomes, in fact potentially way beyond that according to the Intergenerational Transfer of Trauma folk as well as via DNA according to Jablonka et al.

Yes, COVID is an emergency situation with a terribly contagious virus and, from the reading I've done (which is a lot), Delta is even more contagious. YET … there are many noted medical professionals around the world explaining

that while COVID is deadly threat for a portion of the population (the elderly / immune compromised, obese etc) it poses almost no threat to children or healthy working aged folk. There will always be the rare outliers when we're dealing with population level stats (e.g., a 25 yr old who tragically contracts COVID and dies.. but let's not forget the 25 year old who tragically gets the vaccine and dies VAERs). What I would like to see openly and publicly debated very loudly is how many are dying in this country from COVID compared to how many have and will die from the horrific effects of lockdowns. Surely we can isolate and protect those vulnerable, without creating a tsunami of mental health crisis? It actually seems absurd – likely a "can't see the wood for the trees" scenario.

This is an incredibly important conversation which I'm yet to see taken up with the seriousness it deserves. If I've missed one please send me links / papers immediately. From what I've seen, anyone speaking out is either thrown in with the "conspiracy theorists" or "antivaxxers" and immediately ridiculed. Please can you start an open discussion on this, the APS hold the expertise to be hosting an open and public forum.

With hope, yours sincerely,

Ros Nealon-Cook

Annexure 4

COVID CALAMITY

ROS NEALON-COOK

TO

AUSTRALIAN CHILDHOOD FOUNDATION (ACF)

30 JULY 2021

From: Ros Nealon-Cook
Sent: Friday, 30 July 2021 11:30
To: Australian Childhood Foundation <support@childhood.org.au>; info@childhood.org.au <info@childhood.org.au>
Subject: COVID Calamity

Dear Joe & ACF,

I want to raise a serious concern regarding impact on community mental health from lengthy lockdowns, and seemingly lack of concern re the long-term consequences for our country. I appreciate very much the report you wrote last August however, unless I'm mistaken, it's gathering dust with all other reports written in such manner and issues need to be raised again.

As a psychologist working primarily with children and families and residing in a tourist community, I've been beyond concerned about MH outcomes since the beginning and frankly, am at a loss as to WHY there hasn't been more discussion. This area (and much of coastal NSW) was devastated during summer 2020/21 by bushfires + subsequent flooding rains, landslides etc. Many families of course lost their homes, but much more concerningly, was the evaporation of international tourism, which is our, and many other Australian communities' bread and butter. By early 2020, many businesses were lost, families had broken up and all the other impacts on mental health we know well, especially on children. We still hadn't washed the ash off our windows (this is not hyperbole) when this thing called "COVID" rolled into town.

Fast-forward to mid-2021 and the situation is extremely dire. The borders remain closed, so for the last 18 months, local businesses have worked their utmost to build appeal to Australian tourists within the confines of COVID rules - not an easy feat, but desperation certainly drives ingenuity. The streets and businesses prior to each school holidays are pristine, brimming with energy and hope, since those school holidays are the only thing that can keep them afloat. Yet by excruciating coincidence, lockdowns have commenced immediately prior to or within each major holiday period. Xmas 2020 with Northern Beaches, Easter 2021 and finally the July school holidays which, for so many, has been the final straw. Many clients have shared it's like living in a horror movie; yet as I try to work the impossible to support them, silently I agree.

We now have a group of Year 1s, that we refer to as the "Covid Kindies" who are the most stressed and anxious cohort of 6-year-olds I've come across. These are the children whose 2020 entry into formal school was severely compromised as it commenced immediately post the 6-month fire season and just as a worldwide pandemic began. Most already had higher anxiety than normal due to extremely stressed parents, then to add salt to the wound, were not allowed the usual and very important transition with parents on campus etc due to COVID restrictions. Soon after, they were thrown into a period of home-schooling with teachers whose stress-levels were also skyrocketing. You must have seen this 20-fold in Melbourne with your extended lockdowns.

What's finally got me writing is that last week, the only physical piece of mail I received was a fridge magnet and flyer (with balloons and streamers) from the local bottle shop, reassuring folk not to worry because they would deliver during lockdown. We're seeing sky-high rates of active addiction (new and returning) around the world, increases in suicide, self-harm, DV, PTSD in small kids, not to mention the huge increase in PND, which we know is one of primary factors in poor long term mental health outcomes. Yet nobody is talking about this much at all .. and people should be screaming by now. Sure, the government are putting a few extra $$ into Medicare for MH,

but 6+4 (even with the "bonus" COVID 10) sessions aren't going to scratch the surface. We're talking decades and decades (and decades) of long-term negative mental health outcomes, in fact potentially way beyond that according to the Intergenerational Transfer of Trauma folk as well as via DNA according to Jablonka et al.

Yes, COVID is an emergency situation with a terribly contagious virus and, from the reading I've done (which is a lot), Delta is even more contagious. YET … there are many noted medical professionals around the world explaining that while COVID is deadly threat for a portion of the population (the elderly / immune compromised, obese etc) it

poses almost no threat to children or healthy working aged folk. There will always be the rare outliers when we're dealing with population level stats (e.g., a 25 yr old who tragically contracts COVID and dies.. but let's not forget the 25 year old who tragically gets the vaccine and dies VAERs). What I would like to see openly and publicly debated very loudly is how many children's mental health are being severely compromised on top of how many are dying in this country from COVID compared to how many have and will die from the horrific effects of lockdowns. Surely we can isolate and protect those vulnerable, without creating a tsunami of mental health crisis? It actually seems absurd – likely a "can't see the wood for the trees" scenario.

This is an incredibly important conversation which I'm yet to see taken up with the seriousness it deserves. From what I've seen, anyone speaking out is either thrown in with the "conspiracy theorists" or "antivaxxers" and immediately ridiculed. Please can you start an open discussion re the impact of long term on our children (let alone the rest of us); ACF hold the expertise IMHO to be hosting an open, public and very vocal forum. We're way beyond writing reports and IMHO, folk are now too despondent to read anything beyond their side of the now highly polarised media.

Ros Nealon-Cook

Integrated Kids

Ros Nealon-Cook Assoc MAPS, FMCHC
PBA Registered Psychologist PSY0001410196
IFM Accredited Functional Medicine Health Coach

Restore Healthcare Clinic: 69 Megalong Street, Katoomba NSW 2780
PO Box 7137, Leura NSW 2780
T: +61 (02) 4742 0078
www.integratedkids.com.au

Annexure 5

BIU RAPID ADVICE TO INCREASE COMPLIANCE WITH COVID CHECK-IN BEHAVIOURS

INFORMATION RELEASED UNDER THE GOVERNMENT INFORMATION PUBLIC ACCESS ACT (2009) - GIPA-00036-2022

NSW GOVERNMENT

22 AUGUST 2022

BIU rapid advice to increase compliance with COVID check-in behaviours

Business based interventions

Insight 1. Harness social norms and highlight compliance surveillance

- Providing businesses with a relevant comparison to encourage compliance can prompt a movement towards the norm.[1] However, this should be targeted towards businesses that have been identified as falling short of the average compliance rates and should compare businesses in similar industries.
  How
  - Use simple comparisons personalised by industry and/or geographic area. Provide a visual representation of this to help businesses see where they fall; e.g. a graph to depict proportion of COVID check-ins compared with the average.
    - *"Your COVID-19 check-ins are lower than similar businesses in your area."*
  - Harness the surveillance effect to make the consequences salient and appear more likely
    - *"We've noticed your COVID-19 check ins are low. Here's some advice on how to improve uptake..."*
    - *"Our inspectors are targeting businesses - so far have issued x many fines to businesses in your area / like yours"*
    - *"According to our x records, you should have more customer check in etc".*

Insight 2. Help businesses create environmental cues

- Encourage use of QR codes by directing customers to them with salient, visual cues. Visual reminders in the environment can have a larger and cheaper impact than displaying written instructions (this has been effectively used with social distancing markers).[2] This is particularly effective in those venues where checking-in is not an existing norm and a new habit needs to be formed.
  How
  - Provide businesses with 'way finders', to provide visual cues for customers (e.g. stickers on the ground to direct customers to check in points, hanging signs to signpost 'check in here').
  - Provide advice to businesses on how these should be displayed. For example, in larger venues, such as supermarkets or shopping centres, multiple QR codes with hanging 'check in here' signs above them can be used to help people find check-in points, without creating a bottleneck at the entrance.

- Maximise the likelihood of customer check-ins by placing QR codes at points most customers visit, while avoiding crowding
  How
  - Place QR codes at tills, as well as entrances – any point where people may be waiting e.g. escalators, bathrooms, change rooms.
  - Provide businesses with visual examples of effective placement of check-ins at similar businesses, including floor plans with check-in points marked, and photos.

Insight 3. Make it easier for businesses to comply

- Help businesses set up their QR codes
- **How**
  - Provide rules of thumb on the number of posters a business should have up based on the number of customers they have each day, or the size of their venue.
  - Consider an option for businesses who might have trouble printing a QR code – a direct link to send the QR code to a printing company, with printed documents sent back to the business.
  - Frame the QR check in as an easy way to be compliant with COVID regulations, framed as a way to avoid having to do paperwork – "*There is not much paperwork involved, it's an automatic way for you to make sure you've completed reporting correctly*."

- Provide guidance on how to encourage customer compliance
  How
  - Distribute short videos on how staff can prompt customers. Our insight data tells us that high % of respondents use QR codes 'when need to' – for some, prompting by staff will prompt people to sign in.

[1] Janine Bialecki et al., "Improving Tax Compliance: Deductions for Work-Related Expenses Other Uses," 2018, https://www.pmc.gov.au/domestic-policy/behavioural-economics/improving-tax-compliance-.
[2] "Physical Distancing," 2020, https://doi.org/10.1177/0013916512466094.

- Distribute clips that show staff dealing with challenging customers – real and specific examples in particular industries (e.g. café)

Insight 4. Design attractive incentives

- Start a daily lottery for businesses who make it easy for customers to check-in
  How
  - For each QR code displayed at a business, the business gets a ticket in the prize draw (this would be as a proportion of business size so that smaller businesses aren't disadvantaged) – inspectors can verify the winners.
  - Businesses in industries that have been heavily impacted by COVID, or those where check-in rates are low (e.g. hairdressers) automatically get e.g. 10x the number of entries in the draw.

- Reward compliant businesses by making compliance public, and desirable
  How
  - Show consumers the estimated proportion of check-ins to customers for each business (similar to a health and safety rating at a business). Customers are then likely to attend businesses that have a high proportion of check-ins, encouraging businesses to comply.
  - This could be visually depicted in a 'heatmap', which displays a colour coded 'COVID-safe' map, based on the estimated compliance level of each business.

Customer based interventions

Insight 5. Make it fun and provide incentives for customer check-ins

- Incentivise safe check-in with a 'check-in lottery'. However, these must be designed in a way to reduce the risk of incentivising excessive, unnecessary check-ins.
  How
  - Provide customers with an instant prize that's tied to a genuine motivation to visit a venue e.g. $2 discount at till, but only if you can show attendant that you've checked in.
  - Entry into lottery is then validated by person at till when the customer is paying – e.g. each venue has a unique verification code that gets scanned when paying.

- Pair the scanning of a QR code immediate non-financial benefit or admission requirement
  How
  - After scanning customers see a pop-up 'word of the day' or 'fun fact'. Customers should be encouraged to share these 'fun facts' with friends to encourage social networks to check-in.
  - Suggest stores make check-in an admission requirement - access to self-service tills / payment not possible at tills of stores unless check-in is validated by store attendant.

Insight 6. Provide personalised feedback

- Providing relevant feedback on customers' compliance with check-in regulations can help to correct non-compliant behaviour.
  How
  - Ask customers of the Service NSW application to estimate how many businesses they've visited in the past week/month. Then, show customers how many check-ins they've completed, with a score on their compliance based on their estimate.
  - A shorter timeframe is ideal (e.g. estimates for the previous week rather than the previous month), as recall is more accurate and immediate feedback is better than delayed feedback.

Insight 7. Launch a 'Mental model' campaign

- A campaign could illustrate how contact tracing has worked using QR codes. This would emphasise both the benefit to the customer and the benefit to business.
  How
  - Show a 'journey map' or a visual depiction of how QR codes lead to fast contact tracing, giving people a mental model of seeing their action in context.
  - Emphasis should be placed on the speed of tracking that the QR code system helps us achieve – "*QR codes help us outrun the speed of the virus".*
  - Share stories that link fast tracking to help businesses stay open "*we caught this early, so we were able to reopen right away*."

Annexure 6

PRESENTING COVID-19 VACCINATION INFORMATION – BEHAVIOURAL INSIGHTS

INFORMATION RELEASED UNDER THE GOVERNMENT INFORMATION PUBLIC ACCESS ACT (2009) - GIPA-00036-2022

NSW GOVERNMENT

23 AUGUST 2022

An updated advisory from the NSW Behavioural Insights Unit

Overview

- Based on the current state-wise sentiment on vaccinations, 48% of people report they would get vaccinated as soon as eligible, 36% report they might get vaccinated, while 16% report they would 'probably' or 'definitely not' get vaccinated.
- The key behavioural barriers can be summarised as: **convenience**, **complacency** and **confidence**.
- The content and presentation of information can address these behavioural barriers by applying the behavioural insights presented in the advice below. Further research with citizens could help us prioritise these insights and actions.

Confidence: Building trust about effectiveness and safety

Concern over the safety and effectiveness of the vaccine is a significant barrier to take up. Communications should build public trust in the vaccine and correct dangerous misinformation. Note that vaccine hesitancy data will continue to evolve as the vaccine is rolled out and we must avoid assumptions based on international data.

INSIGHT 1. Correct misinformation and manage the illusory truth effect. When providing facts about the vaccine or correcting misinformation avoid repeating any misinformation. Presenting information on the myth can reinforce false beliefs and create the illusion of truth because people tend to mistake familiarity with truth.[1] For example, a 'myths vs. facts' flyer increased the misbelief that vaccines cause autism compared to a flyer which contained only the 'fact' infographics about vaccines.[2]

How to apply to information resources:

- Provide key facts about the vaccination to replace common myths and avoid re-stating or referring to myths, even while disputing them.
- Ensure the facts are clear, presented in multiple languages, and are easy to understand. People are less likely to take in new information when it appears complicated. This is particularly important given that those who report they would not get vaccinated tend to have lower health literacy.[3]

Convenience: Making it easy to get vaccinated

Small frictions to learning about and accessing the vaccine can significantly affect uptake, even among those who intend to get vaccinated. Communications can reduce these frictions to help people follow through on their intention.

INSIGHT 2. Help people overcome the intention-action gap. Presenting information and a case for vaccination is not enough to make people follow through with it. Small frictions can get in the way of people following through with behaviours that they fully intend on completing. Removing frictions and making booking and attending both vaccinations

[1] S Lewandowsky et al., "The Debunking Handbook 2020," 2020, https://doi.org/10.17910/b7.1182.
[2] Sara Pluviano, Caroline Watt, and Sergio Della Sala, "Misinformation Lingers in Memory: Failure of Three pro-Vaccination Strategies," *PLoS ONE* 12, no. 7 (2017), https://doi.org/10.1371/journal.pone.0181640.
[3] Dodd, Rachael et al., "Willingness to Vaccinate against COVID-19 in Australia."

easy is key to ensuring high vaccination rates. In addition, setting clear expectations about what to expect can help people plan how they might overcome any barriers and successfully follow through with their intentions.

How to apply to information resources:

- Include a **booking platform** or link to one on the COVID hub.
- Display 'vaccination venues' close to the user.
- Give users the option to be notified of their appointment via email, sms or ServiceNSW app.
- Give users the option to sign up to be notified of the public availability of the vaccination.
- Provide the customer with key information about the practical features of the vaccination process – such as easy to follow travel routes to reach the location, the average wait time.
- Provide practical, sequential, next steps, which are easy for the customer to follow through and act.

INSIGHT 3. Avoid information overload. Providing too much information can be overwhelming. When too much information is presented, people can become overwhelmed and tend to only take in that which confirms what they've seen elsewhere.

How to apply to information resources:

- Select one or two key points that will encourage the desired behaviour change.
- The information that is most important to facilitate behaviour should be presented first, we're more likely to remember what we see first.
- During the rollout, on the landing page of the hub, pair other COVID-safe behaviours with vaccination to reinforce the ongoing need for them regardless of a vaccine.
- Use short sentences and avoid long paragraphs, opt for bullet points instead.
- While additional and more detailed information may be required for those with specific questions found in a different page of the website or accessible via dropdown menu or link.
- Remove generic information about the priorities of health officials, systems etc. and only include information that a customer will want.

INSIGHT 4. Change the default by framing vaccination as the status quo, and frame not being vaccinated as an intentional choice "if you choose to not be vaccinated"**.** We have a tendency to prefer to do nothing rather than taking action (known as omission bias), changing the default to having the vaccine can help reframe being vaccinated as the norm.

How to apply to information resources:

- Frame vaccination as the status quo: "*When are you getting vaccinated? Pick a date today."*
- Assume that visitors of the site are there because they want to be vaccinated – display a 'thank you' message that acknowledges they're taking the first step to getting vaccinated.

Complacency: Managing low risk perception and motivating vaccination

As COVID-19 cases remain low so does the perceived risk. Communications should ensure this does not lead to complacency towards getting the vaccine.

INSIGHT 5. Harness loss aversion. Framing something as a loss tends to have greater impact than framing it as a gain. This can be strengthened by framing *not* being vaccinated as an intentional choice, as we are more likely to regret something when framed as an active choice.[4]

[4] Marcel Zeelenberg et al., "The Inaction Effect in the Psychology of Regret," *Journal of Personality and Social Psychology* 82, no. 3 (2002): 314–27, https://doi.org/10.1037/0022-3514.82.3.314.

How to apply to information resources:

- Highlight what the individual is losing by being unvaccinated – loss of freedom, loss of an opportunity that Australians have been afforded, loss of priority positions in being vaccinated ahead of others.
- Tap into the personal 'ownership' or right to the vaccine by framing the vaccine as being 'reserved' for individuals. E.g. for eligible cohorts *"you have a vaccine reserved for you"*.

INSIGHT 6. Help people understand their relative risks. Many people struggle to appreciate how unlikely rare events are, and favour risks associated with not acting compared with acting. This means that we wrongly calculate our risks from side effects of vaccination as higher than risk of serious illness from COVID-19. People tend to be more open to known risks compared to unknown risks.[5] This means that some people may avoid the new vaccination because of perceived risk of the unknown.

How to apply to information resources:

- When discussing risks, use the absolute percentage (i.e. 0.000004%) rather than 1 in 250,000. We find it easier to imagine ourselves as the '1' so perceive the risk expressed this way as greater.
- Help individuals contextualise risk by comparing it to other risks.
- Use personal framing around the risk of not being vaccinated to make it more tangible, e.g. *"how would you cope with weeks of feeling unwell due to COVID-19, unable to go to work or care for your family?"*. This could be made specific to certain cohorts.

INSIGHT 7. Manage optimism bias. The motivation to get vaccinated may be low for those who don't perceive they are at risk of catching or getting seriously unwell due to COVID-19.[6] The personal risk and the risk to others of not getting vaccinated can help to increase the intention to get vaccinated.

How to apply to information resources:

- Provide key facts about how the virus has lasting impacts even after recovery.
- Provide a simple visual of the importance of widespread vaccinations – "*We're not safe until we're all vaccinated*".

INSIGHT 8. Manage rationalisation. With the roll out of the vaccine, people may falsely believe that there is no longer any risk.[7] This may result in a reduction of other COVID-safe behaviours such as mask wearing and social distancing.

How to apply to information resources:

- Use visuals to display the vaccination as part of a toolbox of protection, along with masks and social distancing.
- Images and photos of vaccinations occurring should show both medical professional and patient wearing a mask.

[5] Paul K. J. Han et al., "Communication of Scientific Uncertainty about a Novel Pandemic Health Threat: Ambiguity Aversion and Its Mechanisms," *Journal of Health Communication* 25, no. 5 (2018): 435–44, https://doi.org/10.1080/10810730.2018.1461961.
[6] Taehwan Park et al., "Optimistic Bias and Preventive Behavioral Engagement in the Context of COVID-19," *Research in Social and Administrative Pharmacy* 17, no. 1 (January 1, 2021): 1859–66, https://doi.org/10.1016/j.sapharm.2020.06.004.
[7] Michael Hallsworth and Alison Buttenheim, "Challenges Facing a COVID-19 Vaccine: A Behavioural Science Perspective," Behavioural Scientist, 2020, https://behavioralscientist.org/challenges-facing-a-covid-19-vaccine-a-behavioral-science-perspective/.

INSIGHT 9. Explain safety information in plain English. Customers who may be concerned about the safety of the vaccine should hear practical, plain English messages about the rigour involved in its development, and its safety. Avoid using scientific terms and jargon.

How to apply to information resources:

- Provide plain English explanation about how the vaccine is approved, with a question, answer style presentation to help readers digest the information e.g.:
  - *"How are vaccines approved?"*
  - *"How were the vaccines developed so quicky? – Scientists have been working on this vaccine since the SARS outbreak, and for these vaccines we cut out the time we would have spent waiting for funding and approvals, but keep all the medical, scientific and government steps required for development".*

INSIGHT 10. Use the messenger effect. Trusted members of society can help to promote the vaccine and model COVID-safe behaviours.

How to apply to information resources:

- Share stories of health professionals who have been vaccinated.
- When providing medical information, reference trusted health bodies.
- Use community connections to leverage non-health messengers, such as in religious, cultural, sporting groups etc.

INSIGHT 11. Harness social norms. Building a social norm that vaccination uptake is widespread and accepted by the majority of Australians/New South Welshmen can help increase the intentions to get vaccinated.[8] Descriptive norms that demonstrate that most people are, or want to get vaccinated are particularly effective when the social groups are similar to ourselves.

How to apply to information resources:

- Display a tracker with the number of vaccinations provided across NSW – show a visual map of this (this has been done in Canada).
- Encourage people to share that they've been vaccinated on social media.
- Show that trusted members of the public have been vaccinated, e.g. *"95% of nurses in NSW have been vaccinated".*
- Create stickers, badges or other visual indicators that people can display to show they have been vaccinated.

Other considerations Ongoing management of vaccination communication

INSIGHT 12. Managing rollout and wait times. There must be a consistent and transparent message about the intended rollout phases, without these, the public may become distrustful and disillusioned. There should be a clear explanation and display of each of the vaccination phases to avoid confusion in roll out order

How to apply to information resources:

[8] Jeff French et al., "Key Guidelines in Developing a Pre-Emptive COVID-19 Vaccination Uptake Promotion Strategy," *International Journal of Environmental Research and Public Health* 17, no. 16 (August 13, 2020): 5893, https://doi.org/10.3390/ijerph17165893.

- Display a visual schedule of each of the phases in the rollout, a list of groups that are part of each phase.
- Highlight the social benefits of vaccinating front line workers/the elderly first.
- Emphasise that other COVID-safe behaviours will be required regardless of the vaccination.

INSIGHT 13. Gather evidence. While behavioural insights can be applied to improve websites and communications, what works in one setting doesn't always apply to others. Visitors to the website can provide valuable feedback on the effectiveness of the site

How to apply to information resources:

- Consider using a 'feedback widget' to collect information on visitors' likelihood to get vaccinated.
- Use simple A/B testing to test different version of the website and collect feedback from visitors to test what works best.

Additional Resources Where else to go for help

- Report of the sage working group on vaccine hesitancy.
- Behavioural considerations for acceptance and uptake of COVID-19 vaccines: WHO technical advisory group on behavioural insights and sciences for health, meeting report, 15 October 2020.
- COVID-19 vaccines: what can we learn from a French experiment in care homes?
- The COVID-19 Communication and Community Engagement HUB

Annexure 7

COVID-19 FLYER TRIAL

NSW BEHAVIOURAL INSIGHTS UNIT (BIU), THE MINISTRY OF HEALTH (MOH), SYDPATH AND WESTERN SYDNEY LOCAL HEALTH DISTRICT (WSLHD), AND NSW MULTICULTURAL HEALTH COMMUNICATION SERVICE

APRIL 2021

COVID-19 Flyer Trial

Executive results

NSW Behavioural Insights Unit (BIU), the Ministry of Health (MoH), SydPath and Western Sydney Local Health District (WSLHD), and NSW Multicultural Health Communication Service

April 2021

Agenda

01 Executive summary

02 Methods and results

03 Implementation

Section 1

Executive Summary

COVID-19

JUST GOT TESTED FOR COVID-19?

Thank you for getting a COVID-19 test

Go straight home. You must self-isolate until you get your test result. Don't share a room or bathroom with anyone, if possible.

Self-isolation means you must not go to the shops, work, the gym, any public places, or have people over at your home or catch public transport.

Read tips on self-isolation

How do I get my test results?

- We understand this may be a stressful time. You will usually get your COVID-19 result within 24-72 hours.
- If you don't receive your result after 72 hours, follow up with the clinic where you were tested.
- If you registered for an SMS service, you will receive an SMS result.
- If your COVID-19 test is positive, a public health official will contact you as a priority and tell you what to do next. You might be contacted from a private number so please pick up private calls when waiting to hear back about test results. Any treatment costs will be waived, even if you don't have a Medicare card or insurance.

Still have questions?

Call the National Coronavirus Health Information line **1800 020 080** or visit **www.nsw.gov.au/COVID-19**

Don't forget to follow NSW Health on **Twitter**, **Facebook** and **Instagram** for important updates and live information.

I was a close contact of a confirmed COVID-19 case BUT my test is negative

A close contact means you were near a person with COVID-19 while they were infectious, and have a reasonable chance you were infected with COVID-19.

- **IF YOU'RE A CLOSE CONTACT, YOU MUST SELF-ISOLATE EVEN IF YOUR COVID-19 TEST IS NEGATIVE AND YOU ARE FEELING WELL AND HAVE NO SYMPTOMS.**
- You need to self-isolate until 14 days after you last saw the confirmed COVID-19 case or attended a location where that person visited.
- Home isolation for close contacts is enforceable under the Public Health (COVID Self-Isolation) Order (No 3) 2020. Not following these rules is a criminal offence and attracts heavy penalties.
- Read more information on close contacts.

My COVID-19 test is negative AND I no longer have symptoms

If your test is negative and you are not a close contact of a confirmed COVID-19 case, you do not need to self-isolate further. You should continue to watch for COVID-19 symptoms, and if you get symptoms again, get re-tested.

My COVID-19 test is negative AND I still feel unwell

If you're still feeling unwell, you should talk to your GP. If your symptoms become serious (e.g. shortness of breath at rest or difficulty breathing), you should call Triple Zero (**000**).

Remember: if you feel unwell again with even the mildest of symptoms – don't go out, don't see family or friends – get re-tested.

Help and support is available – Speak to a counsellor 24/7

Lifeline **13 11 14** lifeline.org.au or Beyond Blue **1800 512 348** counsellingcloud.beyondblue.org.au

What's the behaviour we want to change?

Previous NSW Health brochure was about **education**. Yet busy people have trouble with too much information (information overload)

As it stands, the NSW public can take multiple actions as a result of the flyer

We were asked to improve behaviour on self-isolation

If the public only does one thing after getting tested, what do they have to do?

A behaviourally-informed patient briefing process and postcard shifts COVID behaviours

1. New A5 multilingual postcard

Salience of highly desired behaviour

2. Enhanced patient briefing process

Simplification
Break down information into easy steps

Address scarcity mindset
Use practical examples of how to plan ahead, for busy people who feel unprepared for self-isolation

Multilingual and graphics convey meaning
Four key languages of LHD on double-sided postcard

- ✓ **Script with call to action**
  Staff provided with quick, standard instructions on self-isolation that mirror the postcard
- ✓ **Teach-back checklist**
  - ❑ Patients asked to repeat key actions from the postcard, and told where to get help
  - ❑ Teach-back ensures clinic staff don't assume patients' understanding and ability to action directions ('health literacy'), and provides opportunity to ask questions and clarify self-isolation issues
  - ❑ Checklist ensures staff don't miss hearing key information (error management)

Additional info from current flyer accessible via **QR code** (manage the experts)

Timeliness
Clear directions provided at the optimum time.
Reinforce 24-hour result is worth the short wait (temporal discounting)

Section 2

Methods and Results

We tested the impact of our behavioural intervention on reported self-isolation and the number of times people left home while awaiting test results

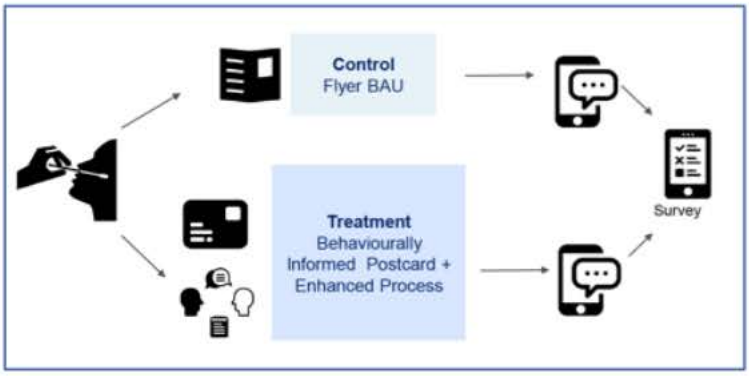
Aim: Increase self-isolation while awaiting test results

9 testing clinics from Western Sydney Local Health District (WSLHD)

4 benchmarking sites in Western Sydney

Valid responses: 10.4% **(n = 7,888)**

Measuring *self-reported* self-isolation. For ethical reasons, we only surveyed people who received negative COVID-19 results



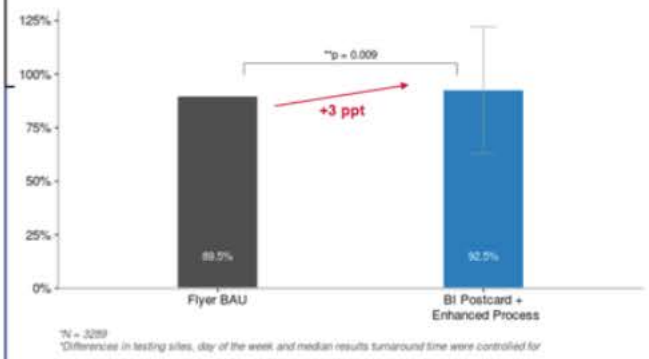
NSW GOVERNMENT

 Behavioural Insights Unit 7

The behaviourally informed postcard and enhanced briefing process is successful: people more likely to report they self-isolated correctly

Key Finding

Percentage of people who reported self-isolating at home during waiting period by conditions



N = 3289
Differences in testing sites, day of the week and median results turnaround time were controlled for

Of the ~8000 survey respondents: We reached the majority not outliers: the intervention did not reduce average number of times people left home (25 of ~3,300 patients left home 3 to 30 times)

Application

Based on **7,000 daily tests**, the Behaviourally Informed Postcard and Enhanced Process could see **1,470 more people** self-isolating correctly at home **each week**, than current practice

Process was stress-tested during Avalon outbreak (9.4/10 satisfaction rating)

- ✓ **Simplified** and **salient** instructions
- ✓ Teach-back **encourages questions** and **allows understanding to be checked** by trusted messenger
- ✓ Scripts and checklists give staff easy and **consistent process** to apply to every patient

NSW GOVERNMENT

 Behavioural Insights Unit 8

Strong customer satisfaction and high compliance with COVID-safe behaviours - reinforce our messages

High customer satisfaction with testing

Satisfaction remained high during outbreak & increased test volume

Satisfaction remained high during outbreak

- **9.4/10 average service rating**
- Intervention did not impact customer satisfaction, even during outbreak
- **3,104 positive comments**
- Staff appreciation, ease of test, thanking process
- **1,219 negative comments**
- Time in line/ self-isolating, test discomfort
- **36% would wait more than 24 hours to get retested**
- Motivation to test may be lower as vaccine rollout proceeds. Communicate that results are quick & experience is positive. Continue to improve process

"The staff at the clinic were absolutely wonderful. They went above and beyond to make me feel comfortable and safe." (Benchmark site, pre-trial)

"Amazing that 60,000 tests could be processed in under 24 hours. An amazing service. Thank you!" (Trial site, post-Avalon)

Behavioural Insights Unit 9

Section 3

Implementation

10

We have integrated our self-isolation postcard with NSW Health Pathology results flyer

Combined COVID-19 results and self-isolation flyer

Getting your COVID-19 result

NSW GOVERNMENT

Step 1: You can register in one of the following ways

Register using your personalised QR code:

- Scan the QR code using your mobile phone camera.
- A text message with your details will appear. Do not make any changes.
- Press send.
- You will receive a confirmation text message, which will include your unique reference code.

This QR code contains your personal details. It cannot be used by anyone else.

Or register via text message:

If you have not been provided a personalised QR code or cannot scan it, text 'my result' to:

0480 050 021

and follow the steps to register.

Or register via Service NSW:

Register using the Service NSW QR code or go to service.nsw.gov.au/transaction/register-your-covid-19-test-result

If you were tested by a GP or private pathology, contact your doctor for your result.

Step 2: Self isolate

- Go straight home and self isolate until you get your result, unless advised otherwise by NSW Health. Don't stop off along the way.
- Even if you don't feel sick stay home. Most people get their results in 24 hours.
- If you need groceries or other essentials, ask family or a friend to drop off what you need. Ask them to leave the goods at the front door.
- If you need to pick up your children, ask another parent or family member to drop them home.

More information:

Call the National Coronavirus and COVID-19 Vaccine Helpline on 1800 020 080 or visit www.nsw.gov.au/COVID-19. **In an emergency call Triple Zero (000) for an ambulance.**

For free help in your language call 13 14 50.

PRIVACY COLLECTION NOTICE

GOVERNMENT

Rollout across NSW in **mid-June 2021**

Teach–back implementation

Clinic leads say:

- Staff and patients were positive
- Teach-back took similar time to BAU
- Process worked well

"It was more personalised interaction and it worked great"

"Nice to have consistency, with all doing the same. Didn't matter which staff member did the information, it was good to have the same education across the board"

"It was easier than going off the top of your head… There was less room for miscommunication"

"As soon as your study was over most of us kept continuing to do it"

State-wide roll out end June 2021:

- ✓ **Implementation** of new flyer and teach-back
- ✓ Use the short **training video**
- ✓ Incorporate teach-back in **daily huddle**

Behavioural Insights Unit 11

Annexure 8

Index
Reference L
Question on Notice
Answer

Reference TT
Question on Notice
Answer

Opinion
Legal Ramifications for Registered Health Practitioners And AHPRA Public Officers Re The AHPRA and the National Boards joint statement of 9 March 2021

A Note to International readers:
This is an Opinion created in Australia, a member of the Commonwealth. Commonwealth laws are often reflective of one another, as such, this Opinion could prove to provide guidance in other Commonwealth nations.

1. On 9 March 2021 AHPRA released a joint statement with the National Boards (***the March statement***):

   https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx

2. The statement is an expression by AHPRA and the National Boards of their 'expectations of registered health practitioners', to fully assist with the national vaccination rollout program, while advising that any statements made by practitioners contrary to the government's public health response, and by implication, government messaging, 'may be subject to regulatory action' by AHPRA and the National Boards, with the implied and explicit presumption being, any contrary statements would be deemed 'anti-vaccination messages' or 'anti-vaccination claims'.

3. The statement goes on to say:

   As the national vaccination program gets underway, registered health practitioners and students remain critical to this success by:
   - *being vaccinated against Covid-19 unless medically contraindicated*

- *being appropriately qualified and trained to administer Covid-19 vaccines if authorised, and*
- providing accurate information and advice about Covid-19 vaccination including in social media and advertising.

And further we find:

'.. all registered practitioners have a key role to play by ensuring they provide accurate, evidence-based information to patients about Covid-19 vaccination.
…

'There is no place for anti-vaccination messages in professional health practice, and any promotion of anti-vaccination claims including on social media, and advertising may be subject to regulatory action.'

(emphasis added)

4. From the outset it should be clear that the joint statement is about 'expectations' of conduct, in so far as that conduct concerns the national Covid-19 vaccination program which has from the outset been a Federal government campaign the State and Territory governments implemented, and in turn further promoted or indeed mandated.

5. In short, AHPRA and the National Boards had via this joint statement, sought to conscript health practitioners to implement a national Covid-19 vaccination program, which AHPRA and the National Boards 'expected' no health practitioners to question, under threat of reprisals.

6. But the *Health Practitioner Regulation National Law ('the **National Law**')* governing registered Health Professionals does not empower AHPRA or National Boards to direct Health Professionals to administer experimental drugs without questioning the need, known safety, or known efficacy of any such drugs; nor does the ***National Law*** empower AHPRA or National Boards to forbid Health Professionals from expressing their expert views with their patients about the need, known safety, or known efficacy of an experimental drug national governments seek to promote in the community. Indeed patients seek out Health Professionals to understand drugs being promoted to them from any source. When that promotion is coming from government about a new experimental drug, then in an environment bereft of any conclusive clinical or historical data on the actual safety and efficacy and risks associated with such a drug, it becomes incumbent upon Health Professionals to share the best information they possess on any such drugs, with their patients and the community.

7. These duties to share information with patients and the community are in fact found within the ***National Law*** itself.

8. To understand this we must walk through the ***National Law*** to see what powers are available to AHPRA and National Boards, then understand those powers in the context of the duties owed by Health Professionals to their patients and community.

9. For this task I shall use the Queensland version of the ***National Law*** shown here:

> **HEALTH PRACTITIONER REGULATION NATIONAL LAW (QUEENSLAND) - As at 6 December 2021 - Act hprnlq of 2009**

10. From the outset we must note in **Section 3A** that the ***Paramount guiding principle*** of the ***National Law*** is:

> '.. that the health and safety of the public are paramount.'

11. Next, the Ministerial Council under **Section 11** has the power over AHPRA and National Boards to:

> '.. give directions to a National Board about the policies to be applied by the National Board in exercising its functions under this Law.'

12. The Ministerial Council is now called the Health Ministers Meeting (HMM). A search was conducted to locate any policy directive from the HMM to AHPRA and National Boards to prepare and release the March statement. No such directive from the HMM

can be located, therefore it can only be assumed AHPRA and the National Boards are responsible for the March statement.

13. Turning then to **Section 30** we find the power in AHPRA to decide 'policies':

> '**Functions of Agency Management Committee**
>
> (1) The functions of the Agency Management Committee are as follows—
> (a) subject to any directions of the Ministerial Council, to decide the policies of the National Agency'

(Note: the National Agency is the formal title given to AHPRA under the ***National Law***. The Agency Management Committee is the internal management committee within AHPRA.)

14. Nowhere does AHPRA assert the March statement is a 'policy' of AHPRA.

15. AHPRA is required to publish all official Policy Directions and guidance on its website, and record them in its Annual Report. In the 2020-2021 Annual Report covering the period during which the March statement was released, we find that AHPRA made no record seeking to place the March statement forward as an official policy.

16. As such, the March statement at its highest can only be called a 'joint statement' or 'position statement' published by AHPRA and the National Boards.

17. This means the March statement holds no special legal nature or force, nor does it appear possible to call the March statement a 'legislative instrument' or 'subordinate legislation'. Instead, the March statement appears to be nothing more than support for the national Covid-19 vaccination program, where in terms, it seeks to state on behalf of Australian governments 'what is expected' of registered practitioners.

18. However the problem for AHPRA and the National Boards is that the March statement directly conflicts with the Codes of Conduct for Health Professionals, particularly

where a significant body of peer-reviewed literature and studies inform expert Health Professionals of dangerous outcomes associated with the use of Covid-19 vaccines, while presenting significant data to evidence Covid-19 vaccines do not prevent transmission nor repeated reinfection with SARS-CoV-2.

See for instance the comprehensive report by Dr Phillip Altman: *The Time of Covid*, released in Australia, August 2022, forming **Annexure 9**.

19. Additionally, expert Health Professionals in Australia have been observing historically unprecedented numbers of adverse event reports submitted in relation to the Covid-19 vaccines, where after 18 months of their deployment in Australia, Covid-19 vaccines have recorded more adverse event reports than those collectively submitted during the prior 50 years of adverse event reporting in Australia.

See for instance the comprehensive report by Lisa Mitchell forming Appendix B to the report by Dr Phillip Altman: *A COMPARISON OF ADVERSE EVENTS RELATED SPECIFICALLY TO THE Covid-19 VACCINES AND NON-Covid-19 VACCINES FROM 1 JAN 1971 TO 31 DEC 2021*, being specific to Australia, forming **Annexure 2**.

20. Codes, or more specifically, ***Codes of Conduct*** as they ultimately become named, are a responsibility of National Boards under the ***National Law***, as seen with **Section 39**, which states:

> '**39 Codes and guidelines**
>
> A National Board may develop and approve codes and guidelines—
>
> (a) to provide guidance to the health practitioners it registers'

21. The functional purpose of ***Codes of Conduct*** is again reinforced under **Section 35(1)(c)(iii)** which states:

'**35 Functions of National Boards**

(1) The functions of a National Board established for a health profession are as follows—
(c) to develop or approve standards, codes and guidelines for the health profession, including—
(iii) the development and approval of codes and guidelines that provide guidance to health practitioners registered in the profession'

22. The *Code of Conduct* for Australian doctors contains very clear professional and ethical responsibilities that directly aid to serve the ***Paramount guiding principle*** contained in **Section 3A**, being again: *the health and safety of the public are paramount*.

23. In contradistinction with the March statement by AHPRA, relevant parts of the ***Code of Conduct*** for doctors read (in-part, emphasis added):

> **1.1 Purpose of the code**
>
> ***Good medical practice*** **(the code)** describes **what is expected of all doctors registered to practise medicine in Australia**. It sets out the principles that characterise good medical practice and **makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers** and the community.
>
> **1.2 Use of the code**
>
> **Doctors have a professional responsibility** to be familiar with Good medical practice and **to apply the guidance it contains**.
>
> This code will be used:
>
> - to assist the Medical Board of Australia in its role of protecting the public, by setting and maintaining standards of medical practice against which a doctor's professional conduct can be evaluated. If your professional

conduct varies significantly from this standard, you should be prepared to explain and justify your decisions and actions. Serious or repeated failure to meet these standards may have consequences for your medical registration

2.1 Professional values and qualities of doctors

Doctors have a duty to make the care of patients their first concern and to practise medicine safely and effectively. They must be honest, ethical and trustworthy.

Doctors have a responsibility to protect and promote the health of individuals and the community.

2.2 Public comment and trust in the profession

While there are professional values that underpin good medical practice, **all doctors have a right to have and express their personal views and values.**

3.1 Introduction

In clinical practice, **the care of your patient is your primary concern.**

3.2 Good patient care

Maintaining a high level of medical competence and professional conduct is essential for good patient care. Good medical practice involves:

3.2.4 **Considering the balance of benefit and harm in all clinical-management decisions.**

3.2.6 Providing treatment options **based on the best available information**.

3.2.7 **Only recommending treatments when there is an identified therapeutic nee**d and/or a clinically recognised treatment, **and a reasonable expectation of clinical efficacy and benefit for the patient**.

4.5 Informed consent

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved. Good medical practice involves:

4.5.1 **Providing information to patients in a way they can understand before asking for their consent.**

4.6 Children and young people

Caring for children and young people brings additional responsibilities and challenges for doctors. Good medical practice involves:
4.6.1 **Placing the interests and wellbeing of the child or young person first.**

4.11 Adverse events

When adverse events occur, **you have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately.**

8.3 Doctors' performance – you and your colleagues

8.3.3 **Taking steps to protect patients from risk posed by a colleague's conduct, practice** or ill health.
8.3.5 **Complying with any statutory reporting requirements, including mandatory reporting requirements under the National Law as they apply in your jurisdiction**.
9.2 Continuing professional development

9.2.1 **Keeping your knowledge and skills up to date.**

10.12 Conflicts of interest

Patients rely on the independence and trustworthiness of doctors for any advice or treatment. A conflict of interest in medical practice arises when a doctor, entrusted with acting in the interests of a patient, also has

financial, professional or personal interests, or relationships with third parties, which may affect their care of the patient.

10.12.4 **Recognising that pharmaceutical and other medical marketing influences doctors and being aware of ways in which your practice may be being influenced.**

13.2 Research ethics

13.2.6 Ensuring that human participation is voluntary and based on an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research.
13.2.8 Seeking advice when research involves children or adults who are not able to give informed consent, to ensure that there are appropriate safeguards in place.
13.2.10 Monitoring the progress of the research and promptly reporting adverse events or unexpected outcomes.

This code is issued under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

24. It is worthy of brief mention at this juncture the *Australian Charter of Healthcare Rights* owed to patients, which relevantly reads (in-part):

> Information
> Clear information about my condition, the possible benefits and risks of different tests and treatments, so I can give my informed consent

25. ***Codes of Conduct*** created by the various National Boards are required to be published on each National Board's website, pursuant to section 40.

26. Critically, and pursuant to **Section 41**, ***Codes of Conduct*** created and approved under the ***National Law***, are admissible in proceedings under the ***National Law*** against a registered practitioner, *as evidence of what constitutes appropriate professional conduct or practice for the health profession*.

27. The evidential weight afforded to the ***Codes of Conduct*** in turn directly assist National Boards when investigating registered practitioners, pursuant to **Section 35(1)(g)** and **(h)** of the ***National Law***:

> '**35 Functions of National Boards**
>
> (1) The functions of a National Board established for a health profession are as follows—
>
> (g) to oversee the assessment and investigation of matters referred to it

by the National Agency about persons who—

(i) are or were registered as health practitioners in the health profession under this Law or a corresponding prior Act;

(h) to establish panels to conduct hearings about—

(i) health and performance and **professional standards matters** in relation to persons who are or were registered in the health profession under this Law or a corresponding prior Act' (emphasis added)

28. The evidential weight and importance afforded to the Codes of Conduct is further reinforced by their use and reference under the Mandatory notifications sections of the National Law, where the definition of notifiable conduct at **Section 140(d)** reads:

'**140 Definition of notifiable conduct**

In this Division—

"notifiable conduct" , in relation to a registered health practitioner, means—

(d) placing the public at risk of harm by practising the profession in a way that constitutes a significant departure from **accepted professional standards**.' (emphasis added)

29. Recall, the March statement by AHPRA and the National Boards is not a formally adopted 'policy' of AHPRA, nor did the March statement change any of the ***Codes of Conduct*** for registered practitioners. Furthermore, there are no provisions of the ***National Law*** that state any bare statements such as the March statement, override any ***Codes of Conduct***, just as we find there are no provisions of the ***National Law*** that state any such bare statements are admissible in proceedings against a registered practitioner, *as evidence of what constitutes appropriate professional conduct or practice for the health profession.*

30. To this end the March statement can be broken down into its simplest elements, being:

    a) AHPRA and the National Boards support the national Covid-19 vaccination program;

    b) As such, AHPRA and the National Boards 'expect' health practitioners to also support the Covid-19 vaccination program;

    c) Which expectation was accompanied by a threat: '*There is no place for anti-vaccination messages in professional health practice, and any promotion of anti-vaccination claims including on social media, and advertising may be subject to regulatory action.*';

    d) Which threat was subtly qualified by recognition of the ***Codes of Conduct***: *'all registered practitioners have a key role to play by ensuring they provide accurate, evidence-based information to patients about Covid-19 vaccination.'*

31. Despite the 'expectations' and 'threats' coming from AHPRA and the National Boards, the March statement clearly defaults to give due recognition to the primacy of adherence with ***Codes of Conduct***, by all health practitioners being, to *provide accurate, evidence-based information to patients about Covid-19 vaccination.*

32. At this point it must be made clear that National Boards and AHPRA owe their existence to the 2008 ***Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions***. This agreement is between the governments of all Australian States, Territories, and the Commonwealth. As such, no one single Australian government is directly responsible for the existence of National Boards and AHPRA, they are all equally responsible. Therefore AHPRA and each National Board hold a unique status for being a 'Federated Body' created pursuant to a national intergovernmental agreement.

33. Since these Federated Bodies exist due to each Australian State and Territory government enacting essentially identical forms of the ***National Law,*** within their respective jurisdictions, the ***National Law,*** so enacted within each State or Territory, is directly amendable to be referenced and interpreted by each State or Territory's equivalent version of an *Acts Interpretation Act*, or *Interpretation Act*. These Acts assist with providing guidance for better interpreting legislation and for better understanding the importance of certain instruments, standards, or codes, subsequently produced by powers granted under legislation, for 'making rules' in the future, being rules or standards or codes not contained within the original legislation. The ***Codes of Conduct*** subsequently created by National Boards under the ***National Law*** are of this nature. Legally speaking, the *Codes* can also be called subordinate legislation, or statutory rules.

