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Senate Community Affairs References Committee Inquiry into Excess Mortality

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Executive Summary

The Australian Medical Professionals' Society (AMPS) is a collective of medical and allied health experts united by a core mission: safeguarding and advancing the interests of our members and their patients, while advocating optimal health outcomes across Australia. We deeply cherish the tenets of medical ethics, prioritising patient well-being through a commitment to our code of conduct consistent with the Declaration of Geneva and the International code of medical ethics issued by the World Medical Association. As staunch proponents of these values, AMPS enthusiastically embraces the chance to offer input to the Senate Community Affairs References Committee Inquiry into Excess Mortality.

This submission aims to provide a comprehensive and critical review of the management of the COVID-19 pandemic from both public health and medical perspectives, examining how these strategies have likely impacted Australia's current excess death statistics. This collaborative effort aims to shed light on the consequences of misguided decision-making during the recent pandemic, resulting in substantial medical, social, and economic costs to the Australian population. Despite overwhelming evidence suggesting physical and psychological harm from the government response, mandates persist, vaccine success is still proclaimed and promoted, and repurposed drugs remain discouraged. Doctors continue to face persecution and censorship for prioritising science over the government narrative.

The increased mortality rates observed in Australia in 2021 should have triggered an investigation with access to accurate raw data, medical notes, and autopsy results. Despite this urgency, on March 23rd last year, the Australian Senate voted against establishing a select committee into Australia's excess mortality. In response, the Australian Medical Professionals Society (AMPS) undertook its own inquiry, collaborating with national and international independent researchers. This investigation culminated in the publication of "*Too Many Dead: An Inquiry into Australia's Excess Mortality*."

This book highlights the silent crisis demanding attention for the health and safety of our families and our nation. It delves deep into potential causes, providing irrefutable evidence and demanding accountability, transparency, and justice.

Terms of Reference

From:
https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ExcessMortality47/Terms_of_Reference

Excess Mortality with particular reference to:

Index	Item	Chapter Reference
(a)	Australian Bureau of Statistics (ABS) data showing excess deaths in recent years, with particular reference to:	NA
(i)	all-cause provisional mortality data reported by the states and territories to the ABS, and	4,5,6
(ii)	the difference between all-cause provisional mortality data for 2021, 2022 and 2023 and the preceding years of 2015 to 2020 (inclusive)	4,5,6
(b)	factors contributing to excess mortality in 2021, 2022 and 2023	1, 2, 3, 4 ,5, 6, 7
(c)	recommendations on how to address any identified preventable drivers of excess mortality	1,2
(d)	any other related matter.	3

Chapters

Chapter 1 Unscientific pandemic responses, healthcare strain, and excess deaths in Australia: A brief analysis by Kara Thomas

Chapter 2 COVID-19 related excess deaths by Dr Andrew McIntyre

Chapter 3 Australian excess deaths: Insights from social listening suggest that injuries and deaths reported to the DAEN do not provide a full picture of COVID-19 vaccine effects by Rebekah Barnett

Chapter 4 The reporting, inaction, action, and investigation of Australian excess mortality by Clare Pain

Chapter 5 Excess mortality in Australia: an in-depth analysis of the numbers by Dr Andrew Madry

Chapter 6 Factors for consideration in the review of excess deaths in Australia: An evaluation of adverse event reports associated with the COVID-19 vaccines by Dr Suzanne Niblett

Chapter 7 Details of the undisclosed vaccinated deaths from the Pfizer COVID-19 vaccine trial at the point of approval by Dr Jeyanthi Kunadhasan

Chapter Summaries

Chapter 1

Unscientific pandemic responses, healthcare strain, and excess deaths in Australia: A brief analysis

by Kara Thomas

This brief review examines the effect of governmental responses to the COVID-19 pandemic on Australia's healthcare systems, and the surge in excess deaths. The analysis begins by showing the inconsistencies and lack of scientific foundation in Australia's pandemic management, leading to profound strain on healthcare facilities and critical staff shortages. AMPS proposes the rise in excess deaths could be partially attributed to delayed access to healthcare services, the mental health toll of prolonged lockdowns, and the neglect of vulnerable populations, including children and culturally-diverse communities.

The findings underscore the urgent need for ethical evidence-based decision-making, transparency in data management, and comprehensive reforms in pandemic responses. Addressing systemic deficiencies, such as critical staff shortages and inadequate mental health support, is crucial to mitigating the long-term consequences of the pandemic. By prioritising these reforms and embracing a holistic approach to public health, Australia can emerge from the pandemic stronger and more resilient, ensuring the wellbeing of its citizens and the sustainability of its healthcare systems.

Chapter 2

COVID-19 related excess deaths

by Dr Andrew McIntyre

This paper examines the excess deaths related to COVID-19 in Australia, particularly focusing on the factors contributing to mortality rates and the effectiveness of public health policies. Despite high vaccination rates, COVID-related deaths persisted, suggesting vaccine failure in preventing transmission and mortality. The study evaluates various factors influencing COVID mortality, including age, obesity, comorbidities, and immunosuppression, and it highlights the failure of public health measures to address these risk factors adequately. The inquiry questions the effectiveness of a vaccine-centric approach and explores the potential benefits of alternative treatments such as early treatment with drugs like Hydroxychloroquine and Ivermectin, and supplementation with Vitamin D, Vitamin C, and Zinc. Real-world data from countries using Ivermectin and Vitamin D supplementation show promising results in reducing COVID mortality. The paper also discusses a complaint made against the Chief Medical Officer regarding misinformation about Ivermectin, underscoring the need for accountability and transparency in public health messaging. Overall, the paper calls for a revaluation of public health policies to mitigate COVID-related deaths and improve outcomes.

Chapter 3

Australian excess deaths: Insights from social listening suggest that injuries and deaths reported to the DAEN do not provide a full picture of Covid vaccine effects

by Rebekah Barnett

This report is prepared by Rebekah Barnett, an independent journalist with a social science background (BA in Communications, Hons). While much of the health and mortality reporting during the period 2021-2023 relies on quantitative data, this alone cannot provide a complete picture. It is essential to collect and analyse qualitative data to fill the gaps, so that the Committee can achieve a holistic view of potential factors driving excess deaths in Australia during this period. The World Health Organisation (WHO) recommends the monitoring of community sentiment through 'social listening' as an important public health tool for informing actionable insights related to vaccine policy. The following section employs social listening to address point (b) in the Terms of Reference, with discussion of the Covid vaccination program as a potential contributing factor to excess mortality 2021-2023, and recommendations for further inquiry.

Chapter 4

The reporting, inaction, action and investigation of Australian excess mortality

by Clare Pain

In 2021, levels of excess deaths reported by the Australian Bureau of Statistics (ABS)'s Provisional Mortality Statistics (PMS), the only timely "indication of excess mortality", were the equivalent of 37 plane crashes with the loss of all 300 people on board. In 2022, the number of reported excess deaths increased to 85 such crashes.

In contrast to the normal investigation of a real plane crash, adequate action to investigate the cause(s) of the excess mortality does not seem to have been taken. One action taken by the ABS was the introduction in July 2023 of a new method of estimating excess mortality, which cut thousands off the estimates for each pandemic year. However, even that method gives numbers equivalent to 99 plane crashes from January 2021 to August 2023 (the most recent data available).

The ABS asserts that deaths "due to" covid were "the main contributor" to excess mortality during 2022. However, this appears to be based on a superficial analysis. Analysis here suggests covid was the cause of at most 29% of excess deaths in 2022. And if some deaths were inappropriately designated as from covid, as seems likely given the broad definitions of the ICD codes used, the proportion due to covid in 2022 was even lower.

If not covid, what were the underlying causes (as listed on death certificates) of the remaining 71% of the excess deaths? Analysis of data until the end of 2022, publicly available from the ABS, shows a rising trend in excess mortality over the pandemic (compared with 2015-2019 averages adjusted for population size) for a diverse range of underlying causes. These include musculoskeletal, endocrinological, neurological, mental health-related, genitourinary, gastroenterological conditions, deaths with abnormal findings, deaths from external causes, and cancer.

This analysis means that we must urgently seek the reasons for the rise in this 'non-covid excess mortality'. Three hypotheses are suggested for investigation. Meanwhile, covid deaths must not be dismissed as inevitable and we need to check that certain pandemic measures did not cause increased covid deaths.

To enable these analyses, highly granular raw data for all deaths during the pandemic, linked to vaccination records, needs to be made publicly available.

Chapter 5

Excess mortality in Australia: an in-depth analysis of the numbers

by Dr Andrew Madry

In the Australian Medical Professionals' Society (AMPS) publication "Too Many Dead", Part 4 (p273), we examined mortality in the state of Queensland in Australia up until the end of 2021 when there was no COVID-19 in the community. This made it possible to investigate trends in mortality without confounding by COVID-19 mortality. It was found that mortality in older age groups started trending upwards from the middle of 2021, from historical consistently lowering rates of mortality.

In this report further analysis is provided for consideration by the Australian Senate Excess Mortality Inquiry.

Estimates are made of the cumulative excess and the non-COVID excess mortality is identified. An official model is reviewed in detail and found to have serious problems. A variety of appropriate models are implemented. By the end of 2023 the non-COVID cumulative excess is found to be approximately 20,000 deaths with the cumulative value linearly trending upwards. This is equivalent to a fixed additional number of deaths each week above what should be expected. As of the end of 2023 there is no sign yet of this turning downwards.

We investigate patterns of mortality in the Australian data and find distinct events and patterns during 2021, when there no COVID-19 in the community, that never occur in the reference period used to model "normal" times.

Analyses are constrained by the limited data made publicly available. A section is devoted to the data that should be made available to independent analysts in the interest of transparency, given the disruptive changes enforced and affecting healthcare in Australia.

What is apparent from this analysis is that the introduction of the COVID-19 vaccines did not prevent death as the public were promised. The vaccines were mandated to stop transmission, prevent serious disease and death. Their contribution to excess deaths, both the COVID-19 deaths and unexplained excess requires further inquiry which can be supported by the other data provided in this submission by AMPS.

Chapter 6

Factors for consideration in the review of excess deaths in Australia: An evaluation of adverse event reports associated with COVID-19 vaccines

by Dr Suzanne Niblett

There is general agreement that excess deaths have occurred during the pandemic. What is still a matter of debate are the details regarding the number of excess deaths, the temporal profile of excess deaths, and the factors that may be contributing to excess deaths.

In this report, five models of excess death are reviewed. Estimates of excess death for the period from January 2021 to December 2023 were calculated to range between approximately 30,000 and 60,000.

The potential contribution of COVID-19 infection to excess deaths is examined and limitations of the diagnostic criteria for COVID-19 are discussed.

The potential role of COVID-19 vaccines to excess deaths is also reviewed through an evaluation of adverse event reports submitted to the Therapeutic Goods Administration Database of Adverse Event Notifications (DAEN) and the AusVaxSafety Program. Unprecedented numbers and rates of adverse event reports, including over one thousand deaths, have been associated with COVID-19 vaccines. A broad range of adverse events was noted that included adverse event terms from all MedDRA standard organ classes, and over 400 adverse events not previously reported over the 52-year history of the DAEN. The data collectively indicate that COVID-19 vaccines may be contributing to ill health and excess death in the population. Additional research is needed.

Chapter 7

Details of the undisclosed vaccinated deaths from the Pfizer COVID-19 vaccine trial at the point of approval

by Dr Jeyanthi Kunadhasan

At the point of consideration for the Pfizer Covid 19 vaccine approval in December 2020 by the FDA, there were more deaths in the vaccinated arm (six deaths) compared to the placebo (five deaths). This was contrary to the scenario presented publicly with more deaths in the placebo arm (four deaths) compared to the vaccine arm (two deaths). This was due to delays in recording deaths into respective patient's Case Report Forms and was in contravention to legal and ethical requirements of the clinical trial.

In the publicly available documents that formed the basis of the approval of the Pfizer Covid 19 vaccine, there is documentation that 2 vaccinated subjects loved ones had notified clinical trial sites of their loved one's deaths in an extremely timely manner. These deaths occurred prior to the data cut-off date but were not disclosed publicly. One of these subjects probably had an autopsy result available. The question must be asked of the TGA, did they come across the undisclosed deaths in the vaccinated arm of the study when they embarked on their vigorous examination of the data?

In my report, there is also a summary of efficacy and safety issues of the Pfizer Covid 19 trial. I have also alerted the TGA of the undisclosed deaths in the vaccinated arm of the trial and enclose my correspondence with Professor Anthony Lawler of the TGA.

Chapter 1
Unscientific Pandemic Responses, Healthcare Strain, and Excess Deaths in Australia: A Brief Analysis

Kara Thomas

Abstract

This brief review examines the effect of governmental responses to the COVID-19 pandemic on Australia's healthcare systems, and the surge in excess deaths. The analysis begins by showing the inconsistencies and lack of scientific foundation in Australia's pandemic management, leading to profound strain on healthcare facilities and critical staff shortages. AMPS proposes the rise in excess deaths could be partially attributed to delayed access to healthcare services, the mental health toll of prolonged lockdowns, and the neglect of vulnerable populations, including children and culturally-diverse communities.

The findings underscore the urgent need for ethical evidence-based decision-making, transparency in data management, and comprehensive reforms in pandemic responses. Addressing systemic deficiencies, such as critical staff shortages and inadequate mental health support, is crucial to mitigating the long-term consequences of the pandemic. By prioritising these reforms and embracing a holistic approach to public health, Australia can emerge from the pandemic stronger and more resilient, ensuring the wellbeing of its citizens and the sustainability of its healthcare systems.

Introduction:

The COVID-19 pandemic has undeniably challenged nations worldwide, testing the resilience of healthcare systems and the efficacy of governmental responses. In Australia, the management of the pandemic has been marked by inconsistencies, controversies and decisions that often lacked a solid scientific foundation. This brief overview critically examines the unscientific governmental responses to the pandemic in Australia, their repercussions on the healthcare sector, and their potential contribution to the surge in excess deaths. Additionally, it delves into recent reports highlighting the profound healthcare staffing crisis that has resulted since the declaration of the pandemic, the challenges posed by long COVID, and the increasing mental health burden, shedding light on the broader context of the pandemic's effect with respect to excess death statistics.

Unscientific Government Responses:

Australia's response to the pandemic has been marred by a series of unscientific and unjustified measures that deviated from previously established pandemic plans built on almost

100 years of scientific evidence[1]. From the onset, reliance on apocalyptic modelling and questionable data from China set a precedent for decisions that were not firmly grounded in scientific evidence[2]. Lockdowns, border closures and vaccine mandates were implemented without a clear understanding of their effectiveness or long-term consequences, deviating from established pandemic preparedness plans[3].

Political expediency often outweighed public health imperatives, leading to the marginalisation of dissenting voices and the suppression of legitimate concerns[4]. The narrative propagated by authorities instilled fear and compliance, sidelining ethical evidence-based approaches and eroding public trust[5]. There has been continued refusal to use evidence and transparent data to justify the way public health decisions were made. It was secret health advice that has led to increased hesitancy to trust any government health advice. This lack of transparency and accountability in decision-making has undermined the credibility of governmental actions, exacerbating the challenges posed by the pandemic[6].

The Effects on Healthcare Systems:

The apparent unscientific and arbitrary nature of governmental responses has placed unprecedented strain on Australia's healthcare systems. Public and private healthcare facilities alike have struggled to cope with staff shortages, delayed treatments and the diversion of resources to COVID-19 management. The consequences have been dire, with reports of ambulances ramping up, patients dying while awaiting care, and widespread short-staffing leading to bed block and increased surgery waiting times[789].

Many private facilities have closed under financial pressures resulting from an almost complete cessation of fee-for-service provisions such as elective surgery, as well as from other contributing factors such as rocketing electricity costs and inflation. From *The Australian*:

> According to figures from the Department of Health, 71 private hospital services have closed in the past five years including 48 day hospitals, four psych hospitals and 17 overnight hospitals.

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[1] https://www.health.gov.au/resources/publications/australian-health-management-plan-for-pandemic-influenza-ahmppi
[2] https://covid19.public-inquiry.uk/wp-content/uploads/2023/10/19170952/INQ000280651.pdf
[3] Independent Panel Review into Australia's response to the pandemic
[4] Inquiry into the Health Practitioner Regulation National Law and Other Legislation Amendment Bill 2022 (the Bill)
[5] Communications Legislation Amendment (Combating Misinformation and Disinformation) Bill 2023
[6] https://www.spectator.com.au/2023/04/restoring-trust-in-public-health/
[7] https://www.9news.com.au/national/woman-dies-in-western-australia-amid-ambulance-staffing-crisis/013f1f5f-9760-4e79-a27d-abe36ca5d388
[8] https://www.9news.com.au/national/man-dies-heart-attack-waiting-half-hour-ambulance-adelaide-south-australia/
[9] https://www.9news.com.au/national/queensland-grandmother-left-seven-hours-waiting-for-ambulance/170ddafb-95dc-4f2b-b95d-974e3228c09d

> At least six private hospitals have closed in the past 16 months, heaping pressure on surrounding public hospitals, while workforce issues have forced the closure of more[10].

Since the declaration of the pandemic, 75,000 highly trained healthcare staff have left the system[11]. That translates to one in five staff leaving, and reports indicate that close to 50% of nursing staff in QLD are considering leaving in the next 12 months[12]. We now have fewer nurses and doctors than we had nearly two decades ago[13]. With an already struggling system, this exodus could push it to the brink of collapse. The result is regular reports of people dying while awaiting surgery, ambulances being ramped up, and patients awaiting care which will only get worse as the system tries to do more with less.

Increased work absenteeism as a result of long Covid is another potential contributing factor to staff reduction and pressure on the system. There have been reports of increased sick leave coincident with the vaccine mandate and Covid-19 community spread[1415]. Long COVID is the persistence of symptoms >12 weeks after the initial severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. The *Australian Journal of General Practice* recently discussed concern that COVID-19 vaccination *per se* might contribute to Long COVID, giving rise to the colloquial term 'Long Vax(x)'[16]. *The Australian Journal of General Practice:*

> One in five of those experiencing long COVID in the UK stopped working and was not back to work six months after disease onset. In Australia, an estimated 240,000 of those with long COVID no longer work full time. Work absenteeism might significantly impact the nation's economy, as in the UK. In the US, long COVID has been declared a national emergency.[17]

Increased sick leave can be observed through the local experience of Buderim Gastroenterology Centre on Queensland's Sunshine Coast, a large specialty day procedure centre that analysed staff absenteeism following the implementation of government healthcare mandates. Dr. Andrew McIntyre, owner and director, stated:

> As a busy day surgery centre endeavouring to control spiralling operational costs, we observed a distinct rise in the rate of sick leave among full-time staff. Subsequently, we

[10] https://www.theaustralian.com.au/nation/politics/private-hospital-financial-crisis-prompt-closures/news-story
[11] https://www.couriermail.com.au/lifestyle/health/abused-stressed-and-overworked-nursing-in-crisis-as-workers-walk-away/news-story
[12] https://www.couriermail.com.au/news/queensland/qld-on-brink-of-mass-nurse-midwife-exodus-due-to-burnout-union-survey-shows/news-story
[13] https://www.couriermail.com.au/news/queensland/queensland-health-crisis-no-doctors-less-nursing-staff-than-a-decade-ago/news-story
[14] https://www.dailymail.co.uk/news/article-10710653/Queensland-Covid-Spike-triple-zero-calls-Covid-hospitalisations-hit-new-high.html
[15] https://www.medrxiv.org/content/10.1101/2022.12.17.22283625v1.full
[16] https://www1.racgp.org.au/ajgp/2024/april/long-covid-sufferers-can-take-heart
[17] https://www1.racgp.org.au/ajgp/2024/april/long-covid-sufferers-can-take-heart

conducted a retrospective analysis of the sick leave data and noticed a substantial difference in the rate of sick leave between vaccinated and unvaccinated staff, with vaccinated staff experiencing 2.4-2.5 times the rate of sick leave. When applied across the entire healthcare landscape, this represents an enormous cost to the system and is reducing the availability of healthcare services.

According to the Australian Register of Therapeutic Goods (ARTG), the only licensed indication for all COVID-19 vaccines is for active immunisation to prevent COVID-19 disease[18]. It has, however, been well established from government reports that the mandated vaccines fail to accomplish their stated goal of stopping or measurably reducing the spread of SARS-CoV-2 from person to person[19]. There is also no licensed indication for prevention of severe disease and death, nor for prevention of long-COVID. Any claims that COVID-19 vaccines reduce risk of severe disease, death and long-COVID refer to off-label use.

The safety data are also severely lacking, with a complete absence of mid- to long-term safety evidence available[20]. Given the unknown risks and the evidence now linking vaccination to both serious adverse events[21] and long-term negative effects on the healthcare workforce, leading to individual health risks and systemic risks, such a control measure has likely caused more harm than benefit[22]. Transparent and comprehensive risk assessments should be undertaken in any future pandemics.

The Nurses Professional Association of Queensland (NPAQ) has highlighted the critical healthcare staffing crisis, citing burnout among nurses, imminent retirement cliffs, and the paradoxical situation of thousands of unemployed nurses mandated out of practice amidst the crisis[23]. These issues have been exacerbated by the pandemic, underscoring the urgent need for comprehensive reforms to address systemic shortcomings and ensure the sustainability of healthcare services.

Furthermore, the reduced availability of medical services outside of urban centres is also resulting in poorer health outcomes, as clearly seen in our perinatal mortality rates, which have doubled in the last four years[24]. The lack of specialist services in rural and remote areas,

[18] https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf
[19] Submission to the Education and Employment Committee COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023
[20] https://amps.redunion.com.au/covid19_evidence_based_information
[21] https://pubmed.ncbi.nlm.nih.gov/36055877/
[22] https://amps.redunion.com.au/amps-submission-to-the-senate-covid-discrimination
[23] https://www.aph.gov.au/Parliamentary_Business/Tabled_Documents/5660
[24] https://www.couriermail.com.au/news/queensland/qld-worst-state-for-perinatal-deaths-as-newborn-deaths-double-in-four-years/news-story

as well as reduced after-hours specialist or even medical coverage in those regions, poses a risk to population health and could be a contributing factor to excess mortality statistics[25][26][27].

The outcome of governmental responses to the COVID-19 pandemic on Australia's healthcare systems has been profound and far-reaching. The strain placed on both public and private healthcare facilities has led to severe staff shortages and delayed treatments. Additionally, the emergence of Long COVID has further strained the workforce, leading to increased work absenteeism and reduced productivity.

Immediate action is required to address the underlying issues facing Australia's healthcare systems. Failure to do so could have devastating consequences for both healthcare workers and the patients they serve. The need for transparent and comprehensive risk assessments in future pandemics is paramount.

Excess Deaths and Contributing Factors:

The rise in excess deaths observed during the pandemic can be attributed to a multitude of interconnected factors. Delayed access to healthcare services, including elective surgeries and specialist consultations, has undoubtedly played a substantial role in the increased mortality rate. Patients with chronic conditions or life-threatening illnesses have faced prolonged waits for treatment, leading to preventable deaths and exacerbations of existing health issues.

The mental health toll of prolonged lockdowns and social isolation cannot be overstated. Reports from various organisations, including the CHF and Anglicare Australia, highlight the profound psychological distress experienced by people during the pandemic. Rates of severe psychological distress have remained elevated, with the full extent of the mental health crisis yet to be realised. Dr Monique O'Connor emphasises the pressing need for a Royal Commission to examine the mental health harms arising from pandemic measures, citing worsening mental health indicators and increased demand for mental health services[28].

