



Australian Government

Department of Health

Department Reference: FOI 3175

Mr Matthew Peos

Via email: foi+request-7935-fb5929c5@righttoknow.org.au

Dear Mr Matthew Peos

NOTICE OF DECISION UNDER SECTION 24A OF THE FREEDOM OF INFORMATION ACT 1982

Thank you for your request of 4 October 2021 to the Department of Health seeking access under the *Freedom of Information Act 1982* to documents related to COVID-19. Your request is in the following terms:

Current statistics outlining:

1. Reinfection rates of vaccinated people in Australia
2. Reinfection rates of vaccinated people Globally
3. Reinfection rates of unvaccinated people in Australia
4. Reinfection rates of unvaccinated people Globally
5. Deaths of vaccinated people in Australia
6. Deaths of vaccinated people Globally
7. Deaths of Unvaccinated people in Australia
8. Deaths of Unvaccinated people Globally
9. Rates of infection increase in highly vaccinated areas
10. Rates of infection increase in highly unvaccinated areas
11. Recovery rate of infected populous in vaccinated people
12. Recovery rate of infected populous in unvaccinated people
13. Statistics of Recorded adverse reactions in vaccinated people.
14. Statistics of recorded type of adverse reactions.'

Information about COVID-19 case numbers and deaths

Information on COVID-19 cases and associated deaths, including the epidemiological aspects, can be found on the department's website:

- Daily case summary of cases: <https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers>
- Daily infographic, including previous versions dating back to 5 April 2020: <https://www.health.gov.au/resources/collections/coronavirus-covid-19-at-a-glance-infographic-collection>

- Communicable Diseases Intelligence COVID-19 epidemiology fortnightly report:
https://www1.health.gov.au/internet/main/publishing.nsf/Content/novel_coronavirus_2019_ncov_weekly_epidemiology_reports_australia_2020.htm

COVID-19 cases and associated deaths are reported daily to the department by the states and territories. National notification data on COVID-19 confirmed cases, including associated deaths (based on the below definitions), is collated in the National Interoperable Notifiable Diseases Surveillance System (NINDSS) based on notifications made to state and territory health authorities under the provisions of their relevant public health legislation. The national case definitions for COVID-19 cases and COVID-19 associated deaths are provided in the *Communicable Diseases Network Australia COVID-19: National Guideline for Public Health Units* which is available here:

<https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm>.

- For surveillance purposes, a COVID-19 associated death is defined as a death in a confirmed COVID-19 case, unless there is a clear alternative cause of death that cannot be related to COVID-19 (e.g. trauma). There should be no period of complete recovery from COVID-19 between illness and death. Where a Coroner's report is available, these findings are to be observed.

The NINDSS has implemented fields to capture data on the vaccination status of COVID-19 cases. These fields have been implemented to allow the monitoring of the vaccination status of cases, including for people vaccinated outside Australia. Most jurisdictions are collecting this data, and are in the process of modifying their systems to be able to report these data to the NINDSS, however at this stage, data completeness for these fields are not nationally representative. It is recommended that state and territory health departments be contacted to seek this information.

- Information on the current vaccination status of COVID-19 cases in NSW, including those associated with the current Delta outbreak, are being reported by NSW Health in their COVID-19 weekly surveillance report, which can be accessed via this link: <https://www.health.nsw.gov.au/Infectious/covid-19/Pages/weekly-reports.aspx>.

Additionally, data and information on deaths certified as due to COVID-19 are routinely collated and reported by the Australian Bureau of Statistics (ABS). For recent COVID-19 mortality data from the ABS, we suggest the 'Provisional Mortality Statistics' reports. The ABS also publishes finalised cause of death data annually.

- The ABS finalised annual cause of death data and monthly provisional mortality statistics are available at:
<https://www.abs.gov.au/statistics/health/causes-death>
- These reports provide information on doctor certified deaths and their registered causes, including deaths due to COVID-19, noting that there is an approximate 3 month lag on these data. Please note that these data are

provisional, and do not include deaths that have been referred to a coroner. Further information on the provisional report methodology can be found at: <https://www.abs.gov.au/methodologies/provisional-mortality-statistics-methodology/jan-2020-may-2021>.

