

Australian Government response to the Community Affairs References Committee report:

Excess Mortality

Overview

The Australian Government provides the following responses to the recommendations from the Community Affairs References Committee report into Excess Mortality as well as the dissenting recommendations. Recommendations have been grouped thematically to provide a comprehensive response.

The Australian Government is already working towards many recommendations in the report.

Many of the dissenting recommendations have been previously addressed in submissions to the Inquiry from the Australian Bureau of Statistics (ABS), the Australian Institute of Health and Welfare (AIHW) and the Department of Health, Disability and Ageing and there is no further information that can be added.

Responses to recommendations

<u>Group 1 – Australian Bureau of Statistics and Data related recommendations</u>

Recommendation 1

The committee recommends that the Australian Bureau of Statistics:

- include geographic indicators in its excess mortality estimates; and
- address gaps in the production and publication of data on excess mortality among Aboriginal and Torres Strait Islander people, people with disability, and people in rural and regional areas.

The Australian Government accepts this recommendation.

The ABS produces excess mortality estimates that are methodologically robust and meet community needs. The ABS has produced excess mortality estimates at the national level, by state and territory and by selected age groups.

The ABS released weekly and annual excess mortality estimates for deaths occurring in Australia by remoteness areas¹ on 28 February 2025. Data is reported by date of death occurrence and remoteness area analysis. The analysis includes all deaths that occurred by 31 December 2023 and registered by 31 October 2024.

Aboriginal and Torres Strait Islander data

The ABS has an ongoing work program to enhance the quality of Aboriginal and Torres Strait Islander mortality data. A key focus is to improve the accuracy of Indigenous identification by using multiple sources of information to understand if a deceased person was of Aboriginal and Torres Strait Islander origin. When the ABS introduces an additional source for deriving Indigenous status – as it has done recently – this generally changes the total number of deaths by Indigenous status, usually by increasing the reported number of deaths of both Aboriginal and Torres Strait Islander people and non-Indigenous people and decreasing the number of deaths where the Indigenous status is unknown.

For reports on *Excess Deaths*, the ABS will need several years of quality Aboriginal and Torres Strait Islander mortality data where Indigenous status has been derived consistently to calculate good quality estimates of excess mortality. The ABS do not currently have this time series and so cannot currently produce reliable estimates of excess mortality for Aboriginal and Torres Strait Islander people.

The ABS will continue to work with stakeholders to improve the quality of mortality data for Aboriginal and Torres Strait Islander people.

¹ The five remoteness classes are: major cities, inner regional, outer regional, remote and very remote.

Disability data

Information on disability is not collected as part of the death registration process, unless the disability itself caused or contributed to death and was certified as such by the medical practitioner. The ABS cannot produce estimates of excess mortality for people with disability from the existing mortality data.

Agencies across the Australian Government including the ABS, Department of Social Services and the AIHW have collaborated to create the National Disability Data Asset (NDDA). The NDDA links de-identified data from federal and jurisdictional agencies about individuals with and without disability. The aim is to have a resource which provides insights into the lives of people with disability and improves reporting outcomes for people with disability under *Australia's Disability Strategy 2021-2031*. The NDDA includes mortality data and may provide insights into mortality for people with disability in future. The first release of the NDDA was made available in December 2024 to approved researchers. More data will be available throughout 2025 and the NDDA is expected to be fully operational in 2026. Researchers may apply for access by contacting the ABS at nda@abs.gov.au.

Dissenting Recommendation – Senator Rennick – Recommendation 1

The Australian Bureau of Statistics needs to track and report vaccination status.

The Australian Government does not support this recommendation.

The Department of Health, Disability and Ageing is the data custodian of the Australian Immunisation Register (AIR) which reports and tracks vaccination status of the population. The AIR data is provided to the ABS frequently to link with other Commonwealth administered data sets for access by government agencies and researchers. An example of a project that integrates AIR and the ABS' Person Level Integrated Data Asset (PLIDA) is "Understanding socio-demographic cohorts in the COVID-19 Vaccines Strategy (2021)". Details about this and other PLIDA projects are available from the ABS (https://www.abs.gov.au/about/data-services/data-integration/integrated-data/person-level-integrated-data-asset-plida/plidamadip-research-projects).