In addition, the effect of lockdown policies on vulnerable populations, including children, young people and culturally diverse communities, should not be overlooked. The Murdoch Children's Research Institute (MCRI) highlights the unique needs of children and adolescents that were often disregarded during the pandemic, leading to enduring

[25] https://www.theage.com.au/national/victoria/staff-shortages-trigger-regional-hospital-emergency-declarations-20220425-p5aftv.html
[26] https://www.theguardian.com/australia-news/2022/mar/31/warnings-staff-shortages-at-griffith-hospital-maternity-ward-leaving-mothers-in-pain
[27] https://www.abc.net.au/news/2022-04-14/queensland-health-crisis-locum-doctors-biggenden-hospital-bypass/100990770
[28] https://www.aph.gov.au/Parliamentary_Business/Tabled_Documents/5660

developmental impairments and an impending mental health crisis among the youngest members of society which will likely affect their lifelong health and wellbeing[29].

Conclusion:

The COVID-19 pandemic has laid bare the vulnerabilities of Australia's healthcare systems and the inadequacies of governmental responses. Unscientific measures resulting in critical healthcare staffing shortages reported to be as much as 20% of staff exiting the system since the beginning of COVID, challenges posed by long COVID, and increasing mental health burdens have collectively contributed to a surge in excess deaths and untold suffering. Addressing these systemic deficiencies requires a concerted effort from policymakers, healthcare professionals and the broader community.

It is imperative to prioritise evidence-based decision-making, transparency and accountability in pandemic responses. Reforms aimed at strengthening healthcare systems, addressing staffing shortages and investing in mental health support are urgently needed to mitigate the long-term consequences of the pandemic. By learning from the mistakes of the past and embracing a holistic approach to public health, Australia can emerge from the pandemic stronger and more resilient than before.

[29] https://www.aph.gov.au/Parliamentary_Business/Tabled_Documents/5660

Chapter 2

COVID-19 Related Excess Deaths

Dr Andrew McIntyre

Abstract:

This paper examines the excess deaths related to COVID-19 in Australia, particularly focusing on the factors contributing to mortality rates and the effectiveness of public health policies. Despite high vaccination rates, COVID-related deaths persisted, suggesting vaccine failure in preventing transmission and mortality. The study evaluates various factors influencing COVID mortality, including age, obesity, comorbidities, and immunosuppression, and it highlights the failure of public health measures to address these risk factors adequately. The inquiry questions the effectiveness of a vaccine-centric approach and explores the potential benefits of alternative treatments such as early treatment with drugs like Hydroxychloroquine and Ivermectin, and supplementation with Vitamin D, Vitamin C, and Zinc. Real-world data from countries using Ivermectin and Vitamin D supplementation show promising results in reducing COVID mortality. The paper also discusses a complaint made against the Chief Medical Officer regarding misinformation about Ivermectin, underscoring the need for accountability and transparency in public health messaging. Overall, the paper calls for a revaluation of public health policies to mitigate COVID-related deaths and improve outcomes.

Introduction

The rise in Australian excess deaths began before there was substantial community transmission of the virus. However, after COVID infection rates increased and community transmission occurred, the excess mortality accelerated, with COVID-related deaths becoming a substantial contributor to the excess death numbers.

This occurred despite high vaccination rates, and it is clear that the vaccination failed to prevent transmission, infection and death from COVID.

The question that needs to be examined is: Did our COVID response make the COVID-related mortality worse than it might have been? The data required to answer this question have not been made available to researchers, despite their existence in the vaccine, hospital admission and death statistics. Anonymised data that include ages, comorbidities, vaccination dates, vaccines administered, along with hospital admissions and deaths, would allow this to be examined and the true situation clarified.

Numerous factors, both proven and suspected, influence COVID mortality. These factors include:

1. Age – The mortality increases at least four-fold for each decade, being almost zero in children

2. Obesity
3. Hypertension/Cardiovascular disease
4. Diabetes
5. Immunosuppression – Proved to occur after vaccination
6. Antibody Dependant Enhancement – Vaccines can increase mortality with later variants
7. Vitamin D status – Normal Vitamin D levels markedly reduce covid mortality
8. Early treatment – Substantial evidence for a variety of repurposed drugs
9. Lockdown effects

In the Australian response, which was highly regimented by various authorities, virtually all of these factors were either ignored or suppressed in favour of a 'vaccine-only' strategy. This approach has the potential to exacerbate COVID-related mortality beyond what it might have been had these factors been implemented. When comparing Australian mortality rates, it's important to acknowledge that the main variant was Omicron, which is considered to have lower mortality compared to earlier variants present overseas.

Age-related factors:

Covid-19 differs from seasonal influenza in that it is highly age-sensitive with respect to mortality. In a paper published by John Ioannidis et al. in September 2022, these infection fatality rates (IFR) were published, sourced from multiple countries[1]:

> The IFRs had a median of 0.034% (interquartile range (IQR) 0.013-0.056%) for the 0-59 years old population, and 0.095% (IQR 0.036-0.119%) for the 0-69 years old. The median IFR was 0.0003% at 0-19 years, 0.002% at 20-29 years, 0.011% at 30-39 years, 0.035% at 40-49 years, 0.123% at 50-59 years, and 0.506% at 60-69 years. IFR increases approximately 4 times every 10 years.

Similar differences based on age were known early in the pandemic. Despite this, Australia opted for a population-wide approach to protective measures and restrictions, regardless of age. This potentially resulted in inadequate protection for the most vulnerable, while harmful restrictions were placed on children and working-age adults. These harmful restrictions included economic effects, reduced sunlight exposure and exercise, and worsening dietary quality following a rise in processed food intake. These effects would have exacerbated other risk factors, increasing the risk of death from COVID.

Obesity related factors

Obesity, especially severe obesity, is a significant risk factor for COVID-related mortality[2]. Despite this, Public Health paid virtually no attention to this aspect of risk during the period between the pandemic being declared and widespread community transmission of COVID,

[1] https://pubmed.ncbi.nlm.nih.gov/36341800/
[2] https://pubmed.ncbi.nlm.nih.gov/33661992/

despite having more than 18 months to do so. The widespread lockdowns exacerbated obesity in the population, and there was no concerted effort to make the population aware of these risks and strategies to address the problem[3]. Access to services such as dieticians was restricted, and the availability of fresh food reduced, with a rise in the use of processed takeaway food exacerbating the problem. Rather than addressing this risk factor, public health measures exacerbated it, thereby increasing the risk of death when infection occurred.

Diabetes, hypertension and cardiovascular disease

These conditions all increase the risk of mortality from COVID infection and share common etiological factors, being diseases of insulin resistance/Metabolic syndrome, which are related to processed food intake. The pandemic measures increased the intake of processed food and reduced access to whole foods to varying degrees depending on the strictness of lockdowns. Medical services to manage these conditions were often severely restricted, resulting in suboptimal management and undetected new diseases in many people as a result of the lack of doctor visits[4]. Strong evidence is available that up to 60% of Type 2 diabetes can be safely reversed on Very Low Carb Ketogenic diets within a 12-month timeframe, a treatment now supported by Diabetes Australia[5]. Despite having more than 12 months available before community transmission appeared in Australia, there was no advice from Public Health to raise awareness of treatment options that could have been considered to reduce the risk of severe disease and death from COVID.

Immunosuppression

One of the most common side effects of the mRNA vaccines was the development of COVID infections before people were categorized as fully vaccinated. The combined effect of the lipid nanoparticles, mRNA and resultant spike protein production appears to reduce lymphocyte counts and the interferon response, among other immunologic effects, including the development of tolerance after booster shots through a switch to IgG4 antibody production. This appears to be especially the case with boosters, and the wave of COVID in Australia did coincide with peak vaccination rates and it continued through booster administration[6].

The potential exists that the obtunded immune response to COVID itself, along with the vaccine-related immune tolerance induced by the switch to IgG4 antibodies and immune imprinting to the original COVID strain, effectively made the immune response to the Omicron strain less optimal than in the unvaccinated population, potentially increasing death rates among the vaccinated. Evidence of this was observed in the New South Wales hospitalization and hospital death data, with an underrepresentation of the unvaccinated around February 2021.

[3] https://pubmed.ncbi.nlm.nih.gov/34460991/
[4] https://pubmed.ncbi.nlm.nih.gov/34837637/
[5] https://pubmed.ncbi.nlm.nih.gov/30291062/
[6] https://pubmed.ncbi.nlm.nih.gov/35436552/

Further analysis of this phenomenon is presented elsewhere in this report and is also covered in the affidavit prepared for a Queensland Judicial review of the COVID mandates[7].

Antibody Dependant Enhancement (ADE)

To quote from the referenced paper:

> "Thus, a finite, non-theoretical risk is evident in the medical literature that vaccine candidates composed of the SARS-CoV-2 viral spike and eliciting anti-SARS-CoV-2 antibodies, be they neutralising or not, place vaccinees at higher risk for more severe COVID-19 disease when they encounter circulating viruses. Indeed, studies in mice of prior SARS vaccines revealed this exact phenotype, with four human vaccine candidates eliciting neutralising antibodies and protecting against SARS challenge, but viral re-challenge of thus vaccinated animals resulting in immunopathologic lung disease[8]"

This is highly relevant to Australia, where significant community transmission occurred only with the Omicron variant, while the administered mRNA injections induced antibodies to the ancestral strain. There was no way to test for this in initial trials, and the postulated human trials of a vaccine for SARS-CoV-1 were not conducted because of adverse effects occurring in animal models. These tests spanned over seven years, unlike the accelerated testing of mRNA vaccines, which did not include this type of animal testing for adverse effects such as ADE.

Given that the New South Wales data suggest a lower hospitalization rate for unvaccinated patients, the possibility of antibody-dependent enhancement (ADE) occurring is real. Patient-level vaccination and hospital admission data are required to examine this non-theoretical risk, potentially exacerbating the COVID-related death rate in Australia beyond what it would have been had the vaccine not been used.

Vitamin D status

A recent systematic review and meta-analysis of Vitamin D in COVID confirms what many early studies had shown regarding the beneficial effects of normalising Vitamin D levels for the prevention of COVID, as well as for reducing the severity of the disease and ICU admission[9].

This paper shows "…vitamin D supplementation has a protective effect against the incidence of COVID-19 in RCT studies (OR 0.403, 95% IC 0.218, 0.747), in the incidence of COVID-19 in analytical studies (OR = 0.592, 95% IC 0.476–0.736) and in ICU admission (OR 0.317,

[7] https://www.doctorsagainstmandates.com/wp-content/uploads/2022/09/Expert-Witness-Report-Madry-15-Aug-2022-B.pdf
[8] https://pubmed.ncbi.nlm.nih.gov/33113270/
[9] https://www.mdpi.com/2072-6643/16/5/679

95% IC 0.147–0.680)." In the RCTs performed on HCWs, the overall reduction in risk in the population supplemented with vitamin D was approximately 80%.

Australia had ample time to ensure the population had their Vitamin D levels checked and corrected if low, which would have been expected to result in the documented improvements mentioned above. Public health authorities were informed about the issue of Vitamin D status, but no advice was issued to doctors or the public about the potential benefits, despite the low risk associated with supplementation. In fact, checking Vitamin D levels and supplementation were actively discouraged. This likely worsened the outcomes substantially.
Similar evidence exists for Vitamin C, Zinc, and other supplements, which were also discouraged by public health authorities. The inquiry needs to determine why these safe and inexpensive measures were not encouraged.

Early treatment

Australia effectively banned the off-label and off-patent use of some PBS-approved drugs for COVID, despite excellent safety and suggestive efficacy data. One potential contributor to the excess COVID deaths is the failure to take advantage of the reduced hospitalisation and death rates associated with drugs like Hydroxychloroquine and Ivermectin, among other treatments and supplements. There was a widespread public health failure to address known risk factors like low vitamin D and obesity, although doctors were free to recommend treating these problems to their patients. However, in the case of Ivermectin and Hydroxychloroquine, a government-imposed ban was in place, including, in some cases, the threat of prison sentences.

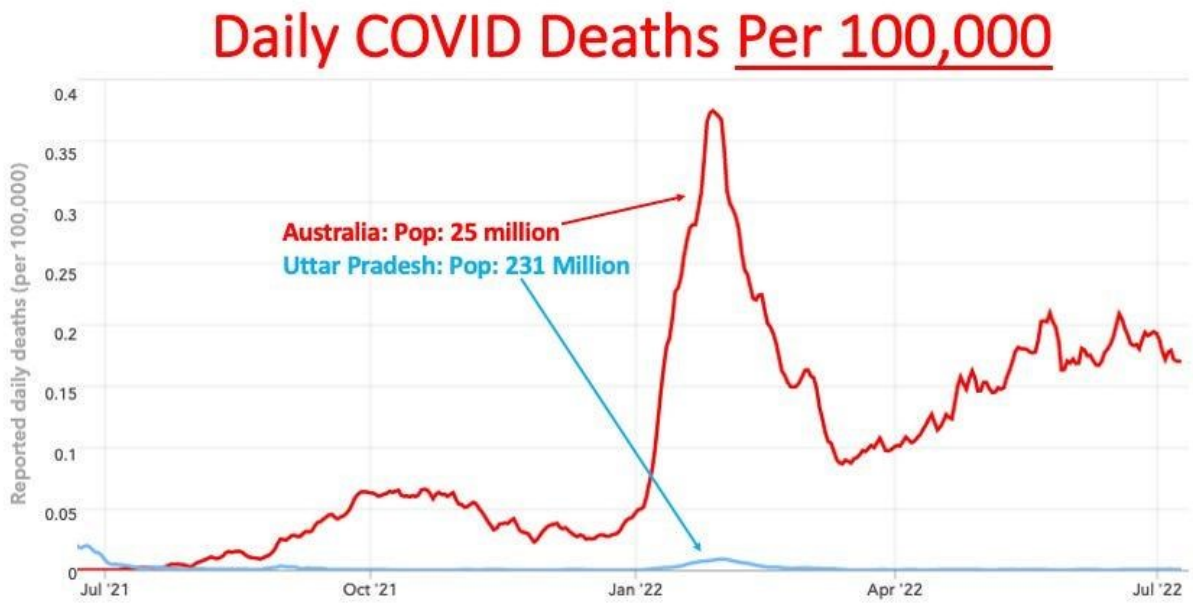
The inquiry should consider the possibility that the excess deaths from COVID would have been fewer had these treatments not been banned but encouraged. Hydroxychloroquine appears most useful in the early phase of the disease; however, Ivermectin has evidence of effectiveness as prophylaxis, early treatment, in the later inflammatory phase in severely ill hospitalized patients, and in long COVID. The effectiveness in reducing death is variously reported but is at least capable of causing a 50% reduction in fatal outcomes, a reduction that would have led to a substantial decrease in COVID deaths in this country.[10] More recently, the mechanism for the rapid improvement in oxygen levels in severely ill patients with COVID has been explained, and it is likely that the use of Ivermectin in ICU patients would have led to an improved outcome.[11]

The evidence for this in real-world usage comes from countries that did use Ivermectin as prophylaxis and for treatment. This includes Uttar Pradesh in India, Peru and Mexico City. The evidence of benefit is not in the form of double-blind controlled trials, a mechanism that is inappropriate in an emergency situation with low risks of treatment and a suggestion of benefit.

Uttar Pradesh is a state in India with a population of around 225 million and a relatively underfunded healthcare system compared to Australia. Based on early studies showing benefit, they began using Ivermectin in 2020, initially for prophylaxis in healthcare workers, and found

[10] https://pubmed.ncbi.nlm.nih.gov/35135310/
[11] https://pubmed.ncbi.nlm.nih.gov/38675987/

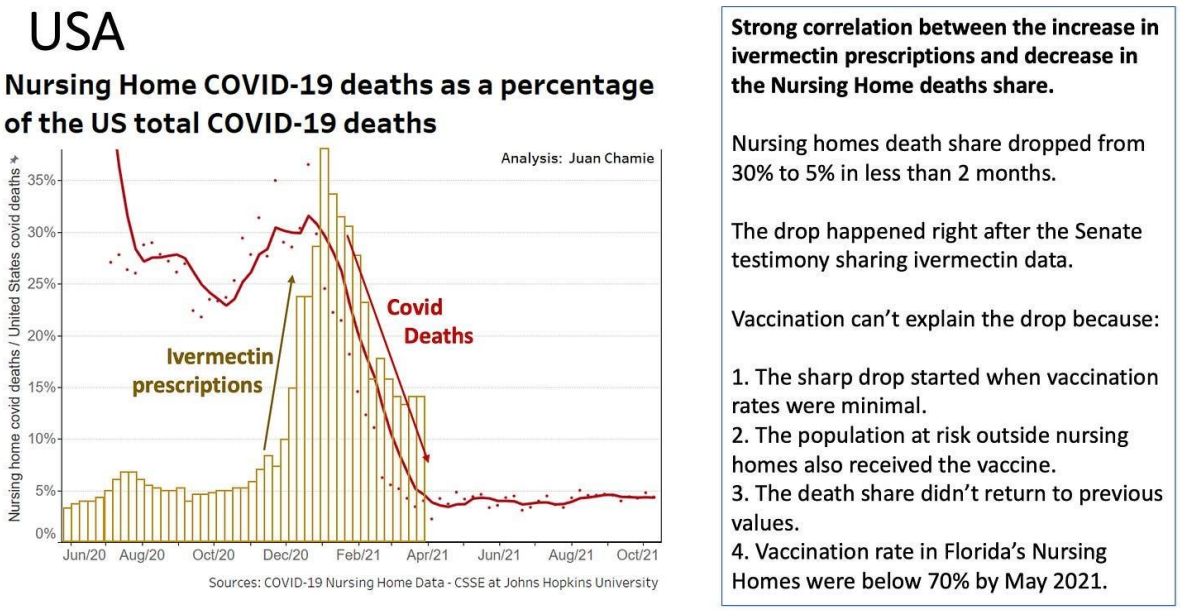
it highly effective. The use was later extended to patients and contacts, yielding impressive results with a very low death rate compared to Indian states using treatment protocols similar to those in Australia. This occurred despite a very low vaccination rate in Uttar Pradesh. A comparison of death rates is presented below:



Source: https://pierrekorymedicalmusings.com/p/the-miracle-not-heard-around-the

In a similar vein, a French nursing home, coincidentally using Ivermectin to treat a scabies outbreak, experienced a markedly reduced death rate compared to surrounding comparable nursing homes.[12] In the USA, nursing homes could directly source Ivermectin without going through a pharmacy, and there is a good correlation between Ivermectin use and mortality in US nursing homes. However, this has not been studied in detail.

[12] https://doi.org/10.3390/v16040647



Strong correlation between the increase in ivermectin prescriptions and decrease in the Nursing Home deaths share.

Nursing homes death share dropped from 30% to 5% in less than 2 months.

The drop happened right after the Senate testimony sharing ivermectin data.

Vaccination can't explain the drop because:

1. The sharp drop started when vaccination rates were minimal.
2. The population at risk outside nursing homes also received the vaccine.
3. The death share didn't return to previous values.
4. Vaccination rate in Florida's Nursing Homes were below 70% by May 2021.

The following is the complaint made about the CMO Professor Paul Kelly's statements about Ivermectin at a press conference on 2/9/2021:

> "At a national Press conference he categorically stated that there have been no positive trials for the use of Ivermectin. This is blatantly untrue, and would influence practitioners not to consider the treatment option potentially causing death in patients who may have potentially responded to the drug. The Chief Medical Officer should be aware of the many studies that show positive results and this represents either incompetent or is a false statement. A meta-analysis has been uploaded, there are many positive studies. Should he not support its use he should state that he does not believe there is enough evidence, but not deny that evidence exists. His behaviour undermines confidence in the Public Health response; it certainly causes me to question everything that has been stated by public health. Is it okay for the Chief Medical Health Officer to engage in misinformation?"

No action was initiated by AHPRA, although the basis of the complaint was not refuted, and no retraction has ever been issued. Given the potential reduction in mortality based on the evidence available at that time, along with the potential improvements with the use of cheap, safe supplements such as Vitamin D, public health policies need to be questioned over these serious failures.

Chapter 3
Australian excess deaths: Insights from social listening suggest that injuries and deaths reported to the DAEN do not provide a full picture of Covid vaccine effects

Rebekah Barnett

This report is prepared by Rebekah Barnett, an independent journalist with a social science background (BA in Communications, Hons). While much of the health and mortality reporting during the period 2021-2023 relies on quantitative data, this alone cannot provide a complete picture. It is essential to collect and analyse qualitative data to fill the gaps, so that the Committee can achieve a holistic view of potential factors driving excess deaths in Australia during this period.

This report addresses point (b) in the Terms of Reference, with discussion of the Covid vaccination program as a potential contributing factor to excess mortality 2021-2023, and recommendations for further inquiry.

In an unprecedented scenario, the Australian population was mass-vaccinated within a 12- to 15-month window during the Covid pandemic, starting from February 2021. The Australian Government reports that by the end of April 2022, 95.5% of Australians aged 16 and over and 80.4% of those aged 12–15 had been double vaccinated. Over two-thirds (69.3%) of eligible people had received a third dose. Among children aged 5–11, 52.8% had received their first dose, and 36.9% had received 2 doses.[1]

Despite keeping detailed records on vaccination rates and coverage, the Australian Government has produced no reports measuring the effect of this mass medical intervention on the health of Australians, as it pertains to either benefits or harms, including "non-specific effects."[2]

A study of the DTP vaccine in Guinea-Bissau, for example, found that it protected against the diseases of diphtheria, tetanus and pertussis, but at the same time was associated with a five-fold increase in child mortality compared to children who did not receive the vaccine, when controlling for background factors.[3]

Notably, data on all-cause mortality by vaccination status have not been made publicly available.

The Therapeutic Goods Administration (TGA) monitors safety concerns arising from the Covid vaccination program. As at April 16 2024, the TGA's safety surveillance database, the DAEN, had received 140,263 reports of injury and 1,021 reports of death in relation to Covid vaccine projects.[4]

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[1] https://www.aihw.gov.au/reports/australias-health/immunisation-and-vaccination#COVID
[2] https://www.bmj.com/content/355/bmj.i5170
[3] https://pubmed.ncbi.nlm.nih.gov/28188123/
[4] https://daen.tga.gov.au/medicines-search/

It is well established that passive surveillance systems, such as the DAEN, and combination passive-active surveillance systems, such as those run by Australia's states and territories, only reflect a portion of total injuries and deaths experienced within a population. This is called the Under Reporting Factor (URF). Estimates within the scientific literature indicate that the URF for vaccine-related adverse event reporting may be 10- to 100-fold, meaning that as few as 1% of adverse events experienced following vaccination may be reported to databases like VAERS and the DAEN.[5]

The URF of Covid vaccine-related injuries and deaths in Australia is unknown. In a Freedom of Information Act response, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) acknowledged that the true rate of Covid vaccine injuries and deaths is unknown, but was not able to provide an estimate of the URF.[6]

The TGA has not attempted to determine how many of the Covid vaccine-related injuries reported to the DAEN are causally linked to the Covid vaccines, instead assigning 'possible' causality to all injury reports. The TGA conducts no routine follow-up on injury reports, so it is unknown how many reported injuries resulted in death since the initial injury report was made.[7]

The TGA does not conduct active surveillance of subclinical injury, which, if unidentified and untreated, can cause sudden early death. A peer-reviewed study of mRNA booster effects found that 1/35 subjects sustained myocardial damage, yet most instances of damage were subclinical, and would therefore have remained unidentified and untreated in the absence of active surveillance.[8]

The TGA acknowledges only 14 deaths as causally linked to the Covid vaccines. However, the TGA has no protocol in place for autopsies to be carried out in cases of death temporally associated with Covid vaccination. Where autopsies have been used to determine cause of death following Covid vaccination, there is evidence that the vaccination is a sole or contributing cause in 73.9% of cases.[9]

Consequently, Australia's published data on Covid vaccine harms are insufficient to estimate the effect of the mass vaccination program on Australian health and excess deaths.