34. In light of the fact ***Codes of Conduct*** are admissible *as evidence of what constitutes appropriate professional conduct or practice for the health profession*, ***Codes of Conduct*** must necessarily be deemed to be statutory rules, in so far as they prescribe minimum levels of conduct and practice to be observed by a health practitioner, in order to be legally deemed an 'appropriately professional' practitioner.

35. In New South Wales there is the *Interpretation Act* of 1987, which sets forth in **Sections 39** through **43** the powers and procedures to be observed when making statutory rules. It does appear that National Boards like the Medical Board of Australia have failed to observe their statutory duties under the Interpretation Act, to publish their Codes of Conduct on the NSW legislation website, and then table a written notice of the making of their Codes of Conduct before each House of Parliament within 14 sitting days: see

section 40. These failures however do not invalidate the ***Codes of Conduct***: see **Section 40(4)**. Generally speaking, (and not wishing to investigate every State and Territory equivalent of NSW's *Interpretation Act)*, it can be fairly surmised that all National Boards have similarly failed to properly publish on respective government legislation websites their ***Codes of Conduct***, and equally have not laid a 'notice' before relevant Houses of Parliament in each State and Territory.

36. However all the National Boards have published their ***Codes of Conduct*** on their respective websites, where they came into 'effect' on the day they were published:

> Medical: https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code- of-conduct.aspx
>
> Psychology: https://www.psychologyboard.gov.au/Standards-and-Guidelines/Code-of-conduct.aspx
>
> Nursing and Midwifery: https://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards.aspx
>
> The remaining 12 Boards – ***Shared Code of Conduct***: https://www.ahpra.gov.au/Resources/Code-of-conduct/Shared-Code-of-conduct.aspx

37. As a consequence of the powers, processes, and procedures given to and observed by National Boards in the creation, publication, and enforcement use of ***Codes of Conduct***, it appears to be beyond question that these ***Codes of Conduct*** created and referenced 'as evidence' of what constitutes acceptable professional practice, are properly to be deemed as statutory rules, which gives them paramountcy as subordinate legislation before any Court of law. Although it is a Commonwealth Act, it is worth noting also that the *Legislation Act 2003* (Cth) defines a legislative instrument in **Section 8** as follows:

> '**Definition of legislative instrument**

(1) A ***legislative instrument*** is an instrument to which subsection (2), (3), (4) or (5) applies.

Note: Instruments that can be legislative instruments may be described by their enabling legislation in different ways, for example as regulations, rules, ordinances or determinations.

(4) An instrument is a ***legislative instrument*** if:
the instrument is made under a power delegated by Parliament; and
any provision of the instrument:
…
(ii) has the direct or indirect effect of … **imposing an obligation**, creating a right, or varying or removing an obligation or right.'
(emphasis added)

The *Note* to **Section 8(1)** above can also be read to include *Codes* and ***Codes of Conduct***. **Section 8(4)** 'imposing an obligation' speaks directly to ***Codes of Conduct*** imposing legal obligations upon registered practitioners, particularly when read again in the context of **Section 41** of the ***National Law***, where they are more clearly understood as legal obligations that serve as evidence of what constitutes appropriate professional conduct or practice for the health profession.

38. In light of the foregoing analysis and conclusion, the following statements hold true at law:

a) The legislative status of the ***Codes of Conduct*** have always prevailed over and before the legally hollow March joint statement;

b) Any aspect of the March joint statement that conflicts with any aspect of a ***Code of Conduct*** is invalid and of no effect;

c) To the extent any conduct 'expected' of registered practitioners as directed under the March joint statement, could or would cause a practitioner to conduct themselves in a manner that would cause them to contravene a ***Code of Conduct***, such 'expectations' were and are invalid and of no effect;

d) The threat of 'regulatory action' against a practitioner for any promotion of claims, including on social media, contrary to the public (government) health response to Covid-19, including Covid-19 vaccination, was always repugnant at law, where such a threat acted as a coercive measure capable of intimidating a practitioner to not fully and completely observe every tenet of their ***Code of Conduct***;

e) While every practitioner has to generally observe public health obligations towards disease control (Medical Code 7.4), those obligations must be read along with all other obligations and responsibilities imposed upon them by their ***Codes of Conduct***, including that they were at all times required to be providing accurate, evidence-based information to patients about Covid-19 vaccination, both before and after the March statement;

f) Every practitioner possessed of evidence-based information capable of reasonably supporting ***claims against any material aspect*** of Covid-19 vaccination, as a possible treatment for SARS-CoV-2 infection, where any such claims ***could materially affect the risk-benefit analysis to be performed by a patient*** prior to their giving Informed Consent to a Covid-19 vaccine, has always remained information a practitioner is required to provide to patients pursuant to their ***Code of Conduct***;

g) Every practitioner possessed of evidence-based information ***capable of reasonably supporting claims against any material aspect*** of Covid-19 vaccination, as a possible treatment for SARS-CoV-2 infection, has always remained entitled to communicate such information via social media or the media, when the presentation of the evidence-based information is done professionally and in accordance with their ***Code of Conduct***.

39. Using again the Medical Board of Australia ***Code of Conduct*** as a point of reference,

and in light of the evidence-based information ('the information') contained in the reports of Dr Phillip Altman and Lisa Mitchell referenced above, every registered practitioner responsible for the provision of a Covid-19 vaccination is required to:

a) Keep their knowledge up to date (Code 9.2.1), which is especially relevant in respect of any provisionally approved Covid-19 vaccine still the subject of Clinical Trials.

b) Be honest and ethical in their appraisal of the information for the protection and promotion of the health of individuals and the community (Code 2.1), in the knowledge all doctors have a right to have and express their personal views and values (Code 2.2). Knowing the care of your patient is your primary concern (Code 3.1) and based upon this best available information (Code 3.2.6), consideration must be given towards the balance of benefit and harm (Code 3.2.4) in respect of Covid-19 vaccination, against whether there is an identified therapeutic need, and a reasonable expectation of clinical efficacy and benefit for the patient (Code 3.2.7).

c) Additionally, a practitioner possessed of the information, is required to provide the information to patients in a way they can understand before asking for their consent (Code 4.5.1) to receive a Covid-19 vaccine, where the information provided enables a patient to understand the benefits and risks involved (Code 4.5). This is so and particularly in respect of children and young people, towards whom a practitioner must place the interests and wellbeing of a child or young person first (Code 4.6.1).

d) When providing the information to patients in a way they can understand before asking for their consent (Code 4.5.1), a practitioner must be careful not to censor or withhold the information due to any conflict of interest they may have, due to their (where relevant) professional relationship with government public health authorities, whose interests could seek to affect a practitioner (Code 10.12), with respect to the information they provide to a patient to enable them to understand the benefits and risks involved (Code 4.5) with Covid-19 vaccination.

e) Should a practitioner be provided fully informed consent to administer a Covid-19 vaccine, after providing all the information needed to properly and reasonably understand the benefits and risks involved, and should after administering the Covid-19 vaccine an Adverse Event occur, the practitioner has the responsibility to be open and honest in their communication with the patient, to review what has occurred and to report appropriately (Code 4.11).

f) Should a practitioner observe another practitioner they know to be aware of the information, fail to properly assess the information, and/or fail to provide the information to a patient in a way they can understand before asking for their consent (Code 4.5.1) to receive a Covid-19 vaccine, where had the information been provided it would have enabled the patient to understand the benefits and risks involved (Code 4.5), then the first practitioner must take steps to protect the patient from the risk posed by the second practitioner's conduct and practice (Code 8.3.3), and the first practitioner must report the second practitioner pursuant to the mandatory reporting requirements under the ***National Law*** (Code 8.3.5 and Section 141 of the ***National Law***).

g) Lastly and perhaps most importantly, the information now available in respect of the Covid-19 vaccines which must be critically evaluated by all registered practitioners, must be considered along with the acknowledged fact that Covid-19 vaccines are only ***provisionally*** approved, meaning they are still globally the subject of Clinical Trials which now incorporate entire national populations, which necessarily requires practitioners to deem the use of these vaccines as '***research involving humans***' (Code 13.1), requiring the observance of research ethics and responsibilities drawn from National Health and Medical Research Council guidelines (Code 13.2).

h) Due to (g) above, a practitioner must ensure their patient is aware they are, by extension, taking part in ***research on humans*** with respect to the Covid-19 vaccine being considered for administration, where the practitioner must establish the patient is taking part in the research on a voluntary basis, based

upon an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research into the Covid- 19 vaccine (Code 13.2.6). When imparting and discussing this knowledge and information about the research with their patient, a practitioner must act with honesty and integrity (Code 13.2.2) for respecting and protecting their patient (Code 13.2.1). A practitioner must acknowledge and share with their patient that the practitioner is assisting with recruiting the patient into research involving humans (Code 13.2.7). In the event all of the foregoing considerations and responsibilities have been satisfied and observed, and a patient provides their fully informed consent and is administered a Covid-19 vaccine, a practitioner must continue to monitor the progress of their patient after administering the Covid-19 vaccine, and promptly report any adverse events or unexpected outcomes (Code 13.2.10).

40. It is now August 2022, and still the March statement of 2021 continues to strike fear into Health Professionals, primarily due to AHPRA very publicly and repeatedly subjecting doctors and Health Professionals to the regulatory actions they threatened would occur, should any practitioner seek to present claims or statements at odds with the public health messaging about Covid-19 vaccines. These public health messages issue primarily from Australian governments, politicians, and bureaucrats, many of which politicians and bureaucrats are not registered health practitioners, which places their actions and statements beyond any legal scrutiny under the ***National Law***, by reference to ***National Law*** subordinate legislation, the ***Codes of Conduct***.

41. Instead, and in simple terms, the March statement of 2021 without any legal basis or force of genuine law, managed to silence and 'gag' registered practitioners from speaking out against the wholly one-sided narrative issuing from Australian governments, concerning SARS-CoV-2 and Covid-19 vaccines.

42. This has resulted in a virtual absence of open scientific and medical discussion, debate, or dialogue concerning the medical and scientific literature that has been emerging throughout 2021 and 2022, a now enormous body of peer-reviewed literature and data

specifically focused on SARS-CoV-2 and the Covid-19 vaccines, as seen collected in the reports of Dr Altman and data expert Lisa Mitchell (Annexures 1 & 2).

43. As a consequence:

a) this has led to a ***negligent and gross absence*** of directly relevant information being provided to millions of Australians, for the purpose of their being able to provide fully-informed ***Informed Consent***, prior to the receipt of these acknowledged experimental treatments.

b) this has led to an abundance of misinformation and misunderstanding about SARS-CoV-2 and Covid-19 vaccines.

c) this has led to a denial of directly relevant information being shared and spread throughout the medical and scientific community, which for medical and health professionals, is information needed by them in order to discharge their legal obligations under the ***National Law***, pursuant to their ***Codes of Conduct***.

d) this has led and caused gross breaches of the ***National Law*** by virtually all registered practitioners who have administered, and who continue to administer, Covid-19 vaccines.

e) And as corollary, this has led to failure of ***mandatory notification*** reporting of registered practitioners, being provisions under the ***National Law*** meant to serve as additional protection measure for the Australian public, which has further derogated and magnified the ***gross and negligent*** failings to afford the Australian people directly relevant information registered practitioners are legally obligated to provide, for the purpose of their patients providing fully-informed ***Informed Consent***, prior to the receipt of these acknowledged experimental treatments.

44. Registered health professionals now in possession of the information annexed to this opinion are, in furtherance of the observance of their ***Codes of Conduct***, required to professionally consider the information with scientific objectivity, for the careful

consideration of their legal responsibilities to comply with their ***Codes of Conduct***, as detailed in paragraph 39(a)-(h) above, or potentially face investigation for complaints received from the general public, or mandatory notifications lodged by other registered practitioners calling for their investigation under the ***National Law***, for professional misconduct.

45. When giving due and professional consideration to the information annexed to this opinion, registered practitioners must be mindful of what constitutes *unprofessional conduct*. Unprofessional conduct is intimately associated with a failure to observe ***Codes of Conduct***, where 'a contravention by [a] practitioner of the ***National Law***' does include a contravention of a ***Code of Conduct***, as **Section 41** clearly stipulates (see paragraph 26 above). **Section 5** of the ***National Law*** sets forth the definition of *unprofessional conduct*, and reads (in-part):

> '**"unprofessional conduct"** , of a registered health practitioner, means professional conduct that is of **a lesser standard than that which might reasonably be expected of the health practitioner by the public** or the practitioner's professional peers, and includes—
>
> (a) **a contravention by the practitioner of this Law**, whether or not the practitioner has been prosecuted for, or convicted of, an offence in relation to the contravention; and
>
> (d) **providing a person with health services of a kind that are excessive, unnecessary or otherwise not reasonably required for the person's well-being**'
> (emphasis added)

46. Despite the forgoing legal analysis, it is expected that many registered practitioners will seek to avoid regulatory action from AHPRA. Practitioners possessed of the type of information annexed to this opinion can simply avoid any regulatory action by desisting from the provision of Covid-19 vaccines, where no detailed public explanation is required. Practitioners who choose to publicy share the information with their patients

and community will risk regulatory action from AHPRA. To date AHPRA has ostensibly relied upon **Section 156** which reads:

> **'156 Power to take immediate action**
>
> (1) A National Board may take immediate action in relation to a registered health practitioner or student registered in a health profession for which the Board is established if—
>
> (a) the National Board reasonably believes that—
>
> (i) because of the registered health practitioner's **conduct**, performance or health, the practitioner poses a serious risk to persons; and
>
> (ii) it is necessary to take immediate action to protect public health or safety'

47. Generally speaking, (where this opinion is not the proper place to discuss legal defences to an action brought under **Section 156**), practitioners seeking to resist an *Immediate Action* will need to carefully compile the evidence-based information that supports any public statement or claim made against Covid-19 vaccines, or in respect of SARS-CoV-2. The information annexed to this opinion is amply referenced to adequately assist. While a clear and repeated articulation by a practitioner defending such an action of their legal responsibilities as derived from their ***Code of Conduct***, as contained in this opinion, will serve as a proper legal basis and defence when supported by evidence-based information.

48. Broadly stated, any public office holders and bureaucrats in possession of the information annexed to this opinion, who would seek to withhold such evidence-based information from registered practitioners, will arguably find themselves publicly liable for gross *misfeasance* for acting in 'bad faith'. Generally stated, public officers and their departments are often afforded immunity from civil actions, but immunity is lost to a public officer and their department when they can be shown to have acted in 'bad faith': see for instance **Section 61A** of the *Therapeutics Goods Act* (Cth) and **Section 236** of the ***National Law***. While further still, a public officer can become personally exposed and personally liable to various forms of civil claims by members of the public,

if they can be shown to have acted outside the scope of their employment duties, when seeking to withhold evidence-based information from registered practitioners, and possibly, where shown to have withheld evidence-based information from the public.

Misfeasance in Public Office – Legal Ramifications for AHPRA Public Officers

49. For this section of the opinion much content and analysis will be drawn from the paper by Emeritus Professor Mark Aronson, *Misfeasance in Public Office: A Very Peculiar Tort*.[1]

50. Before proceeding it should be acknowledged that National Boards and in particular AHPRA[2], are enormously well resourced both financially and in terms of staffing, especially in respect of legal services, and particularly for obtaining legal advices in respect of contemplated actions, like the March 2021 joint statement.

51. The elements of the common law *action* of misfeasance are discussed by Aronson in the following paragraphs.

52. In *Farrington v Thomson*,[3] Smith J:

> 'proposed an action for damages for misfeasance in public office where the public officer .. caused damage to the plaintiff by 'an act which, to his knowledge, amounts to an abuse of his office''[4]

53. This 'abuse of office' aspect is often referred to as 'the illegality issue'.

54. Since *Farrington* four later cases added:

[1] Referenced page number will refer to the PDF version: https://law.unimelb.edu.au/__data/assets/pdf_file/0006/1703517/35_1_1.pdf ; web version here: http://classic.austlii.edu.au/au/journals/MelbULawRw/2011/1.html

[2] https://www.ahpra.gov.au/Publications/Annual-reports/Annual-Report-2021/Finance.aspx

[3] [1959] VR 286

[4] Aronson: page 19.

> ‘a third alternative to the mental elements of misfeasance. They reasoned that there was no moral difference between knowing something on the one hand, and being aware of its possibility but not caring whether it might be true or might occur.[5] This third variant is generally referred to as reckless indifference, but it is not to be imputed — the defendant must have consciously adverted to the relevant circumstance or risk and decided not to care about it.’[6]

55. Aronson clarifies the Australian approach to this third element of reckless indifference:[7]

> ‘.. currently, the reckless indifference requirement applies only to the illegality issue, and not to the risk of harm.[8] The harm must have been foreseeable, but the defendant need not have adverted to its risk.[9]’

56. Addressing the further issue of *bad faith* briefly mentioned in paragraph 48 above, Aronson provides clarification with the following:[10]

> ‘In a much-quoted passage, Brennan J said in *Mengel* that the core of misfeasance lay in ‘the absence of an honest attempt to perform the functions of the office’.[11] His Honour said that there was such an absence if the defendant had acted invalidly and with malice, knowledge or reckless indifference, and he may well have intended that list to be exhaustive.
> There are passages in *Three Rivers* that could be interpreted as requiring

[5] *Mengel* (1995) 185 CLR 307, 347 (Mason CJ, Dawson, Toohey, Gaudron and McHugh JJ), 359 (Brennan J); *Three Rivers* [2003] 2 AC 1, 196 (Lord Steyn), 223 (Lord Hutton), 231 (Lord Hobhouse), 236 (Lord Millett); *Odhavji* [2003] 3 SCR 263, 283 (Iacobucci J for McLachlin CJ, Gonthier, Iacobucci, Major, Bastarache, Binnie, Arbour, LeBel and Deschamps JJ); *Garrett* [1997] 2 NZLR 332, 349 (Blanchard J for Richardson P, Gault, Henry, Keith and Blanchard JJ).
[6] Aronson: page 20.
[7] Aronson: page 22.
[8] *South Australia v Lampard-Trevorrow* (2010) 106 SASR 331, 387–8 [263]–[265] (Doyle CJ, Duggan and White JJ).
[9] Ibid 387–8 [263]–[264].
[10] Aronson: page 22.
[11] *Mengel* (1995) 185 CLR 307, 357.

proof of dishonesty or bad faith as an additional element in all cases.[12] In Australia, proof that defendants knew that they were acting beyond power is all that is needed to establish bad faith.[13]'
(emphasis added)

57. The office holders within AHPRA meet the definition of 'public officers' for the tort of misfeasance to be applicable to them. As Aronson states:[14]

> 'Brennan J referred to an old definition of public officers, which in essence contained two elements. First, they must have been appointed to perform a public duty. Secondly, they must be remunerated, although that may come in the form of money or land from the Crown, or fees from the public.[15]'

58. In the case of AHPRA fees come from registered practitioners and are supplemented by government contributions from time to time.

59. With the above commentary and examination of the law of misfeasance by Aronson, we can return now to the AHPRA March statement to make the following observations.

60. Sections within the joint March publication clearly contain statements wholly inconsistent with ***Codes of Conduct***, (statutory rules), being statements coercing and threatening registered practitioners not to follow and closely observe their ***Codes of Conduct***, under threat of regulatory action, where the clear directive was to comply at all costs with the rollout of the Covid-19 national vaccination program, where the wording is beyond any ambivalence:

---

[12] [2003] 2 AC 1, 246 [41]–[42] (Lord Hope), 267 [121] (Lord Hutton), 289 [175] (Lord Hobhouse), 290–1 [179]–[182] (Lord Millett).
[13] *Federal Commissioner of Taxation v Futuris Corporation Ltd* (2008) 237 CLR 146, 153 [11] (Gummow, Hayne, Heydon and Crennan JJ).
[14] Page 42.
[15] *Mengel* (1995) 185 CLR 307, 355, referring to *Henly v Lyme* (1828) 5 Bing 91, 107–8; 130 ER 995, 1010 (Best CJ).

> ‘All practitioners, including students on placement, **must comply** with local employer, health service or health department policies, procedures and guidelines on Covid-19 vaccinations.’
> (emphasis added)

61. This coercion coupled with threats is the ‘illegality issue’. At no time were the public officers of AHPRA or the National Boards empowered to lawfully coerce or threaten registered practitioners, let alone threaten registered practitioners to not observe their statutory rules (***Codes of Conduct***). AHPRA and the National Boards coerced and threatened registered practitioners to break the ***National Law*** for which AHPRA and National Boards were created to implement and uphold including, implicitly, the ***Codes of Conduct*** created under the ***National Law***. In consequence the March statement can only be deemed as an illegal act and abuse of power by the public officers of the National Boards, and AHPRA. Using the analysis in paragraphs 54, 55, and 56 above, it can be stated AHPRA and the National Boards were ‘recklessly indifferent’ to this abuse of power. That the March statement does not avert to the risks to Australians from having registered practitioners not observe their ***Codes of Conduct*** does not assist AHPRA or the National Boards, as the risks to Australians were foreseeable.

62. As a consequence, it does appear grounds exist for persons injured by Covid-19 vaccines, or the families of those who died from Covid-19 vaccines, to sue the various public officers within AHPRA and the National Boards responsible for the March statement, in actions of misfeasance in public office.

63. The March statement had the real and consequent effect of intimidating practitioners responsible for the administration of Covid-19 vaccines, to not stringently observe their ***Codes of Conduct*** in similar terms as detailed in paragraph 39 above, resulting generally, in millions of Australians not being fully-informed for the purpose of their being able to provide Informed Consent, where had they been fully-informed many persons (perhaps in the thousands or millions), may have clearly ***chosen to not*** receive an experimental Covid-19 vaccine, for a plethora of reasons, many of which arise from the evidence-based information.

64. The evidence-based information was not being shared by practitioners with patients, nor government health authorities who were in possession of the evidence-based information as it was emerging throughout 2021, commensurate with the rollout of the Covid-19 vaccines. Such evidence-based information has always remained a duty of the ***Therapeutic Goods Administration*** (TGA) to collect as soon as it becomes available, as part of its ongoing Pharmacovigilance duties owed to the Australian public. The departments of health within each State and Territory government have similar ongoing duties to collect and disseminate such evidence-based information. A question arises beyond the scope of this opinion, whether the continued failures by the TGA and relevant departments of health to disseminate to registered practitioners the abundance of evidence-based information merging throughout 2021 and 2022, is not yet another instance of misfeasance in public officers, capable of separate legal actions.

65. A separate though relevant issue when suing public officers for misfeasance also requires mention. Since only AHPRA *as a body* could issue the March statement, then it could be shown no individual within AHPRA can be held accountable for misfeasance, which begs the question whether AHPRA as a body would be directly liable in misfeasance for the harm it caused to Covid-19 vaccine victims.[16] On this issue Aronson observes:

> 'In many misfeasance cases, however, only individual staff members will be directly liable because causal responsibility and the requisite mental states resided only in them. The issue then becomes whether the public bodies for which they worked can be fixed with vicarious liability
>
> .. There have long been difficulties in formulating the basis of vicarious liability for deliberately illegal conduct committed without the employer's de facto authority or ratification. The difficulties increase when the primary tortfeasors act in their own interests and against those of their employers[17]

[16] See Aronson page 44 and supporting case law.
[17] Page 45.

.. The High Court has not explored the issue, but its analysis in *Mengel* of the tort's structure and principles proceeded on the premise that 'ordinarily', individual misfeasance tortfeasors would receive no indemnity or contribution from their employing authorities.[18]'

66. With respect to the March statement, it can be said the public officers of AHPRA acted in the interests of Federal, State, and Territory governments seeking to implement a national Covid-19 vaccination program. But AHPRA was not created to serve national government's interests and desires to vaccinate the Australian public. The paramount guiding principle for AHPRA has always been and first 'the health and safety of the public', and 'to facilitate the provision of high quality education .. of health practitioners'. Therefore it does appear that AHPRA as a body could be deemed by a Court as not being vicariously liable for the March statement, leaving then liability only with those AHPRA public officers responsible for the March statement, who acted beyond AHPRA's stated statutory objectives and functions, by intimidating, coercing, and threatening registered practitioners with regulatory action, if they did not cease their full and proper observance of their ***Codes of Conduct***, demanding instead they act without comment or criticism while assisting Australian national governments with a vaccination program, using acknowledged experimental drugs.

67. To this end and brief mention should be made of the common law *offence* of misfeasance, discussed by Aronson as follows:[19]

'The common law *offence* covers acts or omissions of public officers in the course of or in relation to their public office, which amount to misconduct with a degree of culpability that warrants public condemnation and criminal punishment.[20] Speaking for the Hong Kong Court of Final Appeal,

[18] Page 46

[19] Aronson: page 19.

[20] This is an amalgam drawn from *R v Dytham* [1979] QB 722; *R v Bowden* [1996] 1 WLR 98; *A-G's Reference* (No 3 of 2003) [2005] QB 73; *Sin Kam Wah v Hong Kong Special Administrative Region* [2005] 2 HKLRD 375; *R v Quach* (2010) 201 A Crim R 522; Nicholls et al, above n 89, 66–71.

> Sir Anthony Mason NPJ said that whether the misconduct is sufficiently culpable depends on whether it is serious 'having regard to the responsibilities of the office and the office-holder, the importance of the public objects which they serve and the nature and extent of the departure from those responsibilities.'[21]
> (emphasis added)

68. As mentioned above again in paragraph 66, the paramount guiding principle for AHPRA has always been 'the health and safety of the public', and 'to facilitate the provision of high quality education .. of health practitioners'. The illegal departure from observing that principle as evidenced in the March statement, where the foreseeable risks to Australians included death, illnesses, and injuries arising from the experimental Covid-19 vaccines, given to them with a near absence of relevant evidence-based information for being fully-informed for providing Informed Consent, appears to be *sufficiently culpable* conduct and actions to warrant serious consideration towards bringing actions for the common law ***offence*** of misfeasance, against the public officers of AHPRA and the National Boards responsible for the March statement of 2021.

69. Lastly, and as alluded to in paragraph 43 above, registered practitioners who failed to fully observe their ***Codes of Conduct*** when administering Covid-19 vaccines, now stand grossly exposed to significant liability with respect to patients who subsequently suffered adverse effects or death causally due to these drugs. Should such lawsuits and liability be established in such practitioners, then those practitioners sued by their patients could arguably seek to in turn sue the public officers of AHPRA and the National Boards responsible for the March 2021 statement, with the common law action of misfeasance, for the damages arising from patient lawsuits. The degree of success for such actions in misfeasance Re registered practitioners versus AHPRA public officers, will likely be moderated in terms of the contributory negligence of practitioners in failing to observe foremost their ***Codes of Conduct***, despite the illegalities and threats and coercion contained in the March 2021 statement.

[21] *Sin Kam Wah v Hong Kong Special Administrative Region* [2005] 2 HKLRD 375, 391 [45].

Julian Gillespie LLB, BJuris Peter Fam LLB

15 August 2022

Annexure 9

Index
Reference P
Question on Notice
Answer

SUBMISSIONS TO THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH – THERAPEUTIC GOODS ADMINISTRATION TO AMEND THE SCHEDULING OF IVERMECTIN – DELETION OF APPENDIX D, ITEM 10 FROM THE CURRENT S4 POISONS SCHEDULING

26 SEPTEMBER 2022

SUBMISSIONS BY (collectively the 'Co-Signatories'):

Australian Medical Network
Australian Medical Professionals Society
Prof Wendy Hoy, FAA, AO, FRACP, MBBS, BScMed
Emeritus Prof Robert Clancy, AM,BSc(Med), MBBS,PhD DSc, FRACP, FRCP(A), FRS(N)
Prof Philip Morris, AM, MBBS, BSc(Med), PhD, FRANZCP, FAChAM(RACP)
Prof Geoff Taylor (retd.), MSc, Grad.Dip.Bus.Admin, CFAIHS
Prof Ian Brighthope, MBBS, Dip.Ag.Sci, FACNEM, FACHM
Assoc/Prof Christopher Neil, MBBS, FRACP, PhD **Assoc/Prof**
Michael Sladden, MBChB, MAE, MRCP, FACD
Assoc/Prof Peter Parry, MBBS, PhD, FRANZCP, Cert.Child.Adolesc.Psychiatry
Dr Robyn Cosford (retd.), MBBS(Hons), FACNEM, FASLM
Mr Christopher Paul Bellhouse (retd. anaesthetist/intensivist),MBBS,FFARACS, FANZCA
Dr Andrew McIntyre, MBBS(Hons), FRACP
Dr Shirley Prager, MBBS, FRANZCP
Dr Michael Taylor, MBBS,MHSM,DipMDT,Grad.Cert.Clin.Res.Meth,FRACGP,FACRRM, FACEM
Dr Varghese Zachariah, FRACGP, DCH, AFMCP
Dr My Le Trinh, MBBS, FRACGP, DCS
Dr Sarah "Sally" Price, MBBS,FRACGP,DipRACOG,Grad.Dip.PrimaryCare,FACNEM, FASLM
Dr Paul Oosterhuis, MBBS, FANZCA
Dr Robert Brennan, BSc, BHSc(Hons1), MBBS
Dr Duncan Syme, MBBS, FRACGP, DROCG, Dip.Prac.Dermatology (Cardiff) **Dr Jeyanthi Kunadhasan**, MD(UKM), MMED(UM), FANZCA, MMED(Monash) **Dr Annemarie Ward**, MBBS, FRACGP
Dr Camilo Guerra, MBBS, FRACGP
Dr Richard Jerzy Prytula, MBBS, DPM, FRANZCP
Dr Alice Murkies, MD, FRACGP, MBBS
Dr Bruce Wauchope, MBBS, DipOBS, RACOG, DTM&H, FRACGP
Dr Catherine Smyth, MBBS, FANZCA
Dr Lucia Grace Murnane, MBBS, FRACGP, M.Repro.Med, Grad.Dip.Bioethics, DCH
Dr Lynette Hatherley, BSc(Hons), PhD(Chemistry), MBBS, FRACGP
Dr Guy Campbell, MBBS
Dr Linh Tuan Phan, MBBS, FRACGP
Dr Russell Pridgeon, BSc, MB,ChB, FRACGP
Dr Simon Paul Stilgoe, MB,ChB, FRACGP, MMED, Dip.Fam.Med, FSCI
Dr John Scott, Bsc(Hons), BMBS(Hons), FACEM
Dr Susan Cory, MBBS, DTMH, Dip.Obstetrics, FRACGP
Dr Lucas A McLindon, MBBS, FRACGP, FRANZCOG
Dr Renate Mundl, MD, FRANZCP
Dr Julie Sladden, MBBS, B.Med.Sci, PostGrad.Dip.Med.Ed **Dr Mark Hobart**, MBBS, Australian Medical Network Director **Dr M Monique O'Connor**, MBBS, FRANZCP
Dr Randy Juanta, BMBS
Dr Steven Overmeire, MBBS, GDOEH, FAFOEM
Dr Eamonn Mathieson, MBBS, FANZCA
Dr Adrian Sheen, MBBS, Dip.Obst.RACOG, FRACGP **Dr.**
Carmela Caputo, MBBS, B.Med.Sci, FRACP, PhD **Dr.**
Valarie Peers, MBBS, DRANZCOG

Dr. Alistair John Frame MbchB FRACGP DA
Submitted for and on behalf of the Co-Signatories Dr Phillip Altman BPharm(Hons), MSc, PhD Clinical Trial and Regulatory Affairs Consultant

EXECUTIVE SUMMARY OF THE SUBMISSIONS

1. On 1 September 2022, the Secretary of the Australian Department of Health invited public submissions on scheduling proposals referred to the November 2022 meetings of the Advisory committees on Medicines and Chemical Scheduling including specific reference to ivermectin[1]. These submissions are in response to that invitation.

2. These Submissions to amend the Poisons Scheduling of ivermectin are submitted in the National interest. The evidence submitted in support of the proposed deletion of Appendix D, Item 10 in the ivermectin Poisons Scheduling is, arguably, the most important Poison Scheduling change ever considered by the Australian Government as it seeks to remove historically unprecedented restrictions on the prescribing of ivermectin which were primarily introduced during a pandemic response to encourage, rightly or wrongly, Covid-19 vaccine uptake as, in part, specifically stated by the Australian Therapeutic Goods Administration (TGA).

3. It is the view of the Co-Signatories that the introduction of Appendix D, Item 10 to the listing of ivermectin did not take into proper account the extensive existing documentation regarding the safety and efficacy of ivermectin used alone and in combination in relation to the potential management of Covid-19 and various parasitic indications. Since the restrictive scheduling change for ivermectin introduced on September 10 2021, considerable additional clinical safety and efficacy data has become available which adds weight to the compelling body of evidence which demonstrates that ivermectin restrictive scheduling should be normalised to return professional discretion to doctors in relation to off-label prescribing as is the conventional and accepted practice for other drugs.

4. Given the unique nature of the current Covid pandemic and the short time frame to construct these important Submissions, a diverse body of evidence

[1] Australian Government Department of Health, Therapeutic Goods Administration: Consultation: proposed amendments to the Poisons Standard – ACCS, ACMS and Joint ACCS/ACMS meetings, November 2022. 1 Sept. 2022.
https://www.tga.gov.au/resources/consultation/consultation-proposed-amendments-poisons-standard-accs- acms-and-joint-accsacms-meetings-november-2022

and both local and international expert opinion, (including commentary on certain published literature emanating from arguably vested and opposing interests) has been assembled. An attempt has been made to assemble all relevant literature in these Submissions. The Co-Signatories rely heavily upon the impressive historical world-wide safety record of ivermectin including the TGA's own safety assessments prior to the pandemic. These Submissions provide compelling evidence to support the impressive safety record of ivermectin which is matched by few, if any, widely used therapeutic agents in use today.

5. Rightly or wrongly, the Decision to apply Appendix D, Item 10 by the TGA regarding the scheduling change for ivermectin was not made solely upon normal considerations of safety and efficacy of this therapeutic agent. Other logistical and vaccine-centric reasons formed the basis of this unprecedented scheduling change which emanated from the national Covid pandemic policies. Now that the complexion of the pandemic has changed and considerable knowledge has been gained, it is the view of the Co-Signatories that the TGA's invitation for "Consultation" represents an admirable, encouraging and long-awaited sign of reflection and review in the national interest to improve Australia's Covid health policy which must involve the removal of unprecedented and restrictive Poison Scheduling currently impacting the prescribing of ivermectin.

6. Justification for removing Appendix D, Item 10 in the current Poison Scheduling for ivermectin may be summarised as follows:

a. The restrictive Poison Scheduling of ivermectin was introduced, in part, due to misconceived and inappropriate safety concerns. Worldwide use has demonstrated that ivermectin is among the safest drugs available and has a known and established high therapeutic index (or therapeutic ratio).
b. There are no reported and/or credible evidence to suggest that off-label prescribing of ivermectin, for any indication, is associated with an unacceptable incidence of adverse effects or consequences.
c. There have been no reported supply issues relating to ivermectin which may impact public health.

d. There are unintended consequences of the current restrictive prescribing regulations including the elevation of interest in obtaining and using ivermectin which may be counterfeit or of unsuitable quality (eg. veterinary products).
e. With more than 95% of the adult population now considered fully vaccinated, wider ivermectin availability would not be expected to impact the government's Covid vaccine policies.
f. With the introduction of early anti-viral drugs, molnupiravir and Paxlovid, it now appears timely to review the previously restrictive vaccine-only policy which formed the basis of the current restrictive scheduling of ivermectin.

7. SUBMISSION CORRESPONDENCE DETAILS:

Name: Dr. Phillip M. Altman
Clinical Trial and Regulatory Affairs Consultant
Submissions Editor acting for and on behalf of the Co-Signatories
Address: 20 Folly Point, Cammeray, NSW 2062 Australia
Email: phillip.altman@aussiebroadband.com.au
All correspondence and notices to Dr. Altman (but copies to any and all co-signatory organisations and individuals as appropriate)

8. DECLARATION:

The factual matters stated in the report are, as far as I know, are true.
I have made all inquiries, consisting of literature review, considered appropriate. There are no readily ascertainable additional facts which would assist me in reaching more reliable conclusions.
The opinions stated in the report are genuinely held by myself, and The report contains reference to all matters I consider significant.

Signature 26 September 2022

Phillip M. Altman
Clinical Trial & Regulatory Affairs Consultant Submitted
for and on behalf of the Co-Signatories

INTRODUCTION

9. The Poison Scheduling change for ivermectin announced 10 September 2021 to effectively ban its off-label prescribing for the management of Covid-19 was part of a sweeping suite of harsh and extreme public health policies introduced or permitted to meet the challenges of the SARS-CoV-2 pandemic.

10. In retrospect, many of the health policies adopted by Australia and elsewhere have either been shown to have failed (eg. Covid-19 vaccination to stop the spread of the virus) or have attracted widespread and ongoing expert criticism.

11. One of the health policies which has been the focus of considerable criticism relates to the surprising lack of government advice, for the first time ever, that a potentially serious infectious disease should be treated as early as possible. Rather, the government advised, if one was infected, to isolate and wait for either eventual recovery or, if the infection became serious, affected individuals should be directed to hospital for management. The government essentially ruled out early treatment of the infection in deference to a "vaccine-only" policy to meet the challenges of Covid-19. Many clinicians did not agree with this policy and, as history has shown, it is possibly one of the biggest errors of judgement in relation to Covid-19 public health policy.

12. As it turns out, the health policies developed by the U.S. CDC under the leadership of Dr. Fauci and Dr. Birx, which formed a template for a global pandemic response including that of Australia, were not based on data and science. This was recently admitted:

13. In Washington D.C. on 18th of August the US Center for Disease Control Director, Dr. Walensky, told employees: "*To be frank, we are responsible for some pretty dramatic, pretty public mistakes from testing, to data, to communications".*

14. Dr. Deborah Birx, coordinator of the White House coronavirus task force, who set the strategies for early U.S. Covid responses, which were copied by much of the world, has publicly admitted to the poor quality of U.S. Covid data and

said "*it was a pandemic driven by assumptions and perceptions, rather than data and science*"

15. It is apparent now that the change to restrictive ivermectin Poison Scheduling was part of the mistaken assumptions and perceptions in government Covid health policy.

16. One of the most regrettable statements ever made by the U.S. Food and Drug Administration (FDA) was made on 21 August 2021 when it posted a link on Twitter saying "Why you should not use ivermectin" webpage with the message "You are not a horse. You are not a cow. Seriously, y'all. Stop it"[2].

17. This FDA public statement was made despite the well-known safety record of ivermectin. In fact, the Chief Medical Officer for England, Professor Sir Christopher Whitty, has previously stated "*The drug has proven to be safe. Doses up to 10 times the approved limit are well tolerated by healthy volunteers. Adverse reactions are few and usually mild.*" [3]

18. Some Australian Chief Health Officers publicly used exaggerated claims of ivermectin toxicity, calling it a dangerous horse de-worming medication unsuitable for human use. It is inconceivable that these senior health officials could be so ill-informed of the safety record and importance of ivermectin in modern medicine. The most generous and likely interpretation of this regrettable statement is that this claim was made to encourage vaccination uptake. Statements like this have never been retracted or corrected despite the fact that ivermectin is considered to be one of the safest and most valuable drugs used in medicine and is nominated by the World Health Organisation (WHO) to be an essential drug, with billions of doses used worldwide over several decades.

[2] U.S. FDA, Twitter, https://twitter.com/us_fda/status/1429050070243192839?lang=en

[3] Chaccour, C., Lines, J. & Whitty, C. J. M. (2010). Effect of Ivermectin on Anopheles gambiae Mosquitoes Fed on Humans: The Potential of Oral Insecticides in Malaria Control. *Journal of Infectious Diseases*, **202**, 113-116. doi: 10.1086/653208. https://academic.oup.com/jid/article/202/1/113/888773

19. However, if it was the intent of the TGA to pause the availability of ivermectin for early treatment until more recognised anti-viral agents became available, then the change in scheduling, by all accounts, has achieved its goal with the current availability of both molnupiravir and Paxlovid and the scheduling of ivermectin should now revert to its previous pre-pandemic listing with the removal of Appendix D, Item 10.

20. The invitation represents a laudable step to remedy a serious error in health policy. Whether the highly restrictive but ill-advised prescribing of ivermectin via the addition of Amendment D, Item 10 to the Poison Scheduling was made, primarily, in good faith to drive Covid-19 vaccination uptake by the population using an ill-founded claim relating to the lack of safety or whether this change was made under international pressure by the pharmaceutical industry to develop and market new oral agents at higher costs and to harmonise with a similar ban or restriction on ivermectin prescribing in the U.S and elsewhere, remains a matter of speculation. The important thing is that this review of the restrictive prescribing of ivermectin is now being made by the Australian Government and should be applauded.

21. Any casual observer of the official TGA Consultation invitation might be misled into assuming this initiative to review the Poison Scheduling of ivermectin was initiated in response to a single recent submission by general practitioner doctor. This is incorrect.

22. In fact, there have been a large number of written communications and submissions by many experts, including some of Australia's most eminent clinicians, over the course of the pandemic which have sought to place evidence before the health authorities regarding the safety of ivermectin, to argue for the removal of restrictive prescribing and to reinstate the long-standing principles embodied in the sanctity of the doctor-patient relationship.

23. Examples of previous attempts to urge a change in the restrictive prescription policy for ivermectin consist of two open letters directed to the Australian National Covid Clinical Evidence Taskforce dated 21 August 2021 and 14

October 2021 which form part of these submissions. In addition, there was an Australian Government Parliamentary Petition to normalise the Poison Scheduling of ivermectin which attracted more than 100,000 signatures (Petition EN3364 – The Ivermectin Ban – An Authoritarian Threat to Public Health) – none of which have been seen to warrant a response to date.

24. In addition, there have been appeals for a return to a common-sense approach regarding ivermectin prescribing directed to head of the TGA in multiple private communications including those from Prof. Wendy Hoy AO FAA FRACP, Professor of Medicine, University of Queensland and authoritative public statements made in the print media by Emeritus Professor Robert Clancy AM DSc FRACP FRS(N). An "Ivermectin Statement" signed by a large number of medical and scientific experts which supported the removal of extreme restrictions on ivermectin prescribing was also widely distributed to Australia's health officials.

25. It is hoped that these Submissions will be received and treated with the respect it deserves as it presents a compelling case, supported by many health professionals, to reverse the extreme restrictions on the prescribing of ivermectin and normalise its Poisons Scheduling consistent with its important place in medicine.

PROPOSED AMENDMENT TO THE SCHEDULING OF IVERMECTIN

26. It is proposed to delete Appendix D, Item 10 listing in Schedule 4 for ivermectin. All other listing details for ivermectin in Schedules 5 and 7 to remain the same. Appendix D, Item 10 currently reads as follows:

10. Poisons available only when prescribed or authorised for:

(1)	an indication that is accepted by the Secretary of the Australian Government Department of Health in relation to the inclusion of ivermectin in tablet dosage form in the Australian Register of Therapeutic Goods (an approve***d*** indication); or Note: Approved indications are shown in the public summary of the Australian Register of Therapeutic Goods on the Therapeutic Goods Administration website at www.tga.gov.au.
(2)	an indication that is not an approved indication, when the preparation is prescribed or authorised by a medical practitioner registered under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in any of the following specialties or fields of specialty practices: (a) dermatology; (b) gastroenterology and hepatology; (c) infectious diseases; (d) paediatric gastroenterology and hepatology; I paediatric infectious diseases; or
(3)	use in a clinical trial that is approved by, or notified to, the Secretary of the Australian Government Department of Health under the Therapeutic Goods Act 1989.
	IVERMECTIN in preparations for oral administration for human use

REGULATORY BACKGROUND TO THE INTRODUCTION OF APPENDIX D, ITEM 10 RESTRICTION TO THE PRESCRIBING OF IVERMECTIN

27. At the 35th meeting of the Advisory Committee on Medicines Scheduling (8 September 2021, TRIM Reference no. D21-3074411), the Minister's Delegate presented a discussion paper detailing concerns regarding the increased off- label prescribing of oral ivermectin for the prevention and treatment of Covid-19 and requested an urgent scheduling amendment to place prescribing controls on the supply of oral ivermectin[4]. Certain observers to this meeting included individuals with a stated conflict of interest but were allowed to participate in the meeting. The meeting minutes retrieved under Freedom of Information were heavily redacted. The subsequent Decision to restrict the off- label prescribing of oral ivermectin was issued on 10 September 2021[5,6].

28. The stated reasons for the Scheduling change to introduce restrictive prescribing of ivermectin were as follows:

a) "persons taking ivermectin in an effort to prevent Covid-19 consider themselves to be protected against the disease, elect not to be vaccinated as part of the national Covid-19 vaccination program"…..
b) "it is possible that oral ivermectin will be in shortage in Australia" [if used to manage Covid-19].
and
c) "Oral ivermectin also has the potential to cause severe adverse events in persons, particularly when taken in high doses that have recently been described in social media and other sources for the prevention or treatment of Covid-19 infection".

29. The stated Scheduling change was **not** made because ivermectin was considered ineffective in the treatment of Covid-19 but rather because such

[4] Record of the 35th meeting of the Advisory Committee on Medicines Scheduling 08 September 2021. Confidential – Official use only: Information retrieved under Freedom of Information (redacted to remove names of participants)
[5] Poisons Standard Amendment (Ivermectin) instrument 2021 – Authorised Version Explanatory Statement registered 10/09/2021 to F2021L01253
[6] Notice of an amendment to the current Poisons Standard under paragraph 52D(2)(a) of the Therapeutic Goods Act 1989

use might dissuade vaccine uptake by the community, a shortage of ivermectin for approved uses might eventuate and because of a potential but unsubstantiated belief that ivermectin might cause serious adverse effects if used in high doses.

30. The logic and rationale in relation to a) and b) remain in the domain of hypothetical and strategic government health policy and are not directly related to the usual safety and efficacy issues which would normally underpin a review of the use of any therapeutic in sofar as Poisons Scheduling is concerned. Introduction of Poison Scheduling Appendix D, item 10 represented a clear historical departure from conventional scheduling considerations where decisions were made primarily on safety and efficacy and not primarily intended to restrict the prescribers ability to employ off-label prescribing where it was considered justifiable and appropriate.

SCOPE OF THE SUBMISSIONS

31. These Submissions will focus on the safety aspects of ivermectin as this relates to public health. Published documents and references regarding the clinical efficacy of ivermectin in the management of Covid-19 are submitted for background purposes due to their relevance in relation to safety. It should be recognised that reasons a) and b) (above) underpinning the change in ivermectin scheduling no longer apply as the government claims[7] more than 95% of the over 18 years of age population in Australia have now been vaccinated and ivermectin supply has not been reported to be a problem in Australia or world-wide.

32. While these Submissions will focus upon the safety aspects of ivermectin (the one remaining reason why Appendix D, Item 10 was introduced), pivotal clinical trial studies, meta-analyses and commentary on such studies have been included as this information provides valuable background information which impacts any consideration of ivermectin safety.

[7] Australian Government Department of Health and Aged Care: Covid-19 vaccines

33. These Submissions are not intended to be a comprehensive or systematic review of the literature but focuses on key papers and reviews which should assist the TGA in evaluating the proposed normalisation of the Poison Scheduling for ivermectin.

34. In addition, these Submissions will not address the related, but extremely important, ethical and professional considerations regarding the sacred doctor- patient relationship as this was not stated as a reason for the restrictions placed on ivermectin prescribing.

RATIONALE FOR DELETING APPENDIX D, ITEM 10 FROM THE CURRENT SCHEDULING

35. Initially, little was known about the aetiology and pathophysiology of Covid-19. Clinicians were presented with a new, rapidly spreading pathogenic virus which was predicted to have a dramatic impact on the world's population.

36. The potential usefulness of revolutionary, but unproven mRNA gene-based vaccines was believed to be the best answer to the pandemic. Rightly or wrongly, a "vaccine-only" policy was promulgated worldwide which excluded early potential treatment with any existing therapeutics including ivermectin and other therapeutics despite considerable published evidence that ivermectin could be used safety and effectively. Surprisingly, it was the only time it has ever been officially recommended that a serious infection not be treated as soon as possible. The off-label use of ivermectin, according to government policy makers, presented a threat to the implementation of the vaccine-only policy.

