PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000069

Access to data to investigate the link between Covid Vaccination and higher than expected all-cause mortality?

Written

Senator: Ralph Babet

Question:

9. Dr Gould: In 2021, the Australian Public Service Commission published a piece titled "Getting to Know our Data Leaders", Phillip Gould.
In this piece, you said (and I quote):

"One of the themes to emerge in the Department since the bushfire and COVID crises is our dual responsibility to protect and use data in the public interest. This view of the world will guide our decisions over the coming years, as the Department seeks to safely share its data with state and territory governments, as well as the research community…….
Data is only valuable if it's used to guide decisions. Having developed good data sets and improved access, we need to keep challenging ourselves to translate this into real world outcomes. To succeed, we don't just need data literate decision makers, we need data translators."
END QUOTE
www.apsc.gov.au/initiatives-and-programs/aps-professional-streams/aps-data-professional-stream/aps-data-professional-stream-news/getting-know-our-data-leaders-phillip-gould

Dr Gould, the elephant in the room today is potential linkage between vaccine injury and death.
The integrated data has not yet been adequately reviewed or released. Will the department do all that it can to ensure that academics gain access to the relevant data to investigate this issue and help us to either rule in our out the link between Covid Vaccination and higher than expected all-cause mortality?

Answer:

The Department of Health and Aged Care takes its responsibility seriously in ensuring Australian's health data is protected and handled safely and ethically. Access to a range of integrated data for statistical and research purposes is safely managed by the Australian Bureau of Statistics. The following website contains more information: www.abs.gov.au/about/data-services/data-integration/access-and-services.

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Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000068

Covid 19 and the impact on life expectancy

Written

Senator: Ralph Babet

Question:

8. A submission to this inquiry by Professor Tim Adair from the University of Melbourne, Associate Prof Brian Houle and Prof Vladimir Canudas-Romo of the Australian National University. Their submission stated that "mortality due to COVID-19 contributed to 0.24 years of decline in life expectancy since 2017-19 for males and 0.19 years for females……

Notably, lower death rates from respiratory diseases had a combined positive contribution to life expectancy of 0.16 years for males and 0.17 years for females, only slightly less than the negative contribution of COVID-19.

So their analysis shows that COVID-19, even with it's incredibly broad criteria contributed to a reduction in life expectancy that is only marginally greater than the increase in life expectancy that resulted from lower rates of respiratory deaths recorded.

We shut down our nation, closed borders, destroyed the economy, locked people in their homes and coerced them into taking a novel vaccination product, all for a virus that had a marginal impact overall on life expectancy.

It appears that COVID-19 did not have a significant impact on life expectancy. Do you agree?

Answer:

The Australian Bureau of Statistics (ABS) has consistently reported COVID-19 as being the primary driver of excess mortality in Australia from 2021-23.

Please refer to the Australian Institute of Health and Welfare (AIHW) for estimates of life expectancy within Australia. AIHW report that during the pandemic, life expectancy fell for the first time since to 1990s and note that this likely to be driven by COVID-19 mortality. These most recent estimates were published on 6 June 2024 in "Deaths in Australia" (www.aihw.gov.au/reports/life-expectancy-deaths/deaths-in-australia/contents/life-expectancy).

The Department of Health and Aged Care notes that while the AIHW modelling in this report does not consider the potential impacts of COVID-19 on life expectancy in the absence of public health measures, the OECD report "Ready for the Next Crisis? Investing in Health System Resilience" does consider different public health responses as part of its international comparisons. The OECD report found that in 2020-21, Australia had one of the lowest global excess death rates with the excess mortality rate ranking as 5th lowest of 35 studied countries.

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Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000067

Viral infection and genetic therapy products (DNA/RNA vaccines)

Written

Senator: Ralph Babet

Question:

15. Both viral infection and genetic therapy products (e.g. DNA/RNA vaccines) have the theoretical capacity to induce carcinogenesis or oncogenesis (the onset of cancer). There are multiple mechanisms for this to occur and include, but not limited to:

a. Insertional mutagenesis ("insertional oncogenesis"), where the genome of a cell is interrupted or displaced by the introduction of a foreign genetic sequence into the cell

b. microRNA-mediated oncogenesis

c. suppression of cancer repair pathways

d. presence of plasmid DNA and oncogenic sequences, including the SV40 promoter, as contamination from recombinant therapy products where used

Has this been tracked or investigated by the Department of Health?