<u>Dissenting Recommendation – Senator Babet – Recommendation 3</u>

Integrated data assets held by the AIHW and ABS which include both mortality data and the Australian Immunisation Register data should have been reviewed throughout the pandemic to review any possible connection between higher-than-expected all-cause mortality and COVID-19 vaccination. These same data assets must be made available for independent analysis of vaccination status and mortality.

The Australian Government notes this recommendation.

The Department of Health, Disability and Ageing has made AIR data available through both the ABS and AIHW. The department has also analysed mortality by vaccination status using

integrated data assets held by the ABS throughout the pandemic. Direct access to these data assets is managed by the ABS and AIHW.

Death registry information is also available through the ABS' Person Level Integrated Data Asset (PLIDA). AIR data and Death Registrations from State and Territory registrars is available to approved researchers through the safe and secure ABS DataLab facility. Researchers can apply to access this and other PLIDA datasets through the ABS myDATA portal (https://mydataportal.abs.gov.au/). This facility enables ongoing research into Excess Mortality.

The AIHW's COVID-19 Register (https://www.aihw.gov.au/reports-data/covid-linked-data-set), which contains information about all-cause mortality and COVID-19 vaccination, is available to researchers for independent analysis of vaccination status and mortality. Researchers can access information on the COVID-19 Register project approval process on AIHWs website (https://www.aihw.gov.au/reports-data/covid-linked-data-set/accessing-the-data).

<u>Dissenting Recommendation – Senator Babet – Recommendation 5</u>

During a declared pandemic, mortality data should be available to researchers and the general public. The ABS should report monthly mortality data by age, sex and cause of death, which would enable additional analyses on a more regular basis, which can inform policy. Data should be freely available to users, enabling engagement with a range of experts to facilitate a quicker and more in-depth understanding of the impacts of epidemics going forward.

The Australian Government notes this recommendation.

This information is available from the ABS. The ABS publishes regular Provisional Mortality Statistics reports which includes weekly and monthly analysis on mortality data by age, sex, cause of death and jurisdiction. These reports are published monthly (except for January) and are available via the public ABS website (http://www.abs.gov.au). The ABS first published these reports in mid-2020 in response to the COVID-19 pandemic.

The ABS also produces custom requests for stakeholders who require further information. Custom requests are cost recovered.

<u>Dissenting Recommendation - Senator Babet - Recommendation 4</u>

When dealing with a provisionally approved drug, deaths in interim mortality reporting should be analysed by vaccination status by integrating the AIR data, not just relying on death certificates.

According to official data, deaths of young women continue to run at far higher than expected levels, whereas young men do not. The cause/s of this alarming and consistent trend must be immediately identified.

The Australian Government notes these recommendations (Senator Babet Recommendations 4 and 9).

The ABS publishes reports on cause of death by age group. The *Causes of Death Australia* reports include the most comprehensive information on causes of deaths by sex and age group. Many deaths of young people are referred to the coroner and establishing a final cause of death can take some time.

Excess mortality in young people has decreased since 2022. ABS data shows that COVID-19 was the main contributor to excess mortality of young people in 2022. In the ABS submission to the Inquiry into Excess Mortality included the following caution on interpreting excess mortality in young people:

"While there is some excess mortality recorded for the younger groups across 2020-2022, there are small numbers of deaths in these age groups and a large amount of variability in the expected range. This means that the excess mortality percentages in these age groups may reflect natural variation in mortality patterns rather than statistically significant excess mortality."

The ABS findings on excess deaths among young females are supported by the AIHW.

Group 2 – COVID reviews

Recommendation 4

The committee recommends that the Australian Government task the Department of Health, Disability and Ageing with reviewing Australia's public health information communication strategies during the COVID-19 pandemic, to improve the delivery of future public health communication.

The Australian Government notes this recommendation.

The Australian Government is working to improve the delivery of future public health information. The Department of Health, Disability and Ageing is developing a National Health Literacy Strategy to improve the health literacy environment in Australia as well as individuals' self-care capabilities. This Strategy aims to transform the health literacy environment to enhance the ability of people and communities to make informed decisions about their health and wellbeing through access to evidence-based, person-centred, and culturally and linguistically appropriate information.

Additionally, the Australian Centre for Disease Control (CDC) will have a role in developing communication strategies to deliver public health communication during a health emergency. A communication strategy has been developed for the interim CDC as it transitions to an independent entity. This strategy provides a foundation for effective communication to establish the Australian CDC as a trusted, expert, independent public health authority.