Social Listening

Because of the incomplete nature of official data on Covid vaccine harms, supplementation from other sources is required. Qualitative data generated by social listening can provide a thick description of the community experience of harms arising from the vaccination program.

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[5] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf https://i-do-not-consent.netlify.app/media/Pharmacovigilance%20VAERS%20paper%20FINAL_OCT_1_2021.pdf https://link.springer.com/article/10.2165/00002018-200629050-00003

[6] https://www.gov.uk/government/publications/freedom-of-information-responses-from-the-mhra-week-commencing-31-january-2022/freedom-of-information-request-on-the-mhra-figure-for-the-estimated-under-reporting-factor-urf-for-reports-of-vaccine-adverse-reactions-made-to-the

[7] https://news.rebekahbarnett.com.au/p/australias-drug-regulator-admits

[8] https://onlinelibrary.wiley.com/doi/10.1002/ejhf.2978

[9] https://zenodo.org/records/8120771

The World Health Organisation (WHO) acknowledges the importance of social listening in public health in a report titled, 'Finding the Signal through the Noise: A landscape and framework to enhance the effective use of digital social listening for immunisation demand generation'.[10]

Social listening is the practice of monitoring community sentiment through a combination of tools including conducting interviews, monitoring social media discourses, and other desk research.

The WHO, in partnership with vaccine alliance Gavi, says that social listening is an important tool for informing actionable insights related to vaccine policy.

In Australia, insights gleaned from social listening indicate that the scope of Covid vaccine injuries and deaths reflected in the national safety surveillance database, the DAEN, may just be the tip of the iceberg in terms of the real damage perceived within the community. Following, I discuss social listening findings from three social media case studies, followed by my experience as an interviewer for the Covid vaccine injury testimonies project Jab Injuries Australia.

Case studies

Three social media case studies demonstrate a disconnect between official messaging and reporting on Covid vaccine harm, and community sentiment.

First, an article published by the Herald Sun on 8 April 2024 titled 'Rise in compo claims from people including Victorian workers who had mandatory jabs for work.'[11]

In the comments section, readers have listed personal testimonies of injuries and deaths occurring with temporal nearness to vaccination, of which multiple commentors said they had not reported, and or had not sought compensation. Similar comments were found under the *Herald Sun*'s Facebook and Instagram posts about the article.[12] A selection of screenshotted comments can be viewed here.[13]

Contrary to official assurances that the injuries and deaths reported in the DAEN are reflective of the totality of suspected injuries and deaths sustained in relation to the Covid vaccination program, the comments under the *Herald Sun* article indicate that not all Australians have reported injuries and deaths that they believe to be linked to Covid vaccination.

While official sources state that most Covid vaccination side effects are mild and resolve quickly, multiple commenters discussed life-changing injuries rendering themselves or their loved ones unable to walk, work or participate in society. Some are actively looking to access euthanasia because of their suffering.

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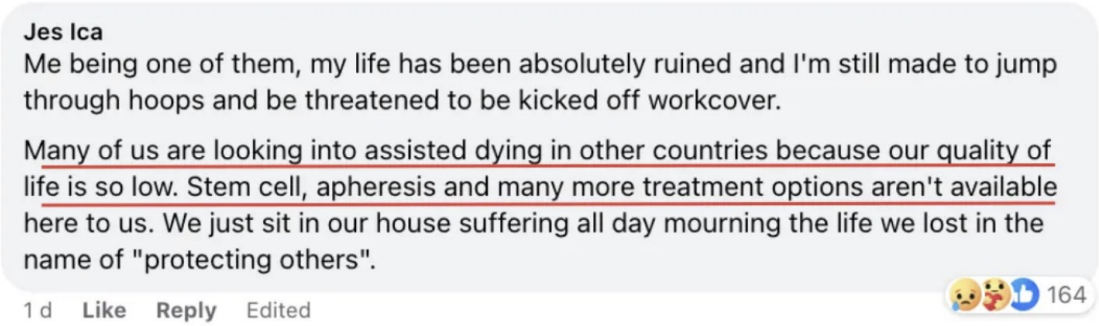
[10] https://www.gavi.org/sites/default/files/2021-06/Finding-the-Signal-Through-the-Noise.pdf

[11] https://archive.is/Uzwf1#selection-1721.0-1745.86

[12] https://www.facebook.com/heraldsun/posts/pfbid0qQNKZmMWdcHPwNi5NkieVdHyvjRnvrh7Pmz9uBJjpDZAispHS4HTZYspa3iNaAKcl

[13] https://news.rebekahbarnett.com.au/p/millions-paid-out-for-mandated-covid



Source: Facebook, Herald Sun

Second, a social media call-out by Nine News posted to Facebook on either January 10 or 11 2023 (precise date unknown as the original post has since been deleted) requesting that users who had experienced a heart attack contact the network. A screenshot of the post is included below.

Source: Facebook 9 News Sydney, now deleted

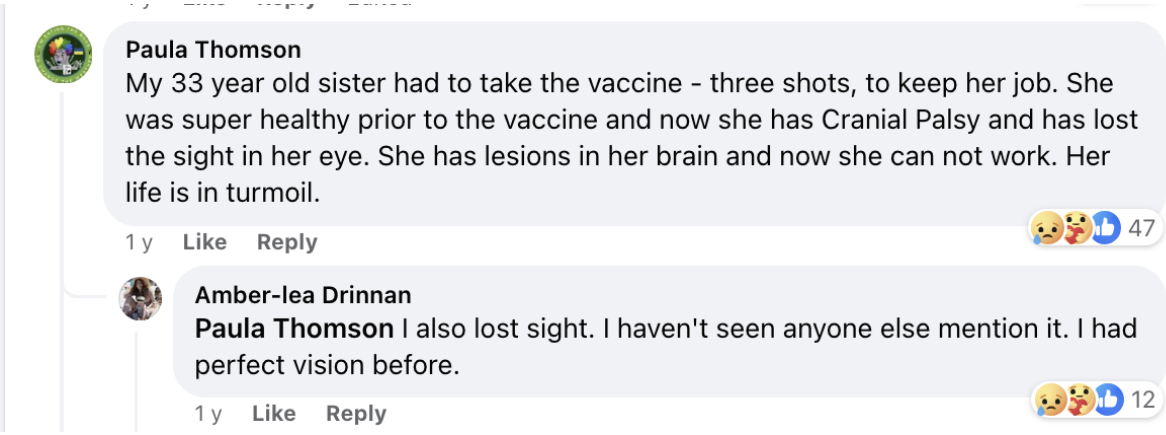
Comments under the post feature testimonies of people having suffered cardiac injury after Covid vaccination. A selection of screen-shotted comments can be viewed here.[14]

[14] https://news.rebekahbarnett.com.au/p/9-news-asked-for-people-to-come-forward

Within 24 hours, Nine News had deleted the post along with all the comments.[15] However, a subsequent post promoting a new vaccine, posted to Facebook on 11 January 2023, garnered over 500 comments, many expressing anger, from users wanting to know why the previous heart attack post had been deleted, and offering more stories of cardiac injuries from Covid vaccination. The post and the comments under it are available here.[16]

Commenters discussed not being able to get exemptions from future shots despite severe injury, having to see multiple doctors to get a diagnosis, and high saturation of apparent injuries within their social networks. Life-altering side effects were discussed. Some reported strokes and deaths of loved ones in close temporal proximity to Covid vaccination, where deaths were attributed to something else.

Importantly, a high proportion of comments expressed frustration at Nine News having deleted the heart-attack-related post, indicating that this issue is important to the community. Many comments also expressed doubts about the safety profile of the Covid vaccines.



Source: Facebook 9 News Sydney

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https://www.facebook.com/story.php?story_fbid=pfbid0BDmLhkVmnbKQQWr66D7b897ipTXuEwMVt21jDkUQ45PLVNUdybUDwtDCtqAHehJol&id=251142965231407&mibextid=qC1gEa&paipv=0&eav=AfZIt3kg0jiG2YUAPssZD_49QEjh00I1u5N2CfofFRE9pIDgYmZjZfB3kzT_td9dx_Q&_rdr

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https://www.facebook.com/story.php?story_fbid=pfbid02hhL5vhyx1w49oeh2VpYooTgrvg7CzA6nmEVLxfaxYefVDYxX9dz9WnHPUwrFaFqjl&id=251142965231407&mibextid=qC1gEa&paipv=0&eav=AfanGcikq9tDpjSijRmcVuf5yJoaQdsGTfD0cNnPa38GgtsBf6GWfl3BJ1_oAbCLuJg&_rdr

Third, an ABC news article title 'Did your period change after getting your COVID-19 vaccine? A new study suggests you weren't imagining it' was posted to the ABC's Instagram page in October 2022.[17]

The post garnered hundreds of comments within 24 hours, with women detailing their menstrual disorders after Covid vaccination, and expressing anger and frustrating at having been gaslit when they reported their symptoms to medical professionals or on social media. A sample of screenshotted comments can be viewed here.

Some commenters noted that the ABC specifically had participated in this gaslighting of women over their health, as evidence by a previous 'fact check' denying the link between Covid vaccines and menstrual disorders.[18] The ABC responded by deleting all the comments and closing the comments section to prevent further comments being added.

The reaction to this post on social media indicates that a high level of frustration and distress was felt within the community over menstrual disorders following vaccination being dismissed and not being taken seriously by medical professionals.

Interviews

In my own experience interviewing scores of Australians who suffered severe injuries in temporal relation to Covid vaccination as an interviewer for the testimonies project Jab Injuries Australia, I observed that most of my interviewees were dismissed multiple times by doctors before being taken seriously and finally receiving a diagnosis and proper treatment.

Interviewees reported that obtaining a proper diagnosis can take many months or even years, at great expense, and some abandoned this process because they could not afford the mounting costs. Most (if not all) interviewees reported that, aside from a routine administrative call to confirm personal details upon lodging their injury report, the TGA never followed up on their case. As many users find the DAEN difficult to navigate, some injury reports remain out of date without eventual diagnoses being updated. In some cases, neither the injured party nor their health professional made a report to the DAEN or the State or Territory vaccine safety surveillance system.

It was common for people presenting with shortness of breath to report that they were prescribed anti-depressants or anti-anxiety medication on numerous occasions before finally being given the appropriate tests to diagnose myocarditis, pericarditis, or other cardiac injuries arising from their Covid vaccinations.

Several parents of young people who died of mysterious, sudden-onset conditions soon after Covid vaccination reported that medical staff refused to note Covid vaccination as a potential contributing factor. In one case, a parent said that a coroner had verbally advised that they were not prepared to mention Covid vaccination as attributing cause of death on the deceased's official record despite there being no other plausible medical explanation for the young person's death.

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[17] shot-impacts-menstrual-cycles-periods-study/101485682

[18] https://www.abc.net.au/news/2021-04-30/coronacheck-menstruation-periods-vaccines-misinformation-facts/100099778

Interviewees often noted the stark contrast between the exceedingly high bar for attributing an injury or death to Covid vaccination, compared to the willingness of coroners and the medical profession to attribute an injury or death to Covid if a causal chain can be identified in temporal proximity to an infection.

Covid vaccine-injured Australians reported that they are unable to access effective treatment for their presenting conditions, as medical professionals don't understand their injuries or how to treat them, and there is a dearth of research for the injured and their doctors to refer to.

A selection of Jab Injuries Australia interview subjects who I have personally interviewed, and who faced difficulties in attaining appropriate testing, diagnosis and treatment include:

Duncan and Emma https://au.jabinjuriesglobal.com/duncan-and-emma-2/
Grace https://au.jabinjuriesglobal.com/grace-3/
Julita https://au.jabinjuriesglobal.com/julita/
Karri https://au.jabinjuriesglobal.com/karri/
Katie https://au.jabinjuriesglobal.com/katie-2/
Melanie https://au.jabinjuriesglobal.com/melanie-2/
Pete https://au.jabinjuriesglobal.com/peter/
Scott https://au.jabinjuriesglobal.com/scott-2/
Talida https://au.jabinjuriesglobal.com/talida/

Many more testimonies can be viewed on the Jab Injuries Australia website.

Insights

Through social listening on social media and in interviews, the following insights can be gleaned:

1. Australians feel that they have been dismissed and censored by the medical profession and the media when reporting their negative health outcomes following Covid vaccination.
2. Not all injured Australians or families of those deceased in temporal relation to Covid vaccination have reported these injuries and deaths to the passive safety surveillance systems. The true number of injured Australians is unknown.
3. The barriers to a person's obtaining the admission a Covid vaccine injury are high, with numerous Australians being misdiagnosed with psychiatric conditions before being given proper tests for physical injuries.
4. Medical professionals and coroners display an extreme reluctance to draw links to Covid vaccination where injuries and deaths have occurred with no other reasonable explanation.
5. Some injured Australians have suffered without proper care because they don't know that they can report their injuries and claim compensation to get adequate support.

In relation to excess deaths, the above insights suggest that it is plausible that:

a) Some the unexplained excess deaths may be due to Covid vaccination, whether reported to the DAEN or not.
b) Some of the unexplained excess deaths may be downstream of undiagnosed and untreated injuries arising from Covid vaccination.

Social listening in other countries

Surveys of the US population indicate that roughly half of the population believe they know someone who was injured by their Covid vaccination, and a quarter believe they know someone who was killed by their Covid vaccination. [19]

Conclusion and recommendations

It is essential that Australia's excess death inquiry take into account that the injuries and deaths reflected in the DAEN in relation to the Covid vaccines do not reflect the totality of deaths and injuries arising from the mass vaccination of the Australian population during 2021-2022.

The inquiry should reference other, supplementary forms of data in its attempt to answer the following questions:

1. What is the under-reporting factor of Covid vaccine injuries and deaths in Australia?
2. What is the total estimated effect of unreported injuries and deaths in temporal relation to Covid vaccination on Australia's excess death rate?
3. What effect has mis-diagnosed Covid vaccine injuries resulting in lack of appropriate care for life-threatening conditions had on Australia's excess deaths?
4. How many people who reported injuries to the DAEN in relation to Covid vaccines have since died, and how many of the deaths were related, either directly, or by causal chain, to the reported injury?

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https://www.rasmussenreports.com/public_content/politics/public_surveys/more_than_half_suspect_covid_19_vaccines_have_caused_deaths
https://www.researchgate.net/publication/359380328_The_role_of_social_circle_COVID-19_illness_and_vaccination_experiences_in_COVID-19_vaccination_decisions_a_representative_online_survey_of_the_United_States_population

Chapter 4
The reporting, inaction, action, and investigation of Australian excess mortality

Clare Pain

Introduction

Dear Senators,

Thank you for the important work you are doing in holding this Inquiry.

I entered the covid pandemic with over a decade's experience as a medical journalist working for a leading publication for doctors. As such I was versed in medical ethics and the norms of the medical world of doctors, academics and medical journals.

As we went through the pandemic I noticed concerning changes in the world of medical journalism. I could no longer ask academics questions about their research papers and expect a helpful reply – at least not if that paper was connected with the pandemic. Instead, such emails were ignored. I was also concerned by breaches of long-held tenets of medical ethics, such as: "first do no harm'; informed consent; no coercion to have a medicine; and extreme caution over use of medicines in pregnant and breast-feeding women.

I left my job as a journalist in December 2021. Since then, I have been running various projects to examine the effects of Australian governments' actions during covid, publishing these on my website www.clarityonhealth.org.

Since January 2023, I have been focussing on excess mortality both in Australia and overseas and am now well versed in this topic. Much of this knowledge has come through providing the statistical expertise for the website www.excessdeathstats.com whereby I have met (virtually) people from many countries with expertise in data analysis.

Since August 2023 I have concentrated on understanding how the Australian Bureau of Statistics (ABS) has been reporting excess mortality in Australia and was honoured to have a chapter on this topic included in the book *Too Many Dead*, produced by the Australian Medical Professionals' Society (AMPS).

This submission is in two parts.

Part 1 'Estimates, monitoring, action and inaction' concerns the way the ABS has estimated excess mortality, the way the Department of Health and Aged Care (the Department) appears not to have properly monitored or taken action on excess mortality and then gives an illustration of a simple way the Department could have monitored excess mortality using the Provisional Mortality Statistics (PMS).

Part 2 ‘Investigations of the underlying causes of excess mortality’ explores whether deaths from covid can explain most of Australia’s excess mortality (as the ABS states), notes a lack of detail of the ABS’s investigations, and describes a simple model that suggests there has been significant excess mortality from other underlying causes.

The word 'covid' in lower case is used for COVID-19 throughout this document, for ease of reading. Thank you for reading my submission.

Yours sincerely,
Clare Pain BSc (1st Class Hons, Chemistry), MSc (Operational Research)

PART 1: Estimates, monitoring, inaction and action

1.1 Australia has a serious problem with excess mortality: it’s equivalent to 99 plane crashes over the pandemic.

There is no definitive way of measuring excess mortality. It is an estimate calculated by subtracting an ‘expected number of deaths’ from the ‘actual number of deaths’ in a particular period.

Since actual numbers of deaths are pretty concrete, the choice of the method used to estimate the expected number is important because it determines the excess deaths estimate. For details of the three ways the ABS has estimated expected deaths during the pandemic, please see Appendix 1. Of note, each successive way of estimating excess deaths that the ABS has used has produced lower numbers.

From June 2020 until July 2023, the primary estimate of excess mortality provided by the ABS was the PMS. It provided information on numbers of deaths and gave a comparison with the ABS’s 'baseline' (their term for the estimate of expected deaths). It was also a timely indicator, with about a three-month lag in reporting which seems to be inherent in the process of collecting death records.

Although the ABS took care not to call these statistics excess mortality numbers, describing them as an “indicator of excess mortality”, the PMS was a valid excess mortality estimate, especially in 2020 and 2021. In those years, expected deaths in any week were estimated as the average of the deaths in the corresponding week in the five years before the pandemic (2015-2019). Incidentally, the OECD (Organisation for Economic Co-operation and Development) used a very similar method throughout the pandemic.

In July 2023, the ABS released what it now calls its “official excess mortality estimates” in a publication entitled “Measuring Australia’s excess mortality during the COVID-19 pandemic until the first quarter 2023”. This was updated in December 2023 and my understanding is that there will be updates every six months ongoing.

The table below shows the numbers of excess deaths calculated by the ABS for these two methods of estimating excess deaths.[1]

Table 1.

Excess deaths from the ABS' Provisional Mortality Statistics, ABS Official model and the OECD and translation into plane crashes							
Updated 6th May 2024 https:clarityonhealth.substack.com							
	2020	2021	2022	2023*	Cumulative to date	Cumulative to end 2022	Cumulative from 2021
PMS number of excess deaths (Ref 1)	1,621	11,068	26,185	17,184	56,058	38,874	54,437
PMS % excess mortality	1.0%	6.9%	15.9%	10.4%	8.6%	8.0%	11.1%
PMS excess mortality as plane crashes	**5**	**37**	**87**	**57**	**187**	**130**	**181**
ABS Official number of excess deaths (Ref 2)	-5,250	2,751	19,945	6,905	24,351	17,446	29,601
ABS Official % excess mortality	-3.1%	1.6%	11.7%	6.1%	3.9%	3.4%	6.5%
ABS Official excess deaths as plane crashes	**-18**	**9**	**66**	**23**	**81**	**58**	**99**
OECD number of excess deaths (Ref 3)	1,325	11,130	29,738	15,063	57,256	42,193	55,931
Notes:							
**Data for 2023 is not consistent as it is reported to different time points. The Provisional Mortality Statistics are to December 31st. The Measuring Australia's Excess Mortality is to August 27th and 28th May for Northern Territory data. OECD data is to week 38.*							
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-20			Ref 2				
https://stats.oecd.org/index.aspx?queryid=104676	Downloaded 28-02-24		Ref 3				

Note, in 2023 the various methods cover different time periods. While the PMS numbers are for the entire year, the official excess mortality estimates are only to 27th August for most of Australia and to 28th May for the Northern Territory, and the OECD estimates are to week 38.

Comparing like with like, the estimates of pandemic excess mortality to the end of December 2022 produced by the two methods the ABS has used are 38,874 deaths (PMS) and 17,446 (Official model). The OECD estimate is 42,193.

It is hard to grasp such large numbers of deaths and what they mean. To put them in context they are also reported here as the number of crashes of a plane of the size of an Airbus A380, assuming 300 people are on board and that all lives are lost. This translation is done not to be sensationalist, but to draw attention to the magnitude and importance of the problem.

According to the PMS, the excess mortality from January 2021 to December 2023 is the equivalent of 181 such plane crashes. According to the official model, the excess mortality from January 2021 to August 27th 2023 (the most recent data available at the time of writing) is the equivalent of 99 such plane crashes.

1.2 The Department may not have properly monitored the PMS, nor taken investigative action when excess deaths became apparent

The contrast between the approach taken to the excess mortality endured in Australia over the pandemic and the normal approach to even a single real plane crash is striking. A real plane crash is immediately and exhaustively investigated to determine the root causes and then actions are taken to eliminate or control risks or to protect people from them. But in the pandemic, according to the official estimates, extra deaths equivalent to at least 99 such plane crashes have been suffered and

three years after the first planes crashed, the work of this committee may be the first serious attempt to investigate them.

In manufacturing industry (of which I have experience) quality control is a serious matter, and statistical techniques are used to monitor when a product fails to meet specifications. As soon as a product becomes "out of spec", action is taken to get back within specification and to understand why things went awry. There is an analogous situation with excess mortality. In Australia, through the monthly PMS, the ABS put in place reports which could be used to alert the government if more deaths than expected arose. But was a monitoring system put in place by the Department of Health and Aged Care (hereinafter called 'the Department')? If so, when was this put in place? And what, if any, action was taken?

Senator Ralph Babet put a senate estimate question on notice [2] asking these questions with respect to 2021. I believe it did not answer the questions raised (see Appendix 2). In the Department's reply to Senator Babet, instead of telling us whether they had a system in place for monitoring and taking action on excess deaths shown in the PMS in 2021, they told us that the PMS was not the official way of measuring excess mortality. Surely they cannot be suggesting that it was acceptable to ignore the ABS's chosen estimate that indicated mortality consistently above the normal range, not just for a couple of weeks, but for *at least 18 months* until July 2023, when their 'official' measure was released?

And, when more deaths were occurring than usual in 2021, at a time when there were minimal covid infections but the new genetic covid vaccines were being rolled out, did the Department do any analyses to check that the vaccines were not causing the excess mortality?

For example, was work commissioned to look closely at mortality rates in the age-groups to which the vaccines were being rolled out, to ensure that there was no change in trend coincident or shortly after the rollout? Such an analysis has been done by Dr Andrew Madry for elderly people in Queensland in 2021 and I commend the committee to examine his findings.

It's important to note that these were not just new vaccines, they were a new *type* of vaccine, containing genetic material. No genetic vaccines had ever been used in Australia before, although a DNA viral vector vaccine (similar to Astra Zeneca's Vaxzevria) had been used elsewhere for ebola. Further, mRNA vaccines had never been used anywhere in the *world*. One would hope that the department was aware that, with new technology, may arise new (and perhaps unexpected) risks.

A similar argument can be made for the need for the Department to check that the lockdowns occurring in some states were not increasing mortality in 2021.

It is difficult not to suspect that no such monitoring was done and that no checks on whether either vaccines or lockdowns were responsible for the excess mortality in 2021 were done either. Further it appears that the government may have sat on its hands throughout 2022 and 2023 and the principal action taken was putting in place a new way of estimating excess mortality in July 2023. The Senators are requested to press the Department on these points.