37. In an attempt to dissuade the use of ivermectin, a media-wide campaign was commenced to suggest that ivermectin posed serious toxicological concerns which would outweigh any potential benefit. However, documented evidence over decades of usage showed that ivermectin was a drug with a wide therapeutic margin of safety – in fact, much safer than commonly used non- prescription drugs such as paracetamol. Previously, the TGA itself has acknowledged this wide margin of safety.

38. However, for completeness and with some reluctance, the Co-Signatories need to mention the medical literature has become a battleground with vested commercial interests behind various publications aiming to undermine the perceptions of safety and efficacy of ivermectin. The Co-Signatories have made a special point of including such publications in these Submissions and has provided comment so as to enable a proper and balanced appraisal of the safety and efficacy of ivermectin as it relates to Poisons Scheduling.

39. In these Submissions, the Co-Signatories will rely upon the following:

a) extensive toxicological and clinical safety data in relation to ivermectin
b) meta-analyses and reviews of the published medical literature concerning clinical trials of ivermectin
c) individual important clinical studies of ivermectin (several of these studies have become available subsequent to the imposition of restrictive ivermectin prescribing
d) accounts of the successful national ivermectin programs used by several countries in relation to Covid-19
e) specific rebuttals in response to key publications which purport to argue against the safe and effective use of ivermectin

40. The evidence will show that ivermectin is a particularly safe therapeutic agent and its restrictive Poisons Scheduling embodied in Appendix D, Item 10 is unwarranted and needs to be amended in the national interest as soon as possible. These Submissions focus on the safety aspects of ivermectin and have not been designed as Submissions to support any additional therapeutic indication, however, a number of key clinical studies and meta-analyses have been included in these Submissions insofar as they also relate to safety and provide some guidance in relation to common dosages employed.

41. Apart from the evidence presented in these Submissions regarding the intrinsic and relative safety of ivermectin, it needs to be recognised that there is both substantial clinical interest and public awareness of the potential use of ivermectin. The effective denial of supply, rightly or wrongly, has driven many to consider alternative sources of ivermectin (veterinary products, counterfeit

products and overseas therapeutic products) which carry undetermined safety risks of their own. The Co-Signatories argue that removal of Appendix D, Item 10 of the Poison Scheduling will assist in the provision of medically supervised use by doctors and pharmacists to ensure patients receive adequate patient information and a product of reliable quality suitable for human use.

IVERMECTIN – HISTORICAL PERSPECTIVE AND CLINICAL USE

42. Professor Satoshi Omura, of the Kitasato Institute, discovered a group of pharmacologically active compounds in 1975 called 'avermectins" from an unusual *Streptomyces* bacterium from the soil near a golf course along the Southeast coast of Honshu, Japan. One of these compounds was ivermectin.

43. Ivermectin became one of the most revolutionary drugs ever to be introduced into medicine. Although first introduced to treat parasites in animals, ivermectin has been used in humans since the 1980s[8]. Since then, ivermectin has dramatically improved the health and well-being of hundreds of millions of people mainly in relation to the effective management of parasitic diseases including river blindness and lymphatic filariasis – two of the most disfiguring diseases afflicting the world's poor. Later the use of ivermectin was expanded to include the treatment of scabies and lice.

44. Ivermectin has long since been approved as an antiparasitic by the World Health Organisation (WHO) and the U.S. Food and Drug Administration (FDA). The WHO has also included ivermectin on its list of "Essential Medicines"[9]. The importance of the drug to mankind was recognised by the award of the Nobel Prize in Medicine to the discovers in 2015[10].

45. In the decade leading up to the Covid-19 pandemic, studies showed that ivermectin possessed wide-ranging pharmacological activity including antiviral

[8] Andy Crump & Satoshi Omura, Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations, 70 The Journal Antibiotics 495, 495 (2017), available at https://www.nature.com/articles/ja201711.pdf (hereinafter, "Crump, ivermectin")

[9] World Health Organisation. 2021 List of Essential Medicines. https://list.essentialmeds.org Last visited 15.9.22

[10] The Nobel Prize, Press Release for The Nobel Prize in Physiology or Medicine 2015 (Oct. 5, 2015, https://www.nobelprize.org/prizes/medicine/2015/press-release Last visited 15.9.22

activity against several RNA viruses[11]. In addition, ivermectin was also reported to possess useful anti-inflammatory activity[12]. Subsequently, doctors have been using ivermectin to treat "rosacea, a chronic inflammatory disease" that manifests itself as a reddening of the face and the FDA has approved ivermectin for that purpose[13]. The potential usefulness of ivermectin in the management of inflammatory airway disease was also recognised[14]. In more recent times, there has been intense interest and research regarding the potential use of ivermectin in the management of Covid-19.

IVERMECTIN SAFETY AND TOXICOLOGICAL INFORMATION

46. The U.S. National Institute of Health (NIH) has recognised that "ivermectin has been widely used and is generally well tolerated"[15]. A recent systematic review stated "ivermectin at the usual doses…is considered extremely safe for use in humans"[16]. Ivermectin was added to the 2018 Essential Medicine list for use in scabies and in supporting the application for inclusion in the list, the WHO concluded that the adverse events associated with ivermectin are "primarily minor and transient"[17]. The most recent Australian Public Assessment Report for Ivermectin regarding the safety and efficacy of ivermectin by the TGA in relation to use in scabies found no safety concerns at even 10 times the (then) current approved dose of 200ug/kg[18]. The report said:

[11] Pierre Kory et al, Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of Covid-19, 28 American Journal of Therapeutics 299, 301 (2021), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8088823/ Last visited 15.9.22

[12] Crump, ivermectin, supra, at 499

[13] Leon H. Kircik et al., Over 25 Years of Clinical Experience with Ivermectin: An overview of Safety for an increasing Number of Indications, 15 Journal of Drugs in Dermatology 325, 325 (Mar. 2016), available at https://jddonline.com/articles/dermatology/S1545961616P0325X Last visited 15.9.22

[14] Crump, ivermectin, supra at 499

[15] National Institutes of Health, Covid-19 Treatment Guidelines: ivermectin, https://www.Covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/ Last visited 15.9.22

[16] Andrew Bryant et al., Ivermectin for Prevention and Treatment of Covid-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines, 28 American Journal of Therapeutics 434, 435 (Jul./Aug. 2021), available at https://journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin for prevention and treatment of.7.aspx. Last visited 15.9.22. Hereafter "Bryant ivermectin".

[17] WHO Expert Committee on the Selection and Use of Essential Medicines: Application for inclusion of ivermectin on the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) for the indication of Scabies at 19 (Dec. 2018)

[18] Australian Public Assessment Report for Ivermectin – October 2013 https://www.tga.gov.au/auspar/auspar- ivermectin

47. *"The sponsors have only provided one new study (066) in 40 healthy subjects which showed good tolerability and no safety concerns at doses ranging from 30 to 120 mg, that is, up to 10 times the proposed dose of 200 µg/kg for treatment of scabies."*

48. *"Ivermectin has been used extensively to treat 6 million people in 30 countries for onchocerciasis caused by the filarial worm Onchocerca volvulus. Ivermectin also has proven effective for the human diseases, loiasis, strongyloidiasis, bancroftian filariasis and cutaneous larva migrans. Several studies have now evaluated ivermectin for human scabies. There were no significant safety concerns reported with the use of ivermectin in any of the scabies studies to date, except for one report of fatal complications in patients from a long-term care facility but these were not confirmed in other studies."*

and

49. "*The most comprehensively reported safety data came from the PK study conducted in healthy volunteers (Study 066). In this study oral ivermectin administered in multiple doses of up to 60 mg given 3 times a week or in single doses of up to 120 mg (which is approximately 10 times the proposed dose of 200 µg/kg for treatment of scabies) was generally well tolerated, with no evidence of mydriatic effect or other neurological toxicity. The most commonly reported clinical AE was headache, which occurred in equal proportions of ivermectin and placebo treated subjects. Other AEs, reported in single subjects in each group, were nausea, dizziness and rash.* ***No serious AEs were reported in the study. The clinical evaluator found there were no significant safety concerns reported with the use of ivermectin*** *in any of the published scabies studies, except for one report of fatal complications in elderly patients from a long-term care facility. However, Barkwell's findings were not confirmed in subsequent studies, some of which used even higher doses of ivermectin. Overall, the adverse event profile for ivermectin use in treatment of scabies appeared to be similar to that observed for other indications for which it is approved. In the published randomised clinical trials the main adverse events were headache, abdominal pain, mild diarrhoea and rash. Post marketing data were also provided in the form of a PSUR, covering the period*

April 2010 to April 2011. ***During the reporting period an estimated 1,423,010 patient treatment courses were administered for all indications***." (bolding added for emphasis).

50. An expert toxicological review report based on over 500 articles up to February 2021[19] stated the following:

51. *"The present extensive review of adverse events reportedly associated with ivermectin treatment for therapeutic or prophylactic purpose did not reveal any significant cause for concern. Indeed, with the notable exception of patients with parasitic diseases such as Onchocerciasis or Loa-Loa microfiliaris, serious adverse events temporarily associated with ivermectin were very infrequent. In fact, adverse events were mainly mild to moderate and infrequent. This is confirmed by results reported in patients with scabies or human beings without any ongoing parasitic disease."*

and

52. *"Hundreds of millions of human subjects have been treated with ivermectin for curative or prophylactic purposes worldwide over the last 3 decades. The reference list of this report demonstrates that a large body of data is available, which allows for a detailed analysis of ivermectin medical safety. Undoubtedly, uncertainties remain regarding ivermectin pharmacological effects and mechanisms of action, but when removed, this is not anticipated to alter the main conclusions of this report in any significant way as they rely on an extensive and consistent body of medical publications."*

53. *"Taking into account all the above, the author of the present analysis of the available medical data concludes that the safety profile of ivermectin has so far been excellent in the majority of treated human patients so that ivermectin human toxicity cannot be claimed to be a serious cause for concern."*

[19] Descotes, J. Expert Review Report – Medical Safety of Ivermectin. 3 March 2021 https://www.medincell.com/wp-content/uploads/2021/03/Clinical_Safety_of_Ivermectin-March_2021.pdf

54. An Opinion written by the U.S. Nebraska State Attorney General's Office (14 October 2021) provided a detailed analysis of the arguments regarding ivermectin and off-label prescribing which are instructive[20], a copy of which forms Annexure 1 to these Submissions, which Opinion the Co-Signatories wish to rely upon in full as it pertains to ivermectin.

55. The opinion stated in part:

"For more than three decades, ivermectin has also shown itself to be very safe. Indeed, the National Institutes of Health (NIH) recognize that "ivermectin has been widely used and is generally well tolerated[21]. One recent systematic review similarly states that "ivermectin" at the usual doses….is considered extremely safe for use in humans[22]. Other studies have noted that the medicine "has an established safety profile for human use"[23] and it "provide[s] a high margin of safety for a growing number of indications"[24]. Notably, a December 2018 WHO-supported application to add ivermectin as an essential medicine for scabies reviewed the data and concluded that the adverse events associated with ivermectin are "primarily minor and transient"[25].

and

56. "The available data support this conclusion. The WHO's VigiAccess database, which compiles adverse drug reactions from throughout the world, breaks down the reported side effects for drugs into different categories. The largest reported categories for ivermectin include skin issues, headaches, dizziness and gastrointestinal disturbances such as diarrhea and nausea. The NIH confirms that ivermectin's primary adverse side effects "include dizziness, pruritis [itchy skin], nausea or diarrhea". And a recent review of ivermectin similarly describes

---

[20] U.S. State of Nebraska, Office of the Attorney General. Prescription of Ivermectin or Hydroxychloroquine as Off-Label Medicines for the Prevention or Treatment of Covid-19. 14 October 2021. No. 21-017

[21] National Institutes of Health, Covid-19 Treatment Guidelines: Ivermectin, https://www.Covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/ (last visited 18 Sept. 2022)

[22] Bryant, Ivermectin, supra, at 435

[23] U.S. Nebraska State Attorney General opinion. Prescription of Ivermectin or hydroxychloroquine as Off- Label medicines for the Prevention or Treatment of Covid-19. 14 October 2021 https://ago.nebraska.gov/sites/ago.nebraska.gov/files/docs/opinions/21-017_0.pdf

[24] Kircik, Ivermectin, supra, at 325

[25] WHO Expert Committee on the Selection and Use of Essential Medicines: Application for inclusion of ivermectin on the WHO Model list of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) for the indication of Scabies at 19 (Dec. 2018)

the common side effects as "itching, rash, swollen lymph nodes, joint pain, fever and headache."

and

57. *"The data show not only that the adverse side effects are minor, but also that the percentage of people who report experiencing any adverse events is vanishingly small. The latest statistics available through VigiAccess report only 5,674 adverse drug reactions from ivermectin between 1992 and October 13, 2021[26]. This number is incredibly low considering that "more than 3.7 billion doses" of ivermectin have been administered to humans worldwide since the 1980s."*

and

58. *"To illustrate the safety of ivermectin, compare its VigiAccess report to that of remdesivir, an FDA-approved treatment for Covid-19. Remdesivir was not released for widespread use until 2020. Yet in the short period of time that it has been on the market, people have reported at least 7,491 adverse drug reactions on VigiAccess, more than ivermectin has registered over the last 30 years. What's more, serious adverse reactions from remdesivir are reported in high numbers. For example, in less than two years, those who have used remdesivir have reported over 560 deaths, 550 serious cardiac disorders (such as bradycardia and cardiac arrest), and 475 acute kidney injuries. Since that safety profile is sufficient to retain FDA approval, ivermectin's safety record cannot reasonably be questioned."*

59. The safety and pharmacokinetics of ivermectin, administered in higher and/or more frequent doses than currently approved for human use, were evaluated in a double-blind, placebo-controlled, dose escalation study in 2002[27].

[26] VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://vigiaccess.org/

[27] Guzzo, C.A. et al. Safety, Tolerability, and Pharmacokinetics of Escalating High Doses of Ivermectin in Healthy Adult Subjects. J Clin Pharmacol 2002;42:1122-1133. https://pubmed.ncbi.nlm.nih.gov/12362927/ (last visited 18 Sept. 2022)

60. In contrast to the current recommended single doses of ivermectin for parasitic indications (about 200ug/kg), this study employed both single and multiple doses with an upper single dose of 120mg. Safety assessments addressed both known ivermectin CNS effects and general toxicity. The report stated:

61. "The primary safety endpoint was mydriasis, accurately quantitated by pupillometry. *Ivermectin was generally well tolerated, with no indication of associated CNS toxicity for doses up to 10 times the highest FDA-approved dose of 200ug/kg." ..."This study demonstrated that ivermectin is generally well tolerated at these higher doses and more frequent regimens."*

62. An important systematic review including a meta-analysis of the safety of ivermectin for various parasitic infections following single high dose ivermectin (up to 800ug/kg or four times the recommended dose) has provided evidence of the wide margin of safety of this widely used drug[28]. The results and conclusions were summarised as follows:

63. "Results: The systematic search identified six studies for inclusion, revealing no differences in the number of individuals experiencing adverse events. A descriptive analysis of these clinical trials for a variety of indications showed no difference in the severity of the adverse events between standard (up to 400 lg/kg) and higher doses of ivermectin. Organ system involvement only showed an increase in ocular events in the higher-dose group in one trial for the treatment of onchocerciasis, all of them transient and mild to moderate in intensity."

64. "Conclusions: Although within this review the safety of high-dose ivermectin appears to be comparable to standard doses, there are not enough data to support a recommendation for its use in higher-than-approved doses. Ocular adverse events, despite being transient, are of concern in onchocerciasis patients. These data can inform programme managers and guide operational

[28] Navarro, M. et al: Safety of high-dose ivermectin: a systematic review and meta-analysis. J Antimicrob Chemother 2020; 75: 827–834 doi:10.1093/jac/dkz524 Advance Access publication 20 January 2020. https://academic.oup.com/jac/article/75/4/827/5710696

research activities as new approaches for the use of ivermectin are evaluated.
"

65. A recent clinical trial using ivermectin for the management of 34 severe hypoxic Covid-19 patients warrants special mention as it provides both useful high dose ivermectin safety data as well as impressive oxygen saturation data[29]. Remarkably, all but three of these 34 patients had significantly increased SpO2 values within 24 hours after the first ivermectin dose. However, in relation to safety the authors stated:

66. *"As evidence of IVM safety and tolerability accrued following its use beginning in August 2020, its stat dose of 10 mg as used for the earliest patients was increased on 11 September 2020 to 10–12 mg every four days for three doses. Subsequently, the dosage was further increased to 12 mg IVM on the day of admission and then on Days 4 and 8 plus doxycycline (100 mg b.i.d.) and zinc sulfate (60 mg/day). The latter regimen was used up through December 2020, when the second pandemic wave emerged in Zimbabwe. At that time, additional evidence of the safety and tolerability of this regimen supported further dose escalation to a standard IVM dose regimen of 12 mg daily for five consecutive days, with adjunct use of doxycycline and zinc sulfate continued at the doses noted. In some cases, for which this standard treatment regimen did not yield significant clinical gains within a few days, even higher doses of IVM were used, in some cases as high as 100 mg for a single dose. Transient adverse effects (Aes) such as blurred vision characteristic of high-dose IVM often occurred at those dose levels, but no serious AEs [adverse effects] associated with IVM were manifested in any patient. "*

[29] Stone, J.C. et al: Changes in SpO2 on Room Air for 34 Severe Covid-19 Patients after Ivermectin-Based Combination Treatment: 62% Normalization within 24 Hours. *Biologics* **2022**, *2*, 196–210. https://doi.org/10.3390/biologics2030015 . https://www.mdpi.com/2673-8449/2/3/15

67. *Similarly* impressive clinical efficacy results using ivermectin for the management of Covid-19 were reported in another study[30]. In relation to the important issue of ivermectin safety the authors commented:

68. *"Five such studies for IVM treatment of Covid-19 recently published in top-tier medical journals have all shown multiple clinical benefits for IVM versus controls, most of these with high statistical significance on the order of $p < 0.002$ [6–10]. At much greater than the standard single anti-parasite dose of 200 µg/kg, IVM is well tolerated [11,12] and has been used in RCTs for Covid-19 treatment at cumulative doses of 1500 µg/kg [13] and 3000 µg/kg [14,15] over 4 or 5 days either without or with mild and transient adverse effects. Not surprisingly, IVM has become extensively used in the prevention and early disease management of Covid-19, particularly in non-Western countries."*[references omitted]

COMPARATIVE SAFETY INFORMATION REGARDING MOLNUPIRAVIR AND PAXLOVID

69. *Any* consideration of the normalisation of Poison Scheduling of ivermectin would be incomplete without regard to the clinical juxtaposition of an assessment of the safety of the recently "Provisionally Approved" anti-virals, molnupiravir and Paxlovid, which have a vastly inferior and uncertain safety record by comparison to ivermectin[31].

70. *Molnupiravir* is an old drug which has been repurposed to treat Covid-19. Previously, commercial interest was abandoned in this drug due to concerns regarding its mutagenic potential[32] (cancer risk or transgenerational pathology)

---

[30] Hazan, S. et al: Effectiveness of ivermectin-based multidrug therapy in severely hypoxic, ambulatory Covid-19 patients. Future Microbiol. 2022 Mar;17:339-350. doi: 10.2217/fmb-2022-0014. Epub 2022 Feb 9. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8826831/

[31] Clancy, R.: The Suppression of Useful Covid-19 Treatments. Quadrant, 8 August 2022. https://quadrant.org.au/opinion/public-health/2022/08/the-suppression-of-useful-Covid-19-treatments/

[32] Zhou, S. et al: β-d-N^4-hydroxycytidine Inhibits SARS- CoV-2 Through Lethal Mutagenesis but Is Also Mutagenic to Mammalian Cells. Journal of Infectious Diseases, 2021:224 (1 August) pp415-419. https://pubmed.ncbi.nlm.nih.gov/33961695/

and concerns regarding disappointing clinical efficacy; both resulting in the failure to achieve registration approval in a number of countries.

71. Paxlovid, containing a combination of the antiviral nirmatrelvir, a protease inhibitor, and ritonavir, a cytochrome P450 pathway inhibitor, was also Provisionally Approved for the treatment of Covid-19. However, initial clinical efficacy claims could not be supported, rebound infection was reported and ritonavir is associated with serious toxicity including known toxicity to the liver[33] and fatalities have been reported[34].

72. Ivermectin, in contrast to these two antiviral medications, has a much wider therapeutic index and has a relatively high level of safety following many years of use in many millions of individuals treated for parasitic infections such as river blindness. It should also be noted, in contrast to ivermectin, that these two "Provisionally Approved" antivirals have been used in Covid-19 based on relatively limited clinical safety and efficacy data.

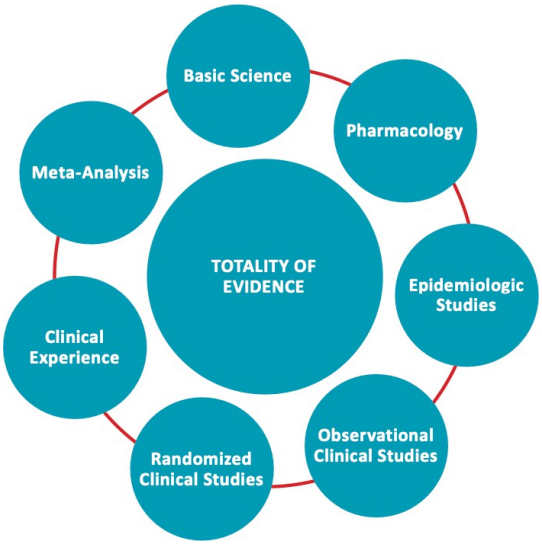
IVERMECTIN CLINICAL STUDIES AND META-ANALYSES FOR UNAPPROVED INDICATIONS – SUBMITTED AS EVIDENCE OF CLINICAL SAFETY

73. The circumstances surrounding the amended Poison Scheduling of ivermectin were as unprecedented as was the level of clinical interest and research in the use of ivermectin since the Covid-19 pandemic began.

74. Since 2012, numerous in-vitro and in-vivo studies began to report the anti-viral and anti-inflammatory efficacy of ivermectin. A review of the totality of evidence supporting ivermectin safety and efficacy derived from diverse sources was published in 2021[35]

[33] Australian Product Information - Paxlovid. Version: pfppaxIt10122. https://www.tga.gov.au/sites/default/files/auspar-nirmatrelvir-ritonavir-220124-pi.pdf [34] U.S. Prescribing Information - Norvir. Revised June 2017. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209512lbl.pdf

[35] Kory, P. et al: review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of Covid-19. American Journal of Therapeutics: May/June 2021 - Volume 28 - Issue 3 - p e299-e318doi: 10.1097/MJT.0000000000001377



75. The dosages of ivermectin varied in relation to the dose per day and the number of days of dosing. Generally, the most common dose was about 12mg or 200ug/kg administered daily for up to about 5 days.

76. This Kory et al meta-analysis concluded:

> *"Meta-analyses based on 18 randomized controlled treatment trials of ivermectin in Covid-19 have found large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance. Furthermore, results from numerous controlled prophylaxis trials report significantly reduced risks of contracting Covid-19 with the regular use of ivermectin. Finally, the many examples of ivermectin distribution campaigns leading to rapid population-wide decreases in morbidity and mortality indicate that an oral agent effective in all phases of Covid-19 has been identified."*

77. Another significant meta-analysis appeared mid-2021[36]. Twenty-four randomized controlled trials involving 3406 participants met the review criteria for inclusion. The authors concluded:

---

https://journals.lww.com/americantherapeutics/fulltext/2021/06000/review_of_the_emerging_evidence_demonstrating_the.4.aspx

[36] see previously "Bryant ivermectin".

78. *"Moderate-certainty evidence finds that large reductions in Covid-19 deaths are possible using ivermectin. Using ivermectin early in the clinical course may reduce numbers progressing to severe disease. The apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS- CoV-2 pandemic globally."*

79. Following Bryant's publication of his team's review, the Elgazzar study, one of the randomised controlled trials included in the meta-analysis, was questioned and placed under review. This issue has attracted considerable attention by the detractors of ivermectin in the literature. This prompted the Bryant's authors to reanalyze the data without the Elgazzar study but the review still found a clear result showing a 49% reduction in mortality in favour of ivermectin[37]. The dosages of ivermectin again varied but were generally either similar to the current recommended single dose for parasitic infection or a multiple of two or three times higher with daily dosing up to 9 days implying a relatively wide margin of safety.

80. A more recent meta-analysis of the clinical safety and efficacy may be found at ivmmeta.com which includes an analysis of 91 studies (of which 41 were randomized controlled trials involving 11,141 patients) as at 9 September 2022[38]. This resource illustrates the high level of international interest in the clinical application of ivermectin for potential use in Covid-19.

81. When taken in totality, the clinical data presented at ivmmeta.com presents a compelling case for the safety and efficacy of ivermectin and more than 20 countries (including India, Mexico, regions of Peru, Argentina, Japan, Dominican Republic and Brazil) have adopted ivermectin for the management of Covid-19. Collectively, the studies strongly suggest that *"ivermectin reduces the risk for Covid-19 with very high confidence for mortality, ventilation, ICU admission, hospitalization, progression, recovery, [number of] cases, viral clearance, and in pooled analysis."* Meta-analysis using the most

[37] Bryant, A et al. Letter to the Editor: Ivermectin for Prevention and Treatment of Covid-19 Infection: A Systematic Review, Meta-analysis and Trial Sequential Analysis to Inform clinical Guidelines. 28 American Journal of Therapeutics 573, 573 (Sept./Oct. 2021), available at https://Covid19criticalcare.com/wp-content/uploads/2021/09/Response-to-Elgazzar.pdf

[38] Ivermectin for Covid-19: real-time meta analysis of 91 studies. Covid Analysis, Sept. 9 2022 Version 198. www.Ivmmeta.com

serious outcome measure shows 62% [57-70%] and 83% [74-89%] improvement for early treatment and prophylaxis".

82. In a mini-review of ivermectin safety in the treatment of Covid-19 it was concluded that ivermectin "has been safely used in 3.7 billion doses since 1987" and that the medicine has been "used without serious [adverse effects] in multiple Covid-19 studies[39].

83. An Australian perspective referred to as the "Ivermectin Statement", supported by several concerned health professionals, supported the use of ivermectin both alone and in combination with other therapeutic agents[40]. The Statement concluded:

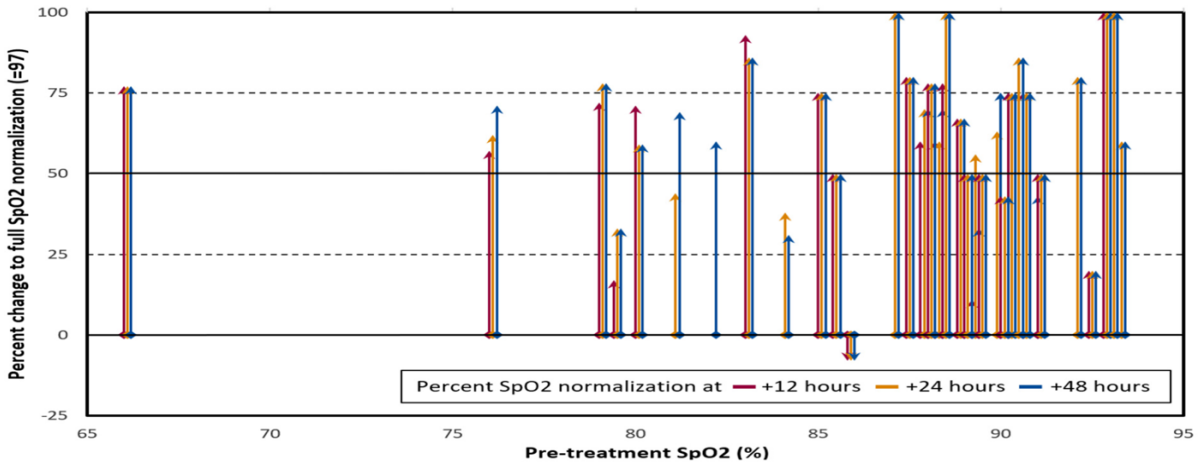
"The information presented in this statement clearly shows the benefit of ivermectin for a prophylactic role in Covid-19, and the value of using ivermectin for early and established Covid-19 infections."

84. The published report of Stone et al[41] (previously referred to above in relation to safety at paragraphs 64-65) warrants repeated mention in that this highly monitored clinical study eloquently illustrates why there is continued and justifiable clinical interest in ivermectin. Dramatic overall improvement in oxygen saturation, an important recovery metric, in 34 ivermectin treated Covid-19 patients, as presented in the figure below, underscores the legitimacy of clinician interest in exploring alternate therapeutic approaches to Covid.

[39] Alessandro D. Santin et al: ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, Covid-19, New Microbes New Infections (Aug. 2021) at https://pubmed.ncbi.nlm.nih.gov/34466270/

[40] Morris, P.: Repurposed drugs to treat Covid-19: Ivermectin. July 22, 2022. www.drphilipmorris.com

[41] Stone, J.C. et al (supra) at footnote 27



85. Despite more than 90 clinical trials being reported in the literature, there are no credible reports of serious or significant adverse events which would argue against the view that ivermectin, compared to almost all other drugs, should be considered a safe therapeutic agent with a wide therapeutic index.

INTERNATIONAL REAL WORLD IVERMECTIN EXPERIENCE IN RELATION TO THE TREATMENT OF Covid-19

86. In light of the very limited amount of controlled clinical trial safety data, international drug regulatory agencies have acknowledged as relevant and frequently referred to "real world" experience to support claims of safety relating to Covid-19 vaccination in children. "Real world" data can, indeed, be useful given the obvious large sample sizes inherent in such data collection.

87. In an early report of correlation between prophylactic ivermectin use and the suppression of Covid-19 incidence[42], data was collected from countries which routinely deploy prophylactic chemotherapy (PCT) using various drugs including ivermectin. The countries could be grouped into two categories: those which include ivermectin in their PCT and those which do not. Data sources included

[42] Hellwig, A and Maia, A: A Covid-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin. International Journal of Antimicrobial Agents 57 (2021 106248. https://pubmed.ncbi.nlm.nih.gov/33259913/

the WHO and the Covid-19 portal published by Johns Hopkins University via the aggregated Worldometer database. All data was current as of 20 October 2020.

88. The authors concluded:

"Here, we show that countries with routine mass drug administration of prophylactic chemotherapy including ivermectin have a significantly lower incidence of Covid-19. Prophylactic use of ivermectin against parasitic infections is most common in Africa and we hence show that the reported correlation is highly significant both when compared among African nations as well as in a worldwide context."

89. Peru deployed mass ivermectin-based Covid-19 treatments from April 2020 through November 2020 throughout its 25 States[43]. An analysis of the impact of ivermectin on excess deaths related to the pandemic showed the following:

"The 25 states of Peru were grouped by extent of IVM distributions: maximal (mass IVM distributions through operation MOT, a broadside effort led by the army); medium (locally managed IVM distributions); and minimal (restrictive policies in one state, Lima). The mean reduction in excess deaths 30 days after peak deaths was 74% for the maximal IVM distribution group, 53% for the medium group and 25% for Lima. Reduction of excess deaths correlated with extent of IVM distribution by state with $p<0.002$ using the Kendall τb test. Nationwide, excess deaths decreased 14-fold over four months through December 1, 2020, after which deaths then increased 13-fold when IVM use was restricted under a new president."

90. A retrospective statistical analysis study of the impact of ivermectin against Covid-19 between the 31 onchocerciasis-endemic countries using the community-directed treatment with ivermectin (CDTI) and the non-endemic 22

[43] Chamie-Quintero J.J. et al: Ivermectin for Covid-19 in Peru: 14-fold reduction in nationwide excess deaths, p<0.002 for effect by state, then 13-fold increase after ivermectin use restricted (Mar. 2021). https://osf.io/9egh4/

countries in Africa. The morbidity, mortality, recovery rate, and fatality rate caused by Covid-19 were calculated from the WHO situation report in Africa[44].

The authors concluded:

91. *"The morbidity and mortality were statistically significantly less in the 31 countries using CDTI. The recovery and fatality rates were not statistically significant difference. The average life expectancy was statistically significantly higher in the non-endemic countries. The morbidity and mortality in the onchocerciasis endemic countries are lesser than those in the non-endemic ones. The community-directed onchocerciasis treatment with ivermectin is the most reasonable explanation for the decrease in morbidity and fatality rate in Africa. In areas where ivermectin is distributed to and used by the entire population, it leads to a significant reduction in mortality."*

92. Real world data derived from Ivermectin National Treatment Programmes were also described in the Altman open letter of 14 October 2021 to the National Covid Clinical Evidence Taskforce (NCCET) in Appendix 1.

93. In this open letter it was stated:

"In addition to the successful national treatment programmes in countries such as Mexico, Argentina and Peru, the NCCET should now be aware of the success in treating Covid-19 individuals with ivermectin in the Indian State of Uttar Pradesh."

94. *"Ivermectin based combination therapy was administered as early and preventative treatment in all family contacts as part of the "Uttar Pradesh Covid Control Model". Using this therapeutic approach, Covid-19 was virtually eliminated in a population of 230 million people with a vaccination rate of less than 6% (compares to the US fully vaccinated rate at the same time of 54%). This result is in direct contrast to the comparable State of Kerala, a small state*

[44] Tanioka, H et al: Why Covid-19 is not so spread in Africa: How does Ivermectin affect it? Preprint. Europe PMC. 26 March 2021.
DOI: 10.1101/2021.03.26.21254377 https://europepmc.org/article/PPR/PPR303143

located in Southern India that is over-dependent on vaccines and restricted ivermectin use to more severe cases and late treatment if used at all."

95. *The* inescapable conclusion provided by the national ivermectin prophylactic campaigns is that ivermectin use correlates closely and consistently across many countries with a beneficial impact on Covid-19. This important observation has been largely ignored to date in favour of highly restrictive ivermectin prescription policies in Australia and elsewhere which do not appear to be justifiable based on the known safety of this well-established therapeutic agent. A strictly controlled ambitious city-wide program in the Southern Brazilian city of Itajai involving 223,128 subjects, the relationship between progressive dose and regularity of dosing of reported reductions in Covid-19 infection, hospitalization and mortality rates previously observed by these same researchers, was explored[45]. The study is of importance from both a safety and efficacy point of view in that the current recommended single dose of ivermectin of 0.2mg/kg/day was used but on two consecutive days every 15 days which represents a total drug exposure well beyond that commonly employed and a dose-response efficacy relationship was observed.

The researchers concluded:

96. *"The non-use of ivermectin was associated with a 10-times increase in mortality risk and a 7-times increased risk of dying from Covid-19, compared to strictly regular use of ivermectin in a dose of 0.2mg/kg for two consecutive days every 15 days, in a prospectively, strictly controlled population. A progressive, dose- and regularity-response pattern for protection from Covid-19 related outcomes was observed and consistent across levels of ivermectin use and all outcomes, except for reduction in infection rate, that was significant and consistent, but irrespective of level of ivermectin use."*

[45] Kerr, L. et al: Regular Use of Ivermectin as Prophylaxis for Covid-19 led up to a 92% Reduction in Covid- 19 Mortality Rate in a Dose-Response Manner: Results of a Prospective Observational Study of a Strictly Controlled Population of 88,012 Subjects. **DOI:** 10.7759/cureus.28624. https://www.cureus.com/articles/82162-ivermectin-prophylaxis-used-for-Covid-19-a-citywide-prospective- observational-study-of-223128-subjects-using-propensity-score-matching

CONTROVERSIAL EVIDENCE/REVIEWS NOT SUPPORTING THE CLINICAL EFFICACY OF IVERMECTIN FOR Covid-19

97. *Any* review of matters relating to the amendment to the current Poisons Scheduling of ivermectin would not be complete without reference to meta- analyses and papers which are not supportive in relation to the use of ivermectin in Covid-19 which have received considerable attention and warrant comment. It is important to note that this information focused on clinical efficacy and in no case was there material evidence suggestive of any safety concern.

The TOGETHER TRIAL

98. The efficacy of ivermectin in preventing hospitalization or extended observation in an emergency setting among outpatients with acutely symptomatic Covid- 19 was studied in 679 ivermectin treated patients and 679 placebo treated patients at a dose level of 400ug per kg for 3 days[46]. The authors concluded that ivermectin did not result in a lower incidence of a composite outcome defined as medical admissions to a hospital due to progression of Covid-19 or, alternatively, prolonged emergency department observation. This “composite" outcome measure was rejected as “inadequate” by both the FDA and NIH in the USA. However, when the study was analysed “per protocol” (that is counting those who completed the trial according to the protocol), protection against admission to hospital was a statistically significant 60%. This result demonstrating clinical efficacy was not reported in the published paper. The critically important outcome of mortality is reported only for an Intention-To-Treat (ITT) group, for which meaningful comparison is invalidated by a wholly anomalous "apparent dropout rate" of 58% in the placebo arm, when per protocol compliance is considered. Anomalies of this magnitude essentially invalidate an ITT analysis and demand primary attention to the per protocol groups. Multiple requests for mortality data in the per protocol groups have however been denied; though clearly available, the data informing the effect on mortality remains unreported.

[46] Reis, G. et al: Effect of Early Treatment with ivermectin among Patients with Covid-19. N Engl J Med 386;18 nejm.org may 5, 2022 https://www.nejm.org/doi/pdf/10.1056/NEJMoa2115869?articleTools=true

99. The authors of the TOGETHER TRIAL have thus far refused to provide de- identified patient-level data, though promised in their Data Sharing Statement "immediately after publication" (30 March 2022), and have for several months mis-directed enquiries to a data repository (ICODA) which denies holding the data. The journal (*NEJM*) which published the study has not to date responded to a letter requesting information from 66 senior international physicians and scientists[47] and has declined to publish any of the many short (< 175 words) Letters to the Editor raising questions about this study. The study appears fraught with data irregularities, the lack of transparency and conflicts of interests which remain to be clarified.

100. It is of some note that even at this relatively high dose, the incidence of all grades of adverse events for ivermectin were lower or about the same compared to placebo, raising the possibility of self-medication with over-the- counter (OTC) ivermectin which is freely available in the study locale. Conducted in the midst of the emergence of the clinically aggressive "Gamma" or "Brazilian" variant, silent non-compliance with protocol by participants would be understandable, and a valid comparison with placebo requires concurrent recruitment, for which insufficient data are yet available to confirm.

101. Similar concerns regarding data integrity and conflicts of interest in the literature with regard to generic drugs with potential therapeutic efficacy in the management of Covid-19 also occurred in the Surgisphere saga which resulted in an embarrassing retraction by The Lancet[48] and parallel papers in NEJM. Unless and until the promised de-identified data set is openly released, this study violates too many norms of scientific conduct to be considered reliable.

[47] Letter from 66 scientists and physicians to the co-authors of Reis et al. 2022 and to others as identified in the correspondence, as emailed on May 10 2022, together with the email thread of follow-up correspondence through July 19, 2022, with all but certain publicly available email addresses redacted at https://drive.google.com/file/d/1eSez1YNIf26PHAPX6oHpw-UFg-QY1cfd/preview

[48] Mehra, M. et al. Retraction-Hydroxychloroquine or chloroquine with or without a macrolide for treatment of Covid-19: A multinational registry analysis. The Lancet, Vol 395, Issue 10240, P1820, June 13 2020. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext

102. THE COCHRANE REVIEW OF IVERMECTIN

Another meta-analysis known as the Popp review[49] has reached more skeptical conclusions which have been subsequently been challenged. The analysis excluded some of the randomised clinical trials that Bryant considered and evaluated only 14 studies with 1,678 participants and determined that the "completed studies are small and few are considered of high quality". The authors expressed "uncertainty about the efficacy and safety of ivermectin used to treat or prevent Covid-19" but Bryant and others[50] contend most of the relevant evidence was excluded from analysis and the Popp analysis suffered from numerous flaws including unsupported assertions and inconsistencies in design which exemplify the literature battleground.

Additional critical comments on the Cochrane Review appears on the extensive online ivermectin data website ivmmeta.com[51] which also is critical of the Popp et al analytical approach including the impact of splitting up studies for analysis (fragmentation of data) which reduced the chance of demonstrating statistical significance and selecting arbitrary time points for outcome measures.

103. THE ROMAN REVIEW

Another meta-analysis, the Roman review[52], restricted the selection of randomised clinical trials for analysis even further and considered only 10 trials and concluded that ivermectin does not reduce all-cause mortality or viral clearance. But since its publication the Roman review has drawn some harsh criticism. The authors of the Bryant review have highlighted four categories of flaws with the Roman analysis: mis-reporting of source data, highly selective study inclusion, "cherry picking" of data and conclusions that do not follow from

[49] Maria Popp et al., Ivermectin for preventing and treating Covid-19, Cochrane Database of Systematic Reviews (July 28, 2021) available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD015017.pub2/full

[50] Edmund J. Fordham et al, The uses and abuses of systematic reviews: the case of ivermectin in Covid-19, OSF Preprints (Oct. 7, 2021) at https://osf.io/mp4f2/

[51] Ivmmeta.com (supra)

[52] Yuani M. Roman et al.: ivermectin for the treatment of Coronavirus Disease 2019: A systematic review and meta-analysis of randomized controlled trials. Clinical Infectious Diseases (June 28, 2021) at https://pubmed.ncbi.nlm.nih.gov/34181716/

the evidence[53] and requested a retraction of the Roman et al meta-analysis. Another report[54] reaffirms the Bryant meta-analysis results and concluded:

104. *"We show that there is overwhelming evidence to support a causal link between ivermectin, Covid-19 severity and mortality, and: i) for severe Covid-19 there is a 90.7% probability the risk ratio favours ivermectin; ii) for mild/moderate Covid- 19 there is an 84.1% probability the risk ratio favours ivermectin. Also, from the Bayesian meta-analysis for patients with severe Covid-19, the mean probability of death without ivermectin treatment is 22.9%, whilst with the application of ivermectin treatment it is 11.7%. The paper also highlights advantages of using Bayesian methods over classical statistical methods for meta-analysis."*

THE NCCET RECOMMENDATION ON IVERMECTIN

105. The National Covid Clinical Evidence Taskforce (NCCET) conducted a review of the clinical data (Communique Ed. 48 – 5.8.21) regarding the use of ivermectin in the management of Covid-19 and concluded:

106. *"The available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin and therefore the Taskforce recommends ivermectin not be used outside of randomised trials. The certainty of the current evidence base varies from low to very low depending which on outcome is being measured, as a result of serious risk of bias and serious imprecision in the 18 included studies."*

107. Two fully documented and comprehensive responses were submitted to the NCCET by Dr. Phillip Altman dated 21 August 2021 (together with a Commentary by Dr. Tess Lawrie and Dr. Edmund Fordham) and 14 October 2021 which were also published in the Quadrant Magazine as Open Letters, however, no reply was ever received. A copy of these letters and commentary is attached as Annexure 2 for the record.

[53] Letter from Andrew Bryant et al to Robert T. Schooley, Editor in Chief, Clinical infectious Diseases at https://bird-group.org/letter-to-editor-of-journal-requesting-retraction-of-roman-et-al-meta-analysis/

[54] Neil, M et al: Bayesian meta Analysis of Ivermectin confirms Bryant et al study that ivermectin works for Covid. July 13, 2021 published on the BIRD website. https://bird-group.org/bayesian-meta-analysis-of- ivermectin-confirms-bryant-et-al-study-that-ivermectin-works-for-Covid/

The 21 August 2021 response, in part, commented:

108. *"The [NCCET] analysis reveals and details (with references) serious flaws in the selective NCCET interpretation of the 'cherry picked' literature. It ignores the broad sweep of clinical evidence from other randomised controlled clinical trials, observational trials and national treatment programs and demands (in the NCCET's own words) as a matter of high priority to review this recommendation in the national interest."*

109. This comment is even more applicable today as considerable clinical safety and efficacy data has been generated since the Altman submissions yet there has been no reconsideration of the position on ivermectin.

STATE OF NEBRASKA
Office of the Attorney General
2115 STATE CAPITOL BUILDING
LINCOLN, NE 68509-8920
(402) 471-2682
TDD (402) 471-2682
FAX (402) 471-3297 or (402) 471-4725

DOUGLAS J. PETERSON
ATTORNEY GENERAL

No. 21-017
STATE OF NEBRASKA
OFFICIAL
OCT 14 2021
DEPT. OF JUSTICE

SUBJECT: Prescription of Ivermectin or Hydroxychloroquine as Off-Label Medicines for the Prevention or Treatment of Covid-19

REQUESTED BY: Dannette R. Smith
Chief Executive Officer
Nebraska Department of Health and Human Services

WRITTEN BY: Douglas J. Peterson, Attorney General
James A. Campbell, Solicitor General
Mindy L. Lester, Assistant Attorney General

INTRODUCTION

On September 16, 2021, you requested our opinion on whether it would be "deemed unlawful or otherwise subject to discipline under [Neb. Rev. Stat. § 38-186] for an appropriately licensed health care provider, once informed patient consent has been appropriately obtained, to prescribe" ivermectin, hydroxychloroquine, or other "off label use" medications "for the treatment or prevention of COVID-19." You requested this opinion in your role as Chief Executive Officer of the Nebraska Department of Health and Human Services ("Department"). Neb. Rev. Stat. § 84-205(4) gives you, as the head of an executive department, the authority to ask our office's opinion on legal questions like this one.

The Department, acting through its Division of Public Health, enforces the Nebraska Uniform Credentialing Act ("UCA"). The purpose of the UCA is to protect public

health, safety, and welfare.[1] One way in which the Department protects the public is by investigating complaints alleging that licensed healthcare professionals have committed UCA violations.[2] After the Department completes an investigation, it refers the matter to the appropriate professional board to consider and make a recommendation to the Attorney General. Neb. Rev. Stat. § 38-186 then gives the Attorney General the authority to file a petition for discipline against the healthcare provider if such action is warranted.

You indicate in your request that "[c]onsumers and health care providers have been and continue to be inundated with information and opinions[] regarding COVID-19 treatment and prevention." You also note that due to the "sheer volume" of conflicting information, questions have been raised "regarding the permissibility of certain medications for the treatment or prevention of COVID-19." This observation is consistent with questions that our office has received from constituents and discussions that our office has witnessed at some of the professional boards' meetings.

After receiving your question and conducting our investigation, we have found significant controversy and suspect information about potential COVID-19 treatments. A striking example features one of the world's most prestigious medical journals—the Lancet. In the middle of the COVID-19 pandemic, the Lancet published a paper denouncing hydroxychloroquine as dangerous.[3] Yet the reported statistics were so flawed that journalists and outside researchers immediately began raising concerns.[4] Then after one of the authors refused to provide the analyzed data, the paper was retracted,[5] but not before many countries stopped using hydroxychloroquine and trials were cancelled or interrupted. The Lancet's own editor in chief admitted that the paper was a "fabrication," "a monumental fraud,"[6] and "a shocking example of research misconduct in the middle of

---

1 Neb. Rev. Stat. § 38-128(1).

2 Neb. Rev. Stat. § 38-1,124.

3 Mandeep R. Mehra et al., *Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis*, The Lancet (May 22, 2020), *available at* https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931180-6 (last visited Oct. 14, 2021).

4 Melissa Davey, *Questions raised over hydroxychloroquine study which caused WHO to halt trials for Covid-19*, The Guardian (May 27, 2020), *available at* https://www.theguardian.com/science/2020/may/28/questions-raised-over-hydroxychloroquine-study-which-caused-who-to-halt-trials-for-covid-19 (last visited Oct. 14, 2021).

5 Sarah Boseley & Melissa Davey, *Covid-19: Lancet retracts paper that halted hydroxychloroquine trials*, The Guardian (Jun. 4, 2020), *available at* https://www.theguardian.com/world/2020/jun/04/covid-19-lancet-retracts-paper-that-halted-hydroxychloroquine-trials (last visited Oct. 14, 2021).

6 Roni Caryn Rabin, *The Pandemic Claims New Victims: Prestigious Medical Journals*, New York Times (Jun. 14, 2020), *available at* https://www.nytimes.com/2020/06/14/health/virus-journals.html (last visited Oct. 14, 2021).

a global health emergency."[7] When fraudulent information is published in a leading medical journal, it understandably leads to skepticism in some physicians and members of the public. Mindful of these concerns about misunderstandings and mistrust, we have drafted a rather lengthy opinion that aims to address the public confusion and outline the relevant scientific literature that supports our legal conclusions.