The department does not hold documents on rates of infection geographically based on vaccination coverage. Data to support such an analysis are available via the following data request mechanism.

Request for national notification case data

National notification data on COVID-19 confirmed cases, including COVID-19 associated deaths and by vaccination status, is collated in the NINDSS based on notifications made to state and territory health authorities under the provisions of their relevant public health legislation (noting that the vaccination status fields are not currently provided by all jurisdictions). A request for the release of data from the NINDSS requires agreement from states and territories via the Communicable Diseases Network Australia. Depending on the sensitivity of the data sought, and proposed use, ethics approval may also be required.

- For information on how to apply to access data from the NINDSS please contact the NINDSS Data Requests inbox (nndss.datarequests@health.gov.au)

Deaths of vaccinated and unvaccinated people in Australia

As of 10 November 2021, there have been 1858 deaths of people in Australia with COVID-19. Information on the number of vaccinated and unvaccinated people who died with COVID-19 may be available on State and Territory health websites.

NSW Health released a report on 4 November 2021 about the number of deaths in vaccinated and unvaccinated people in NSW. It is available at: <https://www.health.nsw.gov.au/Infectious/covid-19/Documents/covid-19-surveillance-report-20211104.pdf>. From 16 June 2021 to 23 October 2021, of the 499 people who died in NSW, 66 were fully vaccinated, 62 were partially vaccinated and 360 had no effective dose.

Deaths of vaccinated and unvaccinated people globally

There have been over 5 million deaths of people with COVID-19, as of 10 November 2021. More information is available at: <https://coronavirus.jhu.edu/map.html>. The data on vaccination and unvaccinated people may have been captured by individual countries but is not available on a global scale. More information is available by visiting the public health websites of individual countries.

UK Health Security Agency released COVID-19 Vaccine Surveillance Reports, including the number of infections, hospitalisations and death in vaccinated and unvaccinated populations. It is available at:

<https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports>

Information about COVID-19 vaccination rates by locations

Vaccination rates by Local Government Area are available on the department's website at: <https://www.health.gov.au/resources/publications/covid-19-vaccination-local-government-area-lga-8-november-2021>

Individual states may collate Vaccination Data by LGA and Cases by LGA, which is available on State and Territory health websites.

Information about COVID-19 vaccine adverse reactions

The Therapeutic Goods Administration (TGA) is responsible for monitoring the safety of all vaccines approved for use in Australia. The TGA closely assesses safety data prior to approval, and continues to monitor the safety of vaccines after they are registered in Australia so that any safety concerns can be detected and responded to. Active surveillance is also occurring through the AusVaxSafety surveillance system, which sends follow up messages to recipients of COVID-19 vaccines to ask if they have experienced any potential side effects.

More information about adverse events can be found in the TGA COVID-19 Vaccine Weekly Safety Report, available at: <https://www.tga.gov.au/covid-19-vaccine-safety-monitoring-and-reporting>

Reporting of an adverse event and the publication of an adverse event in the Database of Adverse Event Notifications does not mean the event was related to a vaccine. There might be no relationship between the adverse event and the medicine or vaccine – it may be a coincidence that the adverse event occurred when the medicine or vaccine was taken, and the symptom may be related to the underlying illness or to other factors. Expert analysis and review of adverse event reports is needed to determine whether there may be a link between reported events and vaccination. The Database of Adverse Event Notifications is available on the TGA website here: <https://www.tga.gov.au/database-adverse-event-notifications-daen>

The TGA analyses adverse event report data and reviews individual reports to identify possible safety issues for investigation. If these investigations confirm a safety signal, the TGA takes appropriate action. There is not a predefined number of adverse event reports that leads to removal of a product from the market because the

type of action depends on the nature of the safety issue identified, including its likelihood and severity and the potential to mitigate the risk (such as through patient selection or monitoring), and the impact of the safety issue on the balance of benefits and risks for the product.

Information about approval, safety and efficacy of COVID-19 vaccines

Before a prescription medicine (including a COVID-19 vaccine) can be legally supplied in Australia, the TGA rigorously assesses the safety, quality and effectiveness to determine if the benefits outweigh the risks.