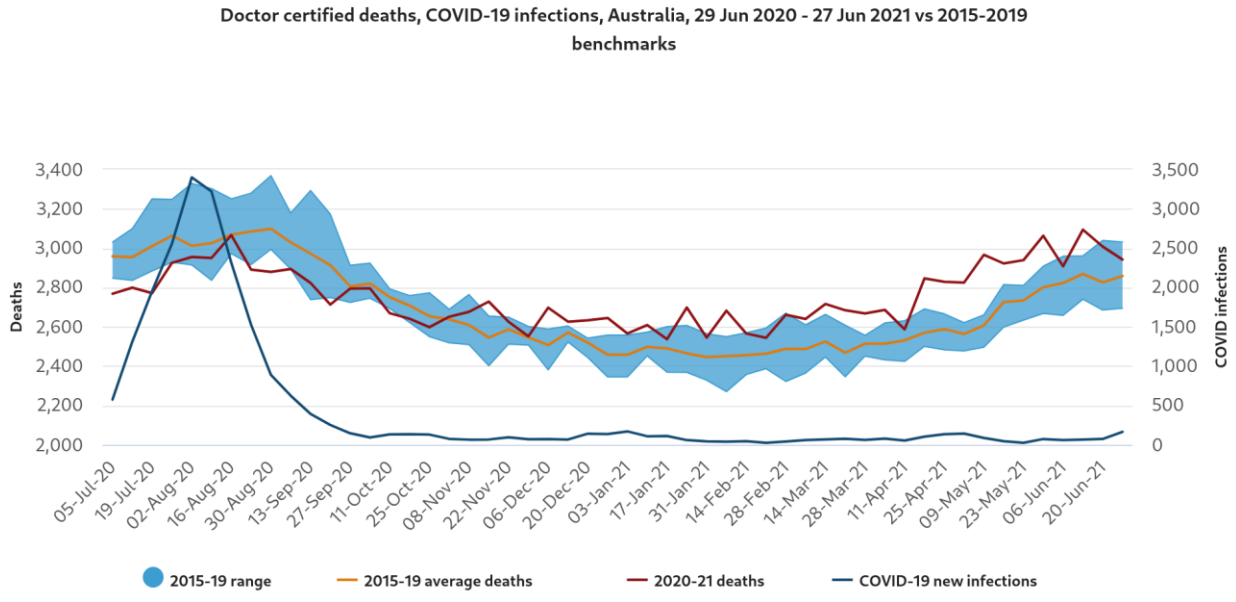
1.3. Rerunning the pandemic, when would a PMS monitoring system have triggered an alarm?

It's instructive to replay the pandemic looking at the information that was available to the Department from the PMS as we went through it. Let's also imagine they had set up a monitoring system that triggered action to investigate further if:

- Deaths were above the blue range on the PMS graphs for four weeks in a row
- And, the total number of deaths above the blue range over those four weeks equalled at least a plane crash (300 people or more)[3].

By 30th September 2021 information was available to all governments and the Department showing 6.2% excess mortality in the first half of 2021 and they could see the information in Graph 1 below and, of course, had the underlying data.

Graph1. Information available to governments on excess mortality at 30th September 2021



a. This graph is compiled by the date the death occurred.
b. This data is considered to be provisional and subject to change as additional data is received.
c. In line with the ISO (International Organization for Standardisation) week date system, weeks are defined as seven-day periods which start on a Monday. Week 1 of any given year is the week which starts on the Monday closest to 1 January, and for which the majority of its days fall in January (i.e. four days or more). Week 1 therefore always contains the 4th of January and always contains the first Thursday of the year. Using the ISO structure, some years (e.g. 2015 and 2020) contain 53 weeks.
d. Refer to explanatory notes on the Methodology page of this publication for more information regarding the data in this graph.
e. Data for the number of COVID-19 infections has been sourced from the COVID-19 daily infections graph published on the Australian Government Department of Health website. Data extracted 13 September 2021.

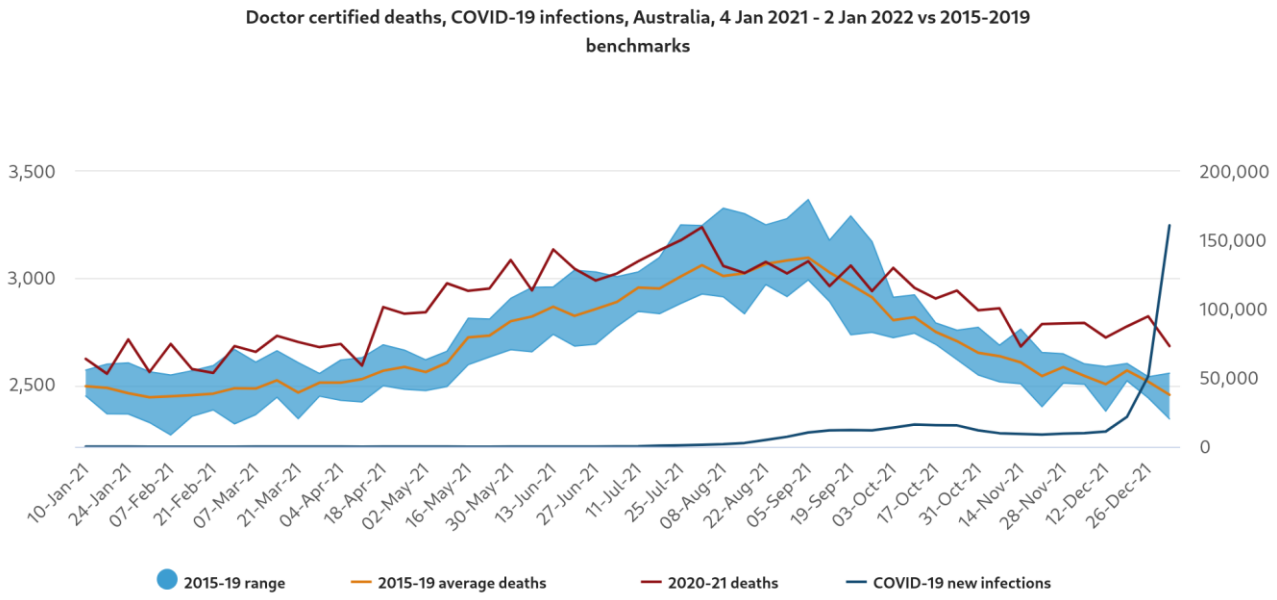
Source: Australian Bureau of Statistics, Provisional Mortality Statistics Jan 2020 - Jun 2021

Not only had deaths (the red line) been above expected levels (the yellow line) for all of 2021 to late June, but monitoring system triggers would have occurred on:

- 27th December 2020 (308 deaths in total above the blue line over the preceding four weeks)
- 4th April 2021 (306 deaths)
- each of the four weeks from 9th May to 30th May 2021 (761 deaths on average)

By 30th March 2022, the government had data for the whole of 2021 and could see Graph 2.

Graph 2. Information available to governments on excess mortality by 30th March 2022



a. This graph is compiled by the date the death occurred.
b. This data is considered to be provisional and subject to change as additional data is received.
c. In line with the ISO (International Organization for Standardisation) week date system, weeks are defined as seven-day periods which start on a Monday. Week 1 of any given year is the week which starts on the Monday closest to 1 January, and for which the majority of its days fall in January (i.e. four days or more). Week 1 therefore always contains the 4th of January and always contains the first Thursday of the year. Using the ISO structure, some years (e.g. 2015 and 2020) contain 53 weeks.
d. Refer to explanatory notes on the Methodology page of this publication for more information regarding the data in this graph.
e. Data for the number of COVID-19 infections has been sourced from the COVID-19 daily infections graph published on the Australian Government Department of Health website. Data extracted 9 March 2022.

Source: Australian Bureau of Statistics, Provisional Mortality Statistics Jan 2020 - Dec 2021

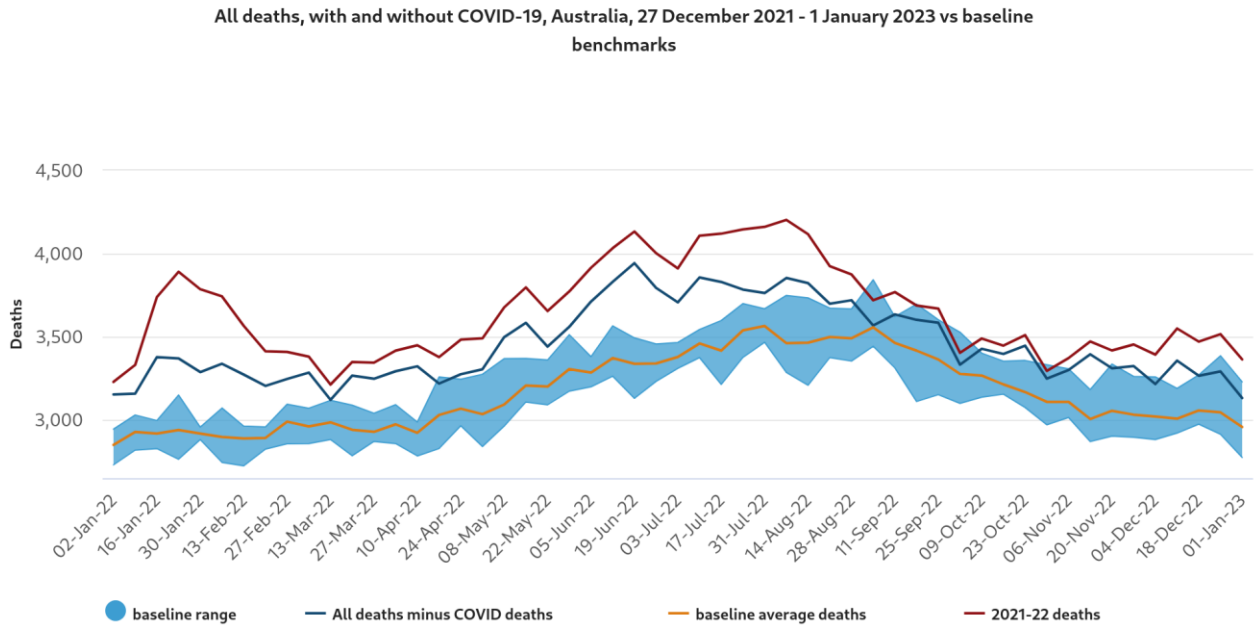
In addition to the triggers already mentioned for the first half of the year, monitoring system triggers would have been given:

- each of the three weeks from 24th October to 7th November (477 deaths on average)
- each of the five weeks from 12th December 2021 to 2nd January 2022 (686 deaths on average).

At this point action was taken by the ABS to introduce a new baseline for the PMS which would have the effect of reducing excess death estimates by 3,438 deaths a year, or 66 deaths per week.

A year later, on 30th March 2023 data were available for the whole of 2022 (see Graph 3) during which of course, the omicron variant had become endemic.

Graph 3. Information available to governments on excess mortality by 30th March 2023



a. Data is by occurrence.
b. Data is provisional and subject to change.
c. Weeks are defined as seven-day periods which start on a Monday as per the ISO week date system. Refer to 'Weekly comparisons' on the methodology page of this publication for more information regarding the data in this graph.
d. The baseline includes deaths from 2015-19 (for 2021) and from 2017-19 and 2021 (for 2022).

Source: Australian Bureau of Statistics, Provisional Mortality Statistics Jan - Dec 2022

As you will see, for this PMS release the ABS plotted a second line (in blue) showing 'actual deaths minus covid deaths' (it is unclear whether this included deaths 'with' covid). The implication was that covid deaths accounted for much of the excess mortality. As will be explained in section 4.3, this approach is flawed. However, if we (temporarily!) allow the Department to use this flawed approach, we can ask whether our hypothetical monitoring system would have produced any triggers as they used the blue line - which presumably was considered to be a measure of excess mortality.

The answer is yes, triggers for excess *non-covid* mortality would have occurred for:

- each of 12 weeks from 23rd January to 10th April 2022, (888 non-covid deaths over the preceding four weeks on average).
- each of 15 weeks from 15th May and 21st August 2022, (783 deaths on average)

What investigative action was taken? We have not been told of anything. **But on July 18th 2023 the ABS released its new way of estimating excess mortality that more than halved the number of excess deaths over the pandemic to the end of 2022 (see Table 1).**

In conclusion, a simple monitoring system would have produced warning signals as early as 27th December 2020, several triggers in the spring and autumn of 2021, and continual triggers for most of 2022. If non-covid deaths had been monitored in 2022, they too would have produced many weeks of triggers.

PART 2: Investigations of the underlying causes of excess mortality

2.1 Most of the excess deaths were not caused by covid

In this section arguments are developed that suggest that, rather than covid being "the main contributor" to excess mortality, as reported by the ABS, covid accounts for at most 29% of the excess mortality.

2.1.1 WHO rules and ICD codes for covid cast a wide net meaning covid deaths have been overcounted worldwide

Before we consider the proportion of excess deaths attributable to covid, it's important to recognise that deaths from covid have been, and continue to be, over-counted. This is the result of World Health Organisation (WHO) definitions and is not specific to Australia. This matters because, if covid deaths are over-counted , deaths from other causes are necessarily under-counted.

a) Covid trumps other conditions

A key WHO principle, which has been adhered to since 1948, is that, although several conditions may be put on a death certificate, every death is assigned a single underlying cause. Even on the latest International Classification of Disease (ICD) code website the WHO states: "It was agreed by the Sixth Decennial International Revision Conference 1948 (for ICD) that the cause of death for primary tabulation should be designated the underlying cause of death."

This underlying cause is given in part 1 of the death certificate, which may list a chain of directly causal events, or just one condition. Normally, if there is a chain of causal events that led to the death, the condition that came first (in time) is designated the underlying cause.

However, since April 20th 2020, the WHO has required that if covid is *anywhere* in the causal chain, it must be recorded as the underlying cause of death. Quoting from these WHO international guidelines for coding covid deaths: "A death due to COVID-19 may not be attributed to another disease (e.g. cancer) and should be counted independently of pre-existing conditions that are suspected of triggering a severe course of COVID-19."

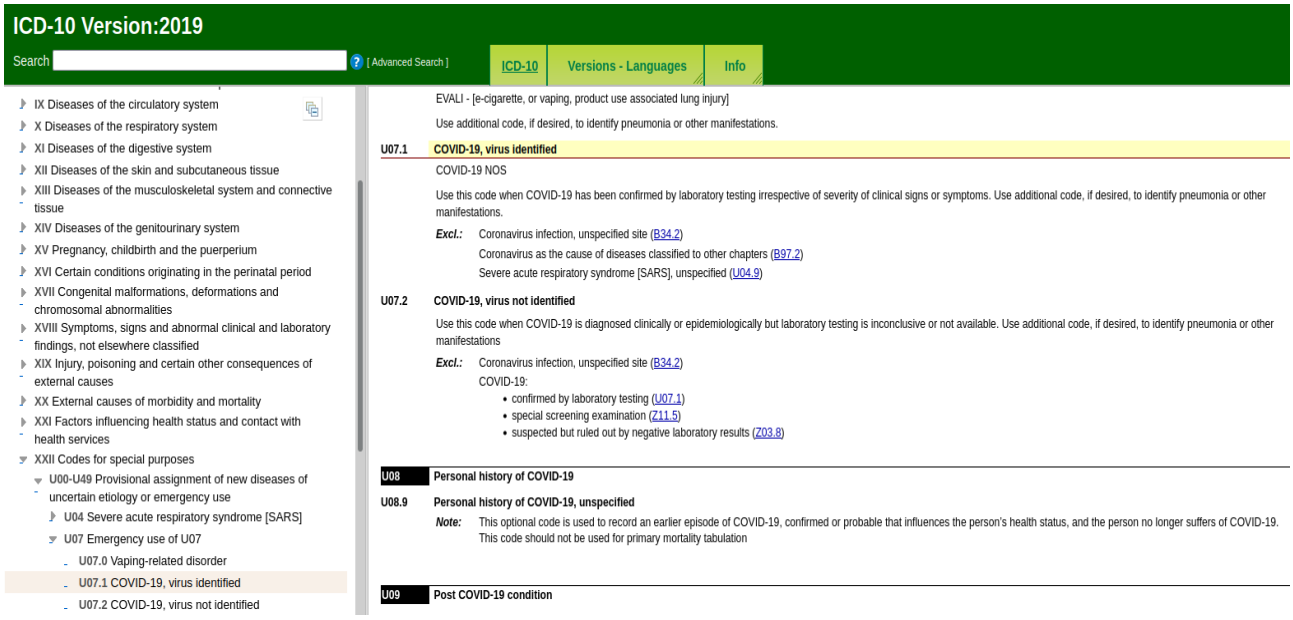
This means, for example, that a person who gets covid severely because they have HIV-AIDS or have had chemotherapy for terminal cancer, will be classified as dying from covid, not AIDS or cancer.

b) The ICD codes for covid are broad and designed to capture an emerging threat.

The ABS uses the International Classification of Disease (ICD-10) codes U07.1 and U07.2 when categorising covid deaths. Quoting from the ABS' most recent report on covid mortality

"All deaths due to COVID-19 in this report have been coded to ICD-10 code U07.1 COVID-19, virus identified or U07.2 COVID-19, virus not identified ..."

The screenshot below shows how these codes are defined



For code U07.1, the virus has been identified by PCR laboratory test, *irrespective* of the severity of signs and symptoms. Of note, PCR tests can be positive even if there are no viable viruses in the sample, but simply fragments of viral genetic material.

For code U07.2, covid has been diagnosed clinically although the virus has *not* been identified by PCR and in some cases the patient may have had an illness with similar symptoms, such as flu. Therefore, for *both* codes it is possible for the patient not to have had covid at all, or that covid was only mild and was not the real underlying cause of death.

Why are the ICD codes for covid defined to be so broad? Strangely, although covid has been with us for four years, the WHO has not yet given it International Classification of Disease (ICD) codes that put covid in "Chapter X – Diseases of the Respiratory System" which includes influenza. Instead covid is put in "Chapter XXII – Codes for special purposes" under a heading entitled "Provisional assignment of new diseases of uncertain etiology and emergency use". Amazingly, this special treatment of covid is continued in the latest version of the ICD code system, ICD-11.

Thus, it appears that the covid codes are broad because they were intended for use to help recognise an emerging threat in 2020. This approach may be reasonable for the purpose of triggering an early warning of a new disease for surveillance purposes, at a time when there are relatively few cases. However, I contend that such a broad categorisation of deaths is not justified for ongoing recording of official deaths statistics.

As a result of the WHO's definitions, it is possible that figures for covid deaths may be highly inflated, and the true causes of death may not be being reported.

2.1.2 Is a death from covid necessarily an excess death?

In the ABS's publication, 'Causes of Death, Australia' for 2022, the median age of death from covid is given as 85.8 years while the median age of death from all causes was only 82.2 years. This means that half of those who died from covid were older than 85.8 years. Further we are told that 33% of those who died from covid had a pre-existing cardiac condition. Thus, many of those who died from covid in 2022 were very old, frail, had comorbidities and might have been expected to die in that year anyway – if not from covid, from something else. It is therefore, I contend, not correct to categorise every death from covid as an excess death.

Is there a way some number could be put on the proportion of covid deaths that should be regarded as excess deaths? Work for the project www.excessdeathstats.com on Sweden provides a back-of-the-envelope estimate. In Sweden there were no lockdowns in 2020 and also, of course, the covid vaccines had not yet been introduced, so the excess deaths in Sweden in 2020 may provide a measure of how many covid deaths are truly excess deaths. There were considerably more covid deaths than excess deaths in Sweden in 2020, supporting the notion that covid deaths are not all excess deaths. Calculation (detailed in Appendix 3) suggests that, in Sweden, an upper bound of 56% of deaths from covid were excess deaths.

Would we be justified in using this number from Sweden in 2020 for Australia in 2022? Since Sweden was facing the more severe early variants while Australia faced the milder omicron variants, it's likely that a smaller proportion of covid deaths would be excess deaths in Australia. Further, Australians had been vaccinated, so should have been more protected from covid, and this might also be expected to reduce the proportion of excess deaths. Hence 56% is likely to be an *overestimate* of the proportion of covid deaths that contribute to excess mortality.

2.1.3 What analysis has the ABS done on covid as the cause of excess deaths?

In the commentary in its December 2023 update of its 'official' model for estimating excess deaths the ABS states: "Deaths due to COVID-19 (as identified on death certificates) were the main contributor to excess mortality during 2022. Excess mortality during this period corresponded with COVID-19 waves".

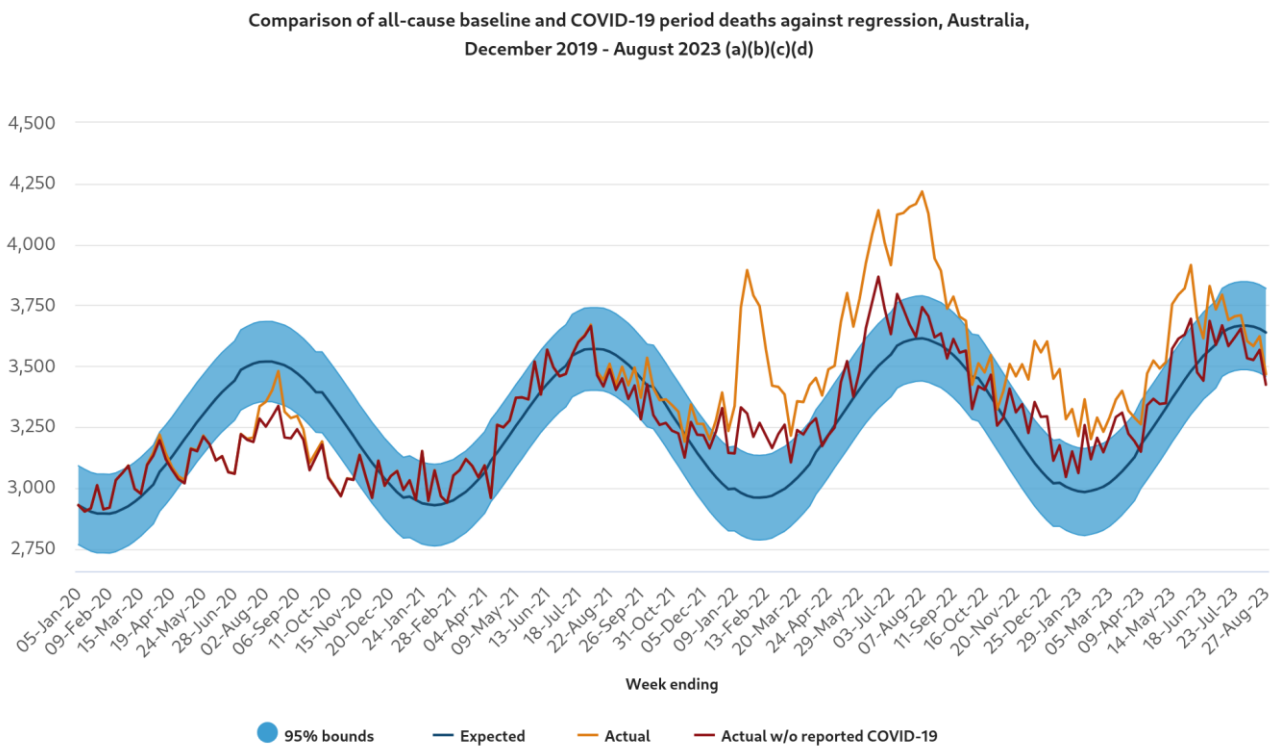
This statement is made seemingly with no supporting evidence, and, surprisingly for a statistical office, the proportion of excess deaths due to covid is not quantified. No evidence for the statement about correspondence with covid waves is presented either, although such a correlation would be required if covid deaths did form part of the excess mortality. Further, such a correlation does not demonstrate that a covid death is necessarily an excess death.

In that ABS report a graph is presented (Graph 4 below) that shows actual deaths in yellow, and a red line which is actual deaths minus deaths 'from and with covid'. (For much of 2020 and 2021 the yellow and red lines coincide). In presenting the data in this manner the ABS has, I contend,

produced a misleading picture. The red line should not be on the graph. The ABS should not be subtracting deaths *with* covid because that is in direct contravention of the WHO's long-standing principle "that the cause of death for primary tabulation should be designated the underlying cause of death."