At the outset, we pause to delineate the parameters of this opinion. The question presented asked about ivermectin, hydroxychloroquine, and other drugs used "off label"—that is, for a purpose other than the specific use approved by the U.S. Food and Drug Administration ("FDA"). To enable us to respond in a timely manner, we have confined our discussion to ivermectin and hydroxychloroquine only. But in doing so, we do not mean to rule out the possibility that other off-label drugs might show promise—either now or in the future—as a prophylaxis or treatment against COVID-19. Also, because our investigation has revealed that physicians who currently use hydroxychloroquine for COVID-19 do so as either a prophylaxis or an early treatment for outpatients (as opposed to a late treatment in hospitalized patients), we will confine our consideration of hydroxychloroquine to those two uses. In addition, we note that there are treatment options the FDA has approved, either through an Emergency Use Authorization ("EUA") or through the regular FDA drug-approval process, for COVID-19 prophylaxis or treatment. These include monoclonal antibodies, vaccines, and remdesivir. We do not take any position on those options because they are outside the scope of the question asked.

In the end, as we explain below, we find that the available data does not justify filing disciplinary actions against physicians simply because they prescribe ivermectin or hydroxychloroquine to prevent or treat COVID-19. If, on the other hand, healthcare providers neglect to obtain informed consent, deceive their patients, prescribe excessively high doses, fail to check for contraindications, or engage in other misconduct, they might be subject to discipline. But based on the evidence that currently exists, the mere fact of prescribing ivermectin or hydroxychloroquine for COVID-19 will not result in our office filing disciplinary actions. While our terminology throughout this opinion focuses on physicians prescribing these medicines, what we conclude necessarily applies to other licensed healthcare professionals who prescribe, participate in, or otherwise assist with a treatment plan utilizing these medications.

ANALYSIS

1. The Nebraska Uniform Credentialing Act and Other Relevant Law

The UCA was enacted by the legislature to license and regulate persons and businesses that provide healthcare and health-related services.[8] The UCA was adopted

---

7 Boseley & Davey, *supra*.

8 Neb. Rev. Stat. §§ 38-102 & 38-104.

to protect public health, safety, and welfare, and to provide for the efficient, adequate, and safe practice of credentialed persons and businesses.[9] "It is the intent of the Legislature," the UCA explains, "that quality health care services and human services be provided to the public" and "that professionals be regulated by the state only when it is demonstrated that such regulation is in the best interest of the public."[10]

The UCA grants the Director of Public Health of the Department's Division of Public Health the authority to deny a credential, refuse a credential renewal, or discipline a credential holder, although the Chief Medical Officer (if one is appointed) shall perform the Director's duties for decisions in contested administrative cases.[11] The Department must provide "the Attorney General with a copy of all complaints it receives and advise the Attorney General of investigations it makes" regarding possible violations of the UCA.[12] Following review and recommendation from the appropriate professional health board, the Attorney General must then determine whether the credential holder has violated any statutes or regulations and decide whether to proceed with administrative action.[13]

If the Attorney General determines that a violation has occurred, he "shall" file a petition for disciplinary action with the Department.[14] The Attorney General cannot prevail in disciplinary proceedings against a licensed healthcare professional unless he proves the claim by clear and convincing evidence.[15]

The grounds for disciplinary action are set forth in Neb. Rev. Stat. § 38-178 and include, among other things, acting with "gross incompetence or gross negligence," practicing in "a pattern of incompetent or negligent conduct," or engaging in "unprofessional conduct" as set forth in Neb. Rev. Stat. § 38-179.[16] Gross incompetence is a very high standard; it occurs only when there is "such an extreme deficiency on the part of a physician in the basic knowledge and skill necessary for diagnosis and treatment that one may reasonably question his or her ability to practice medicine at the threshold level of

---

9 Neb. Rev. Stat. § 38-103.

10 Neb. Rev. Stat. § 38-128(1).

11 Neb. Rev. Stat. §§ 38-176(1) & 38-1,101.

12 Neb. Rev. Stat. § 38-1,107(1).

13 Neb. Rev. Stat. §§ 38-1,107 & 38-1,108.

14 Neb. Rev. Stat. § 38-186.

15 *Poor v. State*, 266 Neb. 183, 190, 663 N.W.2d 109, 115 (2003); *Davis v. Wright*, 243 Neb. 931, 936-37, 503 N.W.2d 814, 818 (1993).

16 Neb. Rev. Stat. § 38-178(6), (24).

professional competence."[17] Neb. Rev. Stat. § 38-179 generally defines unprofessional conduct as a "departure from or failure to conform to the standards of acceptable and prevailing practice of a profession or the ethics of the profession, regardless of whether a person, consumer, or entity is injured, or conduct that is likely to deceive or defraud the public or is detrimental to the public interest."[18] Along these same lines, the regulation governing physicians states that unprofessional conduct includes:

> [c]onduct or practice outside the normal standard of care in the State of Nebraska which is or might be harmful or dangerous to the health of the patient or the public, not to include a single act of ordinary negligence.[19]

Healthcare providers do not violate the standard of care when they "select between two reasonable approaches to . . . medicine."[20] Regulations also indicate that physicians may utilize reasonable "investigative or unproven therapies" that reflect a reasonable approach to medicine so long as physicians obtain "written informed patient consent."[21] "Informed consent concerns a doctor's duty to inform his or her patient," and it includes telling patients about "the nature of the pertinent ailment or condition, the risks of the proposed treatment or procedure, and the risks of any alternative methods of treatment, including the risks of failing to undergo any treatment at all."[22] Regulations require physicians "to keep and maintain" records that disclose the "advice and cautionary warnings provided to the patient."[23]

Prescribing medicines for off-label use—that is, for some purpose other than the use approved by the FDA—often falls within the standard of care. Indeed, "[o]ff-label use is legal, common, and necessary,"[24] and "[c]ourts have repeatedly recognized the propriety of off-label use."[25] This includes the U.S. Court of Appeals for the Eighth Circuit, which has acknowledged that "[d]octors may prescribe an FDA-approved drug for

---

17 *Langvardt v. Horton*, 254 Neb. 878, 895, 581 N.W.2d 60, 70-71 (1998).

18 Neb. Rev. Stat. § 38-179.

19 172 Neb. Admin. Code § 88-009(Q).

20 *Whittle v. Dep't of Health & Hum. Servs.*, 309 Neb. 695, 721-22, 962 N.W.2d 339, 356-57 (2021).

21 172 Neb. Admin. Code § 88-009(B).

22 *Curran v. Buser*, 271 Neb. 332, 337, 711 N.W.2d 562, 568 (2006) (citations omitted).

23 172 Neb. Admin. Code § 88-009(B).

24 James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 76 (1998) (capitalization omitted).

25 *Id.* (collecting cases).

nonapproved uses."[26] And the U.S. Supreme Court, in an analogous context, has affirmed that "'off-label' usage of medical devices" is an "accepted and necessary" practice.[27] Even the FDA recognizes that off-label use is legitimate: it has said for many decades that once it approves a drug, "a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling."[28] Expanding on that point, the FDA has explained that "healthcare providers generally may prescribe [a] drug for an unapproved use when they judge that it is medically appropriate for their patient."[29] Nothing in the federal Food, Drug, and Cosmetic Act ("FDCA") "limit[s] the manner in which a physician may use an approved drug."[30]

Based on these principles, we conclude that governing law allows physicians to use FDA-approved medicines that are unproven for a particular off-label use so long as (1) reasonable medical evidence supports that use and (2) a patient's written informed consent is obtained. In the context of this ever-changing global pandemic, we note that it is appropriate to consider medical evidence outside of Nebraska and to give physicians who obtain informed consent an added measure of deference on their assessment of the available medical evidence.

2. COVID-19 and SARS-CoV-2

The disease known as COVID-19 and the virus that causes it—SARS-CoV-2—took the world by storm in late 2019 and early 2020. While there is still so much that the medical community does not know about SARS-CoV-2 and COVID-19, it is widely recognized that COVID-19 is a multifaceted disease. "[A]dults with SARS-CoV-2 infection can be grouped" into at least three different categories depending on the progression of their disease.[31] The first group has an asymptomatic or presymptomatic infection, meaning that those individuals have "test[ed] positive for SARS-CoV-2" but "have no symptoms

---

[26] *Rhone-Poulenc Rorer Pharms., Inc. v. Marion Merrell Dow, Inc.*, 93 F.3d 511, 514 n.3 (8th Cir. 1996).

[27] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

[28] FDA Drug Bulletin at 5 (Apr. 1982), *available at* https://play.google.com/books/reader?id=3f3YC3Gw6sEC&pg=GBS.PA6&hl=en (last visited Oct. 14, 2021).

[29] U.S. Food & Drug Administration, Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label (last visited Oct. 14, 2021).

[30] FDA Drug Bulletin, *supra*, at 5. Because the question posed to us asks about prescribing drugs for off-label use, any view on the legality of efforts to market drugs for off-label use is outside the scope of this opinion.

[31] National Institutes of Health, Clinical Spectrum of SARS-CoV-2 Infection, COVID-19 Treatment Guidelines (Apr. 21, 2021), *available at* https://www.covid19treatmentguidelines.nih.gov/overview/clinical-spectrum/ (last visited Oct. 14, 2021).

that are consistent with COVID-19."[32] A second group experiences a mild illness that manifests itself through "any of the various signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell)" but does not include "shortness of breath, dyspnea, or abnormal chest imaging."[33] And a third group suffers from a more severe illness marked by "evidence of lower respiratory disease" and deficient "oxygen saturation" levels.[34] When people in this third category reach a critical level, they often "have respiratory failure, septic shock, and/or multiple organ dysfunction."[35]

A recently published paper on COVID-19 recognized that "for reasons that are yet to be clarified, early treatment has not been emphasized" in Western countries like the United States.[36] Despite this, many healthcare providers in the United States advocate for early treatment, particularly for high-risk patients. In fact, scores of treating and academic physicians have published papers in well-respected journals like the American Journal of Medicine explaining that the "multifaceted pathophysiology of life-threatening COVID-19 illness . . . warrants early interventions"[37] and encouraging "outpatient treatment of the illness with the aim of preventing hospitalization or death."[38] Also, a declaration of the International Alliance of Physicians and Medical Scientists—which is apparently signed by over 10,000 physicians and scientists, more than 60 of whom are publicly identified online—supports a doctor's choice to provide early COVID-19 care rather than "advising their patients to simply go home . . . and return when their disease worsens."[39]

---

32 *Id.*

33 *Id.*

34 *Id.*

35 *Id.*

36 Matthieu Million et al., *Early combination therapy with hydroxychloroquine and azithromycin reduces mortality in 10,429 COVID-19 outpatients*, 22 Reviews in Cardiovascular Medicine 1063, 1063 (Sept. 2021), https://rcm.imrpress.com/article/2021/2153-8174/2153-8174-22-3-1063.shtml (last visited Oct. 14, 2021).

37 Peter A. McCullough et al., *Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19)*, 21 Reviews in Cardiovascular Medicine 517, 518 (Dec. 2020), *available at* https://rcm.imrpress.com/article/2020/2153-8174/RCM2020264.shtml (last visited Oct. 14, 2021) (including 57 co-authors) (hereinafter, "McCullough, *Multifaceted*").

38 Peter A. McCullough et al., *Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection*, 134 American Journal of Medicine 16, 16 (Jan. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7410805/pdf/main.pdf (last visited Oct. 14, 2021) (including 23 co-authors) (hereinafter, "McCullough, *Pathophysiological*").

39 Physicians Declaration, Global COVID Summit, International Alliance of Physicians and Medical Scientists (Sept. 2021), https://doctorsandscientistsdeclaration.org/ (last visited Oct. 14, 2021).

These groups of physicians have established protocols for early treatment, and ivermectin and hydroxychloroquine are staples of those treatments.[40] As discussed in greater detail below, while the scientific literature is continuing to grow, some data suggest that ivermectin- or hydroxychloroquine-based early treatments of COVID-19 can be effective in thwarting hospitalization and death.[41]

3. Ivermectin

A. History of Ivermectin

Researchers discovered ivermectin in the 1970s, and while its first use was to treat parasites in animals, ivermectin has been used in humans since the 1980s.[42] In the early years, ivermectin effectively stymied the scourge of two devastating parasitic diseases—onchocerciasis (also known as river blindness) and lymphatic filariasis—"among poverty-stricken populations throughout the tropics."[43] These are two of the most "disfiguring diseases" that "have plagued the world's poor . . . for centuries."[44] Later, the use of ivermectin was expanded to include "the treatment of scabies and lice."[45]

---

40 *E.g.*, McCullough, *Multifaceted*, *supra*, at 519 Table 1 (listing early treatment kits that include both ivermectin and hydroxychloroquine); McCullough, *Pathophysiological*, *supra*, at 18–19 (discussing hydroxychloroquine).

41 *E.g.*, Flavio A. Cadegiani et al., *Early COVID-19 therapy with azithromycin plus nitazoxanide, ivermectin or hydroxychloroquine in outpatient settings significantly improved COVID-19 outcomes compared to known outcomes in untreated patients*, New Microbes and New Infections (Sept. 2021), *available at* https://www.sciencedirect.com/science/article/pii/S2052297521000792 (last visited Oct. 14, 2021) (finding that "the use of nitazoxanide, ivermectin[,] and hydroxychloroquine demonstrated unexpected improvements in COVID-19 outcomes when compared to untreated patients").

42 Andy Crump, *Ivermectin: enigmatic multifaceted 'wonder' drug continues to surprise and exceed expectations*, 70 The Journal of Antibiotics 495, 495 (2017), *available at* https://www.nature.com/articles/ja201711.pdf (last visited Oct. 14, 2021) (hereinafter, "Crump, *Ivermectin*").

43 *Id*.

44 Andy Crump & Satoshi Ōmura, *Ivermectin, 'wonder drug' from Japan: the human use perspective*, 87 Proceedings of the Japan Academy, Series B, Physical and biological sciences 13, 13 (2011), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3043740/pdf/pjab-87-013.pdf (last visited Oct. 14, 2021).

45 Andrew Bryant et al., *Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines*, 28 American Journal of Therapeutics 434, 435 (Jul./Aug. 2021), *available at* https://journals.lww.com/americantherapeutics/fulltext/2021/08000/ivermectin_for_prevention_and_treatment_of.7.aspx (last visited Oct. 14, 2021) (hereinafter, "Bryant, *Ivermectin*").

Given its track record as a medicine for humans, ivermectin has long since been "approved as an antiparasitic" by the World Health Organization (WHO) and the FDA.[46] The WHO has also recognized ivermectin as one of its "Essential Medicines."[47] Further recognizing the importance of this drug, in 2015 its discoverers won the Nobel Prize in Medicine for their work in uncovering it and bringing it to market.[48]

In the decade leading up to the COVID-19 pandemic, studies began to show ivermectin's surprising versatility. By 2017, ivermectin had "demonstrate[d] antiviral activity against several RNA viruses by blocking the nuclear trafficking of viral proteins."[49] One recent systematic review cited more than a handful of studies to "demonstrate that ivermectin has antiviral properties against an increasing number of RNA viruses, including influenza, *Zika*, HIV, [and] *Dengue*."[50] And another review summarized the "antiviral effects of ivermectin" demonstrated through "studies over the past 50 years."[51]

Before the pandemic, scholarly literature had also recognized ivermectin's "anti-inflammatory capacity."[52] Doctors thus have been using ivermectin to treat "rosacea, a chronic inflammatory disease," that manifests itself as a reddening of the face, and the FDA has approved ivermectin for that purpose.[53] Ivermectin's ability to "curb inflammation," one reviewer wrote, may also "be useful in treating . . . inflammatory airway diseases."[54] Summing it up, that same reviewer recognized that "ivermectin is continuing

---

46 *Id.*

47 *Id.*

48 The Nobel Prize, Press Release for The Nobel Prize in Physiology or Medicine 2015 (Oct. 5, 2015), https://www.nobelprize.org/prizes/medicine/2015/press-release/ (last visited Oct. 14, 2021).

49 Crump, *Ivermectin*, *supra*, at 500.

50 Pierre Kory et al., *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, 28 American Journal of Therapeutics 299, 301 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8088823/ (last visited Oct. 14, 2021).

51 Fatemeh Heidary & Reza Gharebaghi, *Ivermectin: a systematic review from antiviral effects to COVID-19 complementary regimen*, 73 The Journal of Antibiotics 593, 593 (2020), *available at* https://www.nature.com/articles/s41429-020-0336-z.pdf (last visited Oct. 14, 2021) ("Several studies reported antiviral effects of ivermectin on RNA viruses . . . . Furthermore, there are some studies showing antiviral effects of ivermectin against DNA viruses . . . .").

52 Crump, *Ivermectin*, *supra*, at 499.

53 Leon H. Kircik et al., *Over 25 Years of Clinical Experience With Ivermectin: An Overview of Safety for an Increasing Number of Indications*, 15 Journal of Drugs in Dermatology 325, 325 (Mar. 2016), *available at* https://jddonline.com/articles/dermatology/S1545961616P0325X (last visited Oct. 14, 2021).

54 Crump, *Ivermectin*, *supra*, at 499; *see also* Arianna Portmann-Baracco et al., *Antiviral and anti-inflammatory properties of ivermectin and its potential use in Covid-19*, 56 Archivos De Bronconeumologia

to surprise and excite scientists, offering more and more promise to help improve global public health by treating a diverse range of diseases."[55]

For more than three decades, ivermectin has also shown itself to be very safe. Indeed, the National Institutes of Health ("NIH") recognize that "ivermectin has been widely used and is generally well tolerated."[56] One recent systematic review similarly states that "ivermectin at the usual doses . . . is considered extremely safe for use in humans."[57] Other studies have noted that the medicine "has an established safety profile for human use,"[58] and it "provide[s] a high margin of safety for a growing number of indications."[59] Notably, a December 2018 WHO-supported application to add ivermectin as an essential medicine for scabies reviewed the data and concluded that the adverse events associated with ivermectin are "primarily minor and transient."[60]

The available data support this conclusion. The WHO's VigiAccess database, which compiles adverse drug reactions from throughout the world, breaks down the reported side effects for drugs into different categories.[61] The largest reported categories for ivermectin include skin issues, headaches, dizziness, and gastrointestinal disturbances such as diarrhea and nausea.[62] The NIH confirms that ivermectin's primary adverse side effects "include dizziness, pruritis [itchy skin], nausea, or diarrhea."[63] And

---

831, 831 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7578741/pdf/main.pdf (last visited Oct. 14, 2021) ("Ivermectin has a demonstrated anti-inflammatory effect *in vivo* and *in vitro*").

55 Crump, *Ivermectin*, *supra*, at 495.

56 National Institutes of Health, COVID-19 Treatment Guidelines: Ivermectin, https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/ (last visited Oct. 14, 2021) (hereinafter, "NIH, COVID-19 and Ivermectin").

57 Bryant, *Ivermectin*, *supra*, at 435.

58 Leon Caly et al., *The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro*, Antiviral Research 178 at 3 (June 2020), *available at* https://www.sciencedirect.com/science/article/pii/S0166354220302011 (last visited Oct. 14, 2021).

59 Kircik, *Ivermectin*, *supra*, at 325.

60 WHO Expert Committee on the Selection and Use of Essential Medicines: Application for inclusion of ivermectin on the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc) for the indication of Scabies at 19 (Dec. 2018), *available at* https://www.who.int/selection_medicines/committees/expert/22/applications/s6.6_ivermectin.pdf (last visited Oct. 14, 2021).

61 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

62 *Id.*

63 NIH, COVID-19 and Ivermectin, *supra*.

a recent review of ivermectin similarly describes the common side effects as "itching, rash, swollen lymph nodes, joint pain[], fever, and headache."[64]

The data show not only that the adverse side effects are minor, but also that the percentage of people who report experiencing any adverse events is vanishingly small. The latest statistics available through VigiAccess report only 5,674 adverse drug reactions from ivermectin between 1992 and October 13, 2021.[65] This number is incredibly low considering that "more than 3.7 billion doses" of ivermectin have been administered to humans worldwide since the 1980s.[66]

To illustrate the safety of ivermectin, compare its VigiAccess report to that of remdesivir, an FDA-approved treatment for COVID-19.[67] Remdesivir was not released for widespread use until 2020. Yet in the short period of time that it has been on the market, people have reported at least 7,491 adverse drug reactions on VigiAccess, more than ivermectin has registered over the last 30 years.[68] What's more, serious adverse reactions from remdesivir are reported in high numbers. For example, in less than two years, those who have used remdesivir have reported over 560 deaths, 550 serious cardiac disorders (such as bradycardia and cardiac arrest), and 475 acute kidney injuries.[69] Since that safety profile is sufficient to retain FDA approval, ivermectin's safety record cannot reasonably be questioned.

B. Ivermectin and COVID-19

As discussed above, ivermectin had shown its antiviral and anti-inflammatory properties long before the pandemic began. So when COVID-19 began to spread across the globe, some in the medical community quickly identified ivermectin as a potential drug for the prevention and treatment of COVID-19. Initially, a group of researchers found that ivermectin significantly inhibited replication of SARS-CoV-2 in cell cultures.[70] Dismissing

---

64 Kory, *supra*, at 314.

65 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

66 Morimasa Yagisawa et al., *Global trends in clinical studies of ivermectin in COVID-19*, 74 The Japanese Journal of Antibiotics 44, 46 (Mar. 2021), *available at* http://jja-contents.wdc-jp.com/pdf/JJA74/74-1-open/74-1_44-95.pdf (last visited Oct. 14, 2021).

67 U.S. Food and Drug Administration, *FDA Approves First Treatment for COVID-19* (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19 (last visited Oct. 14, 2021).

68 VigiAccess, Uppsala Monitoring Centre, WHO Collaborating Centre for International Drug Monitoring, http://www.vigiaccess.org/ (last visited Oct. 14, 2021).

69 *Id.*

70 Caly, *supra*, at 1.

that finding, ivermectin doubters argued that too much of the drug would be needed to achieve this antiviral activity in humans.[71] But peer-reviewed models undermined those concerns by showing that the predicted accumulation of ivermectin in the lungs—the site in the body where the medicine is most needed—would be over 10 times higher than necessary for antiviral activity.[72] In layman's terms, these models indicated that an effective level of the medicine can be reached in lung tissue without creating toxicity in the blood. Plus, other pro-ivermectin doctors have explained that the amount of the drug "required for an effect in cell culture models bear[s] little resemblance to human physiology" because cell cultures lack "an active immune system working synergistically with" the medicine.[73]

The doctors who believed that ivermectin could be effective against COVID-19 also identified its anti-inflammatory properties as an important countermeasure to the disease. One reason why COVID-19 progresses to its severe phase, many believe, is "the provocation of an overwhelming and injurious inflammatory response."[74] Thus, ivermectin's anti-inflammatory effects suggest that it can help COVID-19 patients as the disease worsens.

i. Ivermectin Studies and Meta-analyses

Since the COVID-19 pandemic began, researchers have conducted over 20 randomized controlled trials (RCTs) and more observational trials to evaluate ivermectin's effectiveness in the prevention and treatment of COVID-19.[75] Many of those trials showed promise. On the question of COVID-19 prevention, the Shouman study out of Egypt—a RCT—evaluated ivermectin as a potential prophylaxis for close family members of COVID-19 patients.[76] The test group included 203 family members who took

---

71 Virginia D. Schmith et al., *The Approved Dose of Ivermectin Alone is not the Ideal Dose for the Treatment of COVID-19*, 108 Clinical Pharmacology & Therapeutics 762, 762 (Oct. 2020), *available at* https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1002/cpt.1889 (last visited Oct. 14, 2021).

72 Usman Arshad et al., *Prioritization of Anti-SARS-Cov-2 Drug Repurposing Opportunities Based on Plasma and Target Site Concentrations Derived from their Established Human Pharmacokinetics*, 108 Clinical Pharmacology and Therapeutics 775, 785 (Oct. 2020), *available at* https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1002/cpt.1909 (last visited Oct. 14, 2021).

73 Kory, *supra*, at 301.

74 *Id.*

75 Bryant, *Ivermectin*, *supra*, at 435.

76 Waheed M. Shouman et al., *Use of Ivermectin as a Potential Chemoprophylaxis for COVID-19 in Egypt: A Randomised Clinical Trial*, 15 Journal of Clinical and Diagnostic Research 27, 27 (Feb. 2021), *available at* https://www.jcdr.net/articles/PDF/14529/46795_CE[Ra]_F(Sh)_PF1(SY_OM)_PFA_(OM)_PN(KM).pdf (last visited Oct. 14, 2021).

ivermectin, and only 15 of them (7.4%) developed COVID-19.[77] Compare that to the 101 family members in the control group, 59 of whom (58.4%) tested positive during the study.[78] These outcomes prompted the research team to conclude that ivermectin is "a promising, effective[,] and safe chemoprophylactic drug in management of COVID-19."[79] Also, the Behera study in India tested ivermectin as a prophylaxis in a group of 3,532 healthcare workers.[80] Of the 2,199 workers who took two doses of ivermectin prophylaxis three days apart, only 45 (2%) tested positive for COVID-19.[81] But of the 1,147 workers who did not take ivermectin, 133 (11.6%) contracted the disease.[82] Behera's team thus announced that two doses of ivermectin "as chemoprophylaxis among [healthcare workers] reduced the risk of COVID-19 infection by 83% in the following month."[83]

Moving beyond ivermectin's role as a prophylaxis, other studies have demonstrated its potential as a COVID-19 treatment. The Mahmud study—a RCT that explored ivermectin as an early treatment for 363 individuals—concluded that "[p]atients with mild-to-moderate COVID-19 infection treated with ivermectin plus doxycycline recovered earlier, were less likely to progress to more serious disease, and were more likely to be COVID-19 negative . . . on day 14."[84] And Niaee's research team found that ivermectin can help even hospitalized patients.[85] That group conducted a "randomized, double-blind, placebo-controlled, multicenter clinical trial" with 180 hospitalized patients diagnosed with COVID-19.[86] They concluded that ivermectin "reduces the rate of

---

77 *Id.*

78 *Id.*

79 *Id.*

80 Priyamadhaba Behera et al., *Prophylactic Role of Ivermectin in Severe Acute Respiratory Syndrome Coronavirus 2 Infection Among Healthcare Workers*, Cureus, at 1 (Aug. 2021), *available at* https://assets.cureus.com/uploads/original_article/pdf/64807/20210904-4912-omcmtf.pdf (last visited Oct. 14, 2021).

81 *Id.* at 5.

82 *Id.*

83 *Id.* at 1.

84 Reaz Mahmud et al., *Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial*, Journal of International Medical Research 49(5) (Apr. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8127799/pdf/10.1177_03000605211013550.pdf (last visited Oct. 14, 2021).

85 Morteza Shakhsi Niaee et al., *Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: A randomized multi-center clinical trial*, 14 Asian Pacific Journal of Tropical Medicine 266, 266 (2021), *available at* https://www.apjtm.org/temp/AsianPacJTropMed146266-5371482_145514.pdf (last visited Oct. 14, 2021).

86 *Id.*

mortality . . . and duration of hospitalization in adult COVID-19 patients," and "[t]he improvement of other clinical parameters showed that the ivermectin, with a wide margin of safety, had a high therapeutic effect on COVID-19."[87]

As the data accumulated, scholars began conducting and publishing meta-analyses of the available studies. One such analysis—the Bryant review—focused on 24 total RCTs involving 3,406 participants and found "with moderate certainty that ivermectin treatment in COVID-19 provides a significant survival benefit."[88] It also concluded that "[u]sing ivermectin early in the clinical course may reduce numbers progressing to severe disease" and that "[t]he apparent safety and low cost suggest that ivermectin is likely to have a significant impact on the SARS-CoV-2 pandemic globally."[89] Following Bryant's publication of his team's review, the Elgazzar study—one of the RCTs included in the meta-analysis—was questioned and is now under review. This prompted Bryant's team to reanalyze the data without the Elgazzar study, and that review still found "a clear result, showing a 49% reduction in mortality in favor of ivermectin."[90]

Another meta-analysis known as the Popp review has reached more skeptical conclusions. That analysis, which excluded some of the RCTs that Bryant considered, evaluated only 14 studies with 1,678 participants and determined that the "completed studies are small and few are considered high quality."[91] Thus, the authors expressed "uncertain[ty] about the efficacy and safety of ivermectin used to treat or prevent COVID-19."[92] Recently, however, the Bryant team critiqued the Popp review, highlighting, among other things, that although "Popp claims to provide a 'complete evidence profile,'" it actually "excludes most of the available evidence."[93]

In further contrast, a third meta-analysis expressed doubt about ivermectin. That one—the Roman review—restricted the pool of RCTs even further, considering only 10

---

87 *Id.*

88 Bryant, *Ivermectin*, *supra*, at 451.

89 *Id.* at 435.

90 Andrew Bryant et al., *Letter to the Editor: Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines*, 28 American Journal of Therapeutics 573, 573 (Sept./Oct. 2021), *available at* https://covid19criticalcare.com/wp-content/uploads/2021/09/Response-to-Elgazzar.pdf (last visited Oct. 14, 2021).

91 Maria Popp et al., *Ivermectin for preventing and treating COVID-19*, Cochrane Database of Systematic Reviews, at 2 (July 28, 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8406455/pdf/CD015017.pdf (last visited Oct. 14, 2021).

92 *Id.*

93 Edmund J. Fordham et al., *The uses and abuses of systematic reviews: the case of ivermectin in Covid-19*, OSF Preprints, at 7 (Sept. 3, 2021), *available at* https://osf.io/peqcj/ (last visited Oct. 14, 2021).

of them.[94] After doing this, the authors concluded that ivermectin does "not reduce all-cause mortality, [length of hospital stay], or viral clearance . . . in patients with mostly mild COVID-19."[95] As a result, the researchers announced that ivermectin "is not a viable option to treat patients with COVID-19."[96]

In the days since its publication, the Roman review has drawn some harsh criticism. In particular, the authors of the Bryant review have highlighted four categories of flaws with Roman's work: (1) "mis-reporting of source data," (2) "highly selective study inclusion," (3) "'cherry picking' of data within included studies," and (4) "conclusions that do not follow from the evidence."[97] To illustrate these flaws, consider that Roman's paper initially inverted the treatment and control arms for the Niaee study and thus indicated less mortality in the control group when in fact the opposite was true.[98] Once that error was fixed, the numbers no longer supported the conclusion that ivermectin does "not reduce all-cause mortality."[99] Yet the Roman team did not adjust that statement, and thus its "conclusions are no longer based on the data."[100]

Furthermore, in a letter to the editor of the *American Journal of Therapeutics*, two researchers recently explained that Roman's conclusion of no mortality reduction "is not based on the results of the statistical analysis of the data . . . ; instead, it was based on a somewhat vague and possibly biased subjective assessment of the quality of the trials

---

94 Yuani M. Roman et al., *Ivermectin for the treatment of Coronavirus Disease 2019: A systematic review and meta-analysis of randomized controlled trials*, Clinical Infectious Diseases, at 1 (June 28, 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8394824/pdf/ciab591.pdf (last visited Oct. 14, 2021).

95 *Id.*

96 *Id.*

97 Letter from Andrew Bryant et al. to Robert T. Schooley, MD, Editor in Chief, Clinical Infectious Diseases, at 3, *available at* https://covid19criticalcare.com/wp-content/uploads/2021/07/RomanRebuttal_v7_EF_letterhead_ML-1.pdf (last visited Oct. 14, 2021) (hereinafter, "Bryant Letter to Schooley").

98 *Compare* Yuani M. Roman et al., *Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials*, Preprint Version 1, at 27 Figure 2 (May 25, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.05.21.21257595v1.full.pdf (last visited Oct. 14, 2021) (listing the Niaee study as having four deaths in the control arm and 11 in the ivermectin arm), *with* Yuani M. Roman et al., *Ivermectin for the treatment of COVID-19: A systematic review and meta-analysis of randomized controlled trials*, Preprint Version 2, at 27 Figure 2 (May 26, 2021), *available at* https://www.medrxiv.org/content/10.1101/2021.05.21.21257595v2.full.pdf (last visited Oct. 14, 2021) (correcting the Niaee study to list 11 deaths in the control arm and four in the ivermectin arm).

99 Bryant Letter to Schooley, *supra*, at 2.

100 *Id.*

themselves."[101] Those researchers conducted their own Bayesian analysis, a method of statistical inference, and found that the "probability for the hypothesis of a causal link between COVID-19 severity, ivermectin, and mortality is over 99%."[102] As they concluded, "[i]n our view, this Bayesian analysis, based on the statistical study data, provides sufficient confidence that ivermectin is an effective treatment for COVID-19 and this belief supports the conclusions of Bryant over those of Roman."[103] Those scholars have since published their full analysis in a paper available online.[104]

Additional supportive evidence for Bryant's conclusions is a non-peer-reviewed website that currently maintains a running list of 64 COVID-19-related ivermectin studies—RCTs and others—which include all the relevant ivermectin studies except the few (such as Elgazzar) whose data have been called into question.[105] Of those 64 studies, 31 are RCTs and 44 have been peer-reviewed.[106] That site posts multiple meta-analyses of different groupings of the data and concludes that "[m]eta analysis using the most serious outcome reported shows" that ivermectin leads to 66% "improvement for early treatment" and an 86% "improvement for . . . prophylaxis."[107] These "[r]esults are very robust," the site reports, because "in worst case exclusion sensitivity analysis 53 of 64 studies must be excluded to avoid finding statistically significant efficacy."[108]

Finally, a recent mini-review of ivermectin and COVID-19 considered the studies analyzing ivermectin's safety specifically in the context of COVID-19 treatments.[109] That mini-review—which was authored by Yale Professor Alessandro D. Santin—observed

---

101 Martin Neil & Norman Fenton, *Bayesian Hypothesis Testing and Hierarchical Modeling of Ivermectin Effectiveness*, 28 American Journal of Therapeutics 576, 576 (Sept./Oct. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8415515/pdf/ajt-28-e576.pdf (last visited Oct. 14, 2021).

102 *Id.*

103 *Id.* at 578.

104 Martin Neil & Norman Fenton, Bayesian hypothesis testing and hierarchical modelling of ivermectin effectiveness in treating Covid-19 (Oct. 1, 2021), *available at* https://arxiv.org/ftp/arxiv/papers/2109/2109.13739.pdf (last visited Oct. 14, 2021).

105 Ivermectin for COVID-19: Real-time meta analysis of 64 studies (Oct. 8, 2021), https://ivmmeta.com/ (last visited Oct. 14, 2021).

106 *Id.*

107 *Id.*

108 *Id.*

109 Alessandro D. Santin et al., *Ivermectin: a multifaceted drug of Nobel prize-honoured distinction with indicated efficacy against a new global scourge, COVID-19*, New Microbes New Infections (Aug. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8383101/pdf/main.pdf (last visited Oct. 14, 2021).

that ivermectin "has been safely used in 3.7 billion doses since 1987" and that the medicine has been "used without serious [adverse effects]" in multiple "COVID-19 treatment studies."[110]

The existing ivermectin studies and meta-analyses are subject to vigorous ongoing disputes, and there are large ongoing studies, at least one of which includes the NIH as a collaborator, that will hopefully provide additional clarity.[111] But based on the existing medical literature, we do not find clear and convincing evidence that a physician who prescribes ivermectin for COVID-19 after obtaining informed consent engages in unprofessional conduct or otherwise violates the UCA.

While we find the studies and meta-analyses sufficient to resolve this question, we note that epidemiological evidence—derived by analyzing COVID-related data from various states, countries, or regions—is also instructive in the context of a global pandemic. We highlight just a few examples.

One set of scholars analyzed data comparing the COVID-19 rates of countries that routinely administer ivermectin as a prophylaxis and countries that do not.[112] The research revealed that "countries with routine mass drug administration of prophylactic . . . ivermectin have a significantly lower incidence of COVID-19."[113] This "highly significant" correlation manifests itself not only "in a worldwide context" but also when comparing African countries that regularly administer prophylactic "ivermectin against parasitic infections" and African countries that do not.[114] Based on these results, the researchers surmised that these results "may be connected to ivermectin's ability to inhibit SARS-CoV-2 replication, which likely leads to lower infection rates."[115]

---

110 *Id.* at 4.

111 *E.g.*, U.S. National Library of Medicine, ACTIV-6: COVID-19 Study of Repurposed Medications, https://clinicaltrials.gov/ct2/show/NCT04885530?term=activ-6&draw=2&rank=1 (last visited Oct. 14, 2021) (purpose of this trial involving an estimated 15,000 participants is "to evaluate the effectiveness of repurposed medications" that include ivermectin "in reducing symptoms of non-hospitalized participants with mild to moderate COVID-19"); U.S. National Library of Medicine, COVID-OUT: Early Outpatient Treatment for SARS-CoV-2 Infection (COVID-19), https://clinicaltrials.gov/ct2/show/NCT04510194? term=ivermectin+boulware&draw=2&rank=1 (last visited Oct. 14, 2021) (purpose of this trial involving 1,160 participants is to understand whether ivermectin is superior to other options, including placebo, in "non-hospitalized adults with SARS-CoV-2 disease for preventing Covid-19 disease progression").

112 Martin D. Hellwig & Anabela Maia, *A COVID-19 prophylaxis? Lower incidence associated with prophylactic administration of ivermectin*, International Journal of Antimicrobial Agents (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7698683/pdf/main.pdf (last visited Oct. 14, 2021).

113 *Id.* at 1.

114 *Id.*

115 *Id.*

More specifically, Peru's COVID-19 statistics, which have been analyzed in pre-print studies and discussed in published ivermectin reviews, are also informative.[116] Peru deployed mass ivermectin-based COVID-19 treatments from April 2020 through November 2020 throughout its 25 states.[117] In ten of those states, a maximal amount of "mass [ivermectin] treatments of COVID-19 were conducted through a broadside, army-led effort, *Mega-Operación Tayta (MOT)*."[118] Fourteen other states had a medium distribution of ivermectin administered at the local level.[119] And one state, Lima, distributed a minimal amount of ivermectin due to restrictive government policies.[120] "The mean reduction in excess deaths 30 days after peak deaths was 74% for the maximal [ivermectin] distribution group, 53% for the medium group[,] and 25% for Lima."[121] Furthermore, throughout the country of Peru, "excess deaths decreased 14-fold over four months" leading up to December 1, 2020, "after which deaths then increased 13-fold when [ivermectin] use was restricted under a new president."[122]

---

116 Juan J. Chamie-Quintero et al., *Ivermectin for COVID-19 in Peru: 14-fold reduction in nationwide excess deaths, p < 0.002 for effect by state, then 13-fold increase after ivermectin use restricted* (Mar. 2021), *available at* https://osf.io/9egh4/ (last visited Oct. 14, 2021); *see also* Santin, *supra*, at 3–4 (discussing the Peruvian data); Kory, *supra*, at 311–13 (same).

117 Chamie-Quintero, *supra*, at 2.

118 Santin, *supra*, at 3.

119 Chamie-Quintero, *supra*, at 2.

120 *Id.*

121 *Id.*

122 *Id.*

Ivermectin for COVID-19 in Peru: 14-fold reduction in nationwide excess deaths, p=.002 for effect by state, then 13-fold increase after ivermectin use restricted

Juan J. Chamie-Quintero,[a] Jennifer A. Hibberd,[b] David E Scheim[c]

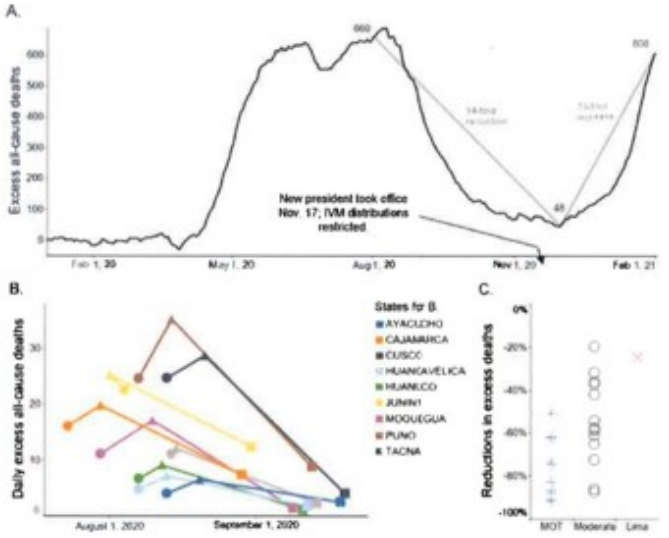


Figure 1. A) **Excess all-cause deaths (all ages), national population of Peru.** These decreased 14-fold August 1 through December 1, 2020; then, after IVM use was restricted, increased 13-fold through February 1. All y values are 7-day moving averages; for B.C. ages ≥ 60. Data are from Peru's National Death Information System (SINADEF).[12] B) Drops in excess deaths for all states of operation *MOT*, an army-led program of mass IVM distributions, but Pasco, which had them on 3 dates. ● *MOT* start date: ▲ peak deaths; ■ day of peak deaths + 30 days. Junin also distributed IVM 13 days before *MOT* start. C) Reductions in excess deaths at +30 days after peak deaths for the 25 states by extent of IVM distributions: maximal-*MOT* (+), mean -74%; moderate-local distributions (○), mean -53%; and minimal-Lima (x), -25%. These reductions for the 25 states correlated with extent of IVM distributions with Kendall τ_b p=0.002.

"Potential confounding factors, including lockdowns and herd immunity, were ruled out using Google community mobility data, seropositivity rates, population densities and geographic distributions of SARS-CoV-2 genetic variations."[123] While these figures do not prove causation, they demonstrate a strong correlation between ivermectin use and mortality reductions.

Moving from Peru to India, the government in the State of Uttar Pradesh—a jurisdiction with a population of more than 200 million—"introduced a large-scale 'prophylactic and therapeutic' use of [i]vermectin" that enabled it "to maintain a lower fatality and

123 Santin, *supra*, at 4.

positivity rate as compared to other states" in India.[124] As one state official explained, "Uttar Pradesh was the first state in [India] to introduce large-scale prophylactic and therapeutic use of Ivermectin."[125] The state's health department introduced ivermectin "as prophylaxis for close contacts of [COVID-19] patients" and "health workers," "as well as for the treatment of the patients themselves."[126] "Despite being [India's] state with the largest population base and a high population density," that state official added, Uttar Pradesh has "maintained a relatively low positivity rate and cases per million of population."[127] Although these statements from the Uttar Pradesh government do not prove ivermectin's effectiveness, they are informative and worthy of some consideration.

ii. U.S. Public Health Agencies on Ivermectin

Many public health agencies in the United States have now addressed the topic of ivermectin and COVID-19. The NIH has adopted a neutral position, saying that "[t]here is insufficient evidence . . . to recommend either for or against the use of ivermectin for the treatment of COVID-19."[128] This position, which the NIH adopted in January 2021, overrode its prior stance of "recommend[ing] against the use of ivermectin for the treatment" of COVID-19.[129] The reason for the change, the NIH recognized, was that "several randomized trials and retrospective cohort studies of ivermectin use in patients with COVID-19 have been published in peer-reviewed journals."[130] And some of those studies reported positive outcomes, including "shorter time to resolution of disease manifestations that were attributed to COVID-19, greater reduction in inflammatory marker levels, shorter time to viral clearance, [and] lower mortality rates in patients who received ivermectin than in patients who received comparator drugs or placebo."[131] The NIH nevertheless decided not to recommend the use of ivermectin for COVID-19 because other studies suggest "no benefits" and the NIH thought that the available studies

---

124 Maulshree Seth, *Uttar Pradesh government says early use of Ivermectin helped to keep positivity, deaths low*, The Indian Express (May 12, 2021), *available at* https://indianexpress.com/article/cities/lucknow/uttar-pradesh-government-says-ivermectin-helped-to-keep-deaths-low-7311786/ (last visited Oct. 14, 2021), and https://www.msn.com/en-in/news/other/uttar-pradesh-government-says-early-use-of-ivermectin-helped-to-keep-positivity-deaths-low/ar-BB1gDp5U (last visited Oct. 14, 2021).

125 *Id.*

126 *Id.*

127 *Id.*

128 NIH, COVID-19 and Ivermectin, *supra*.

129 Yagisawa, *supra*, at 65.

130 NIH, COVID-19 and Ivermectin, *supra*.

131 *Id.*

generally suffered from "methodological limitations."[132] By making a neutral recommendation, the NIH—which is continuing to collaborate on at least one study investigating ivermectin as a treatment for "mild to moderate COVID-19"[133]—clearly signaled that physicians should use their discretion in deciding whether to treat COVID-19 patients with ivermectin.

Ignoring the NIH's official position, officials within its agencies have sent contradictory messages. On August 29, 2021, Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID) within the NIH, went on CNN and announced that "there is no clinical evidence" that ivermectin works for the prevention or treatment of COVID-19.[134] Expanding on that point, he reiterated that "there is no evidence whatsoever" that it works.[135] Yet this definitive claim directly contradicts the NIH's recognition that "several randomized trials . . . published in peer-reviewed journals" have reported data indicating that ivermectin is effective as a COVID-19 treatment.[136]

The FDA has similarly charted a course of confusion. In March 2021, the FDA posted a webpage entitled "Why You Should Not Use Ivermectin to Treat or Prevent COVID-19."[137] Although the FDA's concern was stories of some people using the animal form of ivermectin or excessive doses of the human form, the title broadly condemned any use of ivermectin in connection with COVID-19. Yet there was no basis for its sweeping condemnation. Indeed, the FDA itself acknowledged on that very webpage (and continued to do so until the page changed on September 3, 2021) that the agency had *not* even "reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19."[138] But without reviewing the available data, which had long

---

132 *Id.*

133 U.S. National Library of Medicine, ACTIV-6: COVID-19 Study of Repurposed Medications, https://clinicaltrials.gov/ct2/show/NCT04885530?term=activ-6&draw=2&rank=1 (last visited Oct. 14, 2021).

134 CNN Health, *'Don't do it': Dr. Fauci warns against taking Ivermectin to fight Covid-19* (Aug. 29, 2021), https://edition.cnn.com/videos/health/2021/08/29/dr-anthony-fauci-ivermectin-covid-19-sotu-vpx.cnn (last visited Oct. 14, 2021).

135 *Id.*

136 NIH, COVID-19 and Ivermectin, *supra*.

137 U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (archived Mar. 5, 2021), https://web.archive.org/web/20210305163946/https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021)").

138 *Id.*; *see also* U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (archived Sept. 2, 2021), https://web.archive.org/web/20210902231921/https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Sept. 2, 2021)").

since been available and accumulating, it is unclear what basis the FDA had for denouncing ivermectin as a treatment or prophylaxis for COVID-19.

On that same webpage, the FDA also declared that "[i]vermectin is not an anti-viral (a drug for treating viruses)."[139] It did so while another one of its webpages[140] simultaneously cited a study in *Antiviral Research* that identified ivermectin as a medicine "previously shown to have *broad-spectrum anti-viral activity*."[141] It is telling that the FDA deleted the line about ivermectin not being "anti-viral" when it amended the first webpage on September 3, 2021.[142]

The FDA has additionally assailed ivermectin's safety by suggesting, though not outright stating, that even a proper dose of human ivermectin might be dangerous when used to treat COVID-19. For example, the FDA announced that "[t]aking a drug for an unapproved use can be very dangerous" and "[t]his is true of ivermectin."[143] Yet this ignores the fact that, as discussed above, doctors routinely prescribe medicines for off-label use and that ivermectin is a particularly well-tolerated medicine with an established safety record. Moreover, it is inconsistent for the FDA to imply that ivermectin is dangerous when used to treat COVID-19 while the agency continues to approve remdesivir[144] despite its spottier safety record, as discussed above.

The FDA has also called into question ivermectin's potential effectiveness. When updating the "Why You Should Not Use Ivermectin" webpage on September 3, 2021, the FDA added this entry: "Currently available data do not show ivermectin is effective against COVID-19."[145] But this claim fails to recognize that several RCTs and at least one meta-analysis suggest that ivermectin is effective against COVID-19.

---

139 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

140 U.S. Food and Drug Administration, FAQ: COVID-19 and Ivermectin Intended for Animals (Sept. 3, 2021), https://www.fda.gov/animal-veterinary/product-safety-information/faq-covid-19-and-ivermectin-intended-animals (last visited Oct. 14, 2021).

141 Caly, *supra*, at 1 (emphasis added).

142 U.S. Food and Drug Administration, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19 (updated Sept. 3, 2021), https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19 (last visited Oct. 14, 2021) (hereinafter, "FDA, Why You Should Not Use Ivermectin (Sept. 3, 2021)").

143 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

144 U.S. Food and Drug Administration, FDA Approves First Treatment for COVID-19 (Oct. 22, 2020), https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19 (last visited Oct. 14, 2021).