The COVID-19 vaccines which have received provisional approval in Australia have each been shown to be highly effective in preventing severe illness, hospitalisation, and death from COVID-19, caused by SARS-CoV-2. The risk of a person infected with the SARS-CoV-2 virus developing symptomatic illness and becoming seriously unwell with COVID-19 is significantly reduced if that person has received a COVID-19 vaccine. For each provisionally approved vaccine, the TGA has established the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information.

The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, which provide detailed information regarding the evaluation process and the data that was considered. These include the Australian Public Assessment Report, the Product Information and the Consumer Medicine Information, and they are available at: www.tga.gov.au/covid-19-vaccines.

The TGA has also published several documents in response to previous FOI requests on the TGA's Disclosure Log at: www.tga.gov.au/foi-disclosure-log. These documents offer a useful summary and analysis of the data submitted to the TGA for the purposes of making a regulatory decision regarding the provisional approval of COVID-19 vaccines. You may be particularly interested in FOI 2389 (FOI documents 1 – 7) in relation to the Pfizer vaccine and FOI 2494 (FOI documents 1 – 7) in relation to the AstraZeneca vaccine. Please note, some commercially confidential information and personal information has been redacted from these documents.

Clinical trials to support vaccine registration are typically conducted by sponsors (pharmaceutical companies) of those vaccines and published in medical journals. Data from the same trials are submitted by the sponsor to the TGA as part of the provisional registration application.

The following 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.

AstraZeneca:

- Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK.
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)32661-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32661-1/fulltext)
- Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a pooled analysis of four randomised trials.
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00432-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext)
- Global Statistical Analysis Plan for the combined integrated analysis of studies of ChAdOx1 nCoV-19 (AZD1222) vaccine.
<https://ars.els-cdn.com/content/image/1-s2.0-S0140673620326611-mmc2.pdf>

Pfizer:

- Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine.
<https://www.nejm.org/doi/full/10.1056/NEJMoa2034577>
- Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents.
https://www.nejm.org/doi/full/10.1056/NEJMoa2107456?query=featured_coronavirus

Moderna:

- Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine.
<https://www.nejm.org/doi/full/10.1056/NEJMoa2035389>
- Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents.
https://www.nejm.org/doi/10.1056/NEJMoa2109522?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed#article_Abstract

Johnson & Johnson

- *Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19*, the New England Journal of Medicine.
<https://www.nejm.org/doi/full/10.1056/NEJMoa2101544>
- *Analysis of the Effectiveness of the Ad26.COV2.S Adenoviral Vector Vaccine for Preventing COVID-19*, JAMA Network.
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785664>

Information about COVID-19 infection and reinfection rates

The department does not hold data documentation that disaggregates the reinfection rates among vaccinated or unvaccinated people in Australia. This data information may be available from State and Territory health departments as mentioned above.

However, the following international reports on reinfection among vaccinated and unvaccinated cases are available publicly:

- [Rate and severity of suspected SARS-Cov-2 reinfection in a cohort of PCR-positive COVID-19 patients:](#)
- [Clinical Microbiology and Infection -The durability of immunity against reinfection by SARS-CoV-2: a comparative evolutionary study – ScienceDirect](#)
- [Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections \(medrxiv.org\)](#)

Data on the reinfection rates of vaccinated and unvaccinated people globally has been captured by individual countries but is not available on a global scale. More information is available by visiting the public health websites of individual countries [A study](#) conducted by the US Center for Disease Control in Kentucky from May – June 2021, indicated that the risk of being reinfected was 2.34 times higher for those who were unvaccinated, compared with being fully vaccinated.

Australia's Federal system

Australia has a 'Federal' or 'Commonwealth' Government, and separate Governments for each of the States and Territories. Under Australia's federalism system, power is shared between the different Governments, which limits their powers. Each Government is also comprised of separate departments and agencies. While departments and agencies work together to achieve outcomes, they have different responsibilities. Each Commonwealth, State and Territory department and agency creates, receives and stores different documents relevant to their functions. The department does not have access to all documents created by, received by, or stored by, other Commonwealth, State or Territory government entities.