The strategy offers an evidence-informed approach to communication and prioritises building public trust and credibility, articulating the CDC's role in public health, and showcasing its data-driven capabilities in response to health threats.

The CDC will work in partnership with priority population groups, state and territory governments and others to tailor and target timely, inclusive health messaging on disease threats and issues.

Dissenting Recommendation – Senator Babet Recommendation 1

The federal government must establish a royal commission to examine the Australian response to the COVID-19 pandemic and the consequential impacts on the Australian community. States and Territories should pass complementary legislation that would enable them to participate in the Royal Commission. The terms of reference for the Royal Commission should be adopted from the Senate Standing Committee on Legal and Constitutional Affairs' COVID-19 Royal Commission inquiry report.

The Government does not support this recommendation.

This recommendation replicates recommendations in the inquiry into the appropriate terms of reference for a COVID-19 Royal Commission report

(https://www.aph.gov.au/Parliamentary Business/Committees/Senate/Legal and Constitutional Affairs/COVID19RC47/Report/List of recommendations).

There have been numerous reviews and research into the Commonwealth Government and state and territory governments' responses to COVID-19. The Commonwealth Government COVID-19 Response Inquiry, led by an independent panel of experts, built on these reviews and was a comprehensive analysis of the Commonwealth response to the pandemic. In October 2024, the Inquiry report was published with nine guiding recommendations and 26 actions for both short and longer-term work to improve Australia's preparedness for future pandemics.

The Australian Government is considering the Inquiry report before responding.

Dissenting Recommendation – Senator Babet – Recommendation 10

An appropriate independent body should undertake comprehensive review (including with bereaved families) of every report of death following COVID-19 vaccination. This body should also undertake investigations of each serious adverse event following immunisation (AEFI) report to pharmacovigilance authorities including interviewing each patient and undertaking additional specialised testing where possible. All AEFI reports (including those not deemed "serious") should be individually followed-up to determine the long-lasting consequences of their vaccine reactions (which may include death).

The Australian Government does not support this recommendation.

Adverse event data is made available to the public though the Database of Adverse Event Notifications (DAEN) — medicines. The Australian Government was open and transparent about COVID-19 vaccine safety during its roll-out. For more than two years, the Therapeutic Goods Administration (TGA) published a regular COVID-19 vaccine safety report, initially weekly and then fortnightly.

The safety of the COVID-19 vaccines currently registered in Australia was assessed by the TGA through analysis of large *in vivo* studies (clinical trials) with tens of thousands of individuals. This has since been supported by real-world data from billions of individuals.

Mechanisms for coronial enquiry into deaths, including those which might be attributed to vaccine adverse events, exist in all states and territories of Australia and an independent body as proposed in Recommendation 10 would both exceed Commonwealth jurisdiction and duplicate these systems. Such an enquiry would involve analysis of large amounts of private medical information which the Commonwealth would not normally access or have procedures to handle.

Group 3 – Compensation

Recommendation 2

The committee recommends that the Australian Government consider the design and compensation arrangements of a no-fault compensation scheme for Commonwealth-funded vaccines in response to a future pandemic event.

The Australian Government notes this recommendation.

This recommendation will be addressed through the Government response to the Commonwealth Government COVID-19 Response Inquiry.

<u>Dissenting Recommendation – Senator Babet – Recommendation 6</u>

Extend the COVID-19 Vaccine Claims Scheme and fully review its terms to ensure that victims are adequately compensated.

The Australian Government does not support this recommendation.

The Australian Government established the COVID-19 Vaccine Claims Scheme on 13 December 2021 as a no-fault, time-limited claims scheme to respond to the unprecedented immediate circumstances of the COVID-19 pandemic. As agreed by Government in the 2023-24 Mid-Year Economic and Fiscal Outlook, the scheme closed to new claims on 30 September 2024. Claims submitted by that date continue to be assessed in line with the Scheme Policy.

The Australian Government is working to improve vaccine rollout in the future. The interim Australian CDC led the development of the National Immunisation Strategy 2025–30 (Strategy) in collaboration with key partners, including States and Territories.

The new Strategy outlines a vision and mission to reduce the health impacts of vaccine preventable diseases. It contains priority areas and strategic goals, providing a roadmap for action over the next five years.