145 FDA, Why You Should Not Use Ivermectin (Sept. 3 2021), *supra*.

Moreover, a review of the studies on remdesivir makes it difficult to understand why the FDA would condemn the data supporting ivermectin. The NIH reports only five studies testing remdesivir's efficacy against COVID-19.[146] Three of those five studies show *no benefit* from remdesivir, with the largest of those concluding that remdesivir "did not decrease in-hospital mortality in hospitalized patients."[147] Even the two remaining studies are far from compelling. One found that "[h]ospitalized patients . . . who received 5 days of [remdesivir] had better outcomes," but the difference "was of uncertain clinical importance."[148] And while the other study indicated that remdesivir "reduced time to clinical recovery" for "patients with severe COVID-19," it also found "[n]o observed benefit . . . in patients with mild or moderate COVID-19" and "[n]o statistically significant difference in mortality."[149] Beyond that, in September 2021, the Lancet published the results of a large RCT (the DisCoVeRy trial) that found "[n]o clinical benefit . . . from the use of remdesivir in patients who were admitted to hospital for COVID-19, were symptomatic for more than 7 days, and required oxygen support."[150] The data on ivermectin thus appears at least as strong as the data on remdesivir.

The FDA's most controversial statement on ivermectin came on August 21, 2021, when it posted a link on Twitter to its "Why You Should Not Use Ivermectin" webpage with this message: "You are not a horse. You are not a cow. Seriously, y'all. Stop it."[151]

---

146 National Institutes of Health, Remdesivir: Selected Clinical Data, https://www.covid19treatmentguidelines.nih.gov/tables/table-2a/ (last visited Oct. 14, 2021).

147 *Id.*

148 *Id.*

149 *Id.*

150 Florence Ader et al., *Remdesivir plus standard of care versus standard of care alone for the treatment of patients admitted to hospital with COVID-19 (DisCoVeRy): a phase 3, randomised, controlled, open-label trial*, The Lancet, at 1 (Sept. 14, 2021), *available at* https://www.thelancet.com/action/showPdf?pii=S1473-3099%2821%2900485-0 (last visited Oct. 14, 2021).

151 U.S. FDA, Twitter, https://twitter.com/us_fda/status/1429050070243192839 (last visited Oct. 14, 2021).

This message is troubling not only because it makes light of a serious matter but also because it inaccurately implies that ivermectin is only for horses or cows.

Despite its attempts to impugn ivermectin, the FDA appears to recognize that doctors may prescribe it for COVID-19. On September 3, 2021, a change in its website makes this clear. The "Why You Should Not Use Ivermectin" webpage originally said that "[i]f you have a prescription for ivermectin for an FDA-approved use, get it from a legitimate source and take it exactly as prescribed."[152] That same sentence now omits the limitation on prescriptions to FDA-approved uses. It says that "[i]f your health care provider writes you an ivermectin prescription, fill it through a legitimate source such as a pharmacy, and take it *exactly* as prescribed."[153] This change implicitly acknowledges that ivermectin may be prescribed off-label for COVID-19.

The CDC has followed in the FDA's footsteps of implying that ivermectin is unsafe. On August 26, 2021, the CDC issued an official advisory entitled "Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat COVID-19."[154] Like the FDA, the CDC's

---

152 FDA, Why You Should Not Use Ivermectin (Mar. 5, 2021), *supra*.

153 FDA, Why You Should Not Use Ivermectin (Sept. 3, 2021), *supra*.

154 Centers for Disease Control and Prevention, *Rapid Increase in Ivermectin Prescriptions and Reports of Severe Illness Associated with Use of Products Containing Ivermectin to Prevent or Treat*

sweeping title implies that severe illnesses are arising from the prescribed use of human ivermectin to combat COVID-19, but it supplies no data to indicate that human ivermectin in appropriate doses is harming anyone. On the contrary, the CDC's advisory acknowledges that the actual concerns arise from the "use of veterinary products not meant for human consumption" and that the reported "[a]dverse effects [are] associated with ivermectin misuse and overdose."[155] The CDC's instructions to the public confirm that its concerns arise from the improper use of ivermectin creams or animal formulas: "Do not swallow ivermectin products that should be used on skin (e.g., lotions and creams) or are not meant for human use, such as veterinary ivermectin products."[156]

None of this undermines the use of human ivermectin in proper doses for the treatment or prevention of COVID-19. If anything, the reported uptick in people resorting to animal ivermectin simply reinforces that COVID-19 patients should be encouraged to discuss human ivermectin with their healthcare providers and that those providers should be allowed to consider the available data with their patients. That would be more beneficial for public health than attempting to obscure the demonstrated safety profile of ivermectin.

The media has added to the confusion and misinformation. On August 30, 2021, the New York Times published an article about ivermectin stating that "Mississippi's health department said earlier this month that *70 percent* of recent calls to the state poison control center had come from people who ingested ivermectin from livestock supply stores."[157] Yet two weeks later, on September 13, 2021, the Times amended its story by deleting that sentence and adding this note after the article: "An earlier version of this article misstated the percentage of recent calls to the Mississippi poison control center related to ivermectin. It was 2 percent, not 70 percent."[158]

Similarly, on September 3, 2021, Rolling Stone published a story entitled "Gunshot Victims Left Waiting as Horse Dewormer Overdoses Overwhelm Oklahoma Hospitals,

---

COVID-19, Health Advisory, at 1 (Aug. 26, 2021), *available at* https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf (last visited Oct. 14, 2021).

155 *Id.*

156 *Id.* at 3.

157 Emma Goldberg, *Demand Surges for Deworming Drug for Covid, Despite No Evidence It Works*, New York Times (Aug. 30, 2021), *available at* https://web.archive.org/web/20210830091038/https://www.nytimes.com/2021/08/30/health/covid-ivermectin-prescriptions.html (last visited Oct. 14, 2021) (emphasis added).

158 Emma Goldberg, *Demand Surges for Deworming Drug for Covid, Despite No Evidence It Works*, New York Times (amended Sept. 28, 2021), *available at* https://www.nytimes.com/2021/08/30/health/covid-ivermectin-prescriptions.html (last visited Oct. 14, 2021).

Doctor Says."[159] Soon thereafter, one the hospitals where this doctor supposedly works denied that claim, and "the doctor [did] not respond[] to requests for further comment."[160] Rather than delete the article or substantially rewrite it, Rolling Stone left the article largely unchanged and amended the title to say: "One Hospital Denies Oklahoma Doctor's Story of Ivermectin Overdoses Causing ER Delays for Gunshot Victims."[161] In addition, the magazine added an "update" message stating, among other things, that "[o]ne hospital has denied [the doctor's] claim that ivermectin overdoses are causing emergency room backlogs and delays in medical care in rural Oklahoma, and Rolling Stone has been unable to independently verify any such cases as of the time of this update."[162] In other words, the publication allowed a story based on a discredited and nonresponsive source to remain available to the public. It is no wonder that some people are unsure what to believe about ivermectin.

iii. Foreign Public Health Agencies on Ivermectin

Looking abroad, in March 2021, the WHO "recommend[ed] not to use ivermectin in patients with COVID-19 except in the context of a clinical trial."[163] The basis for this recommendation rested not on proof that ivermectin is ineffective, but on the WHO's belief that the existing studies were of too low quality to support any conclusive determinations.[164] Notably, though, while the WHO questioned the quality of the evidence, its analysis determined, based on data from 1,419 patients in seven studies, that patients treated with ivermectin had a 14 per 1,000 chance of death while patients in the control groups had a 70 per 1,000 chance of death.[165] Also, the WHO considered only

---

159 Peter Wade, *Gunshot Victims Left Waiting as Horse Dewormer Overdoses Overwhelm Oklahoma Hospitals, Doctor Says*, Rolling Stone (Sept. 3, 2021), *available at* https://web.archive.org/web/20210903231939/https://www.rollingstone.com/politics/politics-news/gunshot-victims-horse-dewormer-ivermectin-oklahoma-hospitals-covid-1220608/ (last visited Oct. 14, 2021).

160 Peter Wade, *One Hospital Denies Oklahoma Doctor's Story of Ivermectin Overdoses Causing ER Delays for Gunshot Victims*, Rolling Stone (amended Sept. 5, 2021), *available at* https://www.rollingstone.com/politics/politics-news/gunshot-victims-horse-dewormer-ivermectin-oklahoma-hospitals-covid-1220608/ (last visited Oct. 14, 2021).

161 *Id.*

162 *Id.*

163 World Health Organization, Therapeutics and COVID-19: Living Guideline, at 20 (July 6, 2021), *available at* https://files.magicapp.org/guideline/a6e3f83e-bff5-481c-90ab-130aa86bbe83/published_guideline_5486-6_1.pdf (last visited Oct. 14, 2021) (hereinafter, "WHO COVID-19 Guidelines").

164 *Id.*

165 *Id.* at 23.

ivermectin's effectiveness as a COVID-19 treatment and did not assess its potential as a prophylaxis.[166]

Public health authorities in other countries have declined to follow the WHO's guidance. Most importantly, the NIH continues to embrace its neutral recommendation on ivermectin. Also, in May 2021, the State of Goa in India announced, through its health minister Vishwajit Rane, that "it would give [ivermectin] to all its adult residents" in its efforts to combat COVID-19.[167] Likewise, as discussed above, India's Uttar Pradesh continues to distribute ivermectin to people diagnosed with COVID-19. And El Salvador's Ministry of Public Health has included ivermectin as part of its recommendations for early COVID-19 treatment via home patient kit.[168] We did not conduct an exhaustive search on other countries' practices, so this list is simply intended to be illustrative.

iv. Professional Associations and Physicians on Ivermectin

Professional associations, both here in the United States and abroad, have adopted conflicting positions on ivermectin and COVID-19. The American Medical Association (AMA), American Pharmacists Association (APhA), and American Society of Health-System Pharmacists (ASHP) have issued a statement that "strongly oppose[s] the ordering, prescribing, or dispensing of ivermectin to prevent or treat COVID-19 outside of a clinical trial."[169] But this statement relies solely on the FDA's and CDC's statements. Consider the AMA, APhA, and ASHP's claim that "[u]se of ivermectin for the prevention and treatment of COVID-19 has been demonstrated to be harmful to patients."[170] Their only support for that alarming statement is the CDC Health Alert discussed above.[171] But as we explained, that CDC advisory gave no indication that any severe adverse effects are occurring from the use of human ivermectin in appropriate doses.

---

166 *Id.* at 18.

167 Siladitya Ray, *Indian State Will Offer Ivermectin To Entire Adult Population — Even As WHO Warns Against Its Use As Covid-19 Treatment*, Forbes (May 11, 2021), *available at* https://www.forbes.com/sites/sidityaray/2021/05/11/indian-state-will-offer-ivermectin-to-entire-adult-population---even-as-who-warns-against-its-use-as-covid-19-treatment/?sh=3d45adce6d9f (last visited Oct. 14, 2021).

168 *El Salvador Minister of Public Health Includes Ivermectin as COVID-19 Pandemic Continues*, TrialSite News (Aug. 26, 2021), *available at* https://trialsitenews.com/el-salvador-minister-of-public-health-includes-ivermectin-as-covid-19-pandemic-continues/ (last visited Oct. 14, 2021).

169 American Medical Association, AMA, APhA, ASHP statement on ending use of ivermectin to treat COVID-19 (Sept. 1, 2021), *available at* https://www.ama-assn.org/press-center/press-releases/ama-apha-ashp-statement-ending-use-ivermectin-treat-covid-19 (last visited Oct. 14, 2021) (hereinafter, "AMA, APhA, and ASHP Statement on Ivermectin").

170 *Id.*

171 *Id.*

Those groups' opposition to ivermectin also conflicts with their otherwise steadfast support for healthcare providers' rights to prescribe medicines for off-label use. They call for ivermectin's ban because the FDA has not approved it "to prevent or treat COVID-19" and some public-health agencies have found "insufficient evidence" to support its use.[172] But just last year, these same professional associations, when discussing prescriptions for hydroxychloroquine to treat COVID-19, affirmed that "[n]ovel off-label use of FDA-approved medications is a matter for the physician's or other prescriber's professional judgment."[173] Moreover, the AMA elsewhere recognizes "its strong support for the autonomous clinical decision-making authority of . . . physician[s]" to "lawfully use an FDA approved drug product . . . for an off-label indication when such use is based upon sound scientific evidence."[174] In their recent ivermectin statement, however, the AMA, APhA, and ASHP ignore that some sound scientific evidence, including meta-analyses of RCTs, supports the use of ivermectin for COVID-19.

The AMA, APhA, and ASHP mentioned the statement of Merck—the original patentholder on ivermectin—as an additional basis for their position.[175] Yet that does not provide persuasive support for their opposition to ivermectin. Merck's February 2021 statement expressed its view that there is "[n]o meaningful evidence for . . . clinical efficacy in patients with COVID-19,"[176] but this simply ignores the RCTs demonstrating ivermectin's efficacy. Merck then claimed that there is "[a] concerning lack of safety data in the majority of studies."[177] While worded vaguely, this statement, when read carefully, says next to nothing. It simply acknowledges that many of the studies it references did not track safety data. It is not saying, though it might be implying, that the studies showed the medicine to be dangerous. But Merck, of all sources, knows that ivermectin is exceedingly safe, so the absence of safety data in recent studies should not be concerning to the company.

---

172 *Id.*

173 American Medical Association, Joint statement on ordering, prescribing or dispensing COVID-19 medications (Apr. 17, 2020), *available at* https://www.ama-assn.org/delivering-care/public-health/joint-statement-ordering-prescribing-or-dispensing-covid-19 (last visited Oct. 14, 2021).

174 American Medical Association, Patient Access to Treatments Prescribed by Their Physicians, https://policysearch.ama-assn.org/policyfinder/detail/Patient%20Access%20to%20Treatments%20Prescribed%20by%20Their%20Physicians%20H-120.988%20%20?uri=%2FAMADoc%2FHOD.xml-0-201.xml (last visited Oct. 14, 2021).

175 AMA, APhA, and ASHP Statement on Ivermectin, *supra*.

176 Merck, Merck Statement on Ivermectin use During the COVID-19 Pandemic (Feb. 4, 2021), https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/ (last visited Oct. 14, 2021).

177 *Id.*

Why would ivermectin's original patentholder go out of its way to question this medicine by creating the impression that it might not be safe? There are at least two plausible reasons. First, ivermectin is no longer under patent, so Merck does not profit from it anymore. That likely explains why Merck declined to "conduct[] clinical trials" on ivermectin and COVID-19 when given the chance.[178] Second, Merck has a significant financial interest in the medical profession rejecting ivermectin as an early treatment for COVID-19. "[T]he U.S. government has agreed to pay [Merck] about $1.2 billion for 1.7 million courses of its experimental COVID-19 treatment, if it is proven to work in an ongoing large trial and authorized by U.S. regulators."[179] That treatment, known as "molnupiravir, aims to stop COVID-19 from progressing and can be given early in the course of the disease."[180] On October 1, 2021, Merck announced that preliminary studies indicate that molnupiravir "reduced hospitalizations and deaths by half,"[181] and that same day its stock price "jumped as much as 12.3%."[182] Thus, if low-cost ivermectin works better than—or even the same as—molnupiravir, that could cost Merck billions of dollars.

While one side of the "professional associations" ledger includes the AMA, APhA, and ASHP (with Merck's backing), other associations disagree with their stance. In particular, the Association of American Physicians and Surgeons (AAPS)—a long-established group that has represented doctors in all specialties since 1943—has raised questions concerning those associations' "startling and unprecedented position that American physicians should immediately stop prescribing, and pharmacists should stop honoring their prescriptions for ivermectin for COVID-19 patients."[183] The AAPS pointed "out that many physicians disagree with the AMA, writing around 88,000 ivermectin

---

178 Yagisawa, *supra*, at 61.

179 *U.S. signs $1.2 bln deal for 1.7 mln courses of Merck's experimental COVID-19 drug*, Reuters (Jun. 9, 2021), *available at* https://www.reuters.com/business/healthcare-pharmaceuticals/merck-says-us-govt-buy-about-17-mln-courses-cos-covid-19-drug-2021-06-09/ (last visited Oct. 14, 2021).

180 *Id.*

181 Matthew Perrone, *Merck says COVID-19 pill cuts risk of death, hospitalization*, Associated Press (Oct. 1, 2021), *available at* https://apnews.com/article/merck-says-experimental-covid-pill-cuts-worst-effects-a9a2245fdcee324f6bbd776a0fffcc60 (last visited Oct. 14, 2021).

182 Lewis Krauskopf & Manojna Maddipatla, *Merck COVID-19 pill success slams Moderna shares, shakes up healthcare sector*, Reuters (Oct. 1, 2021), *available at* https://www.reuters.com/business/healthcare-pharmaceuticals/merck-covid-19-pill-success-slams-moderna-shares-shakes-up-healthcare-sector-2021-10-01/ (last visited Oct. 14, 2021).

183 Association of American Physicians and Surgeons, AAPS Challenges the AMA on Efforts to Suppress Ivermectin Use in COVID (Sept. 4, 2021), *available at* https://aapsonline.org/aaps-challenges-the-ama-on-efforts-to-suppress-ivermectin-use-in-covid/ (last visited Oct. 14, 2021).

prescriptions per week."[184] The AAPS has thus publicly resisted these groups' call to "stop[] the off-label use of long-approved drugs."[185]

In addition, the Tokyo Metropolitan Medical Association, as explained by its chairman Haruo Ozaki, recommended the use of ivermectin for COVID-19 patients in February 2021.[186] That organization emphasized that ivermectin should be administered to people diagnosed with COVID-19 because, among other reasons, it has been effective when used in other countries.[187] Other doctors' groups similarly advocate for ivermectin as a staple of early COVID-19 treatment. The Front Line COVID-19 Critical Care Alliance has been an outspoken supporter. Its organization "regard[s] ivermectin as a core medication in the prevention and treatment of COVID-19,"[188] and it includes a five-day course of ivermectin as part of its COVID-19 early treatment protocol.[189] Also, the British Ivermectin Recommendation Development Group (BIRD) is a UK-based association of "clinicians, health researchers[,] and patient representatives from all around the world" that collectively "advocate[s] for the use of ivermectin" against COVID-19.[190]

In summary, the evidence discussed above shows (1) that ivermectin has demonstrated some effectiveness in preventing and treating COVID-19 and (2) that its side effects are primarily minor and transient. Thus, the UCA does not preclude physicians from considering ivermectin for the prevention or treatment of COVID-19.

---

184 *Id.*

185 *Id.*

186 Tokyo Metropolitan Medical Association recommends ivermectin administration to prevent aggravation, Nikkei (Feb. 9, 2021), https://www.nikkei.com/article/DGXZQOFB25AAL0V20C21A1000000/ (last visited Oct. 14, 2021).

187 *Id.*

188 Front Line COVID-19 Critical Care Alliance, Ivermectin in COVID-19, https://covid19criticalcare.com/ivermectin-in-covid-19/ (last visited Oct. 14, 2021).

189 Front Line COVID-19 Critical Care Alliance, Prevention & Treatment Protocols for COVID-19, https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Alliance-I-MASKplus-Protocol-ENGLISH.pdf (last visited Oct. 14, 2021).

190 British Ivermectin Recommendation Development Group, Who are the BIRD Group, https://bird-group.org/who-are-bird/ (last visited Oct. 14, 2021).

4. Hydroxychloroquine

A. History of Hydroxychloroquine

Hydroxychloroquine, a less toxic derivative of a medicine named chloroquine, was first developed in 1946[191] and approved by the FDA in 1955.[192] Since that time, hydroxychloroquine has been widely used as a prophylaxis and treatment for malaria.[193] It has also "prove[n] to be effective in a number of autoimmune diseases," including systemic lupus erythematosus,[194] primary Sjögren's syndrome, and rheumatoid arthritis, and for those uses, it is often taken daily for years at a time.[195] Hydroxychloroquine's success against these autoimmune diseases "is linked to its anti-inflammatory and immunomodulatory effects."[196] Because of its versatility and efficacy, "[m]illions of hydroxychloroquine doses are prescribed annually."[197] In just the year 2019, hydroxychloroquine was prescribed over 5.4 million times in the United States alone.[198]

In 2004, long before the COVID-19 pandemic began, a lab study revealed that chloroquine is "an effective inhibitor of the replication of the severe acute respiratory syndrome coronavirus (SARS-CoV) in vitro" and thus that it should "be considered for immediate use in the prevention and treatment of SARS-CoV infections."[199] The following

---

191 National Institutes of Health, COVID-19 Treatment Guidelines: Chloroquine or Hydroxychloroquine and/or Azithromycin, https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/chloroquine-or-hydroxychloroquine-and-or-azithromycin/ (last visited Oct. 14, 2021) (hereinafter, "NIH, COVID-19 and Hydroxychloroquine").

192 Georgi Fram et al., *Cardiac Complications Attributed to Hydroxychloroquine: A Systematic Review of the Literature Pre-COVID-19*, 17 Current Cardiology Reviews 389, 389 (2021), *available at* https://www.eurekaselect.com/186876/article (last visited Oct. 14, 2021).

193 *Id.*

194 Claudio Ponticelli & Gabriella Moroni, *Hydroxychloroquine in systemic lupus erythematosus (SLE)*, 16 Expert Opinion on Drug Safety 411, 411 (2017), *available at* https://www.tandfonline.com/doi/full/10.1080/14740338.2017.1269168?scroll=top&needAccess=true (last visited Oct. 14, 2021).

195 Eliise Laura Nirk et al., *Hydroxychloroquine in rheumatic autoimmune disorders and beyond*, EMBO Molecular Medicine, at 1 (Aug. 2020), *available at* https://www.embopress.org/doi/epdf/10.15252/emmm.202012476 (last visited Oct. 14, 2021).

196 *Id.*

197 Fram, *supra*, at 389.

198 ClinCalc, Hydroxychloroquine Drug Usage Statistics, United States, 2013–2019, https://clincalc.com/DrugStats/Drugs/Hydroxychloroquine (last visited Oct. 14, 2021).

199 Els Keyaerts et al., *In vitro inhibition of severe acute respiratory syndrome coronavirus by chloroquine*, 323 Biochemical and Biophysical Research Communications 264, 264 (2004), *available at* https://www.sciencedirect.com/science/article/pii/S0006291X0401839X (last visited Oct. 14, 2021).

year, another paper explained that "chloroquine has strong antiviral effects on SARS-CoV infection" and "is effective in preventing the spread of SARS[-]CoV in cell culture."[200]

It is widely recognized in the medical community that hydroxychloroquine is generally safe, so safe in fact that it may be prescribed to pregnant women[201] and "children of all ages."[202] During the beginning of the pandemic, the FDA Commissioner stated that hydroxychloroquine has "a well-established safety profile" for malaria, lupus, and rheumatoid arthritis.[203] According to the CDC, hydroxychloroquine's "most common adverse reactions reported" are minor issues such as "stomach pain, nausea, vomiting, . . . headache," and "itching."[204] While the CDC recognizes that high doses, "such as those used to treat rheumatoid arthritis, have been associated with retinopathy," a serious eye condition, that side effect is "extremely unlikely" when hydroxychloroquine is used in short durations with moderate doses.[205] Notably, the CDC's guidance on hydroxychloroquine does not mention any concerns about cardiac disorders stemming from the drug.

B. Hydroxychloroquine and COVID-19

At the outset of the pandemic, researchers found—consistent with the prior studies demonstrating chloroquine's efficacy against SARS-CoV—that hydroxychloroquine "can efficiently inhibit SARS-CoV-2 infection in vitro."[206] These COVID-19 studies specifically

---

200 Martin J. Vincent et al., *Chloroquine is a potent inhibitor of SARS coronavirus infection and spread*, Virology Journal, at 1 (Aug. 2005), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/pdf/1743-422X-2-69.pdf (last visited Oct. 14, 2021).

201 Ponticelli & Moroni, *supra*, at 411; *see also* Ewa Hałady] et al., *Antimalarials - are they effective and safe in rheumatic diseases?*. 56 Reumatologia 164, 171–72 (2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052376/pdf/RU-56-33240.pdf (last visited Oct. 14, 2021) (noting that hydroxychloroquine "can be continued in the treatment of rheumatic diseases during pregnancy and lactation").

202 Centers for Disease Control and Prevention, Medicines for the Prevention of Malaria While Traveling Hydroxychloroquine (Plaquenil™), https://www.cdc.gov/malaria/resources/pdf/fsp/drugs/Hydroxychloroquine.pdf (last visited Oct. 14, 2021) (hereinafter, "CDC, Malaria Travel").

203 U.S. Food & Drug Administration, Bringing a Cancer Doctor's Perspective to FDA's Response to the COVID-19 Pandemic (Mar. 29, 2020), https://www.fda.gov/news-events/fda-voices/bringing-cancer-doctors-perspective-fdas-response-covid-19-pandemic (last visited Oct. 14, 2021) (hereinafter, "FDA, Bringing Perspective").

204 CDC, Malaria Travel, *supra*.

205 Centers for Disease Control and Prevention, Yellow Book, Chapter 4: Travel-Related Infectious Diseases – Malaria (2020), *available at* https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria#1939 (last visited Oct. 14, 2021).

206 Jia Liu et al., *Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro*, Cell Discovery, at 4 (2020), *available at* https://www.nature.com/articles/s41421-020-0156-0.pdf (last visited Oct. 14, 2021).

showed that hydroxychloroquine "can inhibit [SARS-CoV-2] virus entry, transmission[,] and replication."[207] In addition to this "antiviral activity," hydroxychloroquine also has "anti-inflammatory properties" that help regulate "pro inflammatory cytokines."[208] These characteristics—both the antiviral properties and the anti-inflammatory activity—are important countermeasures against COVID-19.

i. Hydroxychloroquine Studies and Meta-analyses

Many large observational studies suggest that hydroxychloroquine significantly reduces the risk of hospitalization and death when administered to outpatients—particularly high-risk outpatients—as part of early COVID-19 treatment. For example, the Mokhtari study "was a multicenter, population-based national retrospective-cohort investigation of 28,759 adults with mild COVID-19 seen . . . between March and September 2020 throughout Iran."[209] The data showed that "[t]he odds of hospitalization . . . reduced by 38%" and the chance of death decreased by 73% for those who took hydroxychloroquine.[210] Critically, those "effects were maintained after adjusting for age, comorbidities, and diagnostic modality," and "[n]o serious [hydroxychloroquine]-related adverse drug reactions were reported."[211]

In the same vein, the recently published Million study evaluated 10,429 "adult outpatients" in France infected with SARS-CoV-2 who were "treated early" with hydroxychloroquine plus azithromycin.[212] Only five deaths occurred among the 8,315 patients who received hydroxychloroquine plus azithromycin—a mere 0.6 per 1,000 patients—while 11 died among the 2,114 who received either no treatment or azithromycin alone—a much higher rate of 5.2 per 1,000 patients.[213] Based on these figures, the study's authors found that hydroxychloroquine "was associated with a lower risk of death, independently of age, sex[,] and epidemic period."[214] Million's team thus concluded that

---

207 Jyoti Bajpai et al., *Hydroxychloroquine and COVID-19 - A narrative review*, 67 Indian Journal of Tuberculosis 147, 148 (Dec. 2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7836863/pdf/main.pdf (last visited Oct. 14, 2021).

208 *Id.*

209 Majid Mokhtari et al., *Clinical outcomes of patients with mild COVID-19 following treatment with hydroxychloroquine in an outpatient setting*, International Immunopharmacology, at 1 (Jul. 2021), *available at* https://www.sciencedirect.com/science/article/pii/S1567576921002721 (last visited Oct. 14, 2021).

210 *Id.*

211 *Id.*

212 Million, *supra*, at 1063.

213 *Id.* at 1066.

214 *Id.* at 1063.

"[e]arly ambulatory treatment of COVID-19" with hydroxychloroquine plus azithromycin "is associated with very low mortality" and it "improve[s] COVID-19 survival compared to other regimens."[215]

Another group of researchers assessed an elderly population living in a nursing home in the small European state of Andorra.[216] Their study included "100 COVID-19 confirmed cases" in the nursing home "from March 15 to June 5, 2020."[217] After evaluating the numbers, these researchers concluded that "[t]reatment with hydroxychloroquine and azithromycin was associated with lower mortality in these patients."[218] And "the multivariate logistic regression analysis identified hydroxychloroquine plus azithromycin treatment as an independent factor favoring survival compared with no treatment or other treatments."[219] The study also reinforced hydroxychloroquine's longstanding safety profile because "[c]ardiac monitoring was performed by electrocardiogram, and no rhythm changes were observed . . . in any patient."[220]

Added to all this, a preprint of another large observational study by Sulaiman supports the use of hydroxychloroquine as part of early COVID-19 treatment.[221] This "study took place in 238 ambulatory fever clinics in Saudi Arabia" during June 2020.[222] Of the 5,541 participating patients, 1,817 were given hydroxychloroquine, and 3,724 received only supportive care.[223] The researchers found that early hydroxychloroquine-based "therapy was associated with a lower hospital admission" of 9.4% compared to 16.6% for supportive care alone, which equated to a relative risk reduction of 43%. "Adjusting for age, gender, and major comorbid conditions, a multivariate logistic regression model" further confirmed the significant decrease in the hospitalization risk of

---

215 *Id.*

216 Eva Heras et al., *COVID-19 mortality risk factors in older people in a long-term care center*, 12 European Geriatric Medicine 601, 601 (2021), *available at* https://link.springer.com/content/pdf/10.1007/s41999-020-00432-w.pdf (last visited Oct. 14, 2021).

217 *Id.*

218 *Id.*

219 *Id.* at 606.

220 *Id.* at 603.

221 Tarek Sulaiman et al., *The Effect of Early Hydroxychloroquine-based Therapy in COVID-19 Patients in Ambulatory Care Settings: A Nationwide Prospective Cohort Study*, Preprint, at 1 (2020), *available at* https://www.medrxiv.org/content/10.1101/2020.09.09.20184143v1.full.pdf (last visited Oct. 14, 2021).

222 *Id.*

223 *Id.*

patients who received hydroxychloroquine.[224] Regression analysis also demonstrated that hydroxychloroquine reduced the mortality risk by an odds ratio of .36, which equates to a threefold drop in deaths.[225] Other observational studies further suggest that hydroxychloroquine has value as an early COVID-19 treatment.[226]

We acknowledge that other studies and meta-analyses have concluded that hydroxychloroquine has little to no effect on COVID-19.[227] Yet those materials generally blur the important distinction between hydroxychloroquine's efficacy as an early treatment for mild COVID-19 in nonhospitalized patients and its efficacy as a late treatment for severe COVID-19 in hospitalized patients.[228] As explained above, COVID-19 in its early stages, which consists primarily of cold- and flu-like symptoms, is very different from severe COVID-19, which is a lower respiratory disease often accompanied by respiratory failure and multiple organ dysfunction. Thus, evidence about hydroxychloroquine's use "in inpatients[] is irrelevant with regard to the efficacy of [the drug] in early high-risk outpatient disease."[229] So even if hydroxychloroquine is not effective against severe COVID-19, that does not disprove its value as an early treatment against the disease.

The key, then, is to focus on data that assess hydroxychloroquine's effectiveness in early treatment. A prime example of that is a recently published meta-analysis that combined the Million, Mokhtari, and Sulaiman studies discussed above with two other

---

224 *Id.*

225 *Id.* at 14.

226 *E.g.*, Andrew Ip et al., *Hydroxychloroquine in the treatment of outpatients with mildly symptomatic COVID-19: a multi-center observational study*, BMC Infectious Diseases (2021), *available at* https://bmcinfectdis.biomedcentral.com/track/pdf/10.1186/s12879-021-05773-w.pdf (concluding in a study of 1,274 outpatients with SARS-CoV-2 infection that "there was an association between exposure to hydroxychloroquine and a decreased rate of hospitalization from COVID-19"); Yi Su, *Efficacy of early hydroxychloroquine treatment in preventing COVID-19 pneumonia aggravation, the experience from Shanghai, China*, 14 BioScience Trends 408, 408 (2020), *available at* https://www.jstage.jst.go.jp/article/bst/14/6/14_2020.03340/_pdf/-char/en (last visited Oct. 14, 2021) (finding in a study of 616 individuals that "[t]he early use of hydroxychloroquine decreased the improvement time and the duration of COVID-19 detection in throat and stool swabs").

227 Tawanda Chivese et al., *Efficacy of chloroquine and hydroxychloroquine in treating COVID-19 infection: A meta-review of systematic reviews and an updated meta-analysis*, Travel Medicine and Infectious Disease, at 1 (Sept./Oct. 2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8273040/pdf/main.pdf (last visited Oct. 14, 2021) (concluding that hydroxychloroquine is "not effective in treating COVID-19").

228 *Id.* at 3 (noting that this meta-analysis considered studies of people with "confirmed COVID-19, regardless of . . . the severity of illness").

229 Harvey A. Risch, *Early Outpatient Treatment of Symptomatic, High-Risk COVID-19 Patients That Should Be Ramped Up Immediately as Key to the Pandemic Crisis*, 189 American Journal of Epidemiology 1218, 1218 (Nov. 2020), *available at* https://academic.oup.com/aje/article/189/11/1218/5847586 (last visited Oct. 14, 2021).

outpatient studies.[230] Those five studies together included 32,124 total outpatients, and the analysis revealed that hydroxychloroquine is associated with a 69% reduction in mortality when used as an early COVID-19 treatment.[231] In addition, a few months ago, another team of researchers reviewed "nine reports of early treatment outcomes in COVID-19 nursing home patients."[232] Data from those studies revealed that "hydroxychloroquine-based multidrug regimens were associated with a statistically significant > 60% reduction in mortality."[233] And another scholar, Dr. Harvey A. Risch, Professor of Epidemiology at Yale School of Public Health, has published online a non-peer-reviewed meta-analysis of ten studies exploring hydroxychloroquine as an early COVID-19 treatment.[234] He concluded that for people receiving that treatment the odds ratio of hospitalization was .56 and the odds ratio of death was .25. In other words, his meta-analysis demonstrated that when hydroxychloroquine is administered as an early COVID-19 treatment, it can reduce the risk of death by 75%.

To be sure, these data derive from large-scale observational studies rather than RCTs, and we understand that RCTs are considered the gold standard in medicine. But for at least two reasons, we find these observational studies sufficient for our purposes. First, our role is not to set a standard for the practice of medicine. Rather, we must simply confirm whether reasonable medical evidence supports the use of hydroxychloroquine as an early COVID-19 treatment, and we determine that a collection of large-scale observational studies suffices for that purpose. Second, a seminal review of the scientific literature has revealed that "on average, there is little evidence for significant effect estimate differences between observational studies and RCTs, regardless of specific observational study design, heterogeneity, or inclusion of studies of pharmacological interventions."[235] There is thus no basis to cast aside the observational studies demonstrating hydroxychloroquine's efficacy as an early COVID-19 treatment.

---

230 Million, *supra*, at 1070.

231 *Id.*

232 Paul E. Alexander et al., *Early multidrug treatment of SARS-CoV-2 infection (COVID-19) and reduced mortality among nursing home (or outpatient/ambulatory) residents*, Medical Hypotheses, at 1 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8178530/pdf/main.pdf (last visited Oct. 14, 2021).

233 *Id.*

234 Harvey A. Risch, *Hydroxychloroquine in Early Treatment of High-Risk COVID-19 Outpatients: Efficacy and Safety Evidence*, at 11 (Jun. 17, 2021), *available at* https://earlycovidcare.org/wp-content/uploads/2021/09/Evidence-Brief-Risch-v6.pdf (last visited Oct. 14, 2021).

235 Andrew Anglemyer et al., *Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials*, Cochrane Database of Systematic Reviews, at 1 (2014), *available at* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.MR000034.pub2/epdf/full (last visited Oct. 14, 2021).

We turn now to discuss the use of hydroxychloroquine as a prophylaxis, and although the data on that point seem to be smaller, there is some evidence suggesting that it might work for that purpose too. One study was a RCT of migrant workers quarantined in a large dormitory in Singapore, and it compared a group who used hydroxychloroquine as a prophylaxis to a group that received only vitamin C.[236] The hydroxychloroquine group included 432 people, and only 31 of them (7.2%) contracted COVID-19 with acute respiratory symptoms.[237] In contrast, 619 individuals were in the vitamin C group, and 69 of them (11.1%) developed COVID-19 with acute respiratory symptoms.[238] Thus, the researchers concluded that prophylaxis with hydroxychloroquine is "superior to oral vitamin C in reducing SARS-CoV-2 infection."[239] Additionally, an observational study of healthcare workers in Bulgaria found that out of 156 workers who used hydroxychloroquine as a prophylaxis, none of them presented with COVID-19 symptoms.[240] By contrast, in the group of 48 workers who did not take hydroxychloroquine, three of them developed a symptomatic case of COVID-19.[241] These results prompted the administrators at the Bulgarian Cardiac Institute to start a prophylactic strategy for their workers that "includes alternative months of [hydroxychloroquine] intake (200 mg daily) and months without therapy."[242] In addition to these studies, there are a few others, some of which suggest marginal benefits, and some of which suggest that there might not be any. We are not aware of any of these studies showing serious adverse effects from use of low-dose hydroxychloroquine as a COVID-19 prophylaxis.

We pause here to reiterate that it is not our role to resolve the debate on hydroxychloroquine's effectiveness, either as an early COVID-19 treatment or as a preventative measure. These are matters for individual healthcare providers to assess based on the available data in consultation with their patients. Our only point is that reasonable data support the use of hydroxychloroquine as an early COVID-19 treatment and as a prophylaxis, and in light of that, we cannot find clear and convincing evidence

---

236 Raymond Chee Seong Seet et al., *Positive impact of oral hydroxychloroquine and povidone-iodine throat spray for COVID-19 prophylaxis: An open-label randomized trial*, 106 International Journal of Infectious Diseases 314, 314 (2021), *available at* https://www.ijidonline.com/action/showPdf?pii=S1201-9712%2821%2900345-3 (last visited Oct. 14, 2021).

237 *Id.* at 319.

238 *Id.*

239 *Id.* at 314.

240 Iana Simova et al., *Hydroxychloroquine for prophylaxis and treatment of COVID-19 in health-care workers*, New Microbes and New Infections, at 1 (Nov. 2020), *available at* https://www.sciencedirect.com/science/article/pii/S2052297520301657#! (last visited Oct. 14, 2021).

241 *Id.*

242 *Id.*

to file disciplinary actions against physicians who prescribe hydroxychloroquine for either of those purposes.

ii. Hydroxychloroquine, COVID-19, and Safety

During the pandemic, the FDA raised questions about hydroxychloroquine and adverse cardiac events.[243] These kinds of concerns prompted one group of scholars to conduct a systematic review of the hydroxychloroquine safety literature pre-COVID-19. Their review of the data indicated that people taking that medication in appropriate doses "are at very low risk of experiencing cardiac [adverse events], particularly with short term administration" of the drug.[244] The pre-COVID-19 data showed that heart issues occurred—albeit infrequently—only when patients took hydroxychloroquine in dangerously high doses or for many years on end.[245]

As to the increase of adverse cardiac events associated with COVID-19, the researchers questioned the prevalence of the problem by noting that several COVID-19 studies recorded "the use of [hydroxychloroquine] at variable doses without significant cardiac toxicity."[246] They also observed that COVID-19 itself often causes heart issues. As they explained, "[t]he underlying pathophysiology of SARS-CoV-2 contributes to cardiac complications in the population it infects, with estimates ranging from 20-40% incidence."[247] In particular, "[c]ardiac complications of cytokine storm have been well documented to involve fatal cardiac dysrhythmias and acute systolic heart failure."[248] These researchers thus concluded that "the reported increased arrhythmic events in the COVID-19 era appear to be more related with the direct inflammatory effect of the virus (myocarditis) or the concomitant administration of multiple drugs capable of prolonging QT intervals rather than to hydroxychloroquine itself."[249] They did not seem to think the medication itself had "change[d] after 70 years" of widespread use.[250]

---

243 U.S. Food and Drug Administration, FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or (last visited Oct. 14, 2021).

244 Fram, *supra*, at 391.

245 *Id.* at 390–92.

246 *Id.* at 393.

247 *Id.* at 392.

248 *Id.* at 393.

249 *Id.* at 394.

250 *Id.*

Others echoed these views. Another group reviewed the relevant studies and observed that "[m]ost of the available and credible data suggest that [hydroxychloroquine] is a safe drug."[251] That includes the pre-COVID-19 data—in "decades of . . . use by rheumatologists, . . . cardiac toxicity was rarely ever seen"—as well as the COVID-19-related studies—for example, the RECOVERY trial found "no cardiotoxicity" by hydroxychloroquine.[252] Indeed, the RECOVERY trial "prove[d] that [hydroxychloroquine] did not increase cardiac complications in COVID-19 cases despite using 4 times higher dosage than that used by rheumatologists."[253] These authors also emphasized that "[m]ultiple mechanisms cause cardiac complications in patients with COVID-19 infection";[254] thus, the infection's propensity to cause "intrinsic cardiac abnormalities . . . is probably acting as a confounder."[255]

Still another set of researchers reevaluated hydroxychloroquine's safety during the pandemic. They conducted a "meta-analysis to compare the safety of [hydroxychloroquine] versus placebo" for any indication.[256] Although their "meta-analysis of RCTs found a significantly higher risk of skin pigmentation [issues] in [hydroxychloroquine] users versus placebo," they did not find any statistically significant increases in other adverse events, including "cardiac toxicity."[257]

In addition to these data tending to confirm hydroxychloroquine's safety when used in appropriate doses, a few other factors further lessen the cardiac concerns. For starters, one piece of key evidence contributing to the safety concerns surrounding hydroxychloroquine rested on admittedly fraudulent data. As discussed above, it was a study published in the Lancet on May 22, 2020.[258] That study claimed that hydroxychloroquine was "associated with . . . an increased frequency of ventricular

---

251 Shivraj Padiyar & Debashish Danda, *Revisiting cardiac safety of hydroxychloroquine in rheumatological diseases during COVID-19 era: Facts and myths*, 8 European Journal of Rheumatology 100, 100 (2021), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8133889/pdf/ejr-8-2-100.pdf (last visited Oct. 14, 2021).

252 *Id.*

253 *Id.* at 102.

254 *Id.* at 102.

255 *Id.* at 100.

256 Khalid Eljaaly et al., *Hydroxychloroquine safety: A meta-analysis of randomized controlled trials*, Travel Medicine and Infectious Disease at 1 (Jul./Aug. 2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342171/ (last visited Oct. 14, 2021).

257 *Id.*

258 Mehra, *supra*.

arrhythmias when used for treatment of COVID-19."[259] That supposed finding was so startling that "major drug trials" involving hydroxychloroquine "were immediately halted";[260] the WHO started pressuring countries like Indonesia that were widely using hydroxychloroquine to ban it;[261] and some countries—including France, Italy, and Belgium—decided to stop using it for COVID-19.[262]

The problem, however, is that the study was based on false data from a company named Surgisphere, whose founder and CEO Sapan Desai was a co-author on the published paper.[263] The data were so obviously flawed that journalists and outside researchers began raising concerns within days of the paper's publication.[264] Even the Lancet's editor in chief, Dr. Richard Horton, admitted that the paper was a "fabrication," "a monumental fraud,"[265] and "a shocking example of research misconduct in the middle of a global health emergency."[266] Approximately two weeks after its publication, the paper was retracted.[267] An article published in *The Guardian* declared that "[g]iven the seriousness of the topic and the consequences of the paper, this [was] one of the most consequential retractions in modern history."[268] Despite calls to "publish full explanations

---

259 *Id.* at 1.

260 James Heathers, *The Lancet has made one of the biggest retractions in modern history. How could this happen?*, The Guardian (Jun. 5, 2020), *available at* https://www.theguardian.com/commentisfree/2020/jun/05/lancet-had-to-do-one-of-the-biggest-retractions-in-modern-history-how-could-this-happen (last visited Oct. 14, 2021).

261 Kate Lamb & Tom Allard, *Indonesia, major advocate of hydroxychloroquine, told by WHO to stop using it*, Reuters (May 26, 2020), *available at* https://www.reuters.com/article/us-health-coronavirus-indonesia-chloroqu/exclusive-indonesia-major-advocate-of-hydroxychloroquine-told-by-who-to-stop-using-it-idUSKBN23227L (last visited Oct. 14, 2021).

262 *France, Italy, Belgium act to stop use of hydroxychloroquine for COVID-19 on safety fears*, Reuters (May 27, 2020), *available at* https://www.reuters.com/article/health-coronavirus-hydroxychloroquine-fr/update-1-france-italy-belgium-act-to-stop-use-of-hydroxychloroquine-for-covid-19-on-safety-fears-idUKL1N2D911J (last visited Oct. 14, 2021).

263 Boseley & Davey, *supra*.

264 Davey, *supra*.

265 Rabin, *supra*.

266 Boseley & Davey, *supra*.

267 *Id.*

268 Heathers, *supra*.

of what happened," the Lancet has "declined to provide details regarding the retracted stud[y]."[269]

Further reducing the cardiac concerns is important information on the FDA's own website. The FDA "cautions against use of hydroxychloroquine . . . for COVID-19 *outside of the hospital setting* or a clinical trial due to risk of heart rhythm problems."[270] But the agency's referenced support for this cautionary statement concerning *nonhospitalized patients* is its "review of safety issues with the use of hydroxychloroquine . . . to treat *hospitalized patients* with COVID-19."[271] It is questionable, however, to theorize about risks to nonhospitalized patients with mild COVID-19 based on data about heart issues in hospitalized patients with severe COVID-19 because, as explained above, cardiac complications often accompany the late stages of COVID-19. The FDA's concerns thus derive from a context—using hydroxychloroquine to treat hospitalized patients—that we are not addressing in this opinion.

It is important to note that although the medical literature tends to confirm that hydroxychloroquine is a safe medication when used in appropriate doses, any concerns about heart issues, even if resting on limited evidence, are serious. Prevailing principles of informed consent likely require physicians who present patients with the option of using hydroxychloroquine for early treatment of COVID-19 to inform them about the cardiac concerns that the FDA has identified. Also, for patients who have underlying cardiac issues, physicians should carefully consider whether hydroxychloroquine is the right choice for them. Finally, physicians should pay attention to which drugs they combine with hydroxychloroquine and evaluate the potential cardiac risks of those combinations. Failure to take such precautions could result in disciplinary action.

iii. U.S. Public Health Agencies on Hydroxychloroquine

The public health agencies in the United States have addressed the topic of hydroxychloroquine and COVID-19. The NIH "recommends against" its use "for the treatment of COVID-19 in hospitalized patients . . . and in nonhospitalized patients."[272] To justify its position against hydroxychloroquine for nonhospitalized patients, the NIH relied heavily on a RCT conducted by Mitja.[273] While that study did not show great advantages in the hydroxychloroquine group, that group did have, as the NIH's own

---

269 Rabin, *supra*.

270 U.S. Food and Drug Administration, FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or (last visited Oct. 14, 2021) (emphasis added).

271 *Id.* (emphasis added).

272 NIH, COVID-19 and Hydroxychloroquine, *supra*.

273 *Id.*

website reports, a slight reduction in the risk of hospitalization (7.1% risk in the control arm versus 5.9% risk in the treatment arm) and in the time to resolution of symptoms (12 days in the control arm versus 10 days in the treatment arm).[274] As for serious adverse events, more (12) were reported in the control group than the hydroxychloroquine group (8), and the researchers determined that the serious adverse events in the hydroxychloroquine group were not related to the drug.[275] Thus, this study, particularly when considered in light of the large-scale observational studies discussed above, appears to be an insufficient basis to definitively recommend against using hydroxychloroquine as an early COVID-19 treatment.

The FDA, for its part, has questioned not only hydroxychloroquine's safety, as we discussed above, but also its efficacy. The agency's position grew out of its approval and subsequent disapproval of an Emergency Use Authorization (EUA) involving hydroxychloroquine. That EUA was issued on March 28, 2020, and it authorized licensed healthcare providers to use hydroxychloroquine donated to the Strategic National Stockpile to treat patients hospitalized with COVID-19.[276] Though this EUA was necessary to authorize the use of a specific source of hydroxychloroquine for a specific purpose, it was not required to allow healthcare providers to prescribe hydroxychloroquine off-label for COVID-19. That option was already available, as our prior discussion of off-label use makes clear. When the FDA revoked the EUA a few months later, on June 15, 2020, that is when it stated its current position on hydroxychloroquine and COVID-19.[277]

In that revocation, the FDA said that it no longer "believe[s] that oral formulations of [hydroxychloroquine] . . . may be effective in treating COVID-19" or that "that the known and potential benefits of these products outweigh their known and potential risks."[278]

---

274 National Institutes of Health, Table 2b. Chloroquine or Hydroxychloroquine and/or Azithromycin: Selected Clinical Data, https://www.covid19treatmentguidelines.nih.gov/tables/table-2b/ (last visited Oct. 14, 2021) (discussing Oriol Mitjà, *Hydroxychloroquine for Early Treatment of Adults With Mild Coronavirus Disease 2019: A Randomized, Controlled Trial*, Clinical Infectious Diseases (2020), *available at* https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1009/5872589 (last visited Oct. 14, 2021)).