Further, even in subtracting deaths *from* covid on their graph, the ABS is guilty of jumping the gun in assuming that every death from covid is an excess death. As argued in section 2.1.2, this is not necessarily the case at all, and at most 56% of deaths from covid should be counted as excess deaths.

Graph 4. Excess mortality over the pandemic as estimated by 'official' model



Source: Australian Bureau of Statistics, Measuring Australia's excess mortality during the COVID-19 pandemic until August 2023 18/12/2023

It thus appears that only a superficial analysis has been carried out by the ABS into the underlying causes of the excess mortality. At least, only superficial analyses appear to have been reported. The Senators are requested to press the ABS on this point. Their next official excess mortality release could for instance report excess mortality by underlying cause of death, using their new model to predict expected deaths.

2.1.4 Number and proportion of excess deaths due to covid

Because data are not complete for 2023, with ABS data for deaths from covid (reported to November) out of synchrony with ABS official estimates of excess mortality (reported to 27th August), I will concentrate on the 2022 data.

In 2022, there were 10,305 deaths from covid and the ABS estimates that there were 19,945 excess deaths using their official method. It is likely that the number of covid deaths is too high because of WHO definitions, but we will use it in the calculations to give an upper bound on covid's contribution to excess mortality. So, at first glance, covid might be considered as accounting for 52% of the excess mortality in 2022 (10,305/19.945 = 52%). (Recall the ABS described covid as "the main contributor" to covid deaths in 2022).

However, as explained above, not every death from covid is an excess death. If we assume an upper bound of 56% of covid deaths being excess deaths (2.1.2) then, at most, 5771 of the covid deaths were excess deaths. This suggests a maximum contribution of covid to excess mortality of 29% (5,771/19,945 = 29%). In other words, most of the excess deaths have been from something else.

A separate estimate using a simple model to estimate excess mortality by underlying cause of death done in 2.2.2 gives the excess mortality due to covid as 28%.

Hence the ABS's assertion that most of the 2022 excess mortality was due to deaths from covid needs to be challenged.

2.1.5 Covid deaths must be investigated too

There appears to be an assumption by the Department of Health that deaths from covid (whether excess or not) require no investigation.

The ABS reports a total of 16,472 deaths from covid during the pandemic to 30th November 2023. Most of these deaths (10,305) were in 2022, despite a highly vaccinated population and mild strains of covid. Why did so many people die? It seems likely that, if all these deaths had been in unvaccinated people, such findings would have been made public, but this has not taken place.

It is important that we know how the vaccinations affected the chance of dying from covid. We were promised they would protect us from death, but did they? What proportion of the deaths from covid were in people who had been vaccinated? Is it possible the vaccines made no difference? Is it even possible that being vaccinated multiple times *increased* the risk of death from covid? The latter suggestion is not without basis: the public assessment reports produced by the TGA when it provisionally approved the three genetic vaccines (Pfizer, Moderna and Astra Zeneca), all mentioned the "important potential risk" of VAED (Vaccine-Associated Enhanced Disease) including VAERD (Vaccine-Associated Enhanced Respiratory Disease) and required the

manufacturers to carry out further studies on this topic. In other words, the TGA recognised the possibility that vaccination could make covid *worse*.

Only by looking at data for all the deaths from covid in Australia since the vaccines were introduced, together with the vaccination history of those who died, will we be able to assess whether the vaccination program was indeed effective at preventing death from covid, as was claimed.

It's also possible that some of the covid deaths were caused by inappropriate treatment. For example, an analysis has suggested that many covid deaths in UK hospitals and aged care homes in the first wave were deaths, not from covid, but from end-of-life protocols given to elderly patients diagnosed with covid. In the US, questions have been raised about whether putting covid patients on ventilation treatment (for which some hospitals are alleged to have received financial incentives) or on remdesivir, might have killed some patients, rather than covid itself. We need to be alert to the possibility that some treatments used in Australia might have done more harm than good.

2.2 ABS data shows high non-covid excess mortality across a wide range of underlying causes in 2022

2.2.1 A simple model of excess mortality by underlying cause

A preliminary broad-brush attempt is made here to determine which categories of deaths, apart from covid deaths, were in excess in 2022. The source of these data is a spreadsheet download (Underlying causes of death, Australia) available from the ABS release 'Causes of Death, Australia, 2022'

An analogous approach is used to that employed by the ABS in the first two years of PMS statistics. In those publications, the average number of deaths in the five pre-pandemic years 2015-2019 was used as the expected deaths, or 'baseline', with which the deaths in the pandemic were compared, giving "an indication of excess mortality".

Here, average deaths for each major category of underlying cause of death (ICD-10 'Chapters') in those five years is used as the expected number of deaths in each category for the pandemic years.

A crude adjustment is made for the increase in population in the pandemic years compared with the average population during 2015-2019. This assumes that deaths increase in direct proportion to the population size. Of course, the age-structure of the population will be affected by immigration (which occurred in 2022), and this is not modelled here, but the crude approach probably overestimates expected deaths and thus excess mortality can be expected to be *understated* by this adjustment.

Results of excess mortality by major category of underlying cause of death are shown below, arranged in two tables. Table 2 is sorted by the *number* of excess deaths in 2022. Table 3 is sorted by the *percentage* of excess mortality in 2022.

Table 2.

Non-covid excess deaths sorted by number in 2022 ICD-10 Chapter categorising underlying cause of death	2015-2019 Average	2020 excess	2021 excess	2022 excess
Categories in excess in 2022				
CHAPTER XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	1,385	808	1,406	2,557
CHAPTER VI Diseases of the nervous system (G00-G99)	9,299	399	1,476	2,066
CHAPTER XI Diseases of the digestive system (K00-K93)	5,985	285	867	1,687
CHAPTER II Neoplasms (C00-D48)	47,578	-682	969	1,565
CHAPTER V Mental and behavioural disorders (F00-F99)	10,294	-234	505	1,333
CHAPTER IV Endocrine, nutritional and metabolic diseases (E00-E90)	6,865	195	694	1,313
CHAPTER XIV Diseases of the genitourinary system (N00-N99)	3,561	295	668	957
CHAPTER XX External causes of morbidity and mortality (V01-Y98)	11,078	-32	252	818
CHAPTER XIII Diseases of the musculoskeletal system and connective tissue (M00-M99)	1,416	-139	118	257
CHAPTER XII Diseases of the skin and subcutaneous tissue (L00-L99)	567	30	77	228
CHAPTER I Certain infectious and parasitic diseases (A00-B99)	2,648	-459	-188	195
CHAPTER III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)	518	-8	-3	13
CHAPTER XVII Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	642	-10	14	8
CHAPTER VIII Diseases of the ear and mastoid process (H60-H95)	14	-2	-2	6
CHAPTER VII Diseases of the eye and adnexa (H00-H59)	9	-2	0	3
TOTAL of categories in excess		2,013	7,047	**13,004**
Categories in deficit in 2022				
CHAPTER XV Pregnancy, childbirth and the puerperium (O00-O99)	11	-6	-1	-6
CHAPTER XVI Certain conditions originating in the perinatal period (P00-P96)	554	-70	-38	-70
CHAPTER X Diseases of the respiratory system (J00-J99)	15,040	-3,172	-2,089	-715
CHAPTER IX Diseases of the circulatory system (I00-I99)	43,944	-5,231	-3,066	-1,505
TOTAL of categories in deficit		-10,046	-5,386	**-2,295**
TOTALS	**161,409**	**-8,033**	**1,661**	**10,709**
NON-COVID excess mortality %		**-5.0%**	**1.0%**	**6.6%**

Table 3.

Non-covid excess deaths sorted by % excess in 2022 ICD-10 Chapter categorising underlying cause of death	2015-2019 Average	2020 % excess	2021 % excess	2022 % excess
CHAPTER XVIII Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	1,385	62.7%	106.0%	190.4%
CHAPTER XII Diseases of the skin and subcutaneous tissue (L00-L99)	567	9.7%	18.1%	40.2%
CHAPTER XIV Diseases of the genitourinary system (N00-N99)	3,561	12.6%	23.3%	32.7%
CHAPTER XI Diseases of the digestive system (K00-K93)	5,985	9.1%	19.0%	28.2%
CHAPTER VI Diseases of the nervous system (G00-G99)	9,299	8.6%	20.4%	28.1%
CHAPTER IV Endocrine, nutritional and metabolic diseases (E00-E90)	6,865	7.2%	14.6%	25.0%
CHAPTER XIII Diseases of the musculoskeletal system and connective tissue (M00-M99)	1,416	-5.5%	12.8%	24.0%
CHAPTER V Mental and behavioural disorders (F00-F99)	10,294	2.1%	9.4%	18.8%
CHAPTER XX External causes of morbidity and mortality (V01-Y98)	11,078	4.1%	6.8%	13.2%
CHAPTER I Certain infectious and parasitic diseases (A00-B99)	2,648	-13.0%	-2.6%	10.2%
CHAPTER II Neoplasms (C00-D48)	47,578	2.9%	6.5%	9.1%
CHAPTER III Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)	518	2.9%	4.0%	8.3%
CHAPTER XVII Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	642	2.8%	6.7%	7.1%
CHAPTER IX Diseases of the circulatory system (I00-I99)	43,944	-7.6%	-2.5%	2.4%
CHAPTER X Diseases of the respiratory system (J00-J99)	15,040	-16.7%	-9.4%	1.1%
CHAPTER XVI Certain conditions originating in the perinatal period (P00-P96)	554	-8.2%	-2.3%	-6.8%
Other Chapters excluded because too few deaths to be reliable (VII, VIII, XV)	34			
	161,409			

A preliminary analysis of these tables raises the following questions:

- In 2022 there appear to have been 13,004 more deaths than expected over a wide variety of non-covid causes. Why has this happened?
- In 2022 there was also a deficit of 2,295 deaths, mainly respiratory and circulatory deaths. Why? Could some of these have been misclassified as covid deaths?
- Why were respiratory and circulatory deaths so dramatically reduced in 2020 and 2021? One imagines lockdowns were involved, but why were circulatory deaths so reduced? Other factors to be considered are reduced testing for flu, changed practices in accessing health care.
- Why has there been a trend of increasing deaths in category XVIII (Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified) and why is that number almost three times higher than expected in 2022?
- Why were there large percentage increases in deaths in 2021 for diseases of the skin, genitourinary, digestive system, nervous and endocrine systems (ranging from 10.1% to 18.8%), and why are the percentage increases for all these conditions even greater in 2022 (range 18.1% to 32.4%)?
- Why were mental and behavioural disorders 4.9% greater than expected in 2021 and 12.2% greater than expected in 2022?
- Why were external causes of mortality 7.0% higher than expected in 2022?
- What effect have WHO definitions requiring that covid trumps other causes such as terminal cancer or AIDS had on the number of deaths in these categories?

Tables 2 and 3 show that the situation with excess mortality over the pandemic varies by underlying cause. Thus the reasons for excesses or deficits for each cause need to be analysed in detail and properly understood.

2.2.2 What proportion of excess mortality does this model suggest was due to covid?

The model shows 13,004 excess deaths from non-covid causes. The dataset (which was published in September 2023) reports 9,859 deaths from covid.

The model also shows a deficit of respiratory and circulatory deaths and deaths connected with pregnancy. We know covid is over-diagnosed because of WHO reporting rules, so let's assume that the respiratory deaths were incorrectly reported as covid deaths. Covid deaths are then reduced by 715 to 9,144. Probably some of the circulatory deaths were also wrongly assigned to covid, but we will assume none of them were.

Assuming 56% of covid deaths are excess deaths, this gives 5,121 excess deaths from covid.

Thus, the total mortality of conditions where it is in excess is 13,004+5,121 = 18,125 deaths. This is somewhat lower than the ABS's official estimate of 19,945. As noted earlier, the crude adjustment for population used in this simple model is likely to lead to an underestimate of excess mortality.

Hence, we can estimate that covid accounts for 5,121/ 18,125 = 28% of the excess mortality.

This figure is supportive of the 29% calculated in 2.1.4.

Notes

[1] In Table 1, for the PMS data, historical data has, as recommended, been downloaded from the most recent publication (30th April 2024, Spreadsheet entitled 'Deaths by month of occurrence 2015-2023'). This means the numbers may differ from those given in the original PMS releases.

[2] Senator Babet's question was number 448, Portfolio Question Number SQ23-002131 asked of the Department on 11th November 2023. The question and answer are given in Appendix 2.

[3] I am the first to admit that this hypothetical monitoring system has been suggested with the benefit of hindsight and thus may be biased, just as the ABS's official pandemic excess mortality estimates have been produced with the benefit of hindsight.

Appendix 1. The history of how the ABS has reported excess mortality over the pandemic

Summarising part of my chapter in the book *Too Many Dead* produced by the AMPS, the ABS's method of predicting expected deaths used in the PMS for 2020 and 2021 was simple, logical and transparent. Furthermore, the choice of the way to calculate expected deaths was made in advance of large numbers of excess deaths occurring. The main drawback with this approach was that effects of changes in population size and structure on expected deaths were not modelled. However, the ABS are to be congratulated for launching these statistics in June 2020 and providing reports on excess mortality in a timely manner as Australia went through the pandemic. For more detail see "Too Many Dead", p254, section 1.4.1.

Excess mortality was reported in the PMS for 2021. By 30th March 2022, when the full year's data were available, it was clear that there had been many consecutive weeks of excess mortality in the autumn and spring (Graph 2 in main text). At this time, the ABS changed the way they calculated expected deaths to a method that remained simple and transparent but appeared to lack logic. Further the ABS are likely to have been aware that their shift in baseline would *reduce* excess deaths by about 3,400 in 2022. The problems with this change are discussed in detail on p255 of *Too Many Dead*.

On 18th July 2023, after more than 18 months of continuous excess deaths visible in the PMS reports (Graph 3 in 1.3), the ABS changed its model again, moving to the 'official model' which more than halved the pandemic excess mortality to the end of 2022. This model is complicated and far from transparent. There are good points about it, which are described on pages section 1.4.2 (pages 255 and 256) of *Too Many Dead*. Because it uses age-specific death rates (deaths per population in specific age bands) it is able to cope with effects of immigration and changes in age structure, unlike the PMS model. Of course there was negligible immigration in Australia until 2022 because borders were closed, so this refinement is probably unnecessary for those years.

Further, valuable information revealed by this granular analysis is all lost when the results are aggregated and reported at a state or national level. In the interests of transparency the full details of the model, including these granular results, need to be made publicly available so that they can be examined by independent data scientists, statisticians and other researchers.

Since I wrote section 1.4.2 in the book, it has been suggested to me that the sinusoidal pattern of seasonality forced on the official model is bound to be inferior to the true pattern of seasonality (as used in the PMS models), and one wonders why the ABS have used this approach. My concern is that this forced sinusoidal pattern has removed the excess mortality in the autumn and spring of 2021 that was apparent in the PMS graph covering that year (Graph 2 in 1.3 above). No such periods of high excess mortality (outside the blue range) are seen in the spring and autumn of 2021 in the picture painted by the official model seen in Graph 4 (2.1.3).

The most serious criticism of the official model is that it was introduced after more than 18 months of consistently high excess mortality. The picture that the model gives of the pandemic in Graph 4 may thus be subject to bias (whether intentional or unintentional).

Indeed, the Methodology section of the report is vague on how the final model was selected from the various different models examined, but we are told in the section headed "Determining the baseline" that one model was rejected because "Even controlling for 2017, the model was overcompensating for the rate of decline during 2015-2019, resulting in a very low number of expected deaths in 2022 and 2023." In other words, it appears that the ABS had in mind a certain level of expected deaths for 2022 and 2023 and rejected a model (we are not told which one) because the predictions were too low. Of course, low expected deaths lead to high excess deaths. A model for Western Australia was rejected for the same reason. Shouldn't models have been rejected on more fundamental and logical grounds than that the forecasts they produced were 'too low'?

Senator Babet asked the ABS a question on notice about how the model was selected (2023-24, Additional Estimates, Economics Committee, Treasury Portfolio, question AET125). The question asked: "The ABS is requested to list the methods it considered, giving the cumulative excess deaths each method produced to the end of 2022, and list its reasons for selecting the particular method currently being used in the new model". The reply from the ABS said: "The ABS did not produce cumulative excess deaths for every method, rather it tested various aspects such as different reference periods for the baseline. The final decision was based on both robustness of methodology and appropriateness of the model in the Australian setting."

Appendix 2: Senator Babet's Question on Notice concerning monitoring of the PMS

Number 448, Portfolio Question Number SQ23-002131 put to the Department of Health and Aged Care on 11th November 2023

Senate Committee: Community Affairs Committee
QUESTION ON NOTICE
Supplementary Budget Estimates 2023-2024
Outcome: 1 - Health Policy, Access and Support
PDR Number: SQ23-002131
Question Subject: Monitoring excess deaths reported in the Provisional Mortality Statistics in 2021
Type of Question: Written
Senator: Ralph Babet
Question:
1.Monitoring excess deaths reported in the Provisional Mortality Statistics in 2021.
On 24th June 2020 the Australian Bureau of Statistics published its first release of the Provisional Mortality Statistics series, which included comparison of actual deaths data with expected deaths data. Until the release on 19th July 2023 of the now 'official' method of measuring excess deaths, the provisional mortality statistics provided the main publicly available measure of excess deaths. As Australia went through 2021, with minimal COVID-19 deaths for most of that year, the Provisional Mortality Statistics showed a consistent pattern of excess deaths at a level higher than the range of the five years before the pandemic (2015-2019). This occurred for many consecutive weeks during the Spring and the Autumn of 2021.
1.1. What, if any, monitoring system had the Department of Health put in place prior to or during 2021 to trigger some form of action, in the event that the ABS statistics were showing such levels of excess deaths for a number of consecutive weeks and when was this put in place?
1.2. What actions were planned in the event of excess deaths occurring over a number of consecutive weeks?
1.3. During 2021, did the Department of Health at any time consider the possibility that deaths from the new vaccines made by Pfizer, Moderna, and Astra Zeneca might be a contributor to excess mortality, noting that some of these vaccines employed an approach to vaccination never used in Australia before, that enlists the body's own cells to manufacture the spike protein of the virus in unknown amounts.

Answer:
The Department is monitors patterns of death using data from the Australian Bureau of Statistics (ABS) and other sources including the National Notifiable Diseases Surveillance System (NNDSS) and the Australian Institute of Health and Welfare (AIHW) National Mortality Database.

The ABS reports include provisional mortality reports, with mortality measured by assessing all-cause and cause-specific mortality, enabling the identification of changes over time. These reports form the primary national mechanism for understanding mortality in Australia, enabling further investigation and research as appropriate. The provisional mortality statistics published by the ABS are not official estimates of excess mortality as they do not take into account changes in

population size and the age structures of the population. Rather they provide an indication of where counts of death are above or below expectations.

The most recent report by the ABS on all causes of mortality shows that in 2023 there were 106,078 deaths that occurred by 31 July and were registered by 30 September. This is 12.1% more than the baseline average (2017-19 and 2021), but 5.1% fewer than in 2022. The age-standardised death rate (SDR) for July was 45.2 deaths per 100,000 people, below both the baseline average for the period (47.9) and the rate for 2022 (51.9).

On 17 July 2023, the ABS released official excess mortality estimates, exploring how the number of deaths which have occurred during the COVID-19 pandemic (2020-2023) compared to the number of deaths expected based on historical trends and adjusted for population changes. This includes deaths from all causes and not only those related to COVID-19. The ABS also found that COVID-19 was the main contributor to excess mortality in 2022 and COVID-19 associated deaths were still a key contributor to excess mortality in January 2023. The excess deaths reported for 2022 follow a period of low mortality in 2020.

There is no evidence that COVID-19 vaccines have contributed to excess mortality during the pandemic. Rather, the evidence shows that COVID-19 vaccines save lives and prevent the serious harm associated with SARS-CoV-2 infection.

Appendix 3. Using data from Sweden in 2020 to estimate the proportion of deaths from covid that are excess deaths

This appendix describes data obtained for the international project on excess deaths: www.excessdeathstats.com, for which I am the statistical coordinator.

Using a simple annual model for excess mortality that assumes the expected death rate in a pandemic year is equal to the average death rate in the five pre-pandemic years, 2015-2019, we have calculated excess deaths for Sweden in 2020. The data is sourced from the Swedish statistical authority, Statistics Sweden.

In 2020 Sweden did not lock down its citizens and covid spread through the country. As a result of the virus, and presumably of responses to it, Sweden experienced a 4.7% increase in death rate compared with that of the five pre-pandemic years. Using population data from Statistics Sweden, this can be calculated as equating to 4,369 excess deaths in 2020. However, data from the Swedish Health Agency shows that 10,085 people died 'from or with covid' in 2020. (Unfortunately, in the early years of the pandemic, deaths from and with covid were lumped together in most countries). Clearly, not every covid death was an excess death.

So, that gives a ballpark upper estimate of 43.3% of deaths 'from and with' covid being excess deaths (4,369/10,085 = 43.3%).

How does that translate to a proportion of deaths *from* covid? In Australia in 2022, 13,271 deaths were 'from and with' covid (10,305+2966). The figure for deaths from covid is taken from the PMS released 26th March 2023 and that for deaths with covid is taken from the covid mortality report released on 20th December 2023.

Thus, applying the Swedish estimate to deaths from and with covid in Australia we get 43.3% of 13,271 = 5,746 excess deaths.

Thus, the estimate of the percentage of deaths from covid that are excess deaths is 5,746/10,305 = 55.8%. We will round to 56% for use here.

Chapter 5

Excess Mortality in Australia: an in-depth analysis of the numbers

Dr Andrew Madry

Contents

1 Abstract 3
2 Background 3
2.1 Mortality Components – Trend and Seasonality 3
2.2 Models 4
2.3 Trend Fitting 4
2.4 Mortality Displacement 5
2.5 Australia's Life Expectancy 5
2.6 Analysis in this report 7
3 Recap of Queensland Mortality Analysis from AMPS "Too Many Dead" Publication 7
3.1 Queensland Mortality Analysis of Older Ages 7
3.2 Disposals in Queensland 9
3.3 TGA Adverse Events 11
4 Modelling 13
4.1 Excess 13
4.2 Cumulative Excess 13
4.3 COVID-19 Deaths 14
5 "Official" Government Model for Calculating Excess Mortality 18
5.1 Replication of the Official Model 21
5.2 Discussion on Years used for the Baseline 29
5.3 Seasonal Pattern 32
5.4 Error Modelling 36
5.5 Summary of Review of the "Official" Model 39
6 Top Level Annual Mortality Model 40
6.1 All-Ages 40
6.2 Is Year 2020 a Representative Year? 42
6.3 Individual Age Bands 43

6.3.1 Age 85 Plus 44
6.3.2 Ages 75-84 45
6.3.3 Ages 65-74 46
6.3.4 Ages 45-64 47
6.3.5 Ages 0-44 48
6.3.6 Age Specific Rate Trend 49
7 Patterns in the Mortality Data 50
7.1 Differencing 50
8 Modelling Cumulative Excess Mortality 56
8.1 All-Ages Analysis 56
8.1.1 The Curve Should Be Turning Downwards 61
8.2 Age-band Analysis 61
8.2.1 Age 85 plus 62
8.2.2 Age 75-84 63
8.2.3 Age 65-74 64
8.2.4 Age 45-64 65
8.2.5 Age 0-44 66
8.2.6 COVID-19 Deaths for Ages 0-44 70
8.3 Summary of Age Band Analysis 72
8.4 Calculation by Gender Ages 75-84 73
8.4.1 Males 73
8.4.2 Females 74
8.5 Uncertainty Estimates 75
9 ARIMA Modelling 76
9.1 All Ages Model 76
10 Data Transparency 80
10.1 Record Level Data 80
10.2 New Zealand Freedom of Information Request 80
10.3 Aggregated Data 81
11 Summary 84

1 Abstract

In the Australian Medical Professionals' Society (AMPS) publication "Too Many Dead", Part 4 (p273), we examined mortality in the state of Queensland in Australia up until the end of 2021 when there was no COVID-19 in the community. This made it possible to investigate trends in mortality without confounding by COVID-19 mortality. It was found that mortality in older age groups started trending upwards from the middle of 2021, from historical consistently lowering rates of mortality.

