

# PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

**Inquiry into Australian Government's response to the COVID-19 pandemic**

**Written Question on Notice received 26 February 2021**

PDR Number: IQ21-000046

**Limited clinical trials for people aged over 65yrs**

**Written**

**Senator:** Rachel Siewert

**Question:**

While there are no safety concerns for people who are aged over 65 for the AstraZeneca vaccine and it has been approved for use by the Therapeutic Goods Administration (TGA), some constituents have been in touch about reports in the media that there weren't enough people infected with COVID-19 in the clinical trials to determine the efficacy of the AZ vaccine for that age group.

Is there any additional information you can share with Australians in this age group to maintain their confidence in the vaccine plan and to ensure they will feel adequately protected from the virus?

**Answer:**

There were no cases of COVID-19 hospitalisations, severe disease or COVID-19 deaths among trial participants aged over 65 years who received the AstraZeneca COVID-19 vaccine. The clinical trials available at the time that the vaccine was approved by the TGA showed the vaccine produced an immune response in patients aged over 65 years.

The AstraZeneca vaccine is now being used widely in the United Kingdom (UK) and India. The epidemiological data from the UK published in the British Medical Journal on 22 February 2021 showed a reduction in hospital admissions with COVID-19 ([www.bmj.com/content/372/bmj.n523](http://www.bmj.com/content/372/bmj.n523)).

*'The results, available as a preprint, showed that four weeks after the first doses of the Pfizer BioNTech and Oxford AstraZeneca vaccines were administered the risk of hospitalisation from COVID-19 fell by up to 85% (95% confidence interval (CI) 76 to 91) and 94% (95% CI 73 to 99), respectively.'*

Additionally, on 1 March 2021 the Public Health England (PHE) submitted a pre-print of a real-world study ([www.gov.uk/government/news/new-data-show-vaccines-reduce-severe-covid-19-in-older-adults](http://www.gov.uk/government/news/new-data-show-vaccines-reduce-severe-covid-19-in-older-adults)) that shows that both the Pfizer and Oxford-AstraZeneca vaccines are highly effective in reducing COVID-19 infections among older people aged 70 years and over. Since January 2021, protection against symptomatic COVID, 4 weeks after the first dose, ranged between 57 per cent and 61 per cent for one dose of Pfizer and between 60 per cent and 73 per cent for the Oxford-AstraZeneca vaccine.

Additional information on the efficacy of the AstraZeneca COVID-19 Vaccine in adults aged over 65 years is anticipated to be available in late March 2021 and will be obtained from a Phase III clinical trial underway in the United States of America and South America (NCT04516746 - <https://clinicaltrials.gov/ct2/show/NCT04516746>), which has about 32,000 participants enrolled, and aimed to have at least 25 per cent of participants aged over 65 years.

The potential benefits from the vaccine in protection against COVID-19 are greater than the potential risks. However, it should be noted that administration of the vaccine will not negate the need for older people and those around them to follow current precautions and public health guidance to reduce the risk of acquiring COVID-19.