As carcinogenicity and genotoxicity evaluations were specifically excluded (without a satisfactory explanation) in the Australian assessment for the provisional licensing of the nucleic acid products, it was incumbent upon the TGA to have conducted active pharmacovigilance in this area, but this does not appear to have been performed. I would appreciate a detailed answer.

Answer:

Genotoxicity and carcinogenicity studies were not conducted with the final formulation of the Australian approved COVID-19 vaccines, which is consistent with the WHO guidelines on non-clinical evaluation of vaccines available at:
www.who.int/publications/m/item/nonclinical-evaluation-of-vaccines-annex-1-trs-no-927
and the approach used by major international regulators.

The Therapeutic Goods Administration (TGA) has an extensive safety monitoring system in place to monitor the safety of all vaccines and to investigate any potential new safety issues. The TGA's existing safety monitoring system for vaccines involves:

- reviewing and analysing reports of adverse events submitted by health professionals and consumers
- requiring pharmaceutical companies (or sponsors) 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 adverse events detected overseas
- working with state and territory health departments and clinical experts to ensure a coordinated approach.

Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data as described in the *Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements* (at: www.tga.gov.au/publication/pharmacovigilance-responsibilities-medicine-sponsors) document. The sponsor's pharmacovigilance responsibilities outlined in this policy document is embedded within relevant sections and subsections under the legislations (the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*).

Vaccination against COVID-19 remains the most effective way to reduce deaths and severe illness from COVID-19 infection. The published real-world evidence on COVID-19 vaccination demonstrates that the protective benefits of COVID-19 vaccination far outweigh the potential risks, including those of serious but rare adverse events. As with any medicine/vaccine, some rarer risks are only discovered after a vaccine is used in a real-world population. This is why the TGA continually monitors the safety of therapeutic products, including COVID-19 vaccines. For COVID-19 vaccines, many of the TGA's already robust post-market surveillance processes were dramatically enhanced, making it the most intensive safety monitoring of therapeutic goods ever conducted in Australia. For example, the TGA has conducted batch release of every batch of the COVID-19 vaccines released in Australia. The test for residual plasmid DNA is already part of the agreed required testing specifications for mRNA vaccines and each batch released in Australia has passed this test. The TGA reviews the Sponsor's results before the batches can be released and conducts independent tests to verify these results for residual DNA.

Throughout the vaccine rollout, the Department of Health and Aged Care has been open and transparent about COVID-19 vaccine safety. For more than 2 years, the TGA published a regular COVID-19 vaccine safety report, initially weekly and then fortnightly. Adverse Event data is also made available to the public through the Database of Adverse Event Notifications (DAEN) – medicines. To date, neither the TGA nor any international regulator has detected any safety signals to indicate that COVID-19 vaccines are associated with any type of cancer.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000066

Addressing concerns in the public letter by Dr Wilson Sy and Dr Christopher Neil

Written

Senator: Ralph Babet

Question:

7. There are many other criticisms of this study.
I have with me here a public letter by Dr Wilson Sy and Dr Christopher Neil. I would like to table this letter and ask that the Department respond in writing to address their concerns. Is that okay?

Answer:

The referred-to study is the National Centre for Immunisation Research and Surveillance (NCIRS) paper titled "Effectiveness of COVID-19 vaccination against COVID-19 specific and all-cause mortality in older Australians: a population based study" published in *The Lancet*, Regional Health, Western Pacific.

The *Lancet* journals follow best practice guidance on publishing excellence from the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals issued by the International Committee of Medical Journal Editors (ICMJE) and adhere to the Committee on Publication Ethics (COPE) guidelines (https://publicationethics.org/guidance/Guidelines).

All original research articles published in the *Lancet* journals have undergone independent, external peer review, including statistical review. A research article is usually peer reviewed by three clinical or subject-based experts and a statistical reviewer.

Any concerns with the rigor and accuracy of this publication should be directed to the authors.

20 November 2023

Australian Medical Professionals Society
41 Campbell Street
Bowen Hills
QLD 4006

Open letter to, Bette Liu, Sandrine Stepien, Timothy Dobbins, Heather Gidding, David Henry, Rosemary Korda, Lucas Mills, Sallie-Anne Pearson, Nicole Pratt, Claire M. Vajdic, Jennifer Welsh, and Kristine Macartney, authors of:

"Effectiveness of COVID-19 vaccination against COVID-19 specific and all-cause mortality in older Australians: a population based study."