In this report further analysis is provided for consideration by the Excess Mortality Inquiry.

Estimates are made of the cumulative excess and the non-COVID excess mortality is identified. An official model is reviewed in detail and found to have serious problems. A variety of appropriate models are implemented. By the end of 2023 the non-COVID cumulative excess is found to be approximately 20,000 deaths with the cumulative value linearly trending upwards. This is equivalent to a fixed additional number of deaths each week above what should be expected. As of the end of 2023 there is no sign yet of this turning downwards.

We investigate patterns of mortality in the Australian data and find distinct events and patterns during 2021, when there no COVID-19 in the community, that never occur in the reference period used to model "normal" times.

Analyses are constrained by the limited data made publicly available. A section is devoted to the data that should be made available to independent analysts in the interest of transparency, given the disruptive changes enforced and affecting healthcare in Australia.

What is apparent from this analysis is that the introduction of the COVID-19 vaccines did not prevent death as the public were promised. The vaccines were mandated to stop transmission, prevent serious disease and death. Their contribution to excess deaths, both the COVID-19 deaths and unexplained excess requires further inquiry which can be supported by the other data provided in this submission by AMPS.

2 Background

2.1 Mortality Components – Trend and Seasonality

Time series analysis and forecasting is a mature field. There are also new techniques adapted from the field of machine learning which can be applied. A time series signal can be decomposed into components of:

- Seasonality
- Trend and
- Error

The Error is random variation, also called the remainder.

Seasonal means a variation on a fixed period. In this context, that is yearly. There is a pattern in mortality that tends to repeat each year, eg there are typically more deaths in Winter and fewer in Summer.

The decomposed components add together to equate to the actual time series. The aim of decomposition is to minimise factors contributing to the random component and make it truly random. From these components we obtain an understanding of a time series. We can then use the model for these components to forecast forward in time. This assumes the trend continues and seasonal variation is similar.

There are also other components that can be embedded in time series. Examples are cyclical components, which are non-regular variations. Such variations are often components of economic data. Other components are called exogenous components which means they are caused by external influences. The COVID-19 pandemic is such an external component that is not predictable.

Models are generated using data during what is considered “normal” times. These models can then be used to forecast into the future. In this application the models can be used to predict what would have happened had unusual events such as COVID-19 not occurred. Conversely the deviation of actual outcomes from the parameters of expected outcomes defined by the model can be used to determine the impact of the unusual event.

It cannot be denied that COVID-19 disease has had an influence on mortality. What can be argued is the accuracy of attribution of COVID-19 as the underlying cause of death and the actual numbers of deaths caused by COVID-19. The number of people dying from or with the disease has been identified from government-published data and even when taken as being correct we are left with the remaining excess. Other sections of this submission will identify possible contributors to this excess that need to be considered by the Inquiry. These include the physical and medical measures and the societal disruptions imposed by the government response to the pandemic.

2.2 Models

There are various types of models that may be applied to time series, eg:

- Classical
- Modern Machine Learning

Amongst the classical models is:

- ARIMA (Auto Regressive Integrated Moving Average)

ARIMA models have the advantage in providing insights into the underlying processes. Other models such as some of the machine learning models (eg neural network based) are more black-box, providing accurate models but providing limited insight into the factors driving the model.

The ABS has used a model known as the Serfling model, which is effectively what is known as a cyclic regression, where a sine wave is fitted to a seasonal pattern. Section 5 of this report is devoted to an analysis of the official model. Unfortunately, it is found that this is not an appropriate or useful model for the purpose of assessing excess mortality.

2.3 Trend Fitting

The trend is a crucial component of the model. We never really know what the true underlying trend of mortality data is. We can only make assumptions and generate a best fit

based on historical data. The simplest type of fit is a linear one. In many cases this is appropriate because of its simplicity. Depending on the length of the reference window for generating the model a linear fit may often be the best choice. We then predict into the future with the same line.

A linear trend is referred to as “monotonic” which is either constantly increasing or decreasing. A trend can have some curvature and also be “monotonic”, if it is either constantly increasing or decreasing. Including a “second order term” in the trend enables some curvature. In general, in mortality modelling no more than a second order fit is appropriate. A second order fit allows for a simple curvature. For both linear and curved fits the uncertainty becomes larger the further out prediction is performed. In particular, if there is a large curvature care must be taken.

In this report both linear and second order fits are allowed for, and the choice is specified depending on the context. There are other smooth curves that can be fitted for the trend but have not been implemented in the analysis for this report.

2.4 Mortality Displacement

There is a philosophical question about how to handle the effect on mortality caused by specific events such as a bad influenza season. One approach is that this is treated as an unforeseen event and models do not try to fit to this period.

However, if there is a bad season with higher deaths one year there is typically a deficit the following year. This is known as pull-forward effect. Some frail people who may have lasted a little longer have death hastened by a bad bout of flu.

A fundamental of this mortality data we are dealing with is that the event of death is irrevocably going to occur at some point in time, becoming more likely the older we get. Deaths of the elderly may be displaced as a result of external factors, but for those closer to the typical age of death that displacement may be minimal.

It is noted that the term displacement covers forwards and backwards displacement. If everything happens to be going well and there is a low virulence influenza season, that may lead to some people living a little longer than expected.

Appropriate models can handle these dynamics. We find that modelling of cumulative mortality is appropriate as this takes into account mortality displacement.

2.5 Australia’s Life Expectancy

The latest ABS report on Life Expectancy, at time of this submission, is found here:

https://www.abs.gov.au/statistics/people/population/life-expectancy/2020-2022

Life expectancy refers to the average number of additional years a person of a given age and sex could be expected to live, assuming current age-sex specific death rates are experienced throughout their lifetime.

Based on United Nations estimates for 2021, Australia was ranked 3rd in the world for Life Expectancy. The first was Monaco, followed by Japan. For males Australia ranked 2nd in the world and females ranked 6th. Considering Monaco, with a very small, wealthy population, is

not a fair comparator that means for large Western countries Australia effectively ranks first in the world for males and very high for females. This is an enviable position.

Climate, wealth, lifestyle and healthcare systems in Australia all likely contribute to this desirable outcome. Australia is in a privileged position, a "lucky country", some might say. However, it may not take much to disrupt the leaderboard if changes are made to the underlying factors that result in this position. One should not be surprised that Australia could be poised to drop in ranking given that many things have to be going right to have the longest life expectancy in the world.

Also, there may be vulnerable subpopulations, growing in size in a country, as a result of the disruptions, and that can be poised to tip the balance. Certainly, the pandemic measures had the greatest effect on those of lower socioeconomic status.

Many ad hoc, disruptive changes and interventions were instituted during the pandemic. They included physical measures such as lockdowns and new pharmaceutical medications, without long-term testing, mandated on the working classes. In both these areas Australia drove harder than many other countries. Victoria had the longest lockdown period of anywhere in the world and Australia has one of the highest vaccination rates driven by mandates.

From:

https://www.abs.gov.au/statistics/people/population/life-expectancy/latest-release#national

Life expectancy decreased in 2020-2022 for the first time since the mid 1990s.

- Life expectancy at birth for males was **81.2 years and 85.3 years** for females, a decrease of 0.1 years for both.
- Over the past decade, life expectancy increased by 1.3 years for males and 1.0 years for females.
- The gap in life expectancy between males and females is 4.1 years.
- Around 30 years ago (1992), life expectancy at birth was 74.5 years for males and 80.4 years for females, a gap of 5.9 years.

Note that a 3-year period is used for the life expectancy estimate. We can expect further drops in life expectancy once the years 2020 and 2021 drop out of reckoning.

For reference, the median ages of death for 2022 in Australia are found here:

https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022

In 2022 for all-cause mortality:

- The median age at death was **82.2 years (79.7 for males, 85.0 for females)**.

For those who died from COVID-19:

- Their median age at death was **85.8 years**. This is higher than the median age at death for all-cause mortality which was 82.2 years.
- Over half were male (5,484 male deaths and 4,375 female deaths).

It is noted by the ABS that life expectancy improvements in Australia have stalled:

https://www.abs.gov.au/media-centre/media-releases/covid-19-deaths-stall-life-expectancy-increases

It is a cause for grave concern if it turns out that this is not totally driven by COVID-19 disease.

2.6 Analysis in this report

Modelling by the author of this report was performed using the R programming language and Microsoft Excel.

3 Recap of Queensland Mortality Analysis from AMPS "Too Many Dead" Publication

3.1 Queensland Mortality Analysis of Older Ages

A data set was purchased from the ABS with 5-year age band mortality data. This included mortality for the State of Queensland. Key figures from the chapter by this author (Part 4, p273) are reproduced in this section. The purpose of the analysis was to identify when mortality started trending upwards in Australia, uninfluenced by attributions of deaths to COVID-19 disease.

The analysis showed the largest disturbance to mortality was seen in older ages. The age band 80-84 years is shown in Figure 1 below. In this case a trend measure is calculated as the one-year average of the previous year on a weekly basis. This window averages out the seasonal patterns over the yearly period. However, there is still some variation up and down as the magnitude of one season varies with the next. The influence of the 2017 influenza season is an example. This average trend measure (population adjusted) tracked downwards over time for older age bands. We know that rates of death in specific age bands were decreasing. We don't see it though in the oldest age bands. We hit an inevitable stop at the upper limits of age. Australia had an increasing life expectancy up till 2020 (see Section 2.5).

A linear fit can be made to this trend measure to provide a general underlying trend in mortality. We can subtract that trend to see the variation in mortality over time. Figure 1 shows this below.

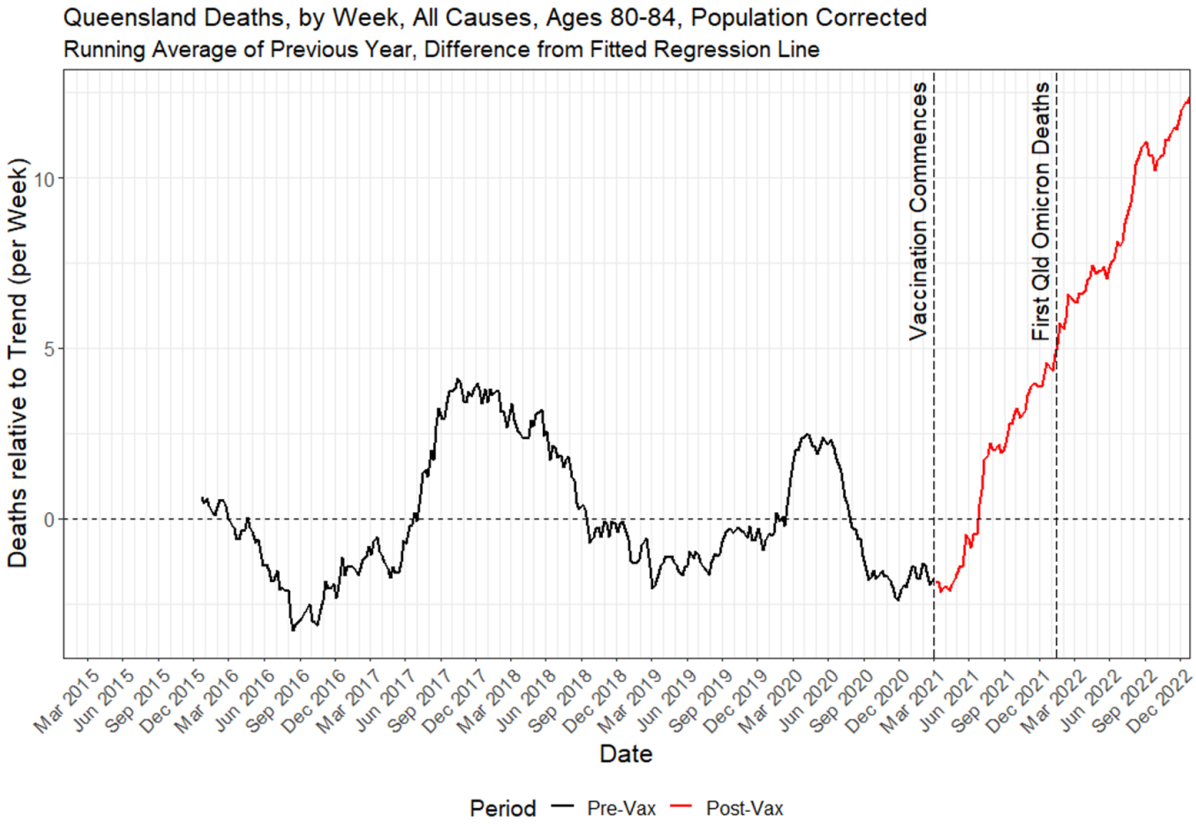


Figure 1. Mortality data for Queensland ages 80-84, with regression line through the one-year average trend values subtracted to show the variation from the underlying trend. Note data are population adjusted.

We see the mortality trend turn upwards from mid-2021 and it does not turn down again up to the end of the available data (end-2022 in this case). This cannot be explained by influenza deaths, pneumonia deaths or respiratory illness deaths as these were reduced in this group.

COVID-19 obviously had an effect on mortality from January 2022 onwards, but what is concerning is that we have seen a rising trend, not influenced by COVID-19, and not based on the seasonal reporting of influenza and pneumonia deaths leading up to 2022. Even though we know COVID-19 contributes to mortality from 2022 there is no physical reason why the factors driving this increasing trend in 2021 would suddenly stop and be replaced by COVID-19. Consequently, we expect a component of the trend upwards from 2022 onwards to be due to the factors already driving it upwards in 2021. One purpose of this submission from AMPS to the Australian Senate Excess Mortality Inquiry is to delve into this further. Estimates of non-COVID excess are made in Section 8, for data up till the end of 2023.

Figure 2 below shows Queensland mortality data for 5-year age bands from age 60 upwards. In this case the general linear trend has not been removed, so the trend downwards can be seen for these older ages. In this graph all the plots are lined up at their minimum value which occurs around March 2021. What is observed is that in all these ages bands, above age 60, the trend turned upwards in mid-2021.

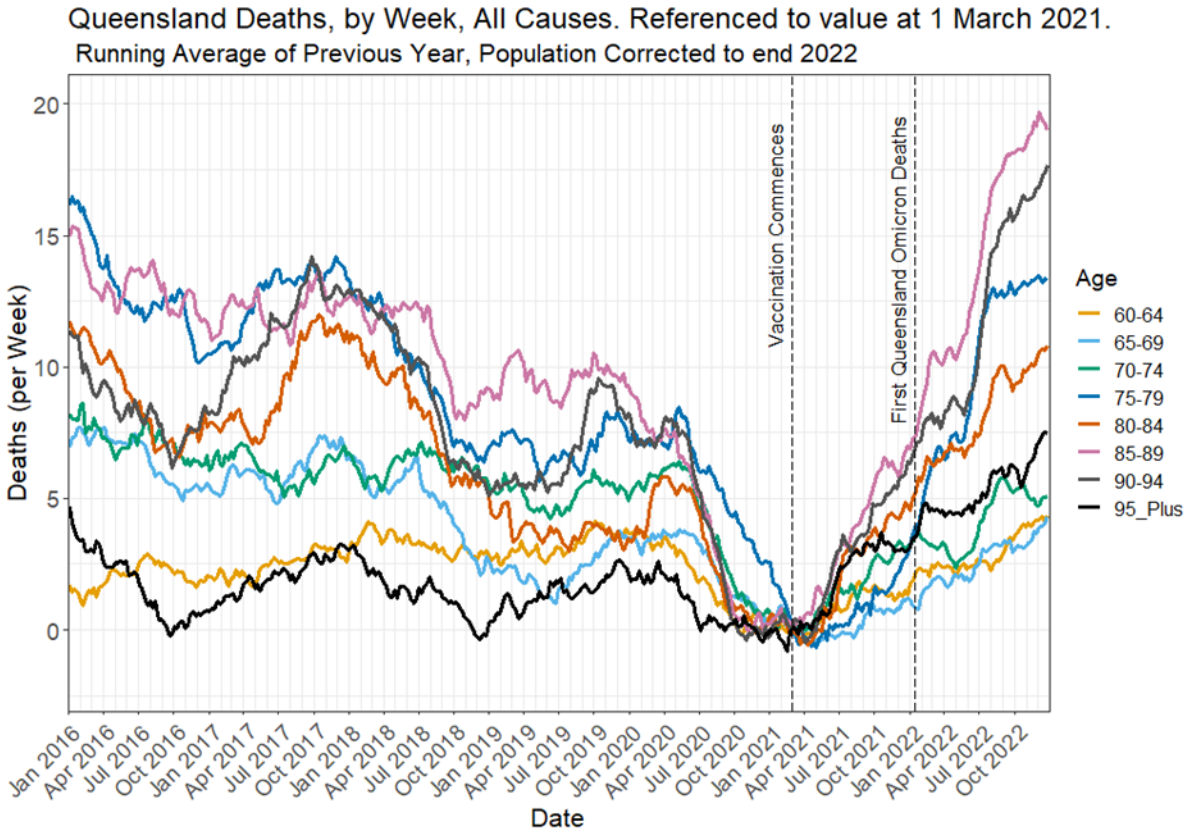


Figure 2.

3.2 Disposals in Queensland

Another dataset from Queensland that is relevant is the deaths by disposal type.

https://www.data.qld.gov.au/dataset/deaths-by-disposal-type-with-statistical-area

Disposal type is either burial or cremation. These data are available from 2017 till 2024 in quarters. Data for all statistical areas were summed, burial and cremation together. The result is shown in Figure 3 below. Small values below 5 for some areas are marked <5 and these were not included in the sum. The line in orange is up till the end of 2020. A trend line fit of those data is shown as the orange dotted line. Blue is data continued from 2021. A peak in Q3 2021, well above the trend is highlighted with a red arrow.

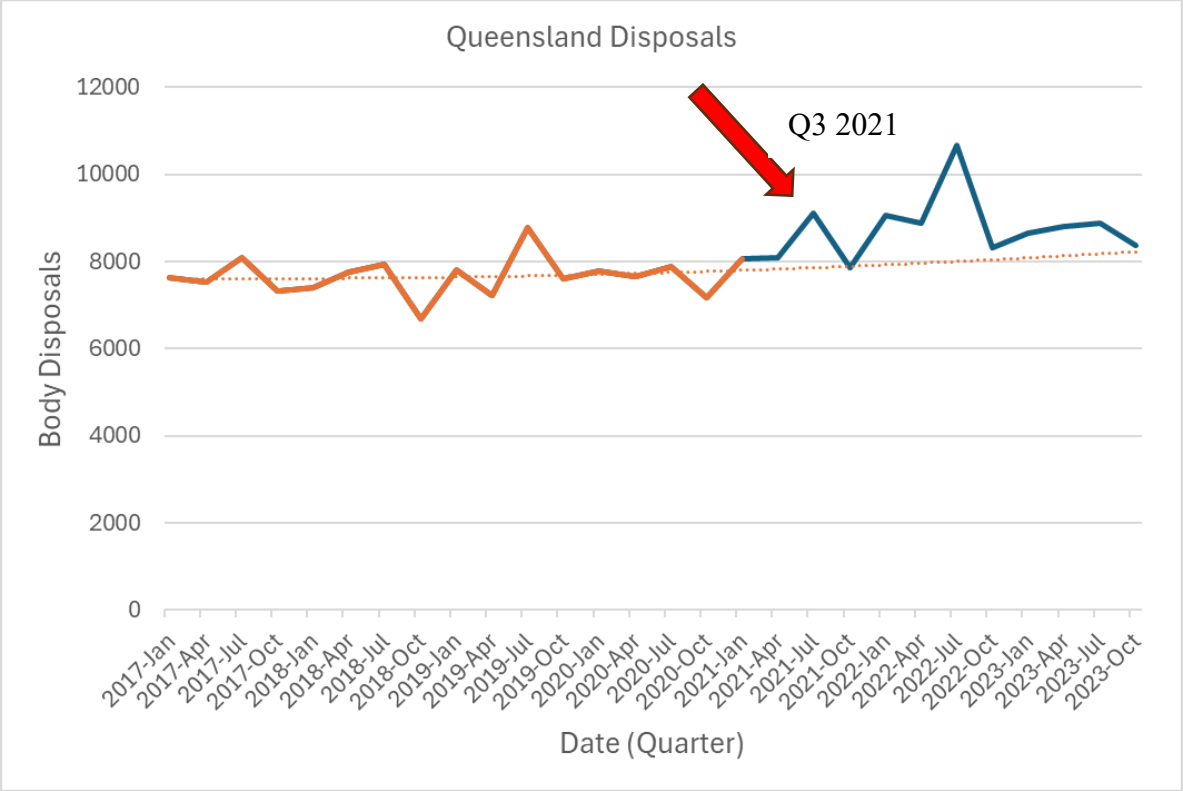


Figure 3. Queensland body disposals.

The influence of COVID-19 is seen from Q1 2022 (first Omicron wave) and then Q3 2022 (Winter wave). Another peak is seen for Q3 2019. Queensland had a particularly bad flu season in 2019. See for example this *Brisbane Times* news article reporting on deaths that season.

https://www.brisbanetimes.com.au/national/queensland/queensland-s-record-flu-season-killed-five-a-week-in-2019-20200114-p53rgv.html

The official Queensland influenza data are found here:

https://www.health.qld.gov.au/__data/assets/pdf_file/0027/1156716/influenza-qld-2022.pdf

with the relevant graph from the report reproduced in Figure 4.

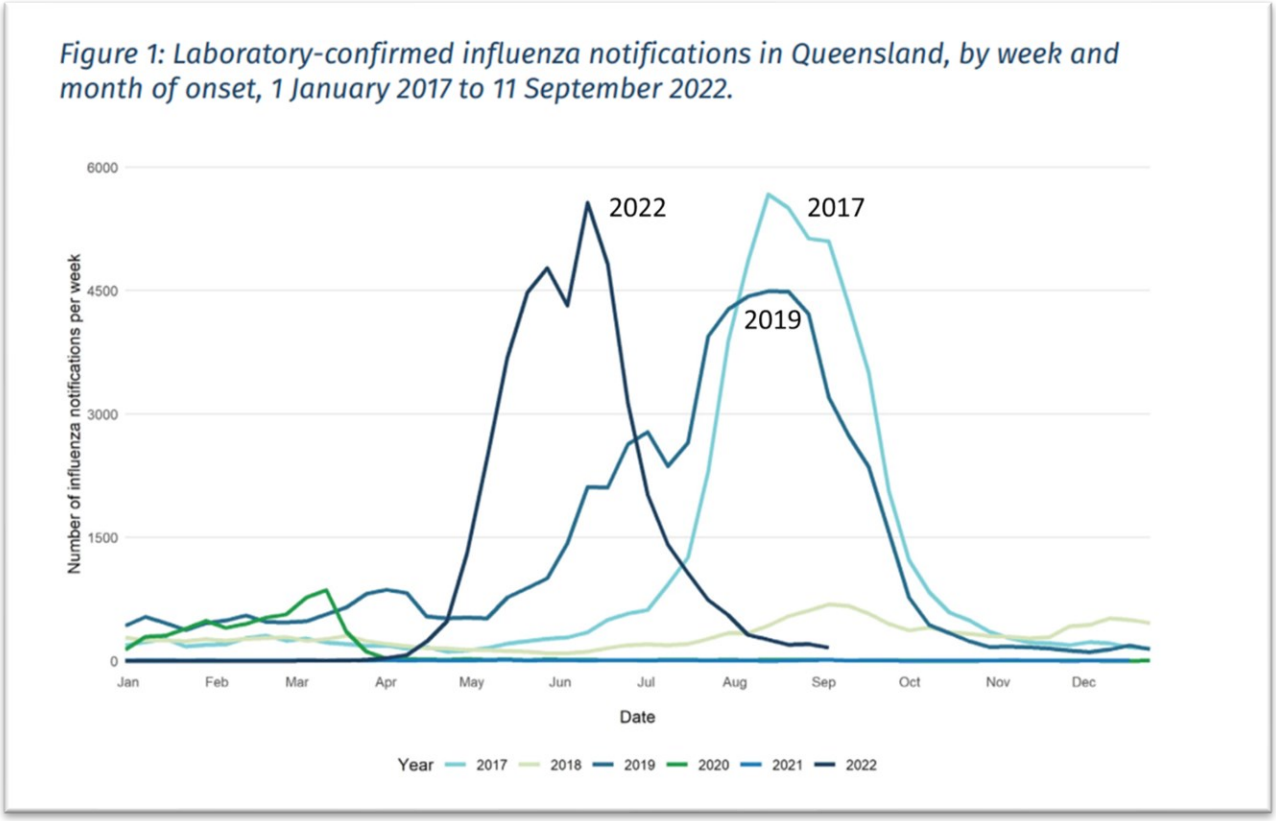


Figure 4. Queensland influenza notifications.