275 *Id.* (discussing Mitjà, *supra*).

276 Letter from Denise M. Hinton, Chief Scientist, U.S. Food and Drug Administration, to Dr. Rick Bright, Director of Biomedical Advanced Research and Development Authority (BARDA), Office of Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS) (Mar. 28, 2020), *available at* https://www.fda.gov/media/136534/download (last visited Oct. 14, 2021).

277 Letter from Denise M. Hinton, Chief Scientist, U.S. Food and Drug Administration, to Gary L. Disbrow, Deputy Assistant Secretary, Director of Medical Countermeasure Programs, Biomedical Advanced Research and Development Authority (BARDA), Office of Assistant Secretary for Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS) (Jun. 15, 2020), *available at* https://www.fda.gov/media/138945/download (last visited Oct. 14, 2021).

278 *Id.* at 2.

Because both the EUA and its revocation deal only with hydroxychloroquine's use in hospitalized patients, they do not address the treatment topic that we are considering in this opinion—hydroxychloroquine's use as an early COVID-19 treatment.

The FDA's EUA revocation included four justifications, none of which establishes—let alone by clear and convincing evidence—that hydroxychloroquine is ineffective as an early treatment of COVID-19. First, the FDA said that the "suggested dosing regimens . . . are unlikely to produce an antiviral effect" because they will not create sufficient "drug concentration" in the body.[279] But as the FDA's revocation itself acknowledged, hydroxychloroquine's "immunomodulatory effects," as opposed to its antiviral effects, are not "predicated on achieving [certain hydroxychloroquine] concentration[]" levels.[280] Moreover, the FDA based its views on the assumption that "free drug concentration in the plasma" are "likely to be equal to free extracellular tissue concentration."[281] But other researchers' simulations showed that hydroxychloroquine's "concentration in lung tissue was much higher than in plasma,"[282] leading them to conclude that moderate doses are "recommended to treat SARS-CoV-2 infection."[283] Thus, the FDA's pessimism about hydroxychloroquine's potential antiviral capacity is open to reasonable debate in the scientific community.

Second, the FDA wrote that "[e]arlier reports of decreased viral shedding" with hydroxychloroquine "treatment have not been consistently replicated."[284] Notice that the FDA did not say that the studies have *disproven* a reduction in viral shedding; rather, the agency recognized that the evidence was still evolving and that some studies did in fact observe a positive "impact on viral shedding."[285] This criticism, on its face, is thus insufficient to dismiss hydroxychloroquine's use as an early COVID-19 intervention. Additionally, doubts about hydroxychloroquine's effect on viral shedding question only one of the drug's many possible mechanisms of action against COVID-19. More salient

---

279 U.S. Food and Drug Administration, Memorandum Explaining Basis for Revocation of Emergency Use Authorization for Emergency Use of Chloroquine Phosphate and Hydroxychloroquine Sulfate, at 1, 4, *available at* https://www.fda.gov/media/138945/download (last visited Oct. 14, 2021) (hereinafter, "FDA EUA Revocation Memo").

280 *Id.* at 4.

281 *Id.*

282 Xueting Yao et al., *In Vitro Antiviral Activity and Projection of Optimized Dosing Design of Hydroxychloroquine for the Treatment of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)*, Clinical Infectious Diseases, at 13 (2020), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7108130/pdf/ciaa237.pdf (last visited Oct. 14, 2021).

283 *Id.* at 2.

284 FDA EUA Revocation Memo, *supra*, at 1.

285 *Id.* at 6.

information is whether the drug is actually decreasing hospitalization and mortality rates when used as an outpatient treatment. As we discussed above, many large observational studies strongly suggest that hydroxychloroquine does in fact keep people diagnosed with COVID-19 out of the hospital and alive. That evidence is far more relevant of the drug's potential efficacy as an early COVID-19 treatment than debates about viral shedding.

Third, the FDA found it compelling that "NIH guidelines now recommend against" using hydroxychloroquine "outside of a clinical trial."[286] But as previously explained, the NIH's recommendation concerning COVID-19 outpatients does not rest on undisputed support. Thus, the NIH's guidelines should not be considered a basis upon which to ban healthcare providers from using hydroxychloroquine for COVID-19.

Fourth, the FDA stressed that "[r]ecent data from a large randomized controlled trial"—the RECOVERY trial mentioned above—"showed no evidence of benefit . . . of [hydroxychloroquine] treatment in hospitalized patients with COVID-19."[287] Yet as we have already discussed, a study about hospitalized patients does not address hydroxychloroquine's efficacy as an outpatient COVID-19 treatment. Indeed, the RECOVERY team itself reported that while its "findings indicate that hydroxychloroquine is not an effective treatment for hospitalized patients with Covid-19," it does "not address [the drug's] use as prophylaxis or in patients with less severe SARS-CoV-2 infection managed in the community."[288] In sum, none of the FDA's four reasons, in isolation or taken together, clearly establish that hydroxychloroquine is ineffective as an early treatment against COVID-19.

Despite raising doubts about hydroxychloroquine's use against COVID-19, the FDA has consistently affirmed that healthcare providers retain the right to use hydroxychloroquine as a part of early COVID-19 treatment. At least four statements demonstrate this.

First, the FDA's current website says (and has said since July 2020) that "[i]f a healthcare professional is considering use of hydroxychloroquine or chloroquine to treat or prevent COVID-19, FDA recommends checking www.clinicaltrials.gov for a suitable clinical trial and consider enrolling the patient." This plainly assumes that healthcare providers have the right to use hydroxychloroquine to treat COVID-19.

Second, on May 29, 2020, then-FDA Commissioner Stephen Hahn acknowledged that "[m]any physicians have . . . prescribed [hydroxychloroquine] for patients with COVID-19 based on an individual assessment of the potential benefits versus the risks

---

286 *Id.* at 1.

287 *Id.*

288 RECOVERY Collaborative Group, *Effect of Hydroxychloroquine in Hospitalized Patients with Covid-19*, 383 The New England Journal of Medicine 2030, 2038 (Nov. 2020), *available at* https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022926?articleTools=true (last visited Oct. 14, 2021).

for an individual patient."[289] He added that "[p]rescribing a product for uses not specifically included in the official labeling is common in the practice of medicine" and that the FDA does not "prohibit[] physicians from prescribing medications" because the agency does "not regulate the practice of medicine."[290] These statements are still posted on the FDA's website, and we are not aware of any subsequent FDA statements revoking them.

Third, in June 2020, after the FDA revoked the hydroxychloroquine EUA, Health and Human Services Secretary Alex Azar said: "At this point, hydroxychloroquine and chloroquine are just like any other approved drug in the United States. They may be used in hospital, they may be used in out-patient, they may be used at home—all subject to a doctor's prescription."[291] Leaving no doubt about this point, Secretary Azar added that "[i]f a doctor wishes to prescribe [hydroxychloroquine], working with a patient, they may prescribe it for any purpose that they wish."[292] We are not aware of any subsequent statement revoking this guidance.

Fourth, in late July 2020, then-FDA Commissioner Hahn reiterated that "whether people should take hydroxychloroquine as a treatment" for COVID-19 is a decision that "should be made between a doctor and a patient."[293] He specifically stated: "A doctor and a patient need to assess the data that's out there, FDA does not regulate the practice of medicine, and that in the privacy of the doctor-patient relationship is where that decision should be made."[294]

iv. Foreign Public Health Agencies, Professional Associations, and Physicians on Hydroxychloroquine

The WHO "recommend[s] against administering hydroxychloroquine . . . for treatment of COVID-19" for "patients with any disease severity and any duration of symptoms."[295] It reached this recommendation after concluding that hydroxychloroquine

---

289 FDA, Bringing Perspective, *supra*.

290 *Id.*

291 Trump White House Archives, Remarks by President Trump in Roundtable Discussion on Fighting for America's Seniors (Jun. 15, 2020), *available at* https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-roundtable-discussion-fighting-americas-seniors/ (last visited Oct. 14, 2021).

292 *Id.*

293 Tal Axelrod, *FDA chief: Hydroxychloroquine use a decision between doctor and patient*, The Hill (Jul. 30, 2020), https://thehill.com/policy/healthcare/509733-fda-chief-hydroxychloroquine-use-a-decision-between-doctor-and-patient?rl=1 (last visited Oct. 14, 2021).

294 *Id.*

295 WHO COVID-19 Guidelines, *supra*, at 26.

"probably do[es] not reduce mortality" and that its "effect on . . . admission to hospital . . . remains uncertain."[296] To the extent that this recommendation purports to address hydroxychloroquine's effectiveness as an early treatment for COVID-19, it arguably rests on weak evidence. Although it is difficult to determine how many of the studied individuals were outpatients, it appears that most were hospitalized. For instance, the WHO says that it consulted 29 studies in concluding that "[h]ydroxychloroquine probably does not reduce mortality," but the only study specifically cited is the RECOVERY trial,[297] which, as we already indicated, included only patients hospitalized with COVID-19.[298] In addition, the WHO's statistics on hospitalization rates, which consisted of one RCT that included 465 outpatients, suggests hydroxychloroquine's efficacy.[299] That trial revealed a hospitalization rate of 47 per 1,000 people in the control group but only 19 of 1,000 people in the hydroxychloroquine arm.[300] It thus seems as if the WHO may have overreached in definitively declaring that hydroxychloroquine holds no promise as an early COVID-19 treatment.

The WHO also "recommend[s] against administering hydroxychloroquine prophylaxis to individuals who do not have COVID-19" because it believes that prophylaxis "hydroxychloroquine has a small or no effect on death and hospital admission" and that it "probably has a small or no effect on laboratory-confirmed COVID-19."[301] Disagreeing with this, the team of researchers conducting the COPCOV trial on prophylaxis hydroxychloroquine has announced that the WHO's conclusions are "scientifically unsound."[302] In their statement on this topic, the COPCOV team explained that the available RCTs "suggest substantial uncertainty as to the benefit of hydroxychloroquine in preventing COVID-19," but the "overall trend [is] towards benefit."[303]

---

296 *Id.* at 27.

297 *Id.* at 28.

298 RECOVERY Collaborative Group, *supra*, at 2030.

299 WHO COVID-19 Guidelines, *supra*, at 29.

300 *Id.*

301 World Health Organization, WHO Living guideline: Drugs to prevent COVID-19, at 12 (Mar. 2, 2021), *available at* https://apps.who.int/iris/bitstream/handle/10665/339877/WHO-2019-nCoV-prophylaxes-2021.1-eng.pdf?sequence=13&isAllowed=y (last visited Oct. 14, 2021).

302 The COPCOV Trial's position statement on "A living WHO guideline on drugs to prevent COVID-19," MORU Tropical Health Network (Mar. 5, 2021), https://www.tropmedres.ac/news/copcov-response-to-latest-who-guidelines-on-hydroxychloroquine-for-covid-19-trials-1 (last visited Oct. 14, 2021).

303 *Id.*

As for the professional associations' and physician groups' views on hydroxychloroquine, it appears that they generally adopt the same position they took on ivermectin. Those like the AAPS that support ivermectin as an option for early COVID-19 treatment generally support hydroxychloroquine too, while those like the AMA, APhA, and ASHP that oppose one typically resist the other. Additionally, many physician groups use early COVID-19 treatment protocols that include hydroxychloroquine. For example, an article co-authored by over 50 doctors in Reviews in Cardiovascular Medicine outlines an early treatment protocol that includes hydroxychloroquine as a key component.[304]

Considering the evidence discussed above, we do not find that clear and convincing evidence would warrant disciplining physicians who prescribe hydroxychloroquine for the prevention or early treatment of COVID-19 after first obtaining informed patient consent.

CONCLUSION

Based on the available data, we do not find clear and convincing evidence that a physician who first obtains informed consent and then utilizes ivermectin or hydroxychloroquine for COVID-19 violates the UCA. This conclusion is subject to the limits noted throughout this opinion. Foremost among them are that if physicians who prescribe ivermectin or hydroxychloroquine neglect to obtain informed consent, deceive their patients, prescribe excessively high doses, fail to check for contraindications, or engage in other misconduct, they might be subject to discipline, no less than they would be in any other context.

As we have stressed throughout, this opinion is based only on the data and information available at this time. If the relevant medical evidence materially changes, that could impact our conclusions. Also, though an opinion from our office about possible UCA violations would ordinarily focus on healthcare practices within Nebraska, the context of a global pandemic necessitates looking for evidence far beyond our State's borders, as we have done here. Thus, the analytical roadmap in this opinion likely has limited application outside the circumstance of a global pandemic.

We emphasize in closing that our office is not recommending any specific treatments for COVID-19. That is not our role. There are multiple treatment options outside the scope of this opinion—including treatments that have been officially approved by the FDA—that physicians and their patients should carefully consider. This opinion takes no position on them. Rather, we address only the off-label early treatment options discussed in this opinion and conclude that the available evidence suggests that they might work for some people. Allowing physicians to consider these early treatments will free them to evaluate additional tools that could save lives, keep patients out of the hospital, and provide relief for our already strained healthcare system.

---

304 McCullough, *Multifaceted*, *supra*, at 522-23.

Very truly yours,

DOUGLAS J. PETERSON
Attorney General

James A. Campbell
Solicitor General

Mindy L. Lester
Assistant Attorney General

Approved by:

Attorney General

ANNEXURE 2 – [Altman et al TGA submissions]

OPEN LETTER

21 August 2021
Dr. Julian Elliott Executive Director
National Covid Clinical Evidence Taskforce Level 4, 553 St Kilda Rd.
Melbourne, Vic. 3004

email: guidelines@Covid19evidence.net.au

Re: Call for an Urgent Review of the NCCET Recommendation regarding the use of ivermectin in the management of Covid-19 within 14 days

I refer to the current recommendation by the National Covid Clinical Evidence Taskforce (NCCET) regarding the use of the drug ivermectin for the management of Covid-19.
The NCCET serves an important role in reviewing and recommending treatment for Covid-19 to peak health professional bodies across Australia. The current recommendation (Communique Ed. 48 - 5.8.21) regarding the use of the drug ivermectin is as follows:

"The available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin and therefore the Taskforce recommends ivermectin not be used outside of randomised trials. The certainty of the current evidence base varies from low to very low depending which on outcome is being measured, as a result of serious risk of bias and serious imprecision in the 18 included studies.

In addition to uncertainty around benefits for patients with Covid-19, there are common side effects and harms associated with ivermectin, including diarrhoea, nausea and dizziness.
Given this uncertainty of benefit, and concerns of harms; we recommend that ivermectin only be provided in research trials, where there is the potential to generate further evidence on the effectiveness, or otherwise, of ivermectin." ....
"This is a high priority recommendation and will be updated as soon as new evidence becomes available."

Ivermectin has been the subject of more than 60 clinical trials, including more than 30 randomised controlled trials and used successfully in national Covid-19 mass treatment campaigns in India, Mexico and several other countries to reduce the number of cases and prevent serious complications of the disease leading to hospitalisation and death.
Despite this, and in the absence of NCCET members' personal experience in treating Covid-19 patients with ivermectin, the NCCET has selected in an arbitrary and imprecise manner a small number of published clinical trials (18) upon which to base its current negative recommendation for ivermectin use. NCCET has failed to apply sophisticated, defined, and

detailed meta-analysis techniques as employed in widely discussed published reviews on ivermectin (see references attached). When lives are at risk, the highest standards of evaluation are required.

The emphasis on minor and generally uneventful "harms associated with ivermectin, including diarrhoea, nausea and dizziness" contained in the above NCCET statement demonstrates a total lack of therapeutic perspective in relation to the much more serious side effects of other drugs used to treat Covid-19. Including many over the counter non-prescription drugs and the dire consequences of a lack of effective therapeutic management of Covid-19 individuals.

The NCCET has sought to respond to critics of its recommendation on ivermectin in the Communique of 5 Aug. 2021 by justifying its limited consideration of the ivermectin literature by posing, and then, answering its own question in the following way:

NCCET: "But hasn't ivermectin been shown to be effective as an early Covid-19 treatment in randomised controlled trials overseas?":

NCCET: "Despite some early suggestions that ivermectin may provide both prophylactic and therapeutic benefit, the available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin. More robust, well-designed randomised controlled trials are needed to demonstrate whether or not ivermectin is effective."

"Some widely discussed meta-analyses of ivermectin studies (e.g. The British Ivermectin Research Development (BIRD) Group meta analysis) have significant weaknesses, for example they include a large trial which has been discredited and retracted (Elgazzar et al.). Even in these reviews, when patient populations are separated by severity and comparisons to active treatments removed, no meaningful effect is found."

Given the national importance of the NCCET advice on ivermectin, I invited internationally recognised and experienced literature review specialist (Tess Lawrie MBBCh PhD) and Edmund Fordham (PhD FlnstP) of Evidence Based Medicine Consultancy Ltd (UK) and EbMCsquared, a Community Interest Company located in Bath, England, to comment on the above NCCET interpretations of the literature. Their expert analysis is attached and entitled, "Commentary upon NCCET Statement" dated 7 August 2021.

The analysis reveals and details (with references) serious flaws in the selective NCCET interpretation of the 'cherry picked' literature. It ignores the broad sweep of clinical evidence from other randomised controlled clinical trials, observational trials and national treatment programs and demands (in the NCCET's own words) as a matter of high priority to review this recommendation in the national interest.

In addition, related to the current NCCET recommendation is the statement by the TGA (18

Aug 2021):

"There is currently insufficient evidence to support the safe and effective use of ivermectin, doxycycline and zinc (either separately, or in combination) for the prevention or treatment of Covid-19. More robust, well-designed clinical trials are needed before they could be considered an appropriate treatment option." requires immediate review in light of the information herein provided." In reality, there is insufficient evidence not to support the use of ivermectin while new and expensive drugs are being expedited through the regulatory process and given provisional approval with far less clinical trial, efficacy and safety data supporting their use.

Australia is in the grip of a pandemic of enormous consequences. Every possible useful therapeutic approach is needed in this crisis. Ivermectin, especially in combination with zinc and doxycycline has shown to be effective in relation to Covid-19 management. Other new antiviral medications have been recently approved by the TGA with relatively minimal safety and efficacy data by comparison to ivermectin.

Ivermectin has been in use for more than three decades. Four billion doses have been administered, it is on the World Health Organisation List of Essential Drugs and is one of the world's most useful and well tolerated drugs available. Its breakthrough discovery is attributed to Prof. Satoshi Omura and Irish biologist William Campbell, who were awarded the Nobel Prize in Medicine in 2015, reflecting the magnitude of their achievement and the importance of ivermectin to medicine.

The current approach to symptomatic Covid-19 individuals is largely to do nothing and simply observe until they either get better or get worse, perhaps much worse, and need to go to hospital. The do-nothing approach places enormous strain on our health care system. Evidence for this 'do nothing, watch and observe' approach is lacking. Ivermectin offers a potentially effective, low cost, safe and rational approach to the management of such individuals with little or no disadvantage. The NCCET recommendation on ivermectin is considered to be misinformation by many experts and is viewed as contributing to needless hospitalisation – but for this recommendation, many Covid-19 infected individuals could be receiving early effective treatment.
Hon. Greg Hunt MP, Minister for Health and Aged Care, has written regarding ivermectin in a reply to Sen. Malcolm Roberts (27 July 2021)." It remains open for doctors to prescribe existing medicines 'off-label' based on their own clinical judgement". Indeed, this has always been the case previously.

Given the evidence available, doctors should be able to prescribe ivermectin as monotherapy or in combination without stigma or hindrance by a restrictive recommendation from the NCCET or the TGA. Both the NCCET and the TGA should re-examine the accumulating international experience with ivermectin from all sources supporting its safe and effective use

and should actively support and encourage ongoing efforts by many to clarify the important role of ivermectin in the management of Covid-19.
I request the NCCET review and issue revised recommendations for the use of ivermectin within 14 days in light of the submitted information as a matter of urgent priority and national interest.

Please confirm receipt of this Open Letter by return email.

Regards,
Phillip M. Altman BPharm(Hons), MSc, PhD
Clinical Trials and Regulatory Affairs Consultant

REFERENCES

Bryant, A, Lawrie, TA, Dowswell, T, Fordham, EJ, Mitchell, S, Hill, SR and Tham, TC.
Ivermectin for Prevention and Treatment of Covid-19 infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines.
American Journal of Therapeutics 28, e434-e460 (2021).

Kory,P, Meduri, U, Varon, J, Iglesias, J and Marik, PE.
Review of the Emerging Evidence Demonstrating the Efficacy of Invermectin in the Prophylaxis and Treatment of Covid-19. American Journal of therapeutics 28, e299-e318 (2021.

COMMENTARY UPON NCCET STATEMENT DATED 7 AUGUST 2021

SUBMITTED AND REFERRED TO IN SUPPORT OF DR. ALTMAN'S NCCET OPEN LETTER OF 21 AUG. 2021 BY DR. TESS LAWRIE AND DR. EDMUND FORDHAM

We have considered the extracts quoted below from the current National Covid Clinical Evidence Taskforce (NCCET) statement regarding the use of ivermectin in Covid-19. Our responses and commentary to these statements follow.

The current recommendation regarding ivermectin is as follows:

"Despite some early suggestions that ivermectin may provide both prophylactic and therapeutic benefit, the available research evidence does not yet provide reasonable certainty to recommend for or against the use of ivermectin."

And a specific critique asserts:

"Some widely discussed meta-analyses of ivermectin studies (e.g. The British Ivermectin Research Development (BIRD) Group meta analysis) have significant weaknesses, for example they include a large trial which has been discredited and retracted (Elgazzar et al.).

Even in these reviews, when patient populations are separated by severity and comparisons to active treatments removed, no meaningful effect is found."

A. Overall assertion.

The available research evidence from **(i)** randomised controlled trials, **(ii)**observational trials, **(iii)** clinical success of multiple unrelated clinicians in many parts of the world, **(iv)** the phenomenology of whole country effects with both temporal correlation to introduction of ivermectin, and the contrasting experimental control of states or other administrative divisions with differing public health policies, all point overwhelmingly to the efficacy of ivermectin in both the prevention and management of Covid-19 [1].

The phrase "reasonable certainty" is undefined and vague, and no declaration as to what level of certainty would be regarded as "reasonable" is given. It is not a "level of certainty" recognised in formal meta-analysis.

The formal review of Bryant et al. [2] found "moderate certainty" evidence which is normally considered more than sufficient for regulatory approval of existing drugs in a new indication. For example, corticosteroids have become a standard of care for inflammatory stage Covid-19 on the basis of a single RCT of dexamethasone [3], on what is generally considered as "moderate certainty" evidence. The review of Bryant et al. [2] found "moderate certainty" evidence over 24 RCTs, not just one.
The prophylaxis trials were assessed as "low certainty" but report quantitative results in prophylaxis fully consistent with much larger observational trials, some very large [4].

"Low" certainty evidence in the past has been sufficient for the inclusion of ivermectin on the WHO Essential Medicines (Children) (EMLc) List in the indication of scabies [5] where measures of effect were in fact inferior to the previously recommended drugs.

On the basis of prior decisions in Covid-19, and for ivermectin in an anti-parasitic indication, the continued hesitancy of regulatory authorities worldwide with respect to ivermectin in Covid-19 is completely anomalous.

"Reasonable" is not recognised in formal meta-analysis, according to PRISMA guidelines [6], which recognise very low, low, moderate, and high certainty, typically from appraisals of Risk of Bias in contributing studies. There is always a measure of subjectivity in such appraisals but allocation of grades and conclusions of "levels of certainty" follow strict rules.

"High" certainty evidence is rare, confined to strong effects in very large clinical trials or meta-analyses pooling several such large studies.

"Moderate" certainty evidence is generally considered extremely powerful, and more than

sufficient for regulatory approval of existing medicines in new indications.

"Low" certainty evidence has led to prior regulatory approvals to meet clear clinical needs. We address subsequent critiques of [2] below, under (B).

Much of the evidence was summarised as early as November 2020 by Kory *et al.* and now published in their narrative review in the *American Journal of Therapeutics* [1] (May- June issue).

The formal systematic review and meta-analysis by Bryant *et al*. [2] (July-August issue of same journal) was an exercise in support of the narrative review of Kory et al. [1], but restricted by deliberate choice to Randomised Controlled Trials (RCTs) only, as conventionally considered the highest quality of medical evidence.

For example, the review protocol excluded by policy notable studies such as the ICON study [7] demonstrating strong advantage in overall mortality in a large propensity- matched retrospective study, with obvious confounders addressed, simply because the patient allocation was not randomised. The most pronounced benefits were seen in severe disease.

Similarly in prophylaxis the very large trial of Behera *et al.* [4] with well over 3000 participants was excluded for the same reasons, though delivering quantitative measures of Risk Reduction (for infection) very close to the meta-analysis of the RCTs.

Including high-quality observational trials was found to lead to results just as reliable as RCTs in the synthesis of Anglemyer [15]. Adding the many known observational trials to the meta-analysis of Bryant *et al.* [2] is likely only to strengthen the findings further.
In any serious scientific appraisal, the evidence presented by these non-randomised trials cannot be dismissed as of no account, just because they lacked certain formal constraints, being part of the experience of hard-working clinicians in stressed circumstances.

(**Authorship note:** To pre-empt widespread misunderstandings, what is called "the BiRD group" or more accurately the British Ivermectin Recommendation Development panel (*not* "Research") was an *ad hoc* panel of clinicians, researchers and other stakeholders, with international representation, convened for an "Evidence to Decision" framework event on 20 February 2021 to hear the evidence summarised in an earlier version of reference [2].

The BiRD panel published its recommendation quite separately from Bryant *et al.* [2]. The authors of Bryant *et al.* [2] comprise: two members of the steering group (who did not vote), four ordinary members of the BiRD panel (consumer representative, health economist and two active clinicians), and one professional systematic reviewer who did not take part in the BiRD panel but contributed extensively to the research.

Hence the authors of Bryant *et al.* [2] are not congruent with the membership of the BiRD panel, a much larger group, and include one major contributor who remains uninvolved with BiRD.)

B. Subsequent critiques of [2]:

Some widely discussed meta-analyses of ivermectin studies (e.g. The British Ivermectin Research Development (BIRD) Group meta analysis) have significant weaknesses, for example they include a large trial which has been discredited and retracted (Elgazzar et al.). Even in these reviews, when patient populations are separated by severity and comparisons to active treatments removed, no meaningful effect is found.

These claims are categorically false, though regularly asserted by those with an agenda driven independently of the actual evidence.

1/ The claim of "*significant weakness*" in [2] is confined entirely to the inclusion of the disputed trial of Elgazzar [8]. The review of [2] was exhaustive of all RCTs found at the review closure and the first anywhere to follow strict PRISMA guidelines [6]. At the time of publication of [2], there was no reason to doubt the veracity of Elgazzar [8]; indeed it would have been a protocol violation to exclude it.

It is untrue to state that the study has been "retracted". Prof. Elgazzar has retracted nothing, asserts defamation and has intimated legal action. The server *ResearchGate* has withdrawn the preprint in response to a complaint, without giving Prof Elgazzar the right of reply. Whether or not the study is "discredited" remains to be determined.

Notwithstanding these uncertainties, a "Letter to the Editor" of *Am. J. Therap.* [9] concerning the Elgazzar dispute has been accepted for publication and should appear shortly. We show explicitly the consequences of deleting the disputed trial in the leading mortality outcome, and in prophyalxis (Elgazzar [8] contributed arms to both outcomes). Whilst the quantitative result inevitably changes, the mortality outcome remains clear, demonstrating a 49% reduction in favour of ivermectin (aRR=0.51, 95% CI 0.27 – 0.95).

Similarly, the prophylaxis outcome remains in quantitative effect virtually unchanged, and in fact slightly improved in that the point estimate for reduction in Covid-19 infection increases from 86% to 87% (aRR=0.13, 95% CI 0.08 – 0.21), with similarly tight 95% Confidence Intervals again fully consistent with the larger observational trials of ivermectin prophylaxis.

NCCET: "W*hen patient populations are separated by severity and comparisons to active treatments removed, no meaningful effect is found*."

This assertion lacks any logic. Removing comparison to active treatments would be a pointless exercise. The pragmatic and pre-specified inclusion of "active" treatment comparators is a strength, not a weakness, of Bryant et al. [2] and would lead to *under*-estimation of the effect of ivermectin, not over-estimation. In other words, Bryant *et al.* [2] is conservative by design, **against** *t*he effect of ivermectin. The fact that consistent positive effects are observed makes the results *more* convincing, not less.

Separation by severity has been dealt with explicitly by Neil and Fenton [10] who apply a Bayesian meta-analysis to the full set of trials in Bryant *et al.* [2], with an explicit separation of disease severity between "severe" and "mild-moderate". The study of Niaee [11] was excluded because disease severity was not distinguished. A "leave one out" sensitivity analysis is performed systematically on the entire data set, including the disputed trial of Elgazzar [8]. Again the conclusions remain robust to the removal of particular studies. For some studies with known heterogeneity the results are actually improved.

Neil & Fenton [10] find for severe disease a 90.7% posterior probability that the risk ratio favours ivermectin, and for mild/moderate Covid-19 there is an 84.1% probability the risk ratio favours ivermectin. They conclude that the results support the conclusions of Bryant *et al.* [2] over other claims such as that of Roman *et* [12]. The removal of Elgazzar [8] (Niaee [11] already excluded) provides the worst reduction in evidence but still result in a Bayesian posterior probability of effective risk reduction of 77%.

Other meta-analyses have been accepted for publication [12], in spite of demonstrated reporting errors available at pre-print stage, with very similar titles to
[2] but asserting the opposite conclusions. Roman *et al.* [12] make a limited selection (1173 patients over 10 trials compared to 3406 patients over 24 trials in [2]) of the trials reviewed in [2]. The assertions in [12] commit the elementary fallacy of supposing that lack of statistically significant evidence (in their highly selective survey) is the same thing as a positive demonstration of no benefit. These claims of Roman *et al.* [12] were dismissed by Neil & Fenton [13], an earlier version of [10].

Similar assertions have been made by propagandists in news media [14] but are simply untrue, as demonstrated explicitly in [9].

The context where essentially all studies are referenced to placebo (or non- pharmaceutical precautions) is prophylaxis. As previously mentioned, the
prophylaxis effect reported in [2] is actually slightly improved by the removal of Elgazzar [8], and consistent with large non-randomised trials of ivermectin prophylaxis. There is no question of categorising by severity in the prophylaxis context and virtually all studies are

referenced against no active comparators. The reduction in infection risk by 87% cannot be said to constitute "no meaningful effect". It is a very strong effect, achieved with ivermectin alone (or in one trial, combined with topical iota-carageenan nasal sprays).

Moreover, there has been no credible challenge to the prophylaxis results. It is not credible that ivermectin should achieve a prophylactic effect (by whatever mechanism) and fail to achieve a therapeutic effect, at least in the initial (viremic) phase of the illness.

The authors are principals of Evidence Based Medicine Consultancy Ltd., in Bath, England

References

1. Kory, P., Meduri, G.U., Varon, J., Iglesias, J., & Marik, P.E. (2021). Review of the emerging evidence demonstrating the efficacy of Ivermectin in the prophylaxis and treatment of Covid-19. *J. Therapeutics,* **28**(3), e299-e318 DOI: 10.1097/MJT.0000000000001377
2. Bryant, A., Lawrie, T. A., Dowswell, T., Fordham, E. J., Mitchell, S., Hill, S. R. & Tham, T. C. (2021). Ivermectin for Prevention and Treatment of Covid-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines. *American Journal of Therapeutics*, 28, e434– e460. doi: 1097/mjt.0000000000001402
3. Horby, P., Lim, W. S., Emberson, J., Mafham, M., Bell, J., Linsell, L., *et al.* (2020). Effect of Dexamethasone in Hospitalized Patients with Covid-19: Preliminary Report. *New England Journal of Medicine*, doi:10.1056/NEJMoa2021436
4. Behera, P., Patro, B. K., Padhy, B. M., Mohapatra, P. R., Bal, S. K., Chandanshive, P. D., *et* (2021). Prophylactic role of ivermectin in SARS- CoV-2 infection among healthcare workers. *Research Square* preprint. doi: 10.21203/rs.3.rs-208785/v1
5. Cantey, P. (2018), 'WHO Expert Committee on the Selection and Use of Essential Medicines: Application for inclusion of ivermectin on the WHO Model List of Essential dicines (EML) and Model List of Essential Medicines for Children (EMLc) in the indication of Scabies. WHO Expert Committee Application. https://who.int/selection_medicines/committees/expert/22 /applications/s6.6_ivermectin.pdf
6. Page, M. J., McKenzie, J. E., Bossuyt, P. M., Boutron, I., Hoffmann, T. C., Mulrow, C. D. *et* (2021). The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*, **372**. doi: 10.1136/bmj.n71 Accessed 22 July 2021.
7. Cepelowicz-Rajter, J., Sherman, M. S., Fatteh, N., Vogel, F., Sacks, J. & Rajter, J.-J. (2020). Use of Ivermectin is Associated with Lower Mortality in Hospitalized Patients with Covid-19 (ICON study). *Chest*, **159**(1), 85- 92. DOI: 1016/j.chest.2020.10.009

8. Elgazzar, A., Hany, B., Youssef, S. A., Hafez, M., Moussa, H. & Eltaweel, A. (2020). Efficacy and Safety of Ivermectin for Treatment and prophylaxis of Covid-19 Pandemic. *Research Square* preprint doi: 10.21203/rs.3.rs- 100956/v2 Accessed 22 July
9. Bryant, , Lawrie, T. A. & Fordham, E. J. (2021). Letter to the Editor, *Am. J. Therapeutics*
10. Neil, M. & Fenton, N. E. (2021). Bayesian Meta Analysis of Ivermectin Effectiveness in Treating Covid-19 (with sensitivity analysis to account for possibly flawed studies). *Research Gate* doi: 10.13140/RG.2.2.19713.58723 Accessed 10 August 2021.
11. Niaee, M. S., Namdar, P., Allami, A., Zolghadr, L., Javadi, A., Karampour, A., ... Gheibi, N. (2021). Ivermectin as an adjunct treatment for hospitalized adult Covid-19 patients: A randomized multi-center clinical trial. *Asian Pacific Journal of Tropical Medicine*, *14*(6), https://doi.org/10.4103/1995- 7645.318304
12. Roman, Y. M., Burela, P. A., Pasupuleti, V., Piscoya, A., Vidal, J. E. & Hernandez, A. V. (2021). Ivermectin for the treatment of Covid-19: A systematic review and meta- analysis of randomized controlled trials. *Clinical Infectious Diseases*, doi: 1093/cid/ciab591
13. Neil, M. & Fenton, N. E. (2021). Bayesian Meta Analysis of Ivermectin Effectiveness in Treating Covid-19 Disease. *Research Gate* preprint doi: 10.13140/RG.2.2.31800.88323 12 July Accessed 22 July 2021
14. Davey, M. (2021). Huge study supporting ivermectin as Covid treatment withdrawn over ethical concerns. *The Guardian,* 15 July. https://theguardian.com/science/2021/jul/16/huge-study- supporting-ivermectin-as-Covid-treatment-withdrawn-over-ethical- concerns Accessed 22 July 2021.
15. Anglemyer, A., Horvath, H. & Bero, L. (2014). Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. *Cochrane Database of Systematic Reviews*, DOI: 10.1002/14651858.MR000034.pub2

OPEN LETTER

14 October 2021

Dr. Julian Elliott Executive Director
National Covid Clinical Evidence Taskforce (NCCET) Level 4, 553 St Kilda Rd.
Melbourne, Vic. 3004

email: guidelines@Covid19evidence.net.au

Re: SECOND CALL for an Urgent Review of the NCCET Recommendation regarding the use of ivermectin in the management of Covid-19

I refer to my previous Open Letter calling for an urgent review of the NCCET

recommendations regarding the use of ivermectin in the management of Covid-19 (dated 21 August) which remains unanswered (see copy attached)

Recent Developments

Since the writing of Open Letter there have been several important developments with regard to the Covid-19 pandemic, including:

1. The issuance of TGA "New restrictions on prescribing ivermectin for Covid-19 (10 Sept. 2021) https://www.tga.gov.au/media-release/new-restrictions-prescribing-ivermectin-Covid-19
2. Notice of an amendment to the current Poisons Standard under paragraph 52D(2)(a) of the Therapeutic Goods Act 1989 (10 Sept. 2021)
3. Reports of the near eradication of Covid-19 in the Indian State of Uttar Pradesh (230 million people) using ivermectin combination therapy despite a vaccination rate below 6%.
4. Multiple reports of diminishing mRNA "vaccine" protection against the Delta Covid-19 virus strain following calls for "vaccine" boosters
5. An orchestrated and irresponsible mainstream "media science" campaign aiming to discredit the use of ivermectin on safety grounds.

Additional Public Information on the Safety of Ivermectin

The current NCCET recommendation continues to question the safety of ivermectin despite its worldwide use (4 billion doses) for more than 3 decades and the inclusion of ivermectin on the World Health Organisation Model List of Essential Medicines.

In fact, ivermectin is known to have a wide margin of safety compared to most drugs including many non-prescription medications.

Prior to the pandemic, the Australian Therapeutics Goods Administration (TGA) previously had no significant concerns regarding the safety of ivermectin. According to the TGA Australian Public Assessment Report for Ivermectin – 2013 (see attached).

- Page 11: "Escalation to a single dose of 120 mg (up to 2 mg/kg), 10 times the approved dose and 5 times the anticipated head lice dose, also produced no mydriatic effect. This supports the safety of ivermectin at the proposed dose and provides a significant margin of safety."

- Page 18: the drug "showed good tolerability and no safety concerns at doses ranging from 30 to 120 mg, that is, up to 10 times the proposed dose of 200 µg/kg for treatment of scabies".

- Page 39: The TGA clinical evaluator found that there were no significant safety

concerns reported with the use of ivermectin in any of the published studies.

There were 3 stated reasons for the TGA action in preventing ivermectin from being used in the treatment of Covid-19:

Reason 1. ivermectin use might dissuade people from being vaccinated

Reason 2. ivermectin was associated with serious adverse events including "severe nausea, vomiting, dizziness, neurological effects such as dizziness, seizures and coma".

Reason 3. ivermectin prescribing for Covid-19 might lead to shortages of this medication for other approved indications.

Reasons 1 and 3 do not justify the prohibition of ivermectin prescribing for the treatment of Covid-19.

With regard to Reason 2 – this contradicts the TGA's prior assessment of the safety of ivermectin (above).

Ivermectin National Treatment Programmes

Clinical trials are fundamentally designed to randomly select a relatively small group of individuals for specified treatments and observe safety and efficacy. The results, if statistically powered correctly, can then be extrapolated to the population at large. However, in the case of ivermectin, not only are there more than 60 published clinical trials available, but several countries have embraced the use of ivermectin for the treatment of Covid-19 with success and treatment data is available on huge populations which provide important efficacy data.

In addition to the successful national treatment programmes in countries such as Mexico, Argentina and Peru, the NCCET should now be aware of the success in treating Covid-19 individuals with ivermectin in the Indian State of Uttar Pradesh.

https://www.thegatewaypundit.com/2021/09/huge-uttar-pradesh-india-announces-state-Covid-19-free- proving-effectiveness-deworming-drug-ivermectin/?utm_source=Twitter&utm_medium=PostTopSharingButtons&utm_campaign=websiteshari ngbuttons

https://www.thedesertreview.com/opinion/columnists/indias-ivermectin-blackout---part-v-the-secret-revealed/article_9a37d9a8-1fb2-11ec-a94b-47343582647b.html

https://osf.io/preprints/socarxiv/r93g4/

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3765018

Ivermectin based combination therapy was administered as early and preventative treatment in all family contacts as part of the "Uttar Pradesh Covid Control Model". Using this therapeutic approach, Covid-19 was virtually eliminated in a population of 230 million people with a vaccination rate of less than 6% (compares to the US fully vaccinated rate at the same

time of 54%). This result is in direct contrast to the comparable State of Kerala, a small state located in Southern India that is over- dependent on vaccines and restricted ivermectin use to more severe cases and late treatment if used at all.
Large scale observational studies such as this can provide valid and reliable real-world data and, in most cases, there is little evidence that the results of observational studies and RCTs systematically disagree (Reference 6).
https://www.researchgate.net/publication/261998443_Healthcare_outcomes_assessed_with_observational_study_designs_compared_with_those_assessed_in_randomized_trials
The regulatory agencies appear willing to provisionally release new drugs to treat Covid-19 on the basis of very limited safety and efficacy data (sometimes involving a relatively limited clinical trial data and/or no long-term safety data (eg. mRNA vaccines, molnupiravir and remdesivir). However, the NCCET appears to largely ignore the compelling body of evidence supporting the safe and effective use of ivermectin in more than 30 randomised clinical trials (RCTs) involving more than 20,000 patients and successful national ivermectin treatment programmes.

Literature Review and Meta-analyses

The NCCET continues to rely (and defends) an arbitrary selection of 18 published clinical trials upon which to base its current negative recommendation for ivermectin use. In contrast to the sophisticated meta-analysis methods employed in the published reviews on ivermectin (References 7 and 8), the NCCET has failed to detail or define its informal method of assessment which were used to arrive at the current recommendation.
Rather than relying on the results of any one clinical trial, properly conducted meta- analyses of a larger number of randomised controlled trials by highly trained and experienced staff are the most powerful tool in drawing reliable conclusions from pooled data. However, biases can be introduced in any meta-analysis. This is why it is important to publish the protocols and methods used in any meta-analysis so the work can be critically assessed for reliability.

A recent meta-analysis of ivermectin was conducted by the Cochrane group (Reference 9). However, according to a response to this meta-analysis by Fordham, Lawrie, MacGilchrist and Bryant (in pre-print, see attached Reference 10), the Cochrane report suffers from no less than 11 significant analytical and methodological defects rendering the conclusions unreliable – not the least of which, to give but one example, was the author's treatment of the important analysis of mortality.
Out of 24 available RCTs identified for the review, the authors chose only 4 to include in their mortality analysis, a small subset of those available. The Cochrane authors split this data up further into two separate analyses. This effectively dilutes theirfindings to the extent that a meaningful result from meta-analysis was not possible. Instead of utilising all available evidence and presenting appropriate caveats around such wider evidence, as would normally be done according to accepted protocols, they present an empty review with considerable bulk but little useful analysis.

Conclusions

The reported diminishing efficacy of the Covid-19 vaccines to protect against the emergence of SARS-Co-2 variants demands an urgent review of the use of ivermectin.

I repeat my previous message (21 August Open Letter) to the NCCET and again request an urgent review of the recommendations regarding ivermectin:
"The current approach to symptomatic Covid-19 individuals is largely to do nothing and simply observe until they either get better or get worse, perhaps much worse, and need to go to hospital. The do-nothing approach places enormous strain on our health care system. Evidence for this 'do nothing, watch and observe' approach is lacking. Ivermectin offers a potentially effective, low cost, safe and rational approach to the management of such individuals with little or no disadvantage. The NCCET recommendation on ivermectin is considered to be misinformation by many experts and is viewed as contributing to needless hospitalisation – but for this recommendation, many Covid-19 infected individuals could be receiving early effective treatment."
Regards,

Phillip M. Altman
BPharm (Hons), MSc, PhD
Clinical Trials and Regulatory Affairs Consultant

REFERENCES

1. Open Letter to NCCET dated 21 August 2021

2. TGA "New restrictions on prescribing ivermectin for Covid-19" – 10 Sept. 2021

3. The TGA Australian Public Assessment Report for Ivermectin (October 2013)

4. Huge: Uttar Pradesh, India Announces State is Covid-19 Free Proving ghe Effectiveness of "Deworming Drug" IVERMECTIN
Jim Hoft, Sept 15 2021, Gateway Pundit
https://www.thegatewaypundit.com/2021/09/huge-uttar-pradesh-india-announces- state-Covid-19-free-proving-effectiveness-deworming-drug-ivermectin/

5. The Desert Review: Justus R Hope – TheDesertReview.com

6. Anglemyer A,Horvath HT,Bero L. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. *Cochrane Database Syst Rev*. 2014;4:MR000034.

7. Bryant, A, Lawrie, TA, Dowswell, T, Fordham, EJ, Mitchell, S, Hill, SR and Tham, TC.

Ivermectin for Prevention and Treatment of Covid-19 infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines.

American Journal of Therapeutics 28, e434-e460 (2021).

8. Kory,P, Meduri, U, Varon, J, Iglesias, J and Marik, PE.
Review of the Emerging Evidence Demonstrating the Efficacy of Invermectin in the Prophylaxis and Treatment of Covid-19.
American Journal of therapeutics 28, e299-e318 (2021.

9. Popp M, Stegemann M, Metzendorf M-I, *et al*. Ivermectin for preventing and treating Covid-19. Cochrane Database Syst Rev 2021;7:CD015017.
Doi:10.1002/14651858.CD015017.pub2

10. Fordham, EJ, Lawrie, TA, MacGilchrist, K and Bryant A. The uses and abuses of systematic reviews: the case of ivermectin in Covid-19. EbMCsquared CIC, Northgate House, Upper Borough Walls, Bath BA1 1RG, UK

Annexure 10

Index
Reference II
Question on Notice
Answer

FREEDOM OF INFORMATION REQUEST FOI 3643

NOTICE OF DECISION

27 FEBRUARY 2022

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5201218

Mr [redacted]
Email: [redacted]

Dear [redacted]

FREEDOM OF INFORMATION REQUEST FOI 3643
Notice of Decision

1. I refer to your request dated 18 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following document:

> *"I request an implementation report on the Covid 19 Vaccine Safety Monitoring Plan as per the key objectives listed in the plan:*
>
> *1. timely collection and management of reports of COVID-19 vaccine adverse events following immunisation*
>
> *2. timely detection and investigation of COVID-19 vaccine safety signals*
>
> *3. timely action to address any COVID-19 vaccine safety concerns*
>
> *4. timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public confidence in vaccines*
>
> *5. close collaboration and coordination of effort with other vaccine safety stakeholder groups*
>
> *I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. I have interpreted your request as being for an evaluation report assessing whether the TGA has achieved the goals and objectives listed in the COVID-19 Vaccine Safety Monitoring Plan.
4. Unfortunately, I am unable to continue to process your request because the document you have requested does not exist. Therefore, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Reasons for Decision

5. Despite a thorough and complete search, the document you have requested does not exist. In these circumstance, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, the FOI Act states:

   requests may be refused if all reasonable steps have been taken to find a document and the document does not exist.

6. Please be assured that the TGA's electronic databases, files and corporate file lists have been searched and following these searches, I am satisfied that all reasonable steps have been taken to find the document requested. However, the document you have requested does not exist.

7. The reasons the document you have requested does not exist is because the TGA does not hold an 'implementation report' on the COVID-19 vaccine safety monitoring plan.

8. While the TGA continues to monitor the progress of the five objectives listed in your request and has ample documentation demonstrating compliance in those objectives, the TGA does not have a single, specific evaluation report outlining progress.

Direction to Publicly Available Information

Objectives 1– 4 of the COVID-19 Vaccine Safety Monitoring Plan

9. Objectives 1-4 of the COVID-19 vaccine safety monitoring plan (as outlined above in the scope of your request) are captured by the Database of Adverse Events Notification (**DAEN**) and the COVID-19 vaccine weekly safety reports.

10. By way of background, all adverse event reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information contained therein is uploaded to the Database of Adverse Event Notifications – medicines (DAEN). The DAEN contains information on all adverse events reported to the TGA following administration of a medicine, including the COVID-19 vaccines.

11. As of 19 August 2021, the TGA has reduced the time between adverse event reports being accepted into our database and published on the DAEN from 90 days to 14 days to address the strong public interest in adverse event reports relating to COVID-19 vaccinations and allows reports for vaccines to be made publicly available more quickly (pursuant to Item 4).