The Lancet, Vol. 40, 100928, November 2023. DOI:
https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(23)00246-8/fulltext

Via A/Prof Bette Liu -

Copied to:
Professor Paul Kelly, Chief Medical Officer -
Dr Tony Lawler, head of the TGA -
Dr Blair Comley Chair of the Department of Health -
Professor Nigel Crawford Chair ATAGI -
Richard Horton (editor of the The Lancet) -
Senator Alex Antic -
Senator Malcolm Roberts -
Senator Gerard Rennick -
Senator Ralph Babet -
Russell Broadbent MP -

Dear Associate Professor Bette Lui

Concerns regarding data integrity and analysis

The retrospective, observational study of 3.8 million Australians of over 65 years, during eleven months of 2022, has reached the following broad conclusion:

> *COVID-19 vaccination is highly effective against COVID-19 mortality among older adults although effectiveness wanes with time since the last dose. Our findings emphasise the importance of continuing to administer booster doses, particularly to those at highest risk.*

This paper and its conclusion have been cited by the Australian Chief Medical Officer in an Australian Senate Estimates inquiry [1] to support government policy of continued vaccination for older adults. The research has been funded by the Australian Government through various government agencies and by pharmaceutical companies.

As it stands, the conclusion of the paper is unclear, if not invalid, because it states that the vaccination is “highly effective”, but “wanes over time”. Can a vaccine be “highly effective” only for

a limited time? How limited? The time limit to effectiveness is one of the key issues to be discussed below.

Data Integrity Issues

Most of the paper, consisting of four large tables occupying most of a printed page each, is a presentation of dosage statistics of the Australian population, which, while not irrelevant, are not germane to the main subject of the paper. The space could be better used.

The main subject and conclusion of the paper depend critically on analysis of the data relating dosage to COVID-19 and all-cause mortality shown in Figures 1 to 3. These "death by vaccination status" data, central to the study, are largely absent from the paper.

Importantly, the conclusion quoted above requires analysis of accurate Australian COVID data, but such data are well-known to have serious integrity issues, errors originating from data collected from disparate sources and from flawed data-recording procedures. For example, someone who dies soon after being vaccinated with one dose may be recorded as the death of an unvaccinated person [2].

Also, COVID-19 mortality is intrinsically an unreliable statistic, because attribution of a COVID death may be erroneous. A death (ICD 10 code U07.1) could be *with* COVID (defined by a positive PCR test) rather than *from* COVID (the disease). Sometimes, COVID deaths (ICD 10 code U07.2) have been assigned by judgement without doing any tests.

Raw COVID-19 mortality data by dosage, essential to the paper, have not been disclosed in the paper, even in a summary form. How were COVID-19 mortality data selected and validated? The authors need to discuss the data of Figure 1 and 2 and should publish their compilation of the raw data, so that readers can replicate the results of their paper.

A further deficiency is: that measuring vaccination effectiveness (VE) by survival rates against only COVID-19 mortality is inadequate because it assumes falsely that vaccination does not have lethal side effects. Even the Therapeutic Goods Administration (TGA) has admitted [3] that there were 14 COVID vaccine-induced deaths to March 2023.

With mass vaccination, non-COVID excess deaths have reached about double COVID-19 deaths [4], and this should be investigated for association with vaccination. Yet, with only a brief discussion suggesting how vaccination may reduce all-cause mortality, the authors have inserted "all-cause mortality" in the title of the paper, insinuating vaccination is also effective against all-cause mortality.

Method and Analysis Issues

Even ignoring data integrity issues, ignoring non-COVID excess deaths and supposing VE is validly measured against only COVID-19 mortality, the paper still suffers seriously from methodological and analytical defects.

Vaccination, COVID-19 mortality and all-cause mortality data are available from 2021 and well into 2023. Why does the paper select and analyse only eleven months of 2022? There were surges in deaths in 2022 accompanying the rollouts of the first and second boosters, but the paper does not consider that they may be related to vaccinations, rather than only to the COVID disease.

Instead of analysing 2022 data as a whole, COVID and all-cause mortality data are analysed in two separate periods: one five-month period and one six-month period. For different dose groups, vaccine effectiveness (VE) is evaluated by COVID-19 survival effectiveness for three windows: less than three months, three to six months and more than six months.

Such divisions of time periods need to be discussed, because analysing survival over multiple fixed time-periods involves unstated assumptions about the time taken for vaccines to have their effects,

and the delay effects should be discussed. The risk of errors is increased on account of survivorship bias, where a proportion of deaths may fall between the cracks that lie between survival windows.

With two data periods, three dosage groups and three survival windows, there are 18 different vaccine mortality rates to compare to two unvaccinated mortality rates.