State and Territory Health website links

NSW Health Data is available at:

<https://www.nsw.gov.au/covid-19/stay-safe/data-and-statistics>

Victoria Health Data is available at:

<https://www.coronavirus.vic.gov.au/victorian-coronavirus-covid-19-data>

ACT Health Data is available at:

<https://app.powerbi.com/view?r=eyJrIjoiZTY4NTI1NzQtYTZhYy00ZTY4LTk3NmQtYjBjNzdiOGMzZjM3IiwidCI6ImI0NmMxOTA4LTAzMzQtNDIzNi1iOTc4LTU4NWVlODhlNDE5OSJ9>

NT Health Data is available at:

<https://coronavirus.nt.gov.au/current-status>

QLD Health Data is available at:

<https://www.qld.gov.au/health/conditions/health-alerts/coronavirus-covid-19/current-status/statistics>

SA Health Data is available at:

<https://www.covid-19.sa.gov.au/home/dashboard>

TAS Health Data is available at:

<https://www.coronavirus.tas.gov.au/facts/tasmanian-statistics>

WA Health Data is available at:

<https://experience.arcgis.com/experience/359bca83a1264e3fb8d3b6f0a028d768>

FOI decision

I am authorised under subsection 23(1) of the FOI Act to make decisions in relation to Freedom of Information requests. I am writing to notify you of my decision in response to your request.

The FOI Act provides a mechanism for individuals to request access to documents held by relevant entities. It is not a mechanism for asking questions or seeking information that the entity does not hold in documents.

Appropriate steps have been taken to find documents you have requested including consultation with relevant departmental officers and searches of departmental file management systems.

I am satisfied, on the basis of the consultation undertaken and the searches conducted, that the department, including the TGA, that the information sought in your request is available in the public domain as described above.

FOI review rights

If you are dissatisfied with my decision, you may apply for a review.

Internal review

Under section 54 of the FOI Act, you may apply for internal review of this decision. In accordance with section 54B of the FOI Act, an application for internal review must be made in writing within 30 days after the day you are notified of this decision (or such further period as the department allows). To assist in the internal review process, please provide reasons you consider the review of my decision is necessary.

The internal review will be carried out by another officer of this department within 30 days of receipt of your application.

An application for an internal review should be addressed to:

Email: FOI@health.gov.au

Mail: FOI Unit (MDP 516)
Department of Health
GPO Box 9848

CANBERRA ACT 2601

Information Commissioner review

Alternatively, under section 54L of the FOI Act, you may apply to the Office of the Australian Information Commissioner (OAIC) for review of my decision by the Information Commissioner (IC).

In accordance with subsection 54S(1) of the FOI Act, an IC review application in relation to a decision covered by subsection 54L(2) (access refusal decisions) must be made in writing within 60 days after the day you are notified of this decision (if you do not request an internal review).

More information about IC review is available on the OAIC website at:

<https://www.oaic.gov.au/freedom-of-information/reviews/>

The OAIC can be contacted by:

Phone: 1300 363 992

Email: enquiries@oaic.gov.au

Complaints

If you are dissatisfied with action taken by the department, you may also make a complaint.

Complaint to the department

Complaints to the department are covered by the department's privacy policy. A form for lodging a complaint directly to the department is available on the department's website:

<https://www.health.gov.au/about-us/contact-us/complaints>

Complaint to the IC

Information about making a complaint to the IC about action taken by the department is available on the OAIC website:

<https://www.oaic.gov.au/freedom-of-information/reviews-and-complaints/make-an-foi-complaint/>

Relevant provisions of the FOI Act

The FOI Act, including the provisions referred to in this letter, can be accessed from the Federal Register of Legislation website:

<https://www.legislation.gov.au/Details/C2021C00382>

Contacts

If you require clarification of any of the matters discussed in this letter you should contact the department's Freedom of Information Unit on (02) 6289 1666 or at FOI@health.gov.au.

Yours sincerely

Stephen Bouwhuis
General Counsel
Advice and Legislation Branch

6 November 2021