12. Adverse event reporting data provides a source from which to detect patterns of events that indicate a possible safety issue, or 'safety signals'. The TGA conducts regular statistical analyses of adverse event data to detect signals, in addition to closely monitoring the occurrence of 'adverse events of special interest'. Investigation of safety signals may involve activities such as more detailed analysis and review of adverse event report data, consideration of published literature or information from medicines regulators in other countries, and review of safety data from international use of the vaccine provided by the vaccine sponsor.

13. The TGA publishes a COVID-19 vaccine weekly safety report, which can be accessed at: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. The report includes summaries of the latest safety information regarding COVID-19 vaccines, including the outcomes of significant safety investigations, and information about regulatory actions taken as a result of TGA's safety monitoring.

Objective 5 of the COVID-19 Vaccine Safety Monitoring Plan

14. The TGA has worked closely with states and territories, other government agencies, overseas regulators, and expert bodies to ensure a coordinated approach to COVID-19 vaccine safety.

15. Examples of this collaboration include:

    a. co-chairing, with the UK Medicine and Healthcare products Regulatory Agency, regular meetings of international medicines regulators to share information about COVID-19 vaccine safety

    b. holding regular meetings with state and territory jurisdictional immunisation coordinators to discuss emerging safety information and communications

    c. providing regular briefings to ATAGI COVID-19 working groups to inform aspects of the vaccine roll-out

    d. working with the National Centre for Immunisation Research and Surveillance to share information and characterise significant vaccine safety issues

    e. seeking expert advice from the Advisory Committee for Vaccines on COVID-19 vaccine monitoring activities and safety issues.

Review and Complaint Rights

16. If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

17. If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

[redacted]
gilance Branch
Therapeutic Goods Administration
27 February 2022

Annexure 11

FREEDOM OF INFORMATION REQUEST FOI 3604

NOTICE OF DECISION

18 FEBRUARY 2022

Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5167274

[redacted]
By email: [redacted]

Dear [redacted],

FREEDOM OF INFORMATION REQUEST FOI 3604
Notice of Decision

1. I refer to your request dated 5 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

   "the following documents relating to the provisional approval of the Pfizer-BionTech BNT162b2 vaccine in January 2021:
   1. *"All documents relating to the TGA's assessment of the risk of and/or presence of **micro-RNA sequences (miRNA)** comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
   2. *All documents relating to the TGA's assessment of the risk of and/or presence of **Oncomirs** (oncogenic miRNA - microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
   3. *All documents relating to the TGA's assessment of the risk of and/or presence of **Stop Codon read-through** (suppression of stop codon activity) arising as a result of the use of pseudouridine in the Comirnaty miRNA active ingredient (mRNA genomic sequence).*
   4. *Any document showing that the TGA has assessed the composition of the **final protein product** (molecular weight and amino acid sequence) produced following injection of the Comirnaty mRNA product in human subjects.*
   5. *All documents relating to the TGA's assessment of the risk of the use of the **AES-mtRNR1 3' untranslated region** of the Comirnaty mRNA product in human subjects."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. Unfortunately, I am unable to continue to process your request because the documents you have requested do not exist.

4. By way of background, I wish to advise you that the Pfizer Comirnaty vaccine has been provisionally approved by the TGA for use in individuals aged 12 years and over; for use in individuals aged 5-11 years; and as a booster dose for individuals aged 16 years and over. The provisional approval pathway balances the benefits of early access with the uncertainties inherent to the fact that additional data are required. This pathway is available for other prescription medicines, not just vaccines. Further details of the

provisional approval pathway are available at: www.tga.gov.au/provisional-approval-pathway-prescription-medicines

5. Before a COVID-19 vaccine can be provisionally approved in Australia, the TGA must establish the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information. This includes clinical studies, non-clinical and toxicological studies, chemistry, risk management and manufacturing information. The pivotal clinical trials supporting the safety and effectiveness of vaccines in the provisionally approved age groups have been peer-reviewed, published in reputable medical journals and are publicly available.

6. A large team of clinical and scientific experts at the TGA carefully review this data and seek advice from the Advisory Committee on Vaccines (**ACV**), an independent clinical expert committee, prior to a senior medical officer making a regulatory decision. Even though this is an expedited process, no element of the evaluation is rushed, and no data or specific safety concerns (such as oncogenic activity) are overlooked. A vaccine is only provisionally approved by the TGA if this rigorous process is completed, and the benefits are considered to be much greater than any potential risks. As part of the provisional approval, sponsors are also required to continue to submit evidence of longer-term safety and efficacy to the TGA.

7. There was no evidence of any concerns relating to *"microRNA"*, *"oncogenic miRNA"*, *"suppression of stop codon activity"*, the *"final protein product"* or *"AES-mtRNR1 3' untranslated region"* identified during the provisional approval process. As such there are no documents falling within the scope of your request. Please be assured that if any relevant safety concerns were identified as possible or likely, they would be investigated thoroughly.

8. The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, which provides detailed information regarding the evaluation process and the data that were considered. These include the Australian Public Assessment Report (**AusPAR**), the Product Information (**PI**) and the Consumer Medicine Information (**CMI**), and they are available at: www.tga.gov.au/covid-19-vaccines.

9. In addition, the TGA, like other regulatory agencies around the world, continues to monitor the safety of vaccines and medicines after they are approved to contribute to a better understanding of their safety profile. General information about the safety of medicines and how the TGA monitors safety is available here: https://www.tga.gov.au/medicines-safety.
   The existing safety monitoring system for vaccines involves:
   - reviewing and analysing reports of suspected side effects (also known as adverse events) submitted by health professionals and consumers.
   - requiring pharmaceutical companies to have risk management plans for the vaccines they supply.
   - proactively reviewing medical literature and other potential sources of new safety information.
   - working with international regulators to assess significant side effects detected overseas.
   - working with State and Territory health departments and clinical experts to ensure a coordinated approach.

10. Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'.

11. Prior to the COVID-19 vaccine rollout, the TGA implemented a number of enhancements to strengthen the existing vaccine safety monitoring system, to allow for early detection and investigation of possible safety issues associated with COVID-19 vaccines, and rapid communication of any confirmed safety issues. These enhancements are described in the COVID-19 vaccine safety monitoring plan, published on the TGA website at: www.tga.gov.au/resource/covid-19-vaccine-safety-monitoring-plan.

12. Adverse event reporting data provides a source from which to detect patterns of events that indicate a possible safety issue, or 'safety signals.' The TGA conducts regular statistical analyses of adverse event data to detect signals, in addition to closely monitoring the occurrence of 'adverse events of special interest'. Investigation of safety signals may involve activities such as more detailed analysis and review of adverse event report data, consideration of published literature or information from medicines regulators in other countries, and review of safety data from international use of the vaccine provided by the vaccine sponsor.

13. This provides confidence that any safety issues will be identified promptly, including any safety issues regarding *"microRNA"*, *"oncogenic miRNA"*, *"suppression of stop codon activity"*, the *"final protein product"* or *"AES-mtRNR1 3' untranslated region"*.

14. If our monitoring confirms a safety issue, we take prompt action to make this information available to health professionals and the public. Each week, the TGA publishes the outcomes of our ongoing monitoring and safety investigations of the COVID-19 vaccines available at: www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

15. I also wish to advise you that the TGA ensures there is an independent quality assessment of every batch of vaccine supplied in Australia, to ensure vaccines meet quality standards prior to being released for use. Tests are performed on a variety of the vaccine's properties, including assessments for composition, identity, potency, purity and adventitious agents (contamination with microorganisms). The testing results, along with the review of the manufacturing documentation for each batch, provides assurance that the vaccine being supplied is in line with registered products on the Australian Register of Therapeutic Goods (**ARTG**).

16. Further information on the batch assessment process, along with the test results for each batch of COVID-19 vaccine that has been tested by the TGA, is publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

17. In addition to the vaccine safety monitoring conducted by the TGA, AusVaxSafety, which is led by the NCIRS and funded by the Australian Government Department of Health, conducts active vaccine safety surveillance of the COVID-19 vaccines in use in Australia to ensure their ongoing safety. This information is updated regularly and is accessible here: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines.

18. AusVaxSafety has published articles explaining how current data gives us confidence about the long-term safety of COVID-19 vaccines and how the TGA monitors side effects. If you would like to learn more, we refer you to: https://www.ausvaxsafety.org.au/how-do-we-know-covid-vaccine-wont-have-long-term-side-effects.

19. As the TGA holds no documents fallen within the scope of your FOI request, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Reasons for Decision

20. The reasons for my decision are set out above. Despite a thorough and complete search, the documents you have requested do not exist. In these circumstances, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, the FOI Act states:

    requests may be refused if all reasonable steps have been taken to find a document and the document does not exist.

21. Please be assured that the TGA's electronic databases, files and corporate file lists have been searched and following these searches I am satisfied that all reasonable steps have been taken to find the documents requested. However, the documents you have requested do not exist.

Review and Complaint Rights

22. If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

23. If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Dr Lisa Kerr, PhD MBA
Assistant Secretary, Laboratories Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
18 February 2022

Annexure 12

RE: NOTICE TO DR OOSTERHUIS TO PRODUCE INFORMATION

30 JUNE 2023

Private

Reference Number:

Kathryn Skardoon

Designated contact

Health Care Complaints Commission (NSW) (**'HCCC'**)

Level 12/323 Castlereagh St, Haymarket NSW 2000

30 June 2023

Dear Kathryn Skardoon,

RE: Notice to Dr Oosterhuis to produce information

1. We refer to correspondence dated 19 June 2023 titled "**Notice to Produce Information under Section 21A(1)(a) of the Health Care Complaints Act 1993 (NSW)**" from Georgina Woods citing file number 23/02952 ('the Notice') in which Georgina invoked the HCCC's power to obtain information in the assessment of a complaint.

2. Dr Oosterhuis is a member of the Australian Medical Professionals' Association (**'AMPS'**), who have assigned William Parry as its case manager for this matter regarding a complaint against Dr Oosterhuis.

3. Please be notified of the following:

    a. AMPS believe that the complaint is frivolous and not-serious and ought to be dismissed pursuant to the relevant considerations within ss 20 and 27 of the *Health Care Complaints Act 1993* (NSW) (**'HCCA'**); and

    b. AMPS further suggest that the scope of relevant conduct requested is unworkably broad, and is publicly available, and therefore requesting such information under s 21A of the HCCA is inappropriate; and

    c. AMPS have a number of questions regarding the procedure resulting in the Notice.

4. Please also be aware that:

a. Dr Oosterhuis hopes to provide HCCC with his perspective on how his conduct is in line with his Code of Conduct[1] in an attempt to comply with the Notice; and

b. Dr Oosterhuis objects, pursuant to s 37A of the HCCA to any of his information provided in compliance with the Notice being used for civil proceedings.

Required background

5. The Notice does not adequately notify Dr Oosterhuis of who made the Complaint to HCCC nor identify what professional conduct is being assessed.

6. We understand the HCCC is assessing a complaint from a confidential complainant that identifies as a health provider from New Zealand which has been shared.

7. The complaint was submitted to the national agency (i.e. AHPRA) on 25 April 2023 (**'the Compliant'**) and presumably the complaint was made by a professional council pursuant s 11 of the HCCA.

    a. ***Could you please provide clarification to Dr Oosterhuis regarding which Professional Council established under s 41B of the Health Practitioner Regulation National Law 2009 (NSW) made the complaint? Or was the Complaint directly made by the national agency?***

    b. Could you further provide information as to whether consultation took place pursuant to s 23(1)(a) of the HCCA or if the Commission wished to investigate the complaint pursuant to s 23(1)(b) of the HCCA?

8. There was little to no evidentiary information provided in the complaint and no safety concerns were identified.

Further assessment does not serve the Objects of the HCCA

9. Section 3 of the HCCA states clearly the objectives of the HCCC:

> *"(1) The primary object of this Act is to establish the Health Care Complaints Commission as an independent body for the purposes of—*
>
> > *(a) receiving and assessing complaints under this Act relating to health services and health service providers in New South Wales, and*
> > *(b) investigating and assessing whether any such complaint is serious and if so, whether it should be prosecuted, and*
> > *(c) prosecuting serious complaints, and*
> > *(d) resolving or overseeing the resolution of complaints.*

[1] Good medical practice: a code of conduct for doctors in Australia, October 2020.

(2) In the exercise of functions under this Act the protection of the health and safety of the public must be the paramount consideration."

10. Dr Oosterhuis operates at all times in the interests of the health and safety of the public as his paramount consideration, both in practice and in research. The Complaint is prima facie, on the face of it, not serious in nature, and ought not to be entertained pursuant to ss 19, 20, & 27 of the HCCA.

There is no specific allegation warranting further assessment

11. Section 20 of the HCCA outlines the purposes of an assessment including subsection (2) as follows:

> *"(2) Unless the Commission decides to decline to entertain a complaint, the Commission is, as part of its assessment of the complaint and as soon as practicable after commencing its assessment—*
>
> *(a) to identify the specific allegations comprising the complaint and the person or persons whose conduct appears to be the subject of the complaint, and*
>
> *(b) to use its best endeavours to confirm with the complainant and with any other person who provided relevant information in relation to the complaint that the matters so identified accord with the information provided by them."*

12. We understand that HCCC is entertaining the Complaint. ***Can HCCC please confirm that the allegation is as follows (from page 1 of the Notice)?***

> *"posts on social media (Twitter) [Dr Oosterhuis] made that are not aligned with current NSW Health Policy."* (**'the Allegation'**)

13. AMPS believe that the Allegation and the Notice are

    a. too broad,

    b. too vague,

    c. fail to identify a breach of the Code of Conduct,

    d. do not identify how Dr Oosterhuis' conduct is not aligned with "current NSW Health Policy", and

    e. fail to identify any serious safety concerns,

    such that the Allegation and the Complaint are not "specific allegations" referred to in s 20(2)(a) of the HCCA.

14. AMPS, therefore, question whether the statutory procedure has been followed in a way that requires Dr Oosterhuis to comply with the Notice and strongly advocates the circumstances for discontinuing dealing with the complaint are already met pursuant to s 27 of the HCCA.

15. Regardless, Dr Oosterhuis prefers to be transparent regarding his dedication to his Code of Conduct.

Psychosocial risks of continued victimisation

16. Please be notified that psychosocial harms may result from unwarranted victimisation.

17. Dr Oosterhuis is a qualified and ethical practitioner with a strong sense of morality, which is guided by the Code of Conduct and a care for the health and safety of the public, and seeks best evidence as much as reasonably practicable to identify where there might be risks to the health and safety of the public.

18. Dr Oosterhuis reports stress from receiving the Notice.

19. It has recently been reported to the public record that at least 16 medical practitioners have been identified as having committed suicide during or following AHPRA notifications or investigations. We would suggest the Notice from HCCC is the beginning of a similar concern.

20. We recognise that HCCC's assessment of complaints is an important regulatory function to ensure the safety of patients and those seeking services from medical practitioners.

21. However, ungrounded or frivolous notifications to competent and discerning medical practitioners for their adherence to the Code of Conduct is extremely damaging and can result in a culmination of psychological harms that have contemporarily been referred to as Moral Injury:[2]

> "Moral injury is understood to be the strong cognitive and emotional response that can occur following events that violate a person's moral or ethical code."[3]

22. Symptoms of moral injury involve depression, stress, physiologically deleterious effects, and in some instances suicidal ideation.

23. Please consider the psychosocial hazards of notifications that curb Freedom of Speech, political expression, and proper evidence-based reasoned discussion and debate that is compliant with the Code and National Law; prior to notices or regulatory actions where there is no need established.

Response to the Materials

---

[2] See *Williamson et al* published in the Lancet, March 2021 <https://doi.org/10.1016/S2215-0366(21)00113-9>.

[3] Litz BT, Stein N, Delaney E et al. Moral injury and moral repair in war veterans: a preliminary model and intervention strategy. Clin Psychol Rev. 2009; 29: 695-706.

24. Notwithstanding that:

    a. the Notification appears frivolous or designed to limit Dr Oosterhuis' freedom of lawful political speech in adherence to the Code; and

    b. That there is simply no Complaint to entertain because the Allegation does not identify serious professional misconduct or other relevant considerations requiring further assessment, as evidenced on the face of the Complaint itself.

25. Dr Oosterhuis is happy to contextualise in an attempt to comply with the Notification, please note Dr Oosterhuis objects to the provision of this information being used in Civil proceedings by another party without his consent. You will find this information attached.

Conclusion

26. Please answer the questions found in paragraphs 7 and 12 to provide clarity in the interests of avoiding a dispute.

27. We hope your assessment is discontinued based upon continued investigation not being pursuant to the Objects of the HCCA nor in the public interest.

Kind regards,

William Parry
Senior Case Manager
Red Union Support Hub
Proud service provider to AMPS

Dr Oosterhuis'compliance with Notice to Produce

Dear Georgina Woods,

RE: File No: 23/02952

In respect of your 19 June 2023 Notice to Produce Information, this is my written response.

The complainant alleges I have been spreading 'misinformation about Covid illness and vaccination', and that I am 'spreading .. conspiracy theories'.

No particulars were provided by the complainant of the alleged misinformation or conspiracy theories.

As the complainant was unable to identify any particular examples of the alleged misinformation or conspiracy theories, the complainant therefore presents no evidence to support the complaint.

In the absence of any evidence going to substantiate the allegations raised by the complainant, I can only state the complaint is without merit and requires no further action on my part.

That the above is the true state of affairs is trite law.

I have a strong mind towards my oath as a doctor and I care deeply about the public health and well-being. My posts on social media uphold, and remain consistent with the code of conduct and good medical practice.

In the Medical Board of Australia's codes and guidelines webpage: "Social media: How to meet your obligations under the National Law" it states:

"When using social media, you can meet your obligations by:

- complying with your professional obligations as defined in your Board's Code of conduct"

In reference to my posts I would draw attention to the following codes of conduct which I affirm I am upholding:

4.5 Informed consent

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved

4.11 Adverse events

When adverse events occur, you have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately. When something goes wrong you should seek advice from your colleagues and from your professional indemnity insurer. Good medical practice involves:

- 4.11.1 Recognising what has happened.
- 4.11.2 Acting immediately to rectify the problem if possible, including seeking any necessary help and advice.
- 4.11.3 Explaining to the patient as promptly and fully as possible in accordance with open disclosure policies, what has happened and the anticipated short-term and long-term consequences.
- 4.11.4 Acknowledging any patient distress and providing appropriate support.
- 4.11.6 Reviewing and reflecting on adverse events and implementing changes to reduce the risk of recurrence (see section 8).

7.3 Health advocacy

Good medical practice involves using your expertise and influence to identify and address healthcare inequity and protect and advance the health and wellbeing of individual patients, communities and populations.

7.4 Public health.

Doctors have a responsibility to promote the health of the community through disease prevention and control, education and screening.

8.2 Risk management

Good medical practice in relation to risk management involves:

- 8.2.1 Acknowledging that all doctors share responsibility for clinical governance.
- 8.2.2 Being aware of the importance of the principles of open disclosure and a non-punitive approach to incident management.
- 8.2.3 Participating in systems of quality assurance and improvement.
- 8.2.4 Participating in systems for surveillance and monitoring of adverse events and 'near misses', including reporting these events.
- 8.2.5 If you have clinical leadership and/or management responsibilities, making sure that appropriate systems are in place for raising concerns about risks to patients.

10.12 Conflicts of interest

Patients rely on the independence and trustworthiness of doctors for any advice or treatment. A conflict of interest in medical practice arises when a doctor, entrusted with acting in the interests of a patient, also has financial, professional or personal interests, or relationships with third parties, which may affect their care of the patient. Multiple interests are common. They require identification, careful consideration, appropriate disclosure and accountability. When these interests compromise, or might reasonably be perceived by an independent observer to compromise, the doctor's primary duty to the patient, doctors must recognise and resolve this conflict in the best interests of the patient. If in doubt, seek advice from colleagues, your employer, professional organisation or professional indemnity insurer.

Good medical practice involves:

- 10.12.2 Acting in your patients' best interests when making referrals and when providing or arranging treatment or care.
- 10.12.3 Informing patients when you have an interest that could affect, or could be perceived to affect, patient care.
- 10.12.4 ***Recognising that pharmaceutical and other medical marketing influences doctors and being aware of ways in which your practice may be being influenced.***
- 10.12.5 Recognising potential conflicts of interest in relation to medical devices and appropriately managing any conflict that arises in your practice.

  10.12.9 Not allowing any financial or commercial interest in a hospital, other healthcare organisation, or company providing or manufacturing healthcare services or products to adversely affect the way you treat patients. When you or your immediate family have such an interest and that interest could be perceived to influence the care you provide, you must inform your patient.

Information regarding the Complaint

The issue of conflicts of interest raise the question of AHPRA and The Commission in respect to this complainant, who being anonymous to me, raises the question:

> " *What efforts were made to ensure that the anonymous notifier in this complaint was free of conflicts of interest, which may prove to be a breech of the code on the behalf of the complainant?"*

This relates to the code of conduct in section 10.4 on Professional behaviour:

> **10.4 Vexatious complaints**
>
> Legitimate complaints are motivated by genuine concerns about patient safety. ***Vexatious complaints lack substance and have other motivations. They are often characterised by an intention to protect commercial interests and/or cause***

harm to another health practitioner, instead of a genuine concern about patient safety. Good medical practice involves:

- 10.4.1 Raising genuine concerns about risks to patient safety to the appropriate authority (locally and/or the Medical Board) and complying with mandatory reporting requirements.
- 10.4.2 Not making vexatious complaints about other health practitioners.

The Board may take regulatory action against a medical practitioner who makes a vexatious notification about another health practitioner.

Ongoing trial on public at large

On 21 February 2021, in an ABC interview with David Speers, the Health Minister Greg Hunt noted, **" *The world is engaged in the largest clinical trial, the largest global vaccination trial ever."***

This invokes the issue of research ethics, and the code:

13.2 Research ethics

Being involved in the design, organisation, conduct or reporting of health research involving humans brings particular responsibilities for doctors. These responsibilities, drawn from the NHMRC guidelines, include:

- 13.2.1 Respecting and protecting participants.
- 13.2.2 Acting with honesty and integrity.
- 13.2.3 Ensuring that any protocol for human research has been approved by a human research ethics committee, in accordance with the *National statement on ethical conduct in human research*.
- 13.2.4 Disclosing the sources and amounts of funding for research to the human research ethics committee.
- 13.2.5 Disclosing any potential or actual conflicts of interest to the human research ethics committee.
- 13.2.6 Ensuring that human participation is voluntary and based on an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research.
- 13.2.7 Ensuring that any dependent relationship between doctors and their patients is taken into account in the recruitment of patients as research participants.
- 13.2.8 Seeking advice when research involves children or adults who are not able to give informed consent, to ensure that there are appropriate safeguards in place. This includes ensuring that a person empowered to make decisions on the patient's behalf has given informed consent, or that there is other lawful authority to proceed.
- 13.2.9 Adhering to the approved research protocol.
- 13.2.10 Monitoring the progress of the research and promptly reporting adverse events or unexpected outcomes.
- 13.2.11 Respecting the right of research participants to withdraw from any research at any time and without giving reasons.
- 13.2.12 Adhering to the guidelines including about the publication of findings, authorship, peer review and conflicts of interest.
- 13.2.13 Reporting possible fraud or misconduct in research as required under the *Australian code for the responsible conduct of research*.

13.3 Treating doctors and research

When you are involved in research that involves your patients, good medical practice includes:

- 13.3.1 Respecting the patient's right to withdraw from a study without prejudice to their treatment.
- 13.3.2 Ensuring that a patient's decision to not participate does not compromise the doctor–patient relationship or their care.

When evaluating best available evidence, it is particularly important, and in the public interest to consider the sources and the potential of contamination by conflicts of interest.

Unfortunately, I believe that there is an iatrogenic disaster occurring. This is evidenced, partly, via the URL links provided in the Complaint.

I always use the best evidence and wish to discuss this evidence in a responsible manner that does not put the public health at risk, but instead, investigates and discusses issues that are of public importance.

Kind regards,

Dr Paul Oosterhuis

30 June 2023

Reference A: Second Answer – Julian Gillespie LLB, BJuris

[i] Pezzullo et al 2023 Age-stratified infection fatality rate of COVID-19 in the non-elderly informed frompre-vaccination national seroprevalence studies

[ii] Axfors et a 2022 Infection fatality rate of COVID-19 in community-dwelling elderly populations

[iii] ibid

[iv] Ward *et al 2022*: Risk of covid-19 related deaths for SARS-CoV-2 omicron (B.1.1.529) compared with delta (B.1.617.2): retrospective cohort study

[v] Australian Bureau of Statistics: COVID-19 Mortality in Australia: Deaths registered until 31 August 2022e

Reference E: Answer – Dr Lissa Johnson

[vi] Morrison, S., Payne, M., and Hunt, G. (2020). *Update on novel coronavirus (Covid-19) in Australia*. Joint Media Release, March 5. Parliament of Australia website. https://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressrel%2F7223641%22

[vii] Pezzullo, M. (2020). Consolidated Transcript of All Hearings, Royal Commission into Natural Disaster Arrangements, pp. 2712-2741. *Trove*. The National Library of Australia Web Archive. https://webarchive.nla.gov.au/awa/20211005052246/https://naturaldisaster.royalcommission.gov.au/publications/consolidated-transcript-all-hearings

[viii] Royal Commission into Natural Disaster Arrangements. (2020). *Appendices*, p.115. Commonwealth of Australia. https://www.royalcommission.gov.au/system/files/2020-12/Royal%20Commission%20into%20National%20Natural%20Disaster%20Arrangements%20-%20Appendices%20%20%5Baccessible%5D.pdf

[ix] Covid-19 is the name of the infection or illness caused by the SARS-CoV-2 coronavirus strain. After a cluster of pneumonia cases was reported in Wuhan China in December 2019, Covid-19 and SARS-CoV-2 were identified and named, over the course of January and February 2020, before the WHO declared a pandemic on March 11th.

[x] Eg see Alwan NA, Burgess RA, Ashworth S, Beale R, Bhadelia N, Bogaert D, et al. Scientific consensus on the Covid-19 pandemic: We need to act now. Lancet 2020. doi: 10.1016/S0140-6736(20)32153-X

[xi] The authors of the Oxford model rightly stressed the urgent need for ongoing data collection to verify epidemiological models such as their own, and to inform prediction and policy. In line with scientific ethics and transparency, the authors also noted that their own model had "not been peer-reviewed" and involved "new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice." Had the Imperial model included such caveats, government policy may not have proceeded so prematurely down a path that was divorced from evidence and data-collection.

[xii] Two contradictory studies, finding that antibodies are virtually always produced following exposure to SARS-Cov-2, thereby backing the reliance on antibody data alone to gauge natural population immunity, have ties to organisations with interests in vaccine markets and biotech / gene therapy, and/or to government agencies. Authors of the following study https://www.medrxiv.org/content/10.1101/2020.08.14.20174490v1, for instance, work for VIr Bio, whose "collaborators" include the Bill & Melida Gates Foundation; have intellectual property licensed by Sana Technology, a gene therapy company which has received $700m in funding in 2020, including from Jeff Bezos' Bezos Expeditions; serve as founder and chief scientific officer of Geneticure, a company that offers genetically tailored medical treatments, with financiers including Wireframe Ventures, which "led very early investments" in Palantir, a big data / security company with numerous US Government / National Security contracts, and Assurex, owned by Myriad Genetics, whose "key partnerships" include AstraZenica and Johnson & Johnson, both with stakes in Covid-19 vaccine development; And the following study https://www.medrxiv.org/content/10.1101/2020.07.14.20151126v1, which is "partially supported" by Collaborative Influenza Vaccine Innovation Centers (CIVIC) and the NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS), whose director is Antony Fauci, and which collaborate with the Bill and Melinda Gates Foundation on vaccines and epidemic preparedness.

[xiii] Dr. Jay Bhattacharya, professor at Stanford University Medical School, a physician, epidemiologist, health economist, and public health policy expert, Dr. Sunetra Gupta, professor at Oxford University, an epidemiologist with expertise in immunology, vaccine development, and mathematical modeling of infectious diseases, and Dr. Martin Kulldorff, professor of medicine at Harvard University, a biostatistician, and epidemiologist with expertise in detecting and monitoring infectious disease outbreaks and vaccine safety evaluations.

Reference M: First Answer – Peter Fam LLB

[xiv] See *Salgo v Leland Stanford Jr University Board of Trustees* 317 P 2d 170 (1957) (Cal Dist Ct App).

[xv] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 852 at 587.

[xvi] AC 871 at 893.

[xvii] 175 CLR 479.

[xviii] R Ottley, "Duty to Warn" (1993) 7 *Australasian Journal of the Medical Defence Union* 43.

[xix] *Rogers v Whittaker (1992)* 175 CLR 479 at 493.
[xx] *Rogers v Whittaker (1992)* 175 CLR 479 at 493.
[xxi] Division 3, s40.
[xxii] https://www.alrc.gov.au/publication/equality-capacity-and-disability-in-commonwealth-laws-dp-81/10-review-of-state-and-territory-legislation/informed-consent-to-medical-treatment/
[xxiii] https://www.hccc.nsw.gov.au/health-consumers/frequently-asked-questions-health-consumers/consent-for-treatment
[xxiv] *Consent to Medical and Healthcare Treatment Manual*, NSW Department of Health, https://www.health.nsw.gov.au/policies/manuals/Documents/consent-section-4.pdf
[xxv] Informed Consent, Australian Commission on Safety and Quality in Health Case, https://www.safetyandquality.gov.au/our-work/partnering-consumers/informed-consent
[xxvi] *Collins v Wilcock [1984]* 1 WLR 1172, 1177 (Robert Goff LJ).
[xxvii] *Blackstone's Commentaries,* 17th ed. (1830), vol. 3, p 120.
[xxviii] I remember when I was in Uni, during one of the first lectures of a particular unit, one of the most pompous members of my class proceeded to brag to everyone about how Blackstone was his great grandfather. To a brown kid from a housing commission in the Western Suburbs, it was hilarious to be so proud of such a thing.
[xxix] (Mason CJ, Dawson, Toohey and Gaudron JJ).
[xxx] *Marion's Case,* 253 (Mason CJ, Dawson, Toohey and Gaudron JJ)
[xxxi] [1986] 1 AC 112.
[xxxii] *Gilick v West Norfolk and Wisbech Area Health Authority* [1986] 1 AC 112 at [189].
[xxxiii] Ibid.
[xxxiv] Patrick Parkinson, "Children's Rights and Doctors' Immunities: The Implications of the High Court's decision in *Re Marion*" (1992) 6 AJFL at 111.
[xxxv] Diana Brahams, "The Gillick Case: A Pragmatic Compromise" (1986) 136 NLJ 75 at 76; New South Wales Law Reform Commission Report 199: Young People and Consent to Health Care (Sydney, 2008) at 82.
[xxxvi] *Gilick v West Norfolk and Wisbech Area Health Authority* [1986] 1 AC 112 at [189].
[xxxvii] *Gilick v West Norfolk and Wisbech Area Health Authority* [1986] 1 AC 112 at [174].
[xxxviii] See *How Common is Long Covid in Children and Adolescents?* The Pediatric Infectious Disease Journal, Zimmermann, Petra MD, PHD, and Ors, available at https://journals.lww.com/pidj/Fulltext/2021/12000/How_Common_is_Long_Covid_in_Children_and.20.aspx
[xxxix] (1992) 175 CLR 218, 6 May 1992.
[xl] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [7].
[xli] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [27]
[xlii] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [28]
[xliii] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [28]
[xliv] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [31]
[xlv] *Secretary, Department of Health and Community Services v J.W.B. and S.M.B (Marion's Case)* at [31]

Reference O: Second Answer – Professor Robyn Cosford

[xlvi] Kariwa H, Fujii N, Takashima I. Inactivation of SARS coronavirus by means of povidone-iodine, physical conditions, and chemical reagents. Jpn J Vet Res. 2004;52:105–112.
[xlvii] Nagatake T, Ahmed K, Oishi K. Prevention of respiratory infections by povidone-iodine gargle. Dermatology. 2002;204 Suppl 1:32-6. doi: 10.1159/000057722. PMID: 12011518.
[xlviii] Arefin MK. Povidone Iodine (PVP-I) Oro-Nasal Spray: An Effective Shield for COVID-19 Protection for Health Care Worker (HCW), for all. Indian J Otolaryngol Head Neck Surg. 2022 Oct;74(Suppl 2):2906-2911. doi: 10.1007/s12070-021-02525-9. Epub 2021 Apr 8. PMID: 33846691; PMCID: PMC8026810.
[xlix] Sirijatuphat R, Leelarasamee A, Puangpet T, Thitithanyanont A. A Pilot Study of 0.4% Povidone-Iodine Nasal Spray to Eradicate SARS-CoV-2 in the Nasopharynx. Infect Drug Resist. 2022 Dec 21;15:7529-7536. doi: 10.2147/IDR.S391630. PMID: 36575672; PMCID: PMC9790155.
[l] Zarabanda D, Vukkadala N, Phillips KM, Qian ZJ, Mfuh KO, Hatter MJ, Lee IT, Rao VK, Hwang PH, Domb G, Patel ZM, Pinsky BA, Nayak JV. The Effect of Povidone-Iodine Nasal Spray on Nasopharyngeal SARS-CoV-2 Viral Load: A Randomized Control Trial. Laryngoscope. 2022 Nov;132(11):2089-2095. doi: 10.1002/lary.29935. Epub 2021 Nov 9. PMID: 34724213; PMCID: PMC8662040.
[li] Sharma P, Singh A, Singh NP, Takhelchangbam N, Kumar R, Yadav R. Effect of 0.5% povidone-iodine on the nasopharyngeal and oropharyngeal viral loads in patients with COVID-19: A double-blind placebo-controlled randomized clinical trial. J Family Med Prim Care. 2022 Oct;11(10):6320-6326. doi: 10.4103/jfmpc.jfmpc_446_22. Epub 2022 Oct 31. PMID: 36618132; PMCID: PMC9810934.

[lii] Batioglu-Karaaltin A, Yigit O, Cakan D, Akgul O, Yigit E, Yilmaz YZ, Cakir KB, Ciftci G, Boyoğlu NS, Cagliyan A, Can E, Dikme O, Hacioglu Y, Balkan II, Enver O, Ozdogan HA. Effect of the povidone iodine, hypertonic alkaline solution and saline nasal lavage on nasopharyngeal viral load in COVID-19. Clin Otolaryngol. 2023 Jul;48(4):623-629. doi: 10.1111/coa.14056. Epub 2023 Mar 27. PMID: 36973223.

[liii] Hasan MJ, Rumi SKNF, Banu SS, Uddin AKMN, Islam MS, Arefin MK. Virucidal effect of povidone iodine on COVID-19 in the nasopharynx: A structured summary of a study protocol for an open-label randomized clinical trial. Trials. 2021 Jan 4;22(1):2. doi: 10.1186/s13063-020-04963-2. PMID: 33397432; PMCID: PMC7780075.

[liv] Ramezanpour M, Smith JLP, Psaltis AJ, Wormald PJ, Vreugde S. In vitro safety evaluation of a povidone-iodine solution applied to human nasal epithelial cells. Int Forum Allergy Rhinol. 2020 Oct;10(10):1141-1148. doi: 10.1002/alr.22575. Epub 2020 Jun 7. PMID: 32250552.

[lv] Tucker SP, Goodall S,. Julander J,. Mendenhall M, . Friedland P, . Molloy PL. In vitro inactivation of SARS-CoV-2 with 0.5% povidone iodine nasal spray (Nasodine) at clinically relevant concentrations and timeframes using tissue culture and PCR based assays. bioRxiv 2021.01.31.426979; doi: https://doi.org/10.1101/2021.01.31.426979

[lvi] Hale SJM, Lux CA, Kim R, Biswas K, Tucker S, Friedland P, Mackenzie BW, Douglas RG. In vitro Nasodine Can be an Effective Antibiofilm Agent for Biofilms that May Cause CRS. Laryngoscope. 2023 Oct;133(10):2490-2495. doi: 10.1002/lary.30558. Epub 2023 Jan 16. PMID: 36644968.

[lvii] Idrees M, McGowan B, Fawzy A, Abuderman AA, Balasubramaniam R, Kujan O. Efficacy of Mouth Rinses and Nasal Spray in the Inactivation of SARS-CoV-2: A Systematic Review and Meta-Analysis of In Vitro and In Vivo Studies. Int J Environ Res Public Health. 2022 Sep 25;19(19):12148. doi: 10.3390/ijerph191912148. PMID: 36231450; PMCID: PMC9566636.

[lviii] Mezarina Mendoza JPI, Trelles Ubillús BP, Salcedo Bolívar GT, Castañeda Palacios RDP, Herrera Lopez PSG, Padilla Rodríguez DA, Uchima Koecklin KH. Antiviral effect of mouthwashes against SARS-COV-2: A systematic review. Saudi Dent J. 2022 Mar;34(3):167-193. doi: 10.1016/j.sdentj.2022.01.006. Epub 2022 Feb 1. PMID: 35125835; PMCID: PMC8806023

[lix] Ziaeefar P, Bostanghadiri N, Yousefzadeh P, Gabbay J, Shahidi Bonjar AH, Ghazizadeh Ahsaie M, Centis R, Sabeti M, Sotgiu G, Migliori GB, Nasiri MJ. The efficacy of mouthwashes in reducing SARS-CoV-2 viral loads in human saliva: A systematic review. New Microbes New Infect. 2022 Nov-Dec;49:101064. doi: 10.1016/j.nmni.2022.101064. Epub 2022 Dec 12. PMID: 36530834; PMCID: PMC9743687.

[lx] Pannuti CM, Reis INRD, Souza NV, Souto MLS, Silva CGB, Bezinelli LM, Machado CM, Romito GA, Villar CC. Efficacy of mouthrinses in reducing oral SARS-COV-2 load: a review. Braz Oral Res. 2023 Apr 28;37:e038. doi: 10.1590/1807-3107BOR-2023.vol37.0038. PMID: 37132726.

[lxi] Zarabanda D, Vukkadala N, Phillips KM, Qian ZJ, Mfuh KO, Hatter MJ, Lee IT, Rao VK, Hwang PH, Domb G, Patel ZM, Pinsky BA, Nayak JV. The Effect of Povidone-Iodine Nasal Spray on Nasopharyngeal SARS-CoV-2 Viral Load: A Randomized Control Trial. Laryngoscope. 2022 Nov;132(11):2089-2095. doi: 10.1002/lary.29935. Epub 2021 Nov 9. PMID: 34724213; PMCID: PMC8662040.

[lxii] Pannuti CM, Reis INRD, Souza NV, Souto MLS, Silva CGB, Bezinelli LM, Machado CM, Romito GA, Villar CC. Efficacy of mouthrinses in reducing oral SARS-COV-2 load: a review. Braz Oral Res. 2023 Apr 28;37:e038. doi: 10.1590/1807-3107BOR-2023.vol37.0038. PMID: 37132726.

[lxiii] Alzahrani MM, Bamashmous S, Alkharobi H, Alghamdi A, Alharbi RH, Hassan AM, Darwish M, Bukhari A, Mahmoud AB, Alfaleh MA, Mirza AA, Abuzenadah AM, Abujamel TS, Hashem AM. Mouth rinses efficacy on salivary SARS-CoV-2 viral load: A randomized clinical trial. J Med Virol. 2023 Jan;95(1):e28412. doi: 10.1002/jmv.28412. PMID: 36527332; PMCID: PMC9878137.

[lxiv] Adl A, Sedigh-Shams M, Jamalidoust M, Rajabzadeh Z. Evaluating the effect of gargling with hydrogen peroxide and povidone-iodine on salivary viral load of SARS-CoV-2: A pilot randomized clinical trial. Niger J Clin Pract. 2023 Apr;26(4):391-396. doi: 10.4103/njcp.njcp_320_22. PMID: 37203101.

[lxv] Lin SY, Sun JS, Hung MC, Chang JZ. Effectiveness of mouth rinses against COVID-19: a systematic review and network meta-analysis. J Hosp Infect. 2023 Sep;139:175-191. doi: 10.1016/j.jhin.2023.06.022. Epub 2023 Jul 6. PMID: 37419189.

[lxvi] Sbricoli L, Schiavon L, Brunello G, Brun P, Becker K, Sivolella S. Efficacy of different mouthwashes against COVID-19: A systematic review and network meta-analysis. Jpn Dent Sci Rev. 2023 Dec;59:334-356. doi: 10.1016/j.jdsr.2023.09.003. Epub 2023 Oct 11. PMID: 37854066; PMCID: PMC10579871.

Reference S: First Answer – Dr Angela Jeanes

[lxvii] http://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf

Reference S: Second Answer – Katie Ashby-Koppens LLB

[lxviii] S 140 *Gene Technology Act 2000* (Cth)

[lxix] Dr Bhula's answer at Senate Estimates: https://parlinfo.aph.gov.au/parlInfo/download/committees/estimate/27445/toc_pdf/Community%20Affairs%20Legislation%20Committee_2023_10_26.pdf;fileType=application%2Fpdf#search (page 27)

[lxx] https://www.pfizer.com/science/innovation/mrna-technology

[lxxi] https://www.modernatx.com/en-AU/research/product-pipeline

[lxxii] Pfizer: https://www.tga.gov.au/resources/auspmd/comirnaty

Moderna: https://www.tga.gov.au/resources/auspar/auspar-elasomeran

[lxxiii] Provisional Approval: Pfizer https://www.tga.gov.au/news/media-releases/tga-provisionally-approves-pfizer-covid-19-vaccine#:~:text=COMIRNATY%20is%20provisionally%20approved%20and,years%20of%20age%20and%20older

Moderna https://www.tga.gov.au/news/media-releases/tga-provisionally-approves-modernas-covid-19-vaccine

[lxxiv] Black Triangle Scheme https://www.tga.gov.au/how-we-regulate/monitoring-safety-and-shortages/report-adverse-event-or-incident/report-adverse-events-medicines-and-biologicals/black-triangle-scheme

[lxxv] TGA Register: Pfizer https://www.tga.gov.au/products/covid-19/covid-19-vaccines/covid-19-vaccines-regulatory-status

[lxxvi] Borderforce https://ftalliance.com.au/news/20306

Reference U: First Answer – Dr Astrid Lefringhausen

[lxxvii] Bansal S, Perincheri S, Fleming T, Poulson C, Tiffany B, Bremner RM, Mohanakumar T. Cutting Edge: Circulating Exosomes with Covid Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines. J Immunol. 2021, Nov 15;207(10):2405-2410. doi: 10.4049/jimmunol.2100637.

[lxxviii] Morais, P., Adachi, H., & Yu, Y. (2021). The Critical Contribution of Pseudouridine to mRNA Covid-19 Vaccines. *Frontiers in Cell and Developmental Biology*, **2021,** *9*, 789427. https://doi.org/10.3389/fcell.2021.789427

[lxxix] Doshi, P. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. *BMJ,* **2020;** 371 doi: https://doi.org/10.1136/bmj.m4037

[lxxx] Chandramouly, G., et al. "Polθ reverse transcribes RNA and promotes RNA-templated DNA repair." *Scientific Advances,* **2021,** 7: eabf1771.

[lxxxi] Burn, A. "Ancient Viral DNA Plays a Role in Human Disease and Development." *The Scientist,* **2022,** https://www.the-scientist.com/news-opinion/ancient-viral-dna-plays-a-role-in-human-disease-and-development-70656

[lxxxii] Coffin, J., Blomberg J, Fan H, Gifford R, Hatziioannou T, Lindemann D, Mayer J, Stoye J, Tristem M, Johnson W. ICTV virus taxonomy profile: Retroviridae 2021. *Journal of General Virology*, 2021, 102: 001712. Doi: 10.1099/jgv.0.001712.

[lxxxiii] Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular Reverse Transcription of Pfizer BioNTech Covid-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line. *Curr. Issues Mol. Biol.* **2022,** 44, 1115-1126. https://doi.org/10.3390/cimb44030073

[lxxxiv] Zhang L, Richards A, Barrasa MI, Hughes SH, Young RA, Jaenisch R. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. *Proc Natl Acad Sci U S A.* **2021**, May 25;118(21):e2105968118. doi: 10.1073/pnas.2105968118.

Reference Y: First Answer – Dr Conny Turni

[lxxxv] Servellita V., Morris M.-K., Sotomayor-Gonzalez A., Gliwa A.S., Torres E., Brazer N., Zhou A., Hernandez K.T., Sankaran M., Wang B., Wong D., Wang C., Zhang Y., Reyes K.R., Glasner D., Deng X., Streithorst J., Miller S., Frias E., Hackett Jr. J., Hanson C., Wadford D., Philip S., Topper S., Sachdev D., Charles Y. Chiu C.Y., 2021. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. medRxiv 2021.08.19.21262139; doi: https://doi.org/10.1101/2021.08.19.21262139

[lxxxvi] Public Health England. Investigation of SARS-CoV-2 variants of concern and variants under investigation in England. Technical briefing 19. 23 July 2021. www.gov.uk/government/publications/investigation-of-novel-sars-cov-2-variant-variant-of-concern-20201201

[lxxxvii] Riemersma K.K., Grogan B.E., Kita-Yarbro A., Halfmann P., Kocharian A., Florek K.R., Westergaard R., Bateman A., Jeppson G.E., Kawaoka Y., O'Connor, Friedrich T.C., Grande K.M. 2021. Shedding of infectious SARS-CoV-2 despite vaccination when the Delta variant is prevalent - Wisconsin, July 2021. medRxiv. 2021.07.31.21261387; https://doi.org/10.1101/2021.07.31.21261387 (not peer reviewed)

[lxxxviii] Kamp E.M., Stockhofe-Zurwieden N., van Leengoed L.A., Smits M.A. 1997. Endobronchial inoculation with Apx toxins of Actinobacillus pleuropneumoniae leads to pleuropneumonia in pigs. Infection and Immunity 65, 4350-4354. doi: 10.1128/iai.65.10.4350-4354.1997

[lxxxix] Colunga Biancatelli R.M.L., Solopov P.A., Sharlow E.R., Lazo J.S., Marik P.E., Catravas J.D. 2021. The SARS-CoV-2 spike protein subunit S1 induces Covid-19-like acute lung injury in K18-hACE2 transgenic mice and barrier

dysfunction in human endothelial cells. American Journal of Physiology - Lung Cellular and Molecular Physiology. 321, L477-L484. https://doi.org/10.1152/ajplung.00223.2021

[xc] Jiang H, Mei YF. 2021, SARS-CoV-2 spike impairs DNA damagerepair and inhibits V(D)J recombination in vitro. Viruses 13, 2056. https://doi.org/10.3390/v13102056

[xci] Seneff, S. and Nigh, G. 2021. Worse than the disease? Reviewing some possible unintended consequences of the mRNA vaccines against Covid-19. International Journal of Vaccine Theory, Practice, and Research. 2, 38 – 79.

[xcii] Lyons-Weiler J. 2020. Pathogenic priming likely contributes to serious and critical illness and mortality in Covid-19 via autoimmunity. Journal of Translational Autoimmunity. 3:100051. doi: 10.1016/j.jtauto.2020.100051

[xciii] Hasan A., Al-Mulla M.R., Abubaker J., Al-Mulla F. (2021). Early insight into antibody-dependent enhancement after SARS-CoV-2 mRNA vaccination, Human Vaccines & Immunotherapeutics. doi: 10.1080/21645515.2021.1969855

[xciv] Kelleni M.T. 2021. SARS CoV-2 vaccination autoimmunity, antibody dependent Covid-19 enhancement and other potential risks: beneath the tip of the iceberg. International Journal of Pulmonary & Respiratory Sciences, 5. doi: 10.19080/IJOPRS.2021.05.555658

[xcv] Classen JB. 2021. Covid-19 RNA based vaccines and the risk of prion disease. Microbiological Infectious Diseases. 5, 1-3. https://scivisionpub.com/pdfs/Covid19-rna-based-vaccines-and-the-risk-of-prion-disease-1503.pdf

[xcvi] Idrees D., Kumar V. 2021. SARS-CoV-2 spike protein interactions with amyloidogenic proteins: Potential clues to neurodegeneration. Biochemical and Biophysical Research Communication 554, 94-98. doi: 10.1016/j.bbrc.2021.03.100

[xcvii] Finisterer J., Scorza, F.A. 2021. SARS-CoV-2 vaccines are not free of neurological side effects. Acta Neurology Scandinavia 144, 109-110. doi: 10.1111/ane.13451

[xcviii] Nonaka T., Hasegawa M. 2018. TDP-43 Prions. Cold Spring Harbor Perspectives in Medicine 8, a024463. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5830907/

[xcix] Kircheis R. 2021. Coagulopathies after vaccination against SARS-CoV-2 may be derived from a combined effect of SARS-CoV-2 spike protein and adenovirus vector-triggered signaling pathways. International Journal of Molecular Science. 22, 10791. doi: 10.3390/ijms221910791

[c] Anand, P., Stahel, V.P. 2021. The safety of Covid-19 mRNA vaccines: a review. Patient Safety in Surgery 15, 20. https://doi.org/10.1186/s13037-021-00291-9

[ci] Walsh E.E., Frenck R.W., Falsey A.R. Jr., Kitchin N., Absalon J., Gurtman A., Lockhart S., Neuzil K., Mulligan M.J., Bailey R. 2020. Safety and immunogenicity of two RNA-based Covid–19 vaccine candidates. New England Journal of Medicine 383, 2439–50.