As may be expected, there are 18 different VE measures with a wide range of results depending on the various combinations. Importantly, the results appear random with no consistent VE pattern across the two time periods or between the dose groups.

In their main findings, the best and most convenient cases were selected for reporting. For example, from Figure 1 in the first period, the main finding reported was "*VE of a 3rd COVID-19 vaccine dose within 3 months was 93% (95% CI 93–94%) whilst VE of a 2nd dose >6 months since receipt was 34% (26–42%)*".

Among unfavourable findings (see below), the most favourable finding has been cited by the authors to show COVID-19 vaccination is highly effective, but only relatively and "wanes with time". Some of those unfavourable findings are masked by what appear as glaring anomalies, probably serious errors collected in the table below.

From Figure 1 of the paper, the "Dose3>180 days" group has a higher mortality rate (per 100 person-year) than the unvaccinated, yet they have positive vaccine effectiveness of 63.4 percent (COVID-19 VE (%) column below). This and a few other examples are shown in the table below, where a "Relative Risk Reduction (%)" column (should be the same as COVID-19 VE (%)) has been added with shaded cells, simply calculated from the mortality rates given.

Figure 1-3: Period and Group	Mortality Rate (per 100 PY)	Relative Risk Reduction (%)	COVID-19 VE (%)	All-Cause VE (%)
Jan-May 2022				
Unvaccinated	0.929	ref	ref	
Dose2>180 days	0.927	0.2	34	-15.8
Dose3>180 days	1.139	-22.6	63.4	-2.5
Jun-Nov 2022				
Unvaccinated	0.49	ref	ref	
Dose2 8-90 days	1.218	-148.6	13.9	-18.8
Dose2 91-180 days	0.595	-21.4	21.8	-11.9

In the June to November period of Figure 1, the "Dose2 8-90 days" group had 1.218 mortality rate per 100 PY, compared to 0.49 for the unvaccinated. This shows that even in the short-term of less than three months, that vaccinated group (second shaded cell from the bottom) had 2.5 times higher risk of dying from COVID than the unvaccinated. How could the authors claim for that case (second last column in the above table) a positive VE of 13.9 percent in their paper?

The paper needs to disclose the sorts of adjustments used to achieve positive "COVID-19 VE (%)" for those cases where the vaccinated groups had higher mortality rates than the unvaccinated. Those negative relative risk-reduction results calculated here for those cases, if unexplained, would invalidate the main conclusion of the paper that COVID-19 vaccination is highly effective.

Similar criticisms can be raised against the analysis in Figure 2 and Figure 3, where the method of adjustment for obtaining VE results for all-cause mortality is also not transparent, even though the

raw all-cause data would be more accurate than COVID-19 data for reasons explained and discussed above.

On all-cause mortality the authors made unsubstantiated comments such as "COVID-19 vaccines also appeared effective against other specific causes of death…those who are more likely to get multiple vaccine doses, or *to be vaccinated earlier are healthier and less likely to die from any cause*…". Emphasis added. On Pfizer/BioNTech's COMIRNATY vaccines alone, the TGA's DAEN database [5] recorded (subject to underreporting) over 82,000 adverse events associated with many different diseases. Moreover, those comments are contradicted by the authors' own analysis.

Figure 3 of the paper shows clearly that the authors' own calculated VE against all-cause mortality (rates not shown) are all negative for those cases shown in the above table (last column). Therefore, COVID-19 vaccination was ineffective and had increased all-cause mortality among some groups of older adults. Their evidence of ineffectiveness is consistent with Australian macro-data where all-cause mortality has increased substantially for older Australians vaccinated since 2021 [4].

Summary of Critique

- The approach of this study depends on official COVID data with integrity issues, which the paper does not acknowledge.
- Only 11 months in 2022 of official data out of possibly more than 24 months have been selected for the study.
- The "death by vaccination status" data which link dosages with mortality data have not been discussed or disclosed. The key data used need to be publicly available for replication of the findings.
- The unseen key data collection has been selectively analysed, by dividing into separate time periods, dose groups and survival durations, producing 18 comparisons. The method of analysis is unsound and has led apparently to random results, without identifiable regularity.
- The vaccination effectiveness results were not simply calculated, but adjusted. The details of the adjustments need to be disclosed.
- The unadjusted results contradict the general conclusion that "COVID-19 vaccination is highly effective against COVID-19 mortality among older adults*"*.
- Out of 18 comparisons of adjusted results, the most favourable and convenient findings have been selected and presented to draw the main conclusion, which is not generally valid.