It is noted that in 2021 there was hardly any influenza reported with a blue line tracking close to zero. Consequently, it is impossible that additional deaths reported in 2021 are due to influenza.

Queensland saw a marked increase in mortality trend in 2021 commencing mid-year. There was a distinct increase in Q3 of cremations and burials. This was at a time of no COVID-19 in the community and no influenza. Ascertaining the factors contributing to this deviation in trend is vital.

3.3 TGA Adverse Events

An investigation of deaths reported to the TGA in the Database of Adverse Event Notifications (DAEN) following COVID-19 vaccination is provided in the *Too Many Dead* book chapter on Queensland mortality (see Section 12 of the chapter). Figure 5 below, reproduced from the chapter, shows reported deaths in a 3D bar plot. The months from the start of the vaccination campaign are along the front axis, March 2021 being number one. 10-year age bands of the date of report to the TGA are shown along the depth axis with different colours used to distinguish age bands for clarity. The height of the bars on the vertical axis is the number of deaths reported in each bin. We can see the peak in deaths reported in the 70-79 years age band in month 2 of the vaccination campaign.

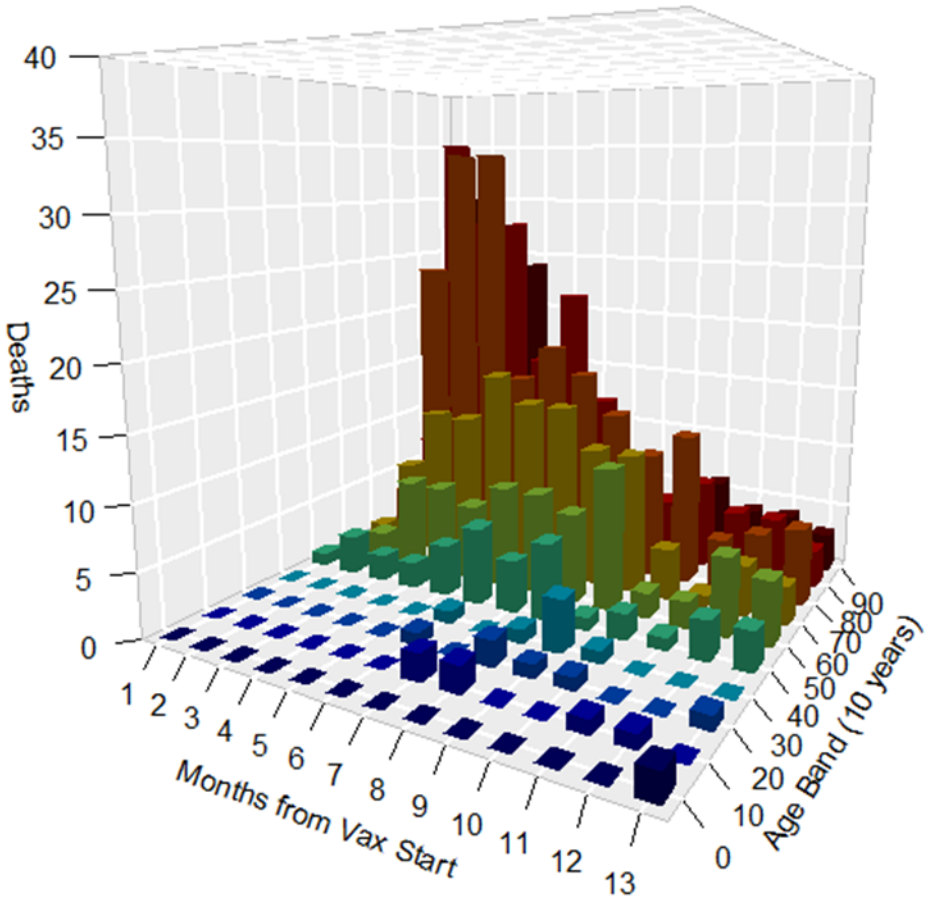
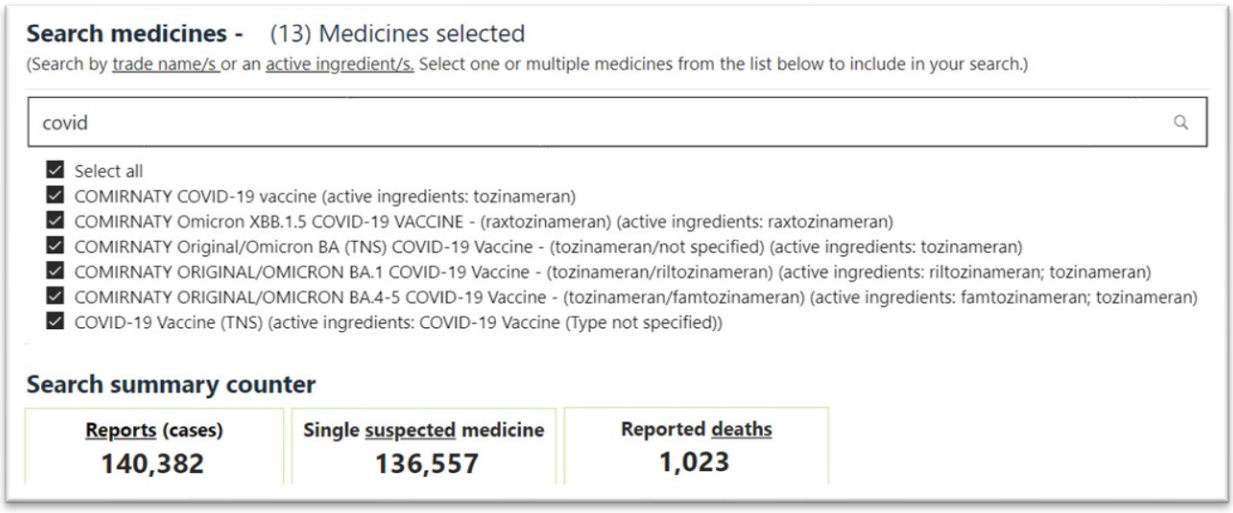


Figure 5. 3D histogram of TGA reported deaths following COVID-19 vaccination. Reported ages are shown in 10-year age bands, against time in months from start of rollout (Month 1 being March 2021).

Clearly adverse events from COVID-19 vaccination have had an effect on mortality in Australia. At time of submission to this Inquiry (13 May 2024 from https://daen.tga.gov.au/medicines-search/) the DAEN has 1023 deaths reported following COVID-19 vaccination.



The majority of these reports are submitted by health professionals. Discussion on the adverse reporting system is covered in detail in other sections provided with this submission to the inquiry.

What we do see is that the timing of introduction of the new medicines is temporally correlated with the increases in mortality. The introduction of the new medicines temporally precedes the increasing mortality. This is one of the conditions of a causal relationship.

4 Modelling

Models generate an estimate of the expected value for the number of deaths at the measurement interval. If the model is good, it will track closely to the actual values during the time period over which it is generated. The model is then used to predict forward in time and can be used to compare with actual values at later times. In this way it can be used to detect external influences where the actual values differ from what is predicted.

Very often models are used to make forecasts of the future for business planning purposes. For mortality modelling in the pandemic, we are using models generated during normal times to compare what we could have expected in the absence of the pandemic. Once COVID-19 hit Australia we know it is one such external affecting agent that may be contributing to more people dying than expected.

There is a possibility of models over-fitting. This means they use too many parameters to closely fit the measured data and they then do not “generalise” and create unrealistic predictions in the future period. There is a balance to be maintained. A full explanation of these concepts is outside the scope of this submission.

4.1 Excess

An Excess is the difference between an actual value and an expected/predicted value. A negative Excess or deficit means less than expected. A good model will have an Excess that hovers evenly above and below the predicted level. It should effectively be random noise.

Now with mortality data the question arises as to whether one should try to fit to certain time periods where there may have been more deaths than normal, for instance, because of a bad influenza season. 2017 is an example. If one were forecasting prior to that year, there is no way to have known it was to be a bad year. Once we know those data there is a question of how to incorporate them. Was it a one-off event? What appears to be the case is that these peaks even out over time. This is a reflection that the older we get the more vulnerable we are and everyone eventually dies.

4.2 Cumulative Excess

After a bad year, with more mortality than expected, it is typically followed by a good year. In data shown later in this report this effect is clearly seen. Advanced models can take this type of pattern into account. We therefore have an expectation that in normal times the Cumulative Excess should vary above and below zero.

A cumulative value is the running sum. For a random value hovering above and below zero this cumulative sum will also always hover around zero.

If the excess is high one year, ie above predictions, it is typically in deficit in the following year(s) when compared in the model. Hence, the cumulative sum has utility for handling this.

One of the methods used in the analysis provided in this report is modelling of the cumulative value of mortality. We expect during the normal years the cumulative mortality should track evenly above and below a reference line. If there is more mortality than expected in one year there is typically less the next year. We can project that reference line forward and compare the actual cumulative mortality with the line we expect. We then have a cumulative excess mortality.

The normal years, as per the terms of reference for the Inquiry, are 2015-2019. There is reason to also consider 2020 a normal year. It is shown in section 6 that annual mortality was close to expected values following trend. COVID-19 had a minimal effect on mortality in Australia in 2020. The main difference in 2020 is that the typical seasonal component was distorted compared to previous years, primarily caused by there being minimal influenza in Australia through blocking of international travellers and quarantine measures.

4.3 COVID-19 Deaths

We expect that many COVID-19 deaths are deaths "brought forward", as described in Section 2.4. For example, an elderly person may die slightly earlier than might have occurred otherwise, had there not been a bad influenza season or COVID-19. Some COVID-19 deaths are those that may have occurred during a typical influenza season. These deaths will average out in the long-term excess, that is if these deaths occur within the forecast period. Currently the forecast is from 2020 to 2023. Of course, if a death has been brought forward by say five years, we will not be seeing that in the current data. The very rare case of a young person dying from COVID, who had no underlying health conditions, would be an example. This is equivalent to an accident where that person had every expectation to keep living a long life except for the adverse event.

COVID-19 had the biggest effect for the elderly and also for those with multiple comorbidities. The median age of death from COVID-19 is greater than median age from all causes (see Section 2.5). From the ABS report, "COVID-19 Mortality in Australia: Deaths registered until 30 September 2023":

https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-30-september-2023

The proportion of deaths from COVID-19 which had a chronic condition recorded has increased from a low of 65.1% in 2021 to 85.2% in 2023.

Number of deaths due to COVID-19 that had associated conditions

Download

Reported with:	2020	2021	2022	2023	Total
Reported alone on certificate	102	102	343	103	650
Reported with causal sequence of events only	136	371	1,394	398	2,299
Reported with pre-existing chronic conditions only	300	218	2,630	864	4,012
Reported with causal sequence of events and pre-existing chronic conditions	368	664	5,917	2,010	8,959

a. Includes COVID-19 death registrations only. Numbers will differ to disease surveillance systems.
b. Includes all COVID-19 deaths (both doctor and coroner certified) that occurred and were registered by 30 September 2023.
c. Deaths due to COVID-19 in this report have an underlying cause of either ICD-10 code U07.1 COVID-19, virus identified; U07.2 COVID-19, virus not identified as the underlying cause of death; or U10.9 Multisystem inflammatory syndrome associated with COVID-19.
d. Data is provisional and subject to change.
e. Refer to the methodology for more information regarding the data in this graph.

The last two rows are those with chronic conditions which are 85% of the total in 2023. For 2022 there were 10,284 COVID-19 deaths, 1,355 for 2021. The total of right column is 15,920 deaths. These are deaths due to COVID-19. The number will be larger to end of year 2023.

From latest available COVID-19 mortality report:

https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-january-2024

The proportion of deaths where COVID-19 was the only condition recorded on the medical certificate has declined since the pandemic began to 3.3% of deaths in 2023, from 11.3% in 2020. The proportion of deaths with both causal sequence conditions and pre-existing chronic conditions has increased from around 40% in 2020 to nearly 60% in 2023.

Number of deaths due to COVID-19 that had associated conditions

Download

Reported with:	2020	2021	2022	2023	2024	Total
Reported alone on certificate	102	101	343	149	7	702
Reported with causal sequence of events only	136	369	1,394	529	25	2,453
Reported with pre-existing chronic conditions only	301	219	2,642	1,268	46	4,476
Reported with causal sequence of events and pre-existing chronic conditions	367	666	5,922	2,579	111	9,645

17,105 COVID-19 deaths to end 2023.

An extract of a spreadsheet downloaded from ABS report “Causes of Death, Australia”, reference period 2022, found here:

https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022

is shown in Figure 6 below.

Australian Bureau of Statistics

3303.0 Causes of Death, Australia, 2022

Released at 11.30am (Canberra time) 27 September 2023

Table 10.1 Multiple causes of death, All causes, Number of deaths by number of causes reported, 2022

Underlying cause of death and ICD-10 code	Reported alone	Reported with... One other cause	Two other causes	Three other causes	Four or more other causes	Mean number of causes
Total deaths	**35,753**	**38,132**	**36,355**	**29,218**	**51,481**	**3.5**
CHAPTER XXII Codes for special purposes						
COVID-19 (U07.1-U07.2)	346	1,551	2,182	2,055	3,722	4.2
Post COVID-19 condition (U09)	0	0	0	0	0	—
Multi-system inflammatory syndrome associated with COVID-19 (U10)	0	0	1	0	2	5.0
COVID-19 vaccines causing adverse effects in therapeutic use (U12)	0	0	1	0	0	3.0

— nil or rounded to zero (including null cells)

Figure 6. Extract from ABS dataset. 3303.0, Causes of Death, Australia, 2022.

From this Causes of Death report for 2022 there are a total of 9,856 COVID deaths shown for 2022, with the average number of comorbidities equal to 4.2. This must therefore not include COVID-related deaths, ie deaths with COVID.

The ABS COVID-19 mortality report to end September 2023, referenced above, has 10,284 COVID-19 deaths in 2022 (approximately 400 higher than Causes of Death report). It has 15,920 COVID-19 deaths from the start of the pandemic till the end of September 2023. In addition, the COVID-19 Mortality report states:

> *For death registrations received by the ABS up to 30 September 2023, there were 4,250 people who died with COVID-19 rather than directly from the virus itself. In this article, these deaths are referred to as COVID-19 related deaths.*

Care must be taken with counting COVID-19 deaths. Official reports of numbers keep changing. Some datasets, for example that used by the ABS to calculate excess mortality, include the related deaths. The data downloaded from the ABS mortality model report –

https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023

– has 20,095 COVID-19 deaths till the end of August 2023. This number therefore includes deaths from and with COVID-19.

In the Provisional Mortality Statistics (PMS) dataset there are 16,320 COVID-19 deaths to the end of 2023, so this is only deaths from COVID-19.

From: https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-january-2024

Deaths due to COVID-19 by year and month of occurrence

Year of death	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2020	0	0	23	79	12	3	145	473	146	16	8	1	906
2021	2	1	1	2	0	0	13	98	316	443	260	219	1355
2022	1646	1034	425	716	929	889	1408	1129	447	254	456	968	10301
2023	753	232	268	433	633	598	335	161	153	202	395	362	4525
2024	189	na	na	na	na	na	na	na	na	na	na	na	189

Total 17,087 deaths till end 2023.

COVID-19 related deaths by year and month of occurrence

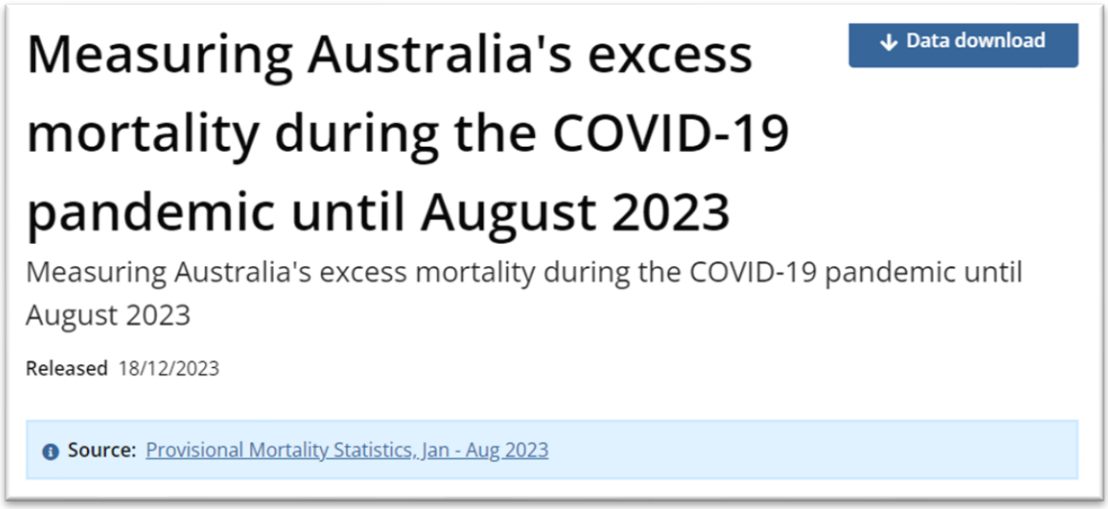
Year of death	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2020	0	0	0	1	0	1	0	5	2	0	0	0	9
2021	0	0	0	0	0	0	1	1	4	15	19	25	65
2022	231	208	125	216	298	283	466	446	186	97	139	275	2,970
2023	221	108	112	147	187	191	92	74	49	53	94	116	1,444
2024	63	na	na	na	na	na	na	na	na	na	na	na	63

Total 4,488 deaths till end 2023.

5 “Official” Government Model for Calculating Excess Mortality

The ABS has published a report on Australia’s Excess Mortality. The most recent update covers data up to end of August 2023, found here:

https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023



At the time of the report, released in December 2023, it refers to the Provisional Mortality Statistics (PMS) found here:

https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/jan-aug-2023.

These data are not the latest available at the time of submission to the inquiry. The most recent PMS at the time of submission to the Inquiry is found here:

https://www.abs.gov.au/methodologies/provisional-mortality-statistics-methodology/jan-dec-2023

covering up to the end of 2023.

Datasets downloaded from both these pages are used in analysis presented in this submission. The main result of the ABS analysis is shown in the following Figure 7 taken from the report.

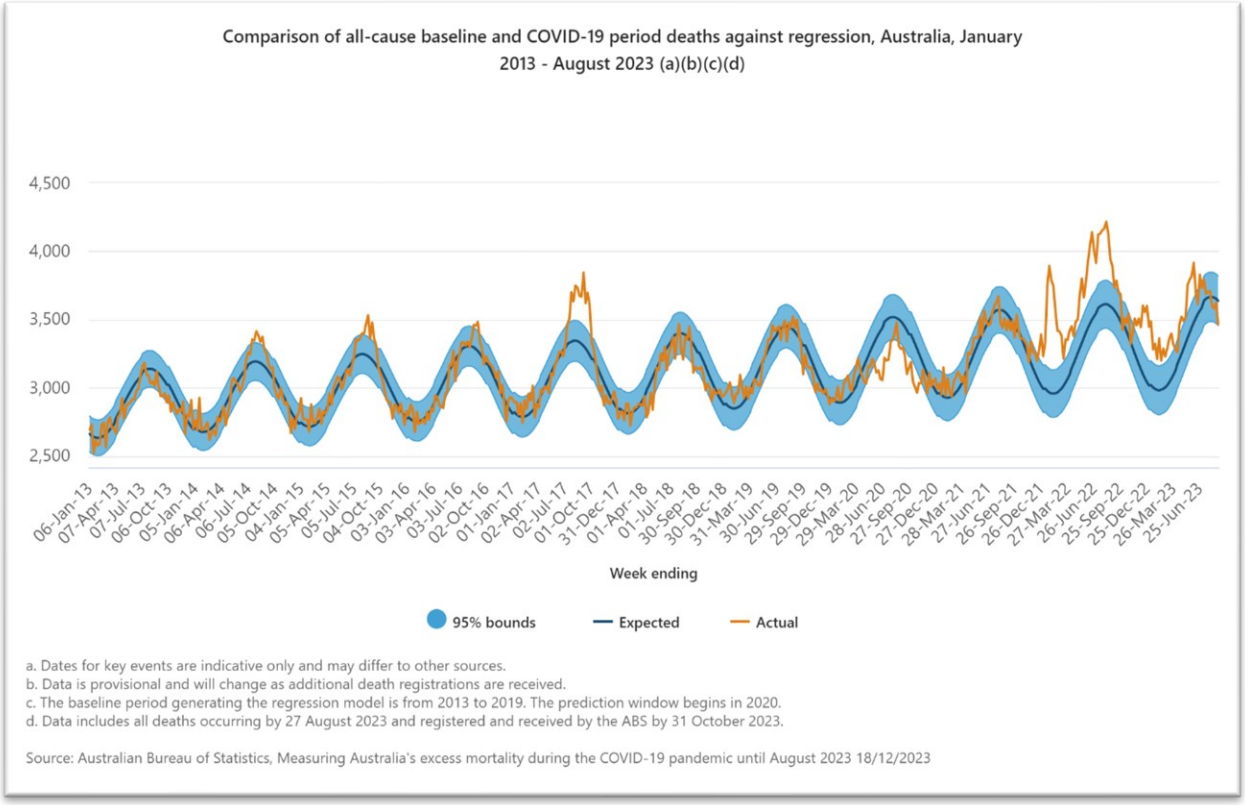


Figure 7. ABS model for Excess Mortality.

Figure 7 shows the estimated baseline (in blue) and the actual deaths (in orange). The Methodology section of the ABS report explains the method and adaptations used by the ABS. Unfortunately, several details are left out, which does not allow the independent analyst to reproduce the analysis. The model used is called the Serfling model which is actually a method called cyclic regression. From the ABS report:

> *The analysis of 2020-2023 mortality data is based on a model developed by Serfling and later adapted by the US Centers for Disease Control (CDC) and New South Wales Health (NSW Health). This section provides an overview of how the model has been developed over time, key aspects of the model, and how the model has been adapted and applied by the ABS in this analysis.*

The Serfling model is not one which would typically be used for time series analysis, because of many limitations. An example of classical time-series modelling method is provided in Section 9. To get an idea of what the limitations of the Serfling model are we use ChatGPT 4:

You
What are the limitations of the Serfling model for mortality modelling?