[cii] Saito S., Nakashima A., Shima T., Ito M. 2010. Th1/Th2/Th17 and regulatory T-cell paradigm in pregnancy. American Journal of Reproductive Immunology 63, 601–10.

Seneff, S. and Nigh, G. 2021. Worse than the disease? Reviewing some possible unintended consequences of the mRNA vaccines against Covid-19. International Journal of Vaccine Theory, Practice, and Research. 2, 38 – 79.

[ciii] Helmo F.R., Alves E.A.R., Moreira R.A.A., Severino V.O., Rocha L.P., Monteiro M., Reis M.A.D., Etchebehere R.M., Machado J.R., Correa R.R.M. 2018. Intrauterine infection, immune system and premature birth. Journal of Maternal Fetal Neonatal Medicine 31, 1227–33.

[civ] Gundry SR. mRNA Covid vaccines dramatically increase endothelial inflammatory markers and ACS risk as measured by the PULS cardiac test: a warning. Presented at: AHA Scientific Sessions 2021; November 13-15, 2021. Poster VMP41.

[cv] https://www.smh.com.au/politics/federal/more-than-10-000-australians-have-filed-coronavirus-vaccine-injury-claims-20211115-p598yy.html

[cvi] Alghamdi A.N., Alotaibi M.I., Alqahtani A.S., Al Aboud D., Abdel-Moneim A.S. 2021. BNT162b2 and ChAdOx1 SARS-CoV-2 Post-vaccination side-affects among Saudi vaccinees. Frontiers in Medicine 8, 1796. https://doi.org/10.3389/fmed.2021.760047

[cvii] Subramanian, S.V., Kumar, A. 2021. Increases in Covid-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. European Journal of Epidemiology. https://doi.org/10.1007/s10654-021-00808-7

[cviii] Brown C.M., Vostok J., Johnson H., Burns, M., Gharpure, R., Sami, S., Sabo, R.T., Hall, N., Foreman, A., Schubert, P.L., Gallagher, G.R., Fink, T., Madoff, L.C., Gabriel, S.B., MacInnis, B., Park, D.J., Siddle, K.J., Harik, V., Arvidson, D., Brock-Fisher, T., Dunn, M., Kearns, A., Laney, A.S., 2021. Outbreak of SARS-CoV-2 infections, including Covid-19 vaccine breakthrough infections, associated with large public gatherings - Barnstable County, Massachusetts, July 2021. MMWR Morbidity and Mortality Weekly Reports 70, 1059-1062.

[cix] Singanayagam, A., Hakki, S., Dunning, J., Madon K.J., Crone M.A., Koycheva A., Derqui-Fernandez N., Barnett J.L., Whitfield, M.G., Varro R., Charlett A., Kundu R., Fenn J., Cutajar J., Quinn V., Conibear E., Barclay W., Freemont P.S., Taylor G.P., Ahmad S. Zambon M., Ferguson N.M., Lalvani A. 2021. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in the UK: a retrospective, longitudinal, cohort study. Lancet Infectious Disease 29:S1473-3099

[cx] Fontana L.M., Villamagna A.H., Sikka M.K., McGregor J.C. 2021. Understanding viral shedding of severe acute respiratory coronavirus virus 2 (SARS-CoV-2): Review of current literature. Infection Control & Hospital Epidemiology 42, 659-668. doi: 10.1017/ice.2020.1273.

[cxi] Zhang L., Richards A., M. Barrasa I.M., Hughes S.H., Young R.A., Jaenisch R. 2021. Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. Proceedings of the National Academy of Sciences 118. doi: 10.1073/pnas.2105968118.

[cxii] Servellita V., Morris M.-K., Sotomayor-Gonzalez A., Gliwa A.S., Torres E., Brazer N., Zhou A., Hernandez K.T., Sankaran M., Wang B., Wong D., Wang C., Zhang Y., Reyes K.R., Glasner D., Deng X., Streithorst J., Miller S., Frias E., Hackett Jr. J., Hanson C., Wadford D., Philip S., Topper S., Sachdev D., Charles Y. Chiu C.Y., 2021. Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. medRxiv 2021.08.19.21262139; doi: https://doi.org/10.1101/2021.08.19.21262139

[cxiii] Keehner J., Horton L.E., Binkin N.J., Laurent L.C., Pride D., Longhurst C.A., Abeles S.R., Torriani F.J. 2021. Resurgence of SARS-CoV-2 infection in a highly vaccinated health system workforce. New England Journal Medicine 385, 1330-1332. doi: 10.1056/NEJMc2112981

[cxiv] Public Health England. Investigation of SARS-CoV-2 variants of concern and variants under investigation in England. Technical briefing 19. 23 July 2021. www.gov.uk/government/publications/investigation-of-novel-sars-cov-2-variant-variant-of-concern-20201201

[cxv] Shimazawa, R., Ikeda, M. 2021. Potential adverse events in Japanese women who received tozinameran (BNT162b2, Pfizer-BioNTech). Journal of Pharmaceutical Policy and Practice. 14, 46. https://doi.org/10.1186/s40545-021-00326-7

[cxvi] Turni, C.; Lefringhausen, A. Covid-19 vaccines—An Australian Review. J. Clin. Exp. Immunol. **2022**, 7, 491–508. https://doi.org/10.33140/jcei.07.03.03

[cxvii] Zhou Y., Peng Z., Seven E.S., Leblanc R.M. 2018. Crossing the blood-brain barrier with nanoparticles. Journal of Controlled Release 270, 290-303.

[cxviii] Wick P., Malek A., Manser P., Meili D., Maeder-Althaus X., Diener L., Diener P.A., Zisch A., Krug H.F., von Mandach U. 2010. Barrier capacity of human placenta for nanosized materials. Environtal Health Perspectives 118, :432-436. doi: 10.1289/ehp.0901200.

[cxix] Dopp K., Seneff S. Covid-19 and All-Cause Mortality Data by Age Group Reveals Risk of Covid Vaccine-Induced Fatality is Equal to or Greater than the Risk of a Covid death for all Age Groups Under 80 Years Old as of 6 February 2022. 1-21. https://skirsch.com/Covid/Seneff_costBenefit.pdf

[cxx] Kostoff, R.N., Calina, D., Kanduc, D., Briggs, M.B., Vlachoyiannopoulos, P., Svistunov, A.A., Tsatsakis, A.. 2021. Why are we vaccinating children against Covid-19? Toxicology Reports. 8, 1665-1684.

[cxxi] Turni, C.; Lefringhausen, A. Covid-19 vaccines—An Australian Review. *J. Clin. Exp. Immunol.* **2022**, 7, 491–508. https://doi.org/10.33140/jcei.07.03.03

[cxxii] Bansal S, Perincheri S, Fleming T, Poulson C, Tiffany B, Bremner RM, Mohanakumar T. Cutting Edge: Circulating Exosomes with Covid Spike Protein Are Induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to Development of Antibodies: A Novel Mechanism for Immune Activation by mRNA Vaccines. J Immunol. 2021 Nov 15;207(10):2405-2410. doi: 10.4049/jimmunol.2100637.

[cxxiii] Domazet-Lošo T. mRNA vaccines: Why is the biology of retroposition ignored? Genes, https://www.mdpi.com/2073-4425/13/5/719

[cxxiv] Lyons-Weiler J. 2020. Pathogenic priming likely contributes to serious and critical illness and mortality in Covid-19 via autoimmunity. Journal of Translational Autoimmunity. 3:100051. doi: 10.1016/j.jtauto.2020.100051

[cxxv] Lee, M. N., et al. (2022). "Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination " Science Advances 8, eabm7201(2022). doi: 10.1126/sciadv.abm7201

[cxxvi] Issakov, G., et al. 2023. "Abnormal Uterine Bleeding Among Covid-19 Vaccinated and Recovered Women: a National Survey." Reproductive Sciences 30: 713–721.

[cxxvii] Muhaidat, N., et al. (2022). "Menstrual Symptoms After Covid-19 Vaccine: A Cross-Sectional Investigation in the MENA Region." Internationa Journal of Womans Health 14: 395-404.

[cxxviii] Chandramouly, G., et al. (2021). "Polθ reverse transcribes RNA and promotes RNA-templated DNA repair." Scientific Advances 7: eabf1771

Reference Y: Second Answer – Dr Astrid Lefringhausen

[cxxix] Burn, A. (2022). "Ancient Viral DNA Plays a Role in Human Disease and Development." The Scientist https://www.the-scientist.com/news-opinion/ancient-viral-dna-plays-a-role-in-human-disease-and-development-70656

[cxxx] Watson, O.J.; Barnsley, G.; Toor, J.; Hogan, A.B.; Winskill, P.; Ghani, A.C. Global impact of the first year of Covid-19 vaccination: A mathematical modelling study. Lancet Infect. Dis. **2022**, 22, 1293–1302. [PubMed]

[cxxxi] Rid, A.; Lipsitch, M.; Miller, F.G. The Ethics of Continuing Placebo in SARS-CoV-2 Vaccine Trials. JAMA 2021, 325, 219–220.

[cxxxii] WHO Ad Hoc Expert Group on the Next Steps for Covid-19 Evaluation; Krause, P.R.; Fleming, T.R.; Longini, I.M.; Peto, R.; Beral, V.; Bhargava, B.; Cravioto, A.; Cramer, J.P.; Ellenberg, S.S.; et al. Placebo-Controlled Trials of Covid-19 Vaccines—WhyWe Still Need Them. N. Engl. J. Med. 2021, 384, e2.

[cxxxiii] Beattie, K.A. (2021) Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with Covid-19: A BigData Analysis of 145 Countries. Department of Political Science University of Alberta, Alberta, Canada.

[cxxxiv] Keehner, J., Binkin, N.J., Laurent, L.C., Pride, D. (2021). Resurgence of SARS-CoV-2 Infection in a Highly Vaccinated Health System Workforce. The New England Journal of Medicine, 385, 1330-1332. DOI: 10.1056/NEJMc2112981.

[cxxxv] Chau, N. V. V., Ngoc, N. M., Nguyet, L. A., Quang, V. M., Ny, N. T. H., Khoa, D. B., ... & OUCRU Covid-19 research group (2021). An observational study of breakthrough SARSCoV-2 Delta variant infections among vaccinated healthcare workers in Vietnam. EClinicalMedicine, 41, 101143.

[cxxxvi] Hetemäki, I., Kääriäinen, S., Alho, P., Mikkola, J., Savolainen-Kopra, C., Ikonen, N., Nohynek, H., Lyytikäinen, O. (2021). An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021. Eurosurveillance, 26, 2100636 (2021), https://doi.org/10.2807/1560-7917.ES.2021.26.30.2100636

[cxxxvii] Acharya, C. B., Schrom, J., Mitchell, A. M., Coil, D. A., Marquez, C., Rojas, S., ... & Havlir, D. (2021). No significant difference in viral load between vaccinated and unvaccinated, asymptomatic and symptomatic groups infected with SARSCoV-2 delta variant. MedRxiv.

[cxxxviii] Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Jeppson, G. E., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. MedRxiv, 2021-07.

[cxxxix] Brown C.M., Vostok J., Johnson H., Burns, M., Gharpure, R., Sami, S., Sabo, R.T., Hall, N., Foreman, A., Schubert, P.L., Gallagher, G.R., Fink, T., Madoff, L.C., Gabriel, S.B., MacInnis, B., Park, D.J., Siddle, K.J., Harik, V., Arvidson, D., Brock-Fisher, T., Dunn, M., Kearns, A., Laney, A.S., 2021. Outbreak of SARS-CoV-2 infections, including Covid-19 vaccine breakthrough infections, associated with large public gatherings - Barnstable County, Massachusetts, July 2021. MMWR Morbidity and Mortality Weekly Reports 70, 1059-1062.

[cxl] Servellita, V., Morris, M. K., Sotomayor-Gonzalez, A., Gliwa, A. S., Torres, E., Brazer, N., ... & Chiu, C. Y. (2022). Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California. Nature microbiology, 7(2), 277-288.

[cxli] Risk of Coronavirus Disease 2019 (Covid-19) among Those Up-to-Date and Not Up-to-Date on Covid-19 Vaccination. Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Steven M. Gordon. medRxiv preprint doi: https://doi.org/10.1101/2023.06.09.23290893

[cxlii] NSW Health. NSW Respiratory Surveillance Report—Week Ending 31 December 2022. 2022. Available online: https://www. health.nsw.gov.au/Infectious/Covid-19/Documents/weekly-Covid-overview-20221231.pdf (accessed on 10 July 2023).

[cxliii] Subramanian, S. V., & Kumar, A. (2021). Increases in Covid-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. European journal of epidemiology, 36(12), 1237-1240.

[cxliv] https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-Covid-19-vaccinemoderna-epar-public-assessment-report_en.pdf (p. 491)

[cxlv] Japanese Pharmaceuticals and Medical Devices Agency (PMDA). SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048). 2021. Available online: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf (accessed on 7 April 2023).

[cxlvi] Judicial Watch. Pfizer/BioNTech Study Found Lipid Nanoparticles Materials Outside Injection Site in Test Animals. judicialwatch.org. 2022. Available online: https://www.judicialwatch.org/nanoparticles-materials-outside-injection-site/ (accessed on 12 July 2023).

[cxlvii] Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATYTM). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd. Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf (accessed on 7 April 2023).

[cxlviii] Di, J.; Du, Z.; Wu, K.; Jin, S.; Wang, X.; Li, T.; Xu, Y. Biodistribution and Non-linear Gene Expression of mRNA LNPs Affected by Delivery Route and Particle Size. Pharm. Res. 2022, 39, 105–114.

[cxlix] Japanese Pharmaceuticals and Medical Devices Agency (PMDA). SARS-CoV-2 mRNA Vaccine (BNT162, PF-07302048). 2021. Pp.112-113. Available online: https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf (accessed on 7 April 2023).

[cl] Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATYTM). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd.

Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf (accessed on 7 April 2023).

[cli] Seneff, S., Nigh, G., Kyriakopoulos, A. M., & McCullough, P. A. (2022). Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs. Food and Chemical Toxicology, 164, 113008.

[clii] Passegu, E., Ernst, P.A. (2009). IFN-alpha wakes up sleeping hematopoietic stem cells Natural Medicine, 15 (6), Article 612613. doi: 10.1038/nm0609-612

[cliii] Glas, M., Smola, S., Pfuhl, T., Pokorny, J., Bohle, R.M., Bücker, A., Kamradt J., Volk T. Fatal Multiorgan Failure Associated with Disseminated Herpes Simplex Virus-1Infection: A Case Report. Case Reports in Critical Care, Volume 2012. doi: 10.1155/2012/359360

[cliv] Cosentino, M.; Marino, F. Understanding the pharmacology of Covid-19 mRNA vaccines: Playing dice with the spike? Int. J. Mol. Sci. 2022, 23, 10881.

[clv] McKernan, K.; Kyriakopoulos, A.M.; McCullough, P.A. Differences in vaccine and SARS-CoV-2 replication derived mRNA: Implications for cell biology and future disease. OSF Preprints 2021.

[clvi] Dopp, K.; Seneff, S. Covid-19 and all-cause mortality data by age group reveals risk of Covid vaccine-induced fatality is equal to or greater than the risk of a Covid death for all age groups under 80 years old as of 6 February 2022. Vixra.org 2022, 21, preprint.

[clvii] Bajaj, V.; Gadi, N.; Spihlman, A.P.; Wu, S.C.; Choi, C.H.; Moulton, V.R. Aging, Immunity, and Covid-19: How Age Influences the Host Immune Response to Coronavirus Infections? Front. Physiol. 2020, 11, 571416.

[clviii] Chen, Y.; Li, C.; Liu, F.; Ye, Z.; Song, W.; Lee, A.C.Y.; Shuai, H.; Lu, L.; To, K.K.; Chan, J.F.; et al. Age-associated SARS-CoV-2 breakthrough infection and changes in immune response in a mouse model. Emerg. Microbes Infect. 2022, 11, 368–383.

[clix] Vo, A.D.; La, J.;Wu, J.T.; Strymish, J.M.; Ronan, M.; Brophy, M.; Do, N.V.; Branch-Elliman,W.; Fillmore, N.R.; Monach, P.A. Factors Associated With Severe Covid-19 Among Vaccinated Adults Treated in US Veterans Affairs Hospitals. JAMA Netw. Open 2022, 5, e2240037.

[clx] Röltgen, K.; Nielsen, S.C.A.; Silva, O.; Younes, S.F.; Zaslavsky, M.; Costales, C.; Yang, F.; Wirz, O.F.; Solis, D.; Hoh, R.A.; et al. Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination. Cell 2022, 185, 1025–1040.e14.

[clxi] Fertig, Tudor Emanuel, Leona Chitoiu, Daciana Silvia Marta, Victor-Stefan Ionescu, Valeriu Bogdan Cismasiu, Eugen Radu, Giulia Angheluta, Maria Dobre, Ana Serbanescu, Mihail Eugen Hinescu, and et al. 2022. "Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination" Biomedicines 10, no. 7: 1538. https://doi.org/10.3390/biomedicines10071538

[clxii] Domazet-Lošo, T. mRNA Vaccines: Why Is the Biology of Retroposition Ignored? Genes 2022, 13, 719.

[clxiii] Chen, Z., Chen, H., Meng, H., Xing, G., Gao, X., Sun, B., et al. (2008). Bio-distribution and metabolic paths of silica coated CdSeS quantum dots. *Toxicol. Appl. Pharmacol.* 230, 364–371. doi: 10.1016/j.taap.2008.03.022

[clxiv] Zhao, C., Liao, J., Chu, W., Wang, S., Yang, T., Tao, Y., et al. (2012). Involvement of TLR2 and TLR4 and Th1/Th2 shift in inflammatory responses induced by fine ambient particulate matter in mice. Inhal. Toxicol. 24, 918–927. doi: 10.3109/08958378.2012.731093

[clxv] Li, C., Taneda, S., Taya, K., Watanabe, G., Li, X., Fujitani, Y., et al. (2009). Effects of *in utero* exposure to nanoparticle-rich diesel exhaust on testicular function in immature male rats. *Toxicol. Lett.* 185, 1–8. doi: 10.1016/j.toxlet.2008.11.012

[clxvi] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_protocol.pdf Pfizer study protocol

[clxvii] Günter Oberdörster, Eva Oberdörster, and Jan Oberdörster 2005 Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles. Environmental Health Perspectives 113:7 CID: https://doi.org/10.1289/ehp.7339

[clxviii] Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATYTM). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd. Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf (accessed on 7 April 2023).

[clxix] Dotan, A.; Kunduc, D.; Muller, S.; Makatsariya, A.; Shoenfeld, Y. Molecular mimicry between SARS-CoV-2 and the female reproductive system. American Journal of Reproductive Immunology 2021, 86, e13494, doi: https://doi.org/10.1111/aji.13494

[clxx] Anderson, S. CBER Plans for Monitoring Covid-19 Vaccine Safety and Effectiveness. U.S. Food & Drug Administration (FDA): Vaccines and Related Biological Products Advisory Committee meeting. 2020. Available online: https://www.fda.gov/media/143557/download (accessed on 7 April 2023).

[clxxi] Lee, M.N.; Junkins, E.J.; Luo, C.; Fatima, U.A.; Cox, M.L.; Clancy, B.H. Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination *Science Advances.* **2022**, doi: https://doi.org/abm7201

[clxxii] Issakov, G.; Tzur, Y.; Friedman, T.; Ezue, T. Abnormal uterine bleeding among Covid-19 vaccinated and recovered women: a national survey. Reproductive Sciences 2023, 30, 713–721. doi: 10.1007/s43032-022-01062-2

[clxxiii] Muhaidat, N.; Alshrouf, M.A.; Azzam, M.I.; Karam, A.M.; Al-Nazer, M.W.; Al-Ani, A. Menstrual symptoms after Covid-19 vaccine: A cross-sectional investigation in the MENA region. International Journal of Womens Health 2022, 14, 395-404, doi:10.2147/IJWH.S352167

[clxxiv] Blix, K.; Laake, I.; Juvet, L.; Robertson, A.H.; Caspersen, I.H.; Mjaaland, S.; Skodvin, S.N.; Magnus, P.; Feiring, B.; Trogstad, L. Unexpected vaginal bleeding and Covid-19 vaccination in nonmenstruating women. Sci Adv 2023, 9, eadg1391, doi:10.1126/sciadv.adg1391

[clxxv] Lee, M.N.; Junkins, E.J.; Luo, C.; Fatima, U.A.; Cox, M.L.; Clancy, B.H. Investigating trends in those who experience menstrual bleeding changes after SARS-CoV-2 vaccination *Science Advances.* **2022**, doi: https://doi.org/abm7201

[clxxvi] ClinicalTrials.gov. History of changes for study: NCT04754594. Study to evaluate the safety, tolerability, and immunogenicity of SARS-CoV-2 vaccine candidate (BNT162b2) against Covid-19 in healthy pregnant women 18 years of age and older. 2023. Available online: https://classic.clinicaltrials.gov/ct2/history/NCT04754594?V_2=View (accessed 7 November 2023).

[clxxvii] Taieb, A.; Mounira, E.E. Pilot findings on SARS-CoV-2 vaccine-induced pituitary diseases: a mini review from diagnosis to pathophysiology. Vaccines (Basel) 2022, 10, 2—4. doi: 10.3390/vaccines10122004

[clxxviii] Roncati, L.; Manenti, A. Pituitary apoplexy following adenoviral vector-based Covid-19 vaccination. Brain Hemorrhages 2022, 4, 27–29. doi: 10.1016/j.hest.2022.04.002

[clxxix] Piñar-Gutiérrez, A.; Remón-Ruiz, P.; Soto-Moreno, A. Case report: Pituitary apoplexy after Covid-19 vaccination. Medicina Clínica 2022, 158, 498–499. doi: 10.1016/j.medcli.2021.09.028

[clxxx] Morita, S.; Tsuji, T.; Kishimoto, S.; Uraki, S.; Takeshima, K.; Iwakura, H.; Furuta, H.; Nishi, M.; Inaba, H.; Matsuoka, T.A. Isolated ACTH deficiency following immunization with the BNT162b2 SARS-CoV-2 vaccine: A case report. Endocrine Disorders 2022, 22, 185. doi:1 0.1186/s12902-022-01095-3

[clxxxi] Bouça, B.; Roldão, M.; Bogalho, P.; Cerqueira, L.; Silva-Nunes, J. Central diabetes insipidus following immunization with BNT162b2 mRNA Covid-19 vaccine: A case report. Frontiers in Endocrinology 2022, 13, 13:889074. doi: 10.3389/fendo.2022.889074

[clxxxii] Ankireddypalli, A.R.; Chow, L.S.; Radulescu, A.; Kawakami, Y.; Araki, T. A case of hypophysitis associated with SARS-CoV-2 vaccination. AACE Clinical Case Reports 2022, 8, 204–209. doi: 10.1016/j.aace.2022.06.001

[clxxxiii] Ach, T.; Kammoun, F.E.L.; Fekih, H.; Slama, N.B.H.; Kahloun, S.; Fredj, F.B. Central diabetes insipidus revealing a hypophysitis induced by SARS-CoV-2 vaccine. Therapie 2022, 2002. doi: 10.1016/j.therap.2022.09.007

[clxxxiv] Bujard, M.; Andersson, G. Fertility declines near the end of the Covid-19 pandemic: Evidence of the 2022 birth declines in Germany and Sweden. Stockholm Research Reports in Demography. 2020, Preprint. doi: 10.17045/sthlmuni.20975611.v1

[clxxxv] Kuhbander, C.; Reitzner, M. Estimation of excess mortality in Germany during 2020-2022. 2023, 15, e39371, doi:10.7759/cureus.39371

[clxxxvi] Gat, I.; Kedem, A.; Dviri, M.; Umanski, A.; Levi, M.; Hourvitz, A.; Baum, M. Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors. Andrology 2022, 10, 1016-1022. doi: 10.1111/andr.13209

[clxxxvii] Olana, S.; Mazzilli, R.; Salerno, G.; Zamponi, V.; Tarsitano, M.G.; Simmaco, M.; Paoli, D.; Faggiano, A. 4BNT162b2 mRNA Covid-19 vaccine and semen: What do we know? Andrology **2022**, 2022. doi: 10.1111/andr.13199

[clxxxviii] Irrgang, P.; Gerling, J.; Kocher, K.; Lapuente, D.; Steininger, P.; Habenicht, K.; Wytopil, M.; Beileke, S.; Schäfer, S.; Zhong, J.; et al. Class switch toward noninflammatory, spike-specific IgG4 antibodies after repeated SARSCoV-2 mRNA vaccination. Science Immunology 2023, 8, eade2798. doi: 10.1126/sciimmunol.ade2798

[clxxxix] Dhuli K, Medori MC, Micheletti C, Donato K, Fioretti F, Calzoni A, Praderio A, De Angelis MG, Arabia G, Cristoni S, Nodari S, Bertelli M. Presence of viral spike protein and vaccinal spike protein in the blood serum of patients with long-Covid syndrome. Eur Rev Med Pharmacol Sci. 2023 Dec;27(6 Suppl):13-19. doi: 10.26355/eurrev_202312_34685. PMID: 38112944.

[cxc] Sattar, S.; Kabat, J.; Jerome, K.; Feldmann, F.; Bailey, K.; Mehedi, M. Nuclear translocation of spike mRNA and protein is a novel feature of SARS-CoV-2. Frontiers in Microbiology 2023, 14. doi: 10.3389/fmicb.2023.1073789

[cxci] Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATYTM). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd. Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf (accessed on 7 April 2023).

[cxcii] Jiang, H.; Mei, Y.-F. SARS‑CoV‑2 Spike impairs DNA damage repair and inhibits V(D)J recombination in vitro. Viruses 2021, 13, 2056. doi: 10.3390/v13102056

[cxciii] Johnson, Senator R. Letter to Secretary Austin: Has DOD seen an increase in medical diagnoses among military personal? February 3, 2022, Available online: https://www.ronjohnson.senate.gov/2022/2/sen-johnsonto-secretary-austin-has-dod-seen-an-increase-in-medical-diagnoses-among-military-personnel (accessed on 20 June 2023).

[cxciv] Medicines & Healthcare products Regulatory Agency (MHRA). FOI release: Freedom of Information request on the adverse reactions reported relating to abortions following the Covid-19 vaccination (FOI 21/1069), October 5, 2021. Available online: https://www.gov.uk/government/publications/freedom-of-information-responses-fromthe-mhra-week-commencing-4-october-2021/freedom-of-information-request-on-the-adverse-reactions reported-relating-to-abortions-following-the-Covid-19-vaccination-foi-211069 (accessed on 20 June 2023).

[cxcv] Argueta, L.B.; Lacko, L.A.; Bram, Y.; Tada, T.; Carrau, L.; Rendeiro, A.F.; Zhang, T.; Uhl, S.; Lubor, B.C.; Chandar, V.; et al. Inflammatory responses in the placenta upon SARS-CoV-2 infection late in pregnancy. iScience 2022, 25, 104223. doi: 10.1016/j.isci.2022.104223

[cxcvi] Di Girolamo, R.; Khalil, A.; Alameddine, S.; D'Angelo, E.; Galliani, C.; Matarrelli, B.; Buca, D.; Liberati, M.; Rizzo, G.; D'Antonio, F. Placental histopathology after SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis. American Journal of Obstetrics & Gynecology MFM **2021**, 3, 100468. doi: 10.1016/j.ajogmf.2021.100468

[cxcvii] Celik, E.; Vatansever, C.; Ozcan, G.; Kapucuoglu, N.; Alatas, C.; Besli, Y.; Palaoglu, E.; Gursoy, T.; Manici, M.; Turgal, M.; et al. Placental deficiency during maternal SARS-CoV-2 infection. Placenta 2022, 117, 47-56. doi: 10.1016/j.placenta.2021.10.012

[cxcviii] Dong, L.; Tian, J.; He, S.; Zhu, C.; Wang, J.; Liu, C.; Yang, J. Possible vertical transmission of SARS-CoV-2 from an infected mother to her newborn. JAMA 2020, 323, 1846-1848. doi: 10.1001/jama.2020.4621

[cxcix] Kotlyar, A.M.; Grechukhina, O.; Chen, A.; Popkhadze, S.; Grimshaw, A.; Tal, O. Vertical transmission of coronavirus disease 2019: a systematic review and meta-analysis. American Journal of Obstetrics & Gynecology 2019, 224, 35–53.e33. doi: 10.1016/j.ajog.2020.07.049

[cc] Alouini, S.; Guinard, J.; Belin, O.; Mesnard, L.; Werner, E.; Prazuck, T.; Pichon, C. Maternal-fetal implications of SARS CoV-2 infection during pregnancy, viral, serological analyses of placenta and cord blood. International Journal of Environmental Research and Public Health 2022, 19, 2105. doi: 10.3390/ijerph19042105

[cci] Parcial, A.L.N.; Salomão, N.G.; Portari, E.A.; Arruda, L.V.; de Carvalho, J.J.; de Matos Guedes, H.L.; Conde, T.C.; Moreira, M.E.; Batista, M.M.; M.V., P.; et al. SARS-CoV-2 Is persistent in placenta and causes macroscopic, histopathological, and ultrastructural changes. Viruses 2022, 14, 1885. doi: 10.3390/v14091885

[ccii] Pfizer. BNT162b2 Cumulative Review from Pharmacovigilance Database: Pregnancy and Lactation Cumulative Review, FDA-CBER-2021-5683-0779745. 2021. Public Health and Medical Professionals for Transparency (PHMPT), listed April 3,2023. Available online: https://phmpt.org/wpcontent/uploads/2023/04/125742_S2_M1_pllr-cumulative-review.pdf?ref=uncensored-wisdom (accessed 22 July 2023)

[cciii] Sookaromdee, P.; Wiwanitkit, V. Magnitude of Abortion After Covid-19 Vaccination: How About Rate? Erciyes Medical Journal 2022, 44, 244.

[cciv] Zhang, L.; Richards, A.; Barrasa, M.I.; Hughes, S.H.; Young, R.A.; Jaenisch, R. Reverse-transcribed SARSCoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues. Proceedings of the National Academy of Sciences USA, 2021, 118, e2105968118. doi: 10.1073/pnas.2105968118

[ccv] Aldén, M.; Olofsson Falla, F.; Yang, D.; Barghouth, M.; Luan, C.; Rasmussen, M.; De Marinis, Y. Intracellular reverse transcription of Pfizer BioNTech Covid-19 mRNA Vaccine BNT162b2 in vitro in human liver cell line. Current Issues in Molecular Biology **2022**, 44, 1115-1126. doi: 10.3390/cimb44030073

[ccvi] Chandramouly, G., et al. (2021). "Polθ reverse transcribes RNA and promotes RNA-templated DNA repair." Scientific Advances 7: eabf1771

[ccvii] McKernan, K.; Helbert, Y.; Kane, L.T.; McLaughlin, S. Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. Scienceopen.com 2023. doi: 10.31219/osf.io/b9t7m

[ccviii] McKernan, K. Independent Sanger Sequencing verification of plasmid amplicons in BNT162b2. Writing as 'Anandamide' on Nepetalactone Newsletter, Substack.com, 24 June 2023. Available online: https://anandamide.substack.com/p/independent-sanger-sequencing-verification

[ccix] Konig, B. Report of Professor Brigitte Konig contained in correspondence from Dr Jurgen Kirchner to the German Minister of Health, Professor Karl Lauterbach, dated 16 September 2023. Available online: https://web.archive.org/web/20231010074119/https://www.genimpfstoffe.com/wpcontent/uploads/2023/09/Verblindet-Fax-BMG-Lauterbach-16.-Sept-2023-1.pdf. Google image translation of report by Professor Konig available online: https://twitter.com/Tabavo/status/1704258943105601769?s=20. Noting correction: 'And' appearing in Plasmid column should read 'yes'. (All accessed 6 November 2023).

[ccx] Buckaults, P.J. Testimony before South Carolina Senate hearing 14 September 2023. YouTube video of testimony, available online: https://www.youtube.com/watch?v=IEWHhrHiiTY (accessed 6 November 2023).

[ccxi] Buckhaults, P.J. Twitter.com thread 6 September 2023, available online: https://x.com/P_J_Buckhaults/status/1699113855333589093?s=20 (accessed 6 November 2023).
[ccxii] Buckhaults, P.J. Twitter.com thread 30 August 2023, available online: https://twitter.com/P_J_Buckhaults/status/1696710039124226106?s=20 (accessed 6 November 2023).
[ccxiii] Rosa, S.S.; Prazeres, D.M.F.; Azevedo, A.M.; Marques, M.P.C. mRNA vaccines manufacturing: Challenges and bottlenecks. Vaccine, 2021, 39, 2190-2200. doi: 10.1016/j.vaccine.2021.03.038
[ccxiv] Butel, J.S. Patterns of polyomavirus SV40 infections and associated cancers in humans: a model. Current Opinions in Virology 2012, 2, 508-514. doi: 10.1016/j.coviro.2012.06.004
[ccxv] Dean, D.A.; Dean, B.S.; Muller, S.; Smith, L.C. Sequence requirements for plasmid nuclear import. Experimental Cell Research 1999, 253, 713-722. doi: 10.1006/excr.1999.4716
[ccxvi] McKernan, K. Nuclear permeability during cell division. Writing as 'Anandamide' on Nepetalactone Newsletter, Substack.com, available online: https://anandamide.substack.com/p/nuclear-permeability-during-cell (accessed 5 June 2023).
[ccxvii] McKernan, K.; Helbert, Y.; Kane, L.T.; McLaughlin, S. Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose. Scienceopen.com 2023. doi: 10.31219/osf.io/b9t7m
[ccxviii] Wang, Z., Troilo, P. J., Griffiths, T. G., Harper, L. B., Barnum, A. B., Pacchione, S. J., Pauley, C. J., Lebron, J. A., Wolf, J., & Ledwith, B. J. Characterization of integration frequency and insertion sites of adenovirus DNA into mouse liver genomic DNA following intravenous injection. Gene Therapy 2022, 29, 322-332. https://doi.org/10.1038/s41434-021-00278-2
[ccxix] Brogna, C., Cristoni, S., Marino, L., Viduto, V., Fabrowski, M., Lettieri, G., Piscopo, M. Detection of recombinant Spike protein in the blood of individuals vaccinated against SARS-CoV-2: Possible molecular mechanisms. Proteomics Clinical Applications 2023, 2300048. doi: 10.1002/prca.202300048
[ccxx] Therapeutic Goods Administration (TGA) FOI Reply 2389-6, p.45. Nonclinical Evaluation Report: BNT162b2 [mRNA] Covid-19 Vaccine (COMIRNATYTM). Submission No: PM-2020-05461-1-2. Sponsor: Pfizer Australia Pty Ltd. Australian Government Department of Health and Aged Care: 2021; FOI reply 2389-6. Pp.44-45. Available online: https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf (accessed on 7 April 2023).
[ccxxi] Therapeutic Goods Administration (TGA) documents. Documents released under Section 11C of the Freedom of Information Act 1982, Jul 2021 - Jun 2022. Department of Health and Aged Care 2022, 2389 and 3093. Available online: https://www.tga.gov.au/resources/publication/publications/documents-released-under-section-11c-freedom-information-act-1982-jul-2021-jun-2022 (accessed on 7 April 2023).
[ccxxii] Bresler, S.C.; Menge, T.D.; Tejasvi, T.; Carty, S.A.; Hristov, A.C. Two cases of challenging cutaneous lymphoid infiltrates presenting in the context of Covid-19 vaccination: A reactive lymphomatoid papulosis-like eruption and a bona fide lymphoma. Journal of Cutaneous Pathology 2022, 50, 213-219. doi: 10.1111/cup.14371
[ccxxiii] Goldman, S.; Bron, D.; Tousseyn, T.; Vierasu, I.; Dewispelaere, L.; Heimann, P.; Cogan, E.; Goldman, M. rapid progression of angioimmunoblastic T cell lymphoma following BNT162b2 mRNA vaccine booster shot: a case report. Frontiers in Medicine 2021, 8. doi: 10.3389/fmed.2021.798095
[ccxxiv] Sekizawa, A.; Hashimoto, K.; Kobayashi, S.; Kozono, S.; Kobayashi, T.; Kawamura, Y.; Kimata, M.; Fujita, N.; Ono, Y.; Obuchi, Y.; et al. Rapid progression of marginal zone B-cell lymphoma after Covid-19 vaccination (BNT162b2): a case report. Frontiers in Medicine (Lausanne) 2022, 9, 963393. doi: 10.3389/fmed.2022.963393
[ccxxv] Zamfir, M.-A.; Moraru, L.; Dobrea, C.; Scheau, A.-E.; Iacob, S.; Moldovan, C.; Scheau, C.; Caruntu, C.; Caruntu, A. Hematologic malignancies diagnosed in the context of the mrna Covid-19 vaccination campaign: a report of two cases. Medicina 2022, 58, 874. doi: 10.3390/medicina58070874
[ccxxvi] U.S. Food and Drug Administration (FDA). FDA News Release: FDA Approves First-of-Its Kind Targeted RNA-Based Therapy to Treat a Rare Disease. FDA Newsroom FDA.gov.au. 2018. Available online: https://www.fda.gov/news-events/pressannouncements/fda-approves-first-its-kind-targeted-rna-based-therapy-treat-rare-disease (accessed on 7 April 2023).
[ccxxvii] Dolgin, E. The tangled history of mRNA vaccines. Nature 2021, 597, 318–324.
[ccxxviii] McCann, N.; O'Connor, D.; Lambe, T.; Pollard, A.J. Viral vector vaccines. Curr. Opin. Immunol. 2022, 77, 102210.
[ccxxix] AusVaxSafety. Pfizer Covid-19 vaccine safety data – All participants. Data as at January 23. NCIRS: 2023. Available online: https://ausvaxsafety.org.au/pfizer-Covid-19-vaccine-adult-formulation/pfizer-Covid-19-vaccinesafety-data-all-participants (accessed on 23 April 2023).
[ccxxx] AusVaxSafety. Moderna Covid-19 vaccine safety data – All participants. Data as at January 23. 2023. Available online: https://ausvaxsafety.org.au/Covid-19-vaccines/moderna-bivalent-Covid-19-vaccine (accessed on 23 April 2023).
[ccxxxi] AusVaxSafety. AstraZeneca Covid-19 vaccine safety data – All participants. Data as at January 23. 2023. Available online: https://ausvaxsafety.org.au/Covid-19-vaccines/astrazeneca-Covid-19-vaccine (accessed on 23 April 2023).

Reference Y: Third Answer – Associate Professor Peter Parry

[cexxxii] Bardosh, K.; Krug, A.; Jamrozik, E.; Lemmens, T.; Keshavjee, S.; Prasad, V.; Makary, M. A.; Baral, S.; Høeg, T. B. Covid-19 vaccine boosters for young adults: a risk benefit assessment and ethical analysis of mandate policies at universities. J Med Ethics 2022. doi: 10.1136/jme-2022-108449

Reference Z: First Answer – Dr Astrid Lefringhausen

[cexxxiii] Turni, C.; Lefringhausen, A. Covid-19 vaccines—An Australian Review. J. Clin. Exp. Immunol. **2022**, 7, 491–508. https://doi.org/10.33140/jcei.07.03.03

[cexxxiv] Parry, P.I.; Lefringhausen, A.; Turni, C.; Neil, C.J.; Cosford, R.; Hudson, N.J.; Gillespie, J. 'Spikeopathy': Covid-19 Spike Protein Is Pathogenic, from Both Virus and Vaccine mRNA. Biomedicines **2023**, 11, 2287. https://doi.org/10.3390/biomedicines11082287

[cexxxv] Shrestha, NK, Burke, PC, Nowacki AS, Simon JF, Hagen A, Gordon SM. Effectiveness of the Coronavirus Disease 2019 (Covid-19) Bivalent Vaccine. Open Forum Infectious Diseases **2023**, 10, ofad209. doi: 10.1093/ofid/ofad209

[cexxxvi] Shrestha NK, Burke PC, Nowacki AS, Gordon SM. Risk of Coronavirus Disease 2019 (Covid-19) among Those Up-to-Date and Not Up-to-Date on Covid-19 Vaccination. PLoS ONE **2023**. doi: https://doi.org/10.1371/journal.pone.0293449

Reference AA: First Answer – Dr Jessica Rose

[cexxxvii] Rose J, Hulscher N, McCullough PA. Determinants of Covid-19 vaccine-induced myocarditis. Therapeutic Advances in Drug Safety. 2024;15. doi:10.1177/20420986241226566

Reference AA: Third Answer – Dr Astrid Lefringhausen

[cexxxviii] Mathieu, Edouard, et al. "Coronavirus pandemic (Covid-19)." Our world in data (2020).

[cexxxix] Aarstad, J.; Kvitastein, O.A. Is there a Link between the 2021 Covid-19 Vaccination Uptake in Europe and 2022 Excess All-Cause Mortality?. Preprints 2023, 2023020350. https://doi.org/10.20944/preprints202302.0350.v1

[cexl] Kuhbandner C, Reitzner M. Estimation of Excess Mortality in Germany During 2020-2022. Cureus. 2023 May 23;15(5):e39371. doi: 10.7759/cureus.39371. PMID: 37378220; PMCID: PMC10292034.

[cexli] Scherb, H., & Hayashi, K. Annual All-Cause Mortality Rate in Germany and Japan (2005 to 2022) With Focus on The Covid-19 Pandemic: Hypotheses And Trend Analyses. Med and Clin Sci Vol 5 no. 2, 2023.

[cexlii] Cuschieri, S., Borg, D., Agius, S. *et al.* Covid-19 and vaccination induced changes in hospital activity in Malta, Q1 2020 to Q1 2021: a population-based study. *J. Egypt. Public. Health. Assoc.* **97**, 7 (2022). https://doi.org/10.1186/s42506-021-00101-1

[cexliii] Sun, C.L.F., Jaffe, E. & Levi, R. Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third Covid-19 wave. *Sci Rep* **12**, 6978 (2022). https://doi.org/10.1038/s41598-022-10928-z

[cexliv] Turni, C.; Lefringhausen, A. Covid-19 vaccines—An Australian Review. J. Clin. Exp. Immunol. 2022, 7, 491–508.

Reference OO: Answer – Clare Pain BSc(Hon), MSc

[cexlv] In an email communication on a different topic with Craig Brady, Assistant Director of Health and Vital Statistics at the ABS, he recommended use of the most recent PMS data available, using the 'Deaths by Month of Occurrence' download.

[cexlvi] Levitt M, Zonta F, Ioannidis JPA. Comparison of pandemic excess mortality in 2020-2021 across different empirical calculations. Environmental Research 2022;213:113754, doi: 10.1016/j.envres.2022.113754, https://www.sciencedirect.com/science/article/pii/S0

[cexlvii] Good points about this methodology were: that an average of five years of pre-pandemic data was used, thus smoothing out the effects of a bad flu year such as 2019 and the use of weekly data meant that seasonality (the pattern of having more deaths in the winter) was included in expected numbers automatically. One could argue that the method might have been improved by modelling death rates (deaths per population) rather than numbers of deaths, because this would take account of changes in population size in a broad-brush way. However, as it turns out, with the very static population of Australia in 2020 and 2021, where international borders were closed, this would have made little difference. The other very important advantage was that the model was decided upon in advance – before excess deaths had become a problem.

[cexlviii] https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/jan-dec-2020

[cexlix] https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/jan-2020-dec-2021

[ccl] Using four years rather than five means that the high flu season in 2019 had more effect – giving a higher number of expected deaths; the inclusion of any pandemic year is questionable as presumably the aim was to highlight abnormal numbers of deaths during the pandemic – and this goes against the requirements of Levitt et al; given that the ABS decided to include years from the pandemic why did they include the high death year (2021) and exclude the low death year (2020)? Their choices of baseline increased expected deaths and thus decreased excess deaths.

Reference PP: Third Answer – Dr Deirdre Therese Little

[ccli] European Medicines Agency. *Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC)*. 24-27 October 2022. https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilancerisk-assessment-committee-prac-24-27-october-2022.

[cclii] Gajdova et al. Delayed Effects of Neonatal Exposure to Tween 80 on Female Reproductive Organs in Rats. *Food Chem Toxicol*. 1993;31(3):183-190. https://doi.org/10.1016/0278-6915(93)90092-D.

[ccliii] Australian Government Department of Health. *TGA Nonclinical Evaluation Report: BNT162b2[mRNA] Covid19 vaccine (COMIRNATY™)*. January 2021. Accessed via TGA FOI disclosure log: FOI 2389. https://www.tga.gov.au/sites/default/files/foi-2389-06.pdf.

[ccliv] Blix K et al. Unexpected Vaginal Bleeding and Covid-19 Vaccination in Non-menstruating Women. *Sci. Adv.* 2023;9(38). https://www.science.org/doi/10.1126/sciadv.adg1391.

[cclv] Medicines and Healthcare products Regulatory Agency. *Coronavirus Vaccine-Weekly Summary of Yellow Card Reporting.* Last updated 8 March 2023. https://www.gov.uk/government/publications/coronavirus-Covid-19vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting.

[cclvi] Little D. Abnormal Menstruation Following Covid-19 Vaccines: A Toxicologic Consideration. *J Clin Toxicol*. 2022;12(4):517. https://www.longdom.org/open-access/abnormal-menstruation-following-Covid19-vaccines-atoxicologic-consideration-93970.html.

[cclvii] Little D. Covid Vaccines, Abnormal Menses, PMB: Toxicologic Considerations. Poster presented at: RANZCOG Symposium; 25 July 2023; Sydney, Australia.

Senator Shoebridge to Dr Madry: Dr Andrew Madry – written answer

[cclviii] Mehra, Desai, Ruschitzka, and Patel, 2020, RETRACTED: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of Covid-19: a multinational registry analysis. The Lancet https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31180-6/fulltext

[cclix] Referenced by Magness, April 2022. https://www.aier.org/article/the-failure-of-imperial-college-modeling-is-far-worse-than-we-knew/

[cclx] https://brownstone.org/articles/more-flaws-in-the-vaccine-model-claiming-20-million-lives-saved/

[cclxi] https://www.who.int/news/item/06-07-2022-un-report--global-hunger-numbers-rose-to-as-many-as-828-million-in-2021

[cclxii] Hudson, 2023. Speech to the 50th annual convention of the Actuarial Society of South Africa. youtube.com/watch?v=hNcWbO1tY_E&t=5s

[cclxiii] We do not address here questions of whether any antigens, their vectors, or adjuvants were pathogenic, nor any possible effects of injecting genetic DNA or mRNA instructions, instead of a known amount of the antigen.

[cclxiv] By comparison, diphtheria and tetanus vaccines are of a type that induce immunity to a toxin produced by the body in response to the pathogen, rather than immunity to the pathogen itself.

[cclxv] https://brownstone.org/articles/more-flaws-in-the-vaccine-model-claiming-20-million-lives-saved/

[cclxvi] Dhar et al, 2021, Genomic characterization and epidemiology of an emerging SARS-CoV-2 variant in Dehli, India. Science. https://www.science.org/doi/epdf/10.1126/science.abj9932

[cclxvii] Mettelman RC, Allen EK, Thomas PG. Mucosal immune responses to infection and vaccination in the respiratory tract. Immunity. 2022 May 10;55(5):749-780. doi: 10.1016/j.immuni.2022.04.013. PMID: 35545027; PMCID: PMC9087965.

[cclxviii] https://wherearethenumbers.substack.com/p/why-we-cannot-ignore-the-lancet-claim?r=17y6w5

[cclxix] https://pandata.org/it-is-impossible-that-the-vaccines-saved-14-million-lives-in-2021/

[cclxx] https://hartuk.substack.com/p/imperial-fantasy-of-20-million-lives-saved