Conclusion

As it stands, the paper has serious deficiencies in data integrity, data selection bias, flawed methods of analysis, undisclosed adjustments of results, selective reporting of findings and the drawing of invalid conclusions. The Australian Government has chosen to take this paper as authoritative evidence to justify its health policy, which has been associated with many excess deaths particularly in older Australians, but those deaths have been brushed off without investigation as coincidental, unrelated to vaccination.

The paper, in its currently published form, has serious methodological and analytical defects, resulting in errors and misleading conclusions. Therefore, the paper needs substantial revision to address the issues raised, or else it should be retracted.

Dr Wilson Sy, Director, PhD, Investment Analytics Research
Dr Christopher Neil, MBBS FRACP PhD, President, Australian Medical Professionals Society

References

[1] Senator Gerard Rennick. Data doesn't match the Health Department's statements & claims - Senate Estimates 1.6.23. https://www.youtube.com/watch?v=hABNX7MPkTw&list=PLyUQI7B0E8oTz3aJx7qOMlCoIy9vrh3CY&index=14

[2] Centers for Disease Control and Prevention, COVID-19 Vaccine Breakthrough Case Investigation and Reporting (Updated June 23, 2022), https://www.cdc.gov/coronavirus/2019-ncov/php/hd-breakthrough.html#report

[3] The Therapeutic Goods Administration. COVID-19 vaccine safety report - 23-03-2023. https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-23-03-2023#summary

[4] Australian Bureau of Statistics. Provisional Mortality Statistics. Release 27 October 2023. https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release

[5] The Therapeutic Goods Administration. Database of Adverse Event Notifications (DAEN) – medicines. 5 November 2023. https://daen.tga.gov.au/medicines-search/

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000064

Effectiveness and longevity of the COVID-19 Vaccine

Written

Senator: Ralph Babet

Question:

6. Your submission denies any credible link between COVID-19 Vaccination and excess mortality. You say that "There is no credible evidence to suggest that Covid-19 vaccines have contributed to excess deaths in Australia or overseas".

You refer to a study published in the Lancet Medical Journal titled "Effectiveness of COVID-19 vaccination against COVID-19 specific and all-cause mortality in older Australians: a population based study". The findings of this study have been publicly rebutted by Australian subject matter experts.

The study states that the vaccination is "highly effective", but "wanes over time". Tell me this, can a vaccine be "highly effective" but only for a limited time? How limited?

Answer:

Please refer to Hansard.

This question was answered by representatives from the Department of Health and Aged Care on Thursday, 13 June 2024 at the public hearing.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000062

2021 excess mortality was the result of low 2020 mortality

Written

Senator: Ralph Babet

Question:

12. Death displacement is referred to in the Actuaries Institute (AI) submission. A high mortality year leads to a compensatory downturn, yielding a low mortality year. Therefore the reason for low mortality in 2020 likely relates to the high mortality in 2019 (bad flu year). However, the AI uses this concept in reverse suggesting that the 2021 excess mortality was the result of low 2020 mortality. Is this 'reverse causality'?

Answer:

Questions regarding the submission from the Actuaries Institute and methodologies contained within should be directed to the Institute.

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health and Aged Care

Senate Community Affairs References Committee

Inquiry into Excess Mortality

13 June 2024

PDR Number: IQ24-000061

Excess deaths as a result of the Covid vaccine

Written

Senator: Ralph Babet

Question:

5. If the Covid vaccines were so effective, why are there so many excess deaths across all age groups?

Answer:

As detailed in the Department of Health and Aged Care's submission, 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 number of deaths in the same period. The Australian Bureau of Statistics (ABS) publication *Measuring Australia's excess mortality during the COVID-19 pandemic until August 2023* found that COVID-19 was the main contributor to excess mortality in 2021, 2022 and 2023.

Excess mortality has not been observed consistently across all age groups between 2021 – 2023. Data released by the ABS shows:

- In 2023 there was no excess mortality for those aged under 55 years (for the data available until the end of August 2023).
- There was excess mortality reported in all age groups in 2022.
- In 2021 those aged between 35 and 64 years had no excess mortality.
- In 2020, all age groups except those aged under 34 years recorded lower than expected excess mortality. In this age group 30 deaths above expected were recorded (0.7%).

Real-world evidence has clearly demonstrated the protective benefits of vaccination far outweigh the potential risks, including those of serious but rare adverse events.

Further information on potential drivers for excess mortality have been outlined in the Department of Health and Aged Care's submission and within previous QONs including SQ24-001460, SQ23-000137, SQ23-000142.