The Strategy prioritises the implementation of sustainable reform in vaccine program governance, program delivery and accountability. It focuses on supporting policies that help to improve public confidence in vaccines, and signals the intent to explore the feasibility of establishing a no-fault compensation scheme that covers all National Immunisation Program vaccines.

Dissenting Recommendation – Senator Rennick – Recommendation 4

Pharmaceutical companies should be held responsible for their products. They should be liable for adverse events.

<u>Dissenting Recommendation – Senator Rennick – Recommendation 5</u>

People were disabled by COVID-19 vaccines. In many cases, lives were destroyed. Australians who are unable to live a full and fulfilling life, after doing what they thought was best based on Government advice or to save their livelihoods, should be adequately compensated, not given a hollow promise that it will be considered in the future.

<u>Dissenting Recommendation – Senator Babet – Recommendation 8</u>

In the interest of transparency, existing contracts containing indemnification clauses should be release publicly as they create an unquantifiable contingent liability for Australian taxpayers.

The Australian Government notes these recommendations (Senator Rennick Recommendations 4 and 5 and Senator Babet Recommendation 8).

<u>Group 4 – Therapeutic Goods Administration</u>

<u>Dissenting Recommendation – Senator Rennick – Recommendation 2</u>

The Therapeutic Goods Administration must acknowledge that their testing of the COVID-19 vaccines was insufficient and work to lift their quality assurance.

<u>Dissenting Recommendation – Senator Rennick – Recommendation 3</u>

Adverse events need to be recognised sooner so that faulty products can be recalled. The Australian people should not have their injuries gaslighted.

The Australian Government does not support these recommendations (Senator Rennick Recommendations 2 and 3).

The Government rejects any assertion that the TGA's assessment of COVID-19 vaccines was insufficient. The claim that the TGA 'gaslights' people who have experienced an adverse event is incorrect and not reflective of publicly available evidence.

The TGA comprehensively evaluated each COVID-19 vaccine to ensure that they meet Australia's high standards of safety, quality, and efficacy. Evaluation is based on clinical, non-clinical and toxicological studies, and chemistry, risk management and manufacturing information.

A vaccine is only approved by the TGA if this rigorous assessment process is completed, and the benefits of the vaccine are greater than any potential risks. Once a vaccine has been approved, the TGA has robust processes for the ongoing monitoring of the safety of that product. This post-market safety surveillance system enables the TGA to rapidly detect, investigate and respond to emerging safety issues. Many of these processes were enhanced significantly for COVID-19 vaccines, making it the most intensive safety monitoring of therapeutic goods ever conducted in Australia.

Extensive independent testing was conducted on all batches of the COVID-19 vaccines released for supply to the Australian public. This included testing for composition, strength, purity, integrity, identity and endotoxin. All batches released for supply in Australia met the quality requirements. The TGA has not identified any safety signals that may relate to a quality issue for any COVID-19 vaccine.

<u>Group 5 – Procedural</u>

Recommendation 3

The committee recommends that the Australian Government establish the Australian Centre for Disease Control as soon as practicable.

The Australian Government accepts this recommendation.

On 29 October 2024, the Australian Government announced it is investing \$251.7 million to improve Australia's ability to prepare for, and respond to, public health challenges through the creation of the Australian CDC. The CDC will be established as an independent agency, separate to the Department of Health, Disability and Ageing, from 1 January 2026, subject to the passage of legislation. This builds on the interim CDC, established on 1 January 2024, as part of the Australian Government's commitment to establishing a CDC in a phased approach.

Recommendation 5

The committee recommends that the Senate take note of the following:

- witness participation in public hearings is critical to the committee inquiry process;
- all witnesses who participate in committee public hearings should be treated with respect;
- Senators should be reminded of the Resolution on the Broadcasting of Senate and Committee Proceedings

The Australian Government accepts this recommendation.

The Australian Government is committed to respecting the process and outcomes of Senate Inquiries.

<u>Dissenting Recommendation – Senator Babet – Recommendation 2</u>

Committees must be made to justify in detail the reasons why each individual submission is not uploaded publicly. All efforts must be made to publish submissions publicly, even if some redaction is necessary.

The Australian Government notes this recommendation. Submissions are only published after a decision by the committee. Submissions are not automatically accepted and published. A committee may reject a submission that is not relevant to its inquiry. For more information, contact the Senior Clerk of Committees (seniorclerk.committees.sen@aph.gov.au) or the relevant committee secretary.