ChatGPT
The Serfling model is a seasonal regression model that is often used to estimate excess mortality by fitting a periodic function to baseline mortality data. It was developed by Robert Serfling in 1963 and has been used to estimate expected mortality in the absence of extreme events, like a flu epidemic. While the model has been historically significant and useful, it comes with several limitations, especially when applied to contemporary mortality modeling:

1. **Assumption of Regular Seasonality**: The model assumes that seasonal patterns in mortality data are regular and repeatable year after year. However, this may not account for changes in population behavior, healthcare improvements, or environmental changes that affect mortality rates.
2. **Linear Trends**: Serfling models typically assume a linear trend in mortality over time, which may not hold true in cases where there are non-linear trends due to various demographic, social, and medical factors.
3. **Non-Stationary Data**: The model may not perform well with non-stationary data where the mean, variance, or seasonality may change over time, which is common in mortality data due to long-term improvements in healthcare and changes in population demographics.
4. **Simplicity and Lack of Flexibility**: The Serfling model is relatively simple and may not capture complex interactions or covariates that can affect mortality trends, such as economic factors, disease prevalence, or public health interventions.
5. **Predictive Limitations**: The model is not necessarily designed for prediction and may not perform well in forecasting future mortality rates, especially in the face of new and unforeseen health threats or interventions.
6. **Outliers and Extreme Events**: The model can be sensitive to outliers and extreme events, which can distort the estimated baseline mortality and the assessment of excess deaths.
7. **Data Requirements**: The Serfling model requires several years of historical mortality data to fit the seasonal pattern reliably. In places with poor data collection or rapidly changing demographics, this can be a significant limitation.
8. **Epidemiological Changes**: The model may not adequately capture changes in the causes of death over time, such as a decrease in deaths from some diseases and an increase from others, or the emergence of new diseases.

Given these limitations, the use of the Serfling model may require adaptations or the use of additional methods to account for its shortcomings. In modern applications, it is often replaced or supplemented with more complex statistical models that can account for a wider range of factors and provide more accurate and robust estimates.

The Serfling model is therefore not one that would be used in any modern analysis of mortality. The Serfling model has been used in the past by NSW Health as a method to infer excess deaths due to influenza. The ABS report notes that the model shows excess mortality in 2014, 2015 and 2017. This can be seen in Figure 7 above, where the actual mortality in Winter pops up above the blue shaded region in those years. Mortality is also above the baseline at the peak of the Winter season in 2016 and 2019 as well, in other words just about every year. Another observation is that the year 2013 appears to be the year that it most accurately predicts.

The reason that this model facilitates detecting high seasonal peaks is due to the shape of the sine wave seasonal pattern fitted. The sine wave does not reflect the true seasonal pattern of mortality. The sine wave is in general a useful construct for cyclical behaviour. However, in this context it flattens out at the peak of the cycle which is not what happens in reality. The model consequently has some utility for looking for peaks at the height of the influenza season because it underestimates the shape. This was probably useful in olden days when monitoring excess in mortality was used as a surrogate for detecting influenza. In the era of disease testing, systems are in place to monitor directly for influenza.

As a general time-series model for mortality, it compares poorly with other methods.

5.1 Replication of the Official Model

There are details left out in the ABS report on how the Serfling model was implemented. It is implied in the ABS report that the model was applied to individual age bands. The result for the baseline in the graph may be a combination of modelled individual age band data. We do not know what age bands were used. It is also implied also that individual states were modelled. This makes some sense as in Australia states may be affected differently by influenza year to year. The Northern Territory exhibits different mortality patterns to other States.

Senator Babet asked several questions of the ABS in Question on Notice no. 125, Portfolio question number AET125, 2023-2024 Additional Estimates, Economics Committee, Treasury Portfolio.

Unfortunately, the answer to Senator Babet provides no further useful information to the official report. The answer to a question on what sub-categories were used briefly states:

> *The same age groups were used for modelling for the three most populous states. Other jurisdictions included broader age groups because they have smaller numbers of deaths in a week. Australian excess mortality estimates and jurisdictional excess mortality estimates are modelled separately.*

Unfortunately. we still do not know what the age bands used are for calculating the age specific rates.

This section now goes into a detailed analysis of the official model. A cyclic regression model was fitted to the same ABS data in the modelling report, available till the end of August 2023. The ABS chose to only include a linear term for the trend. The ABS report notes that their previous models included a second order term but that in this analysis, ie for investigating excess mortality, this made the baseline what it calls “unrealistic” at extended times. Implementing a second order fit has a baseline with a small downwards curvature. This means it is lower at extended times. The logic used for certain choices for the model is concerning. Uncertainty bands can be used to quantify any uncertainty. Another concerning statement is related to handling the year 2017. The report states:

> *Even controlling for 2017, the model was overcompensating for the rate of decline during 2015-2019, resulting in a very low number of expected deaths in 2022 and 2023.*

How would one know that the model was “overcompensating”? This is clearly an assumption. There could actually have been a low number of expected deaths in 2022 and 2023 had there not been a pandemic.

Again, the aim appears to be to increase the expected number of deaths in the years in 2021-2023. In the “Determining the Baseline” section of the methodology section the report claims to have done a sensitivity analysis. The problem is that this sensitivity analysis appears to have been driven by trying to find the highest baseline in the years post the model-fitting period. This leads to the lowest possible excess value. A decision was made to reach further back than the 2015-2019 reference period, to 2013, which was a year of low mortality. It is well known that when fitting a linear regression that the points at the end of the data range have what is known as more “leverage”. In other words, they tip up or down the line of best fit with more effect than points centrally located. Hence, effort seems to have been put into adding data for a low mortality year at the beginning of the regression period. Why has so much effort been put into adding data for a low mortality year so far back when the mortality in the most recent years should be the most relevant?

The purpose of a sensitivity analysis is to find the range of values that results when making changes to certain variables. We are given no insight into this process. For example, how does the inclusion of 2013 change the results? It is clear that inclusion of 2013 tips the linear part of the fit upwards, minimising excess in predicted years, up to 10 years later.

It is possible that the underlying assumption made for this analysis was that the total cumulative excess over the pandemic period equates to the total number of COVID deaths. Consequently, the modelling was trying find a minimum excess in years post 2019. This is not a valid assumption, nor is it acceptable in trying to understand whether there is unexplained excess.

The cyclic regression with a linear trend term fitted from 2013-2019 is shown in Figure 8 below.

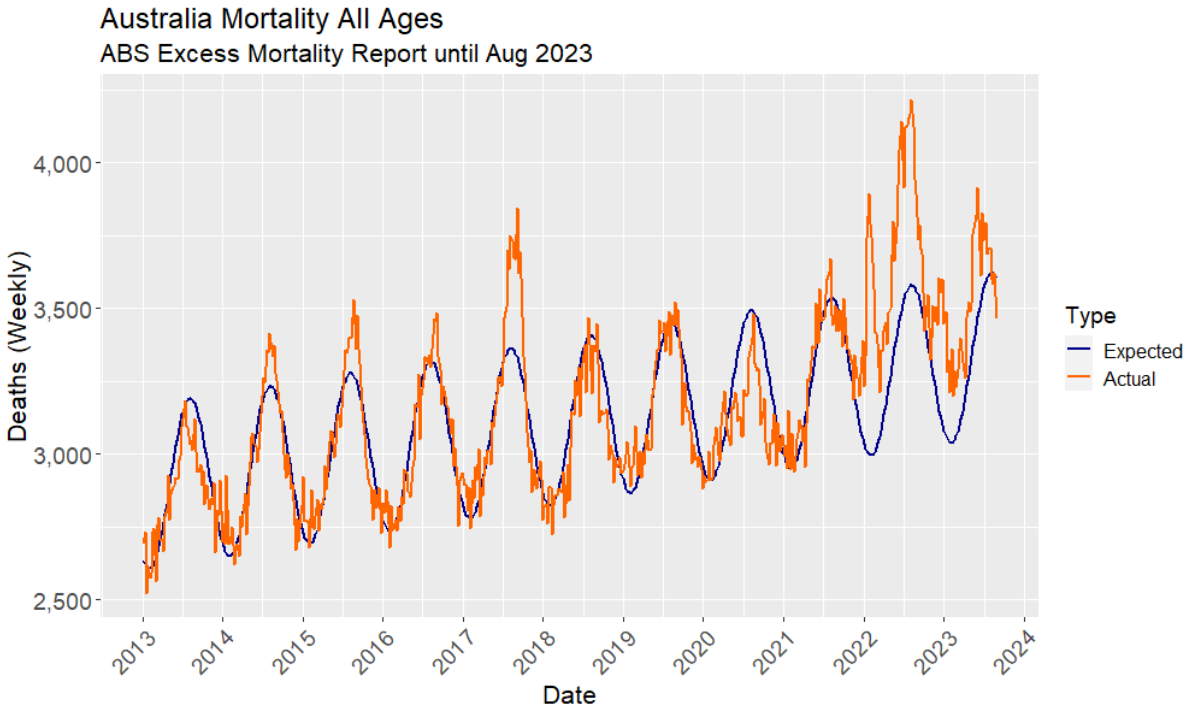


Figure 8. Cyclic regression with linear term fitted to Australia all ages mortality data, with reference period 2013-2019.

Visual inspection shows that this appears to be quite close to the ABS fitted data shown in Figure 7 previously. The calculated baseline (shown as Expected in blue line) is shown together with the ABS calculated baseline (shown as ABS Expected in black line) in Figure 9 below.

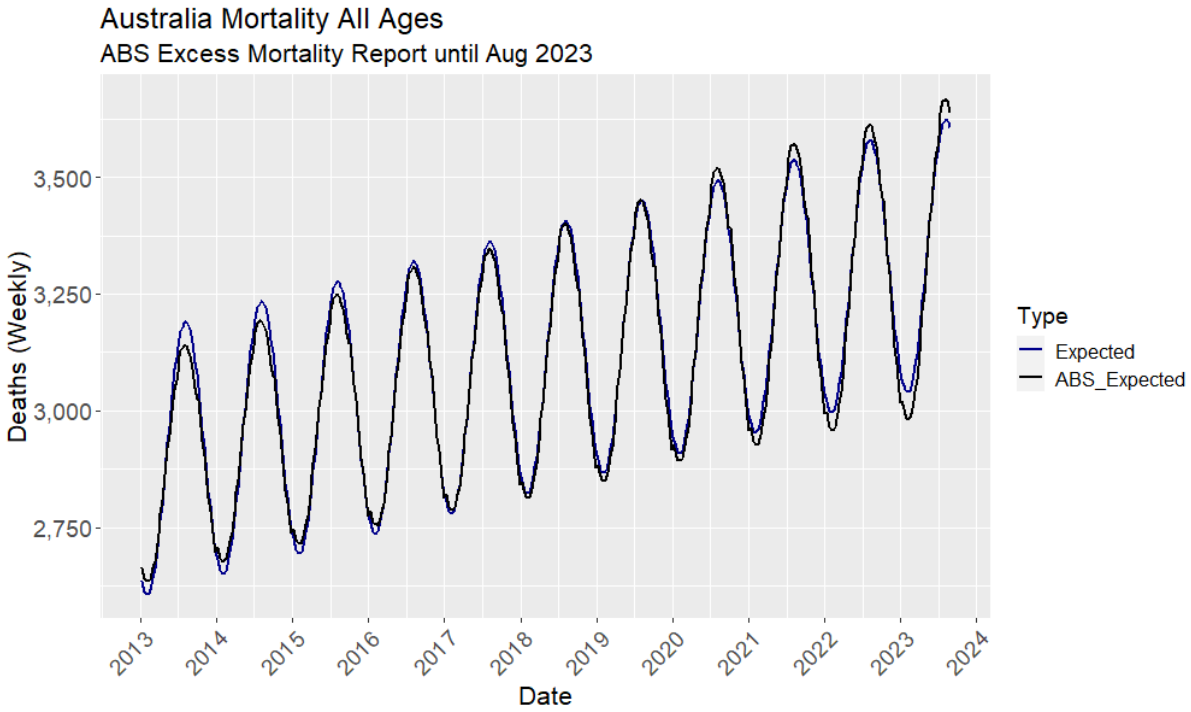


Figure 9. Comparison of ABS model fit (ABS_Expected) and cyclic regression calculated for this report (Expected).

The blue sine-wave-shaped line in Figure 9 is the model fit calculated here, based on all age data, and black is the ABS calculation (for which we do not know what age bands were used). They appear to be fairly close with the largest discrepancies appearing at either end of the 2013 to 2023 period. The ABS baseline estimate data only are shown in Figure 10 below.

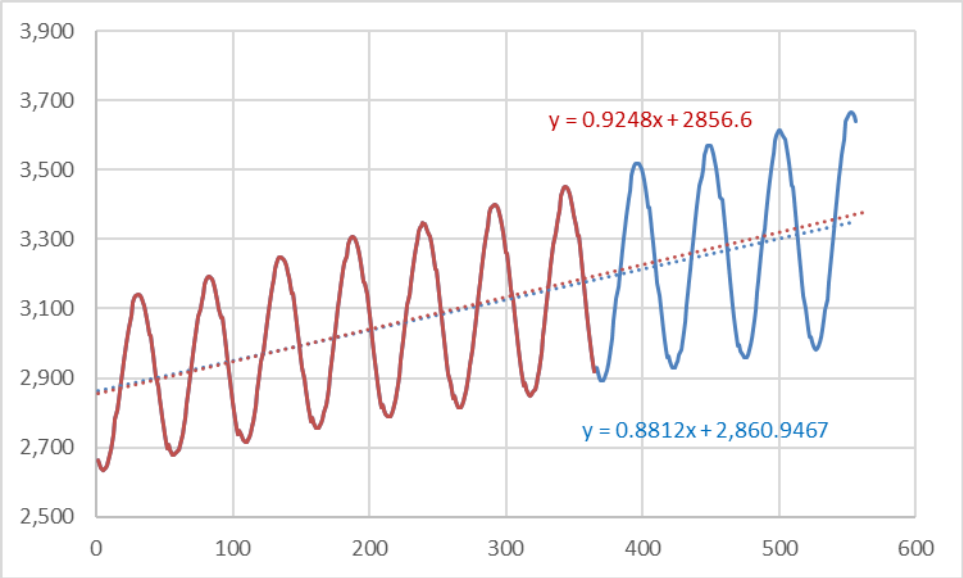


Figure 10. ABS Estimated baseline. Red line is for 2013-2019. Blue line 2020-2023.

The fitted 2013 to 2019 data are shown in red and the projection for 2020-2023 is in blue. Linear trend lines are shown for both the fitted period and the whole period. It appears that the amplitude of the sine wave and the trend changes over time. This must be the result of the ABS fitting to individual age ranges and or states and the addition of individual curves. Subtracting the red trendline from the ABS-estimated baseline gives the result shown in Figure 11 below where this change in amplitude is more clearly seen.

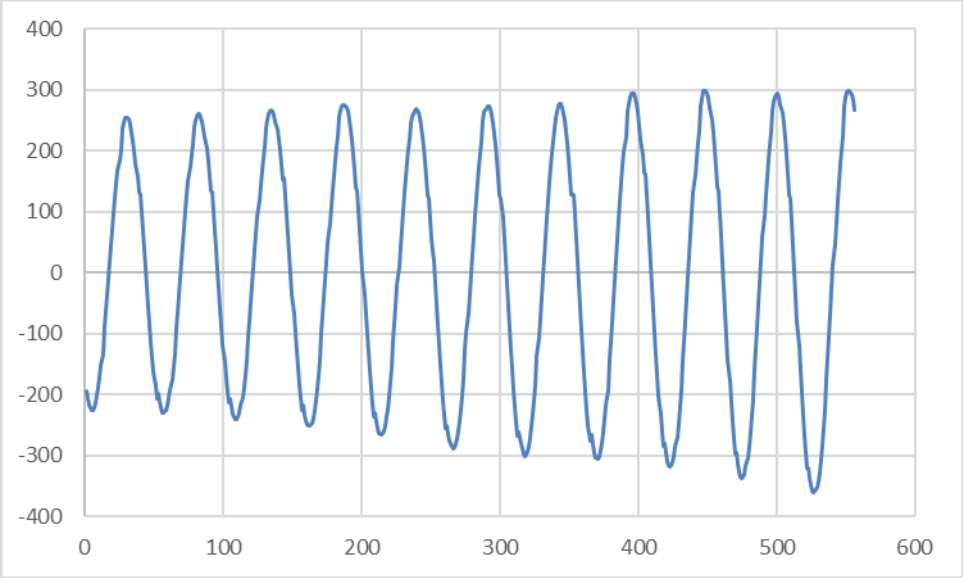


Figure 11. Subtraction of linear trendline from data in Figure 10.

This shows a seasonal pattern that is growing larger. It is not clear if this makes sense. Certainly, visual inspection of the actual seasonal pattern for all ages, Figure 12 below, does not show any increasing amplitude seasonal pattern. If anything, the opposite is the case.

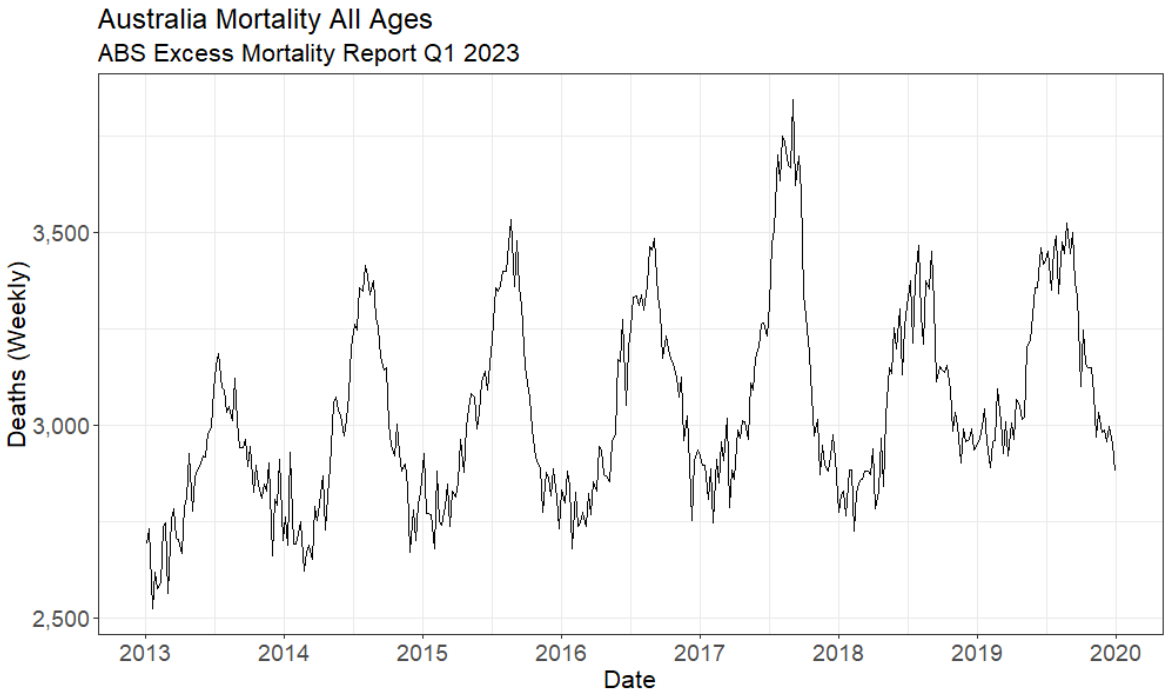


Figure 12. Raw all age mortality data 2013-2019.

We calculate the weekly excess, according to the ABS model, over the whole period 2013 – 2023 See Figure 13 below.

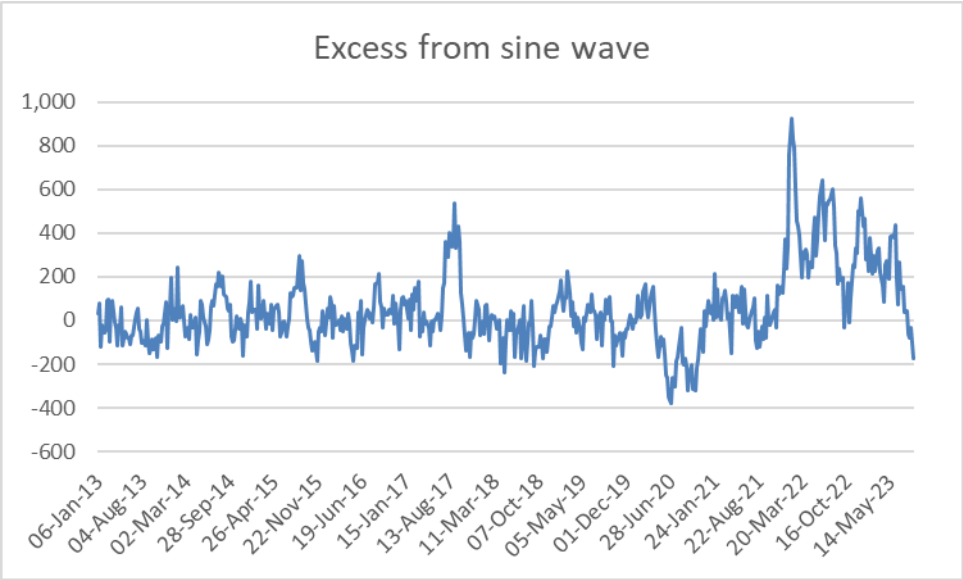


Figure 13. Excess value calculated as the difference of actual values and the ABS estimated baseline.

This shows distinct excess peaks at: 2014, 2015, 2017 and 2019. It shows a deficit in 2020. Calculating the Cumulative Excess, which we should expect to track about zero for a good model, is shown in Figure 14 below.

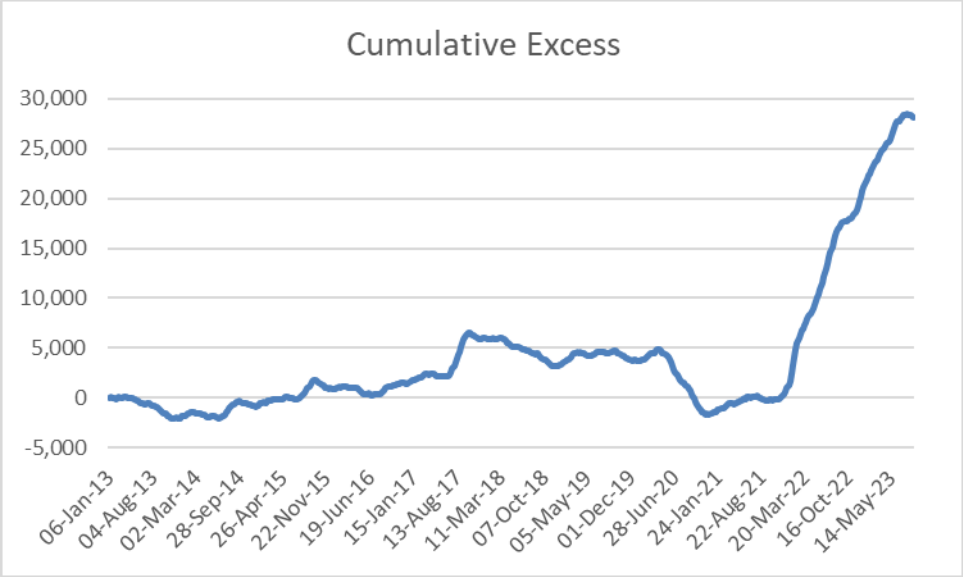


Figure 14.

This cumulative excess is very strange. It is as if the excess was continually accumulating from 2013, levelling out in 2017, with a reset in 2020. The excess from 2017 does not track back to zero till 2020. The take-off occurs at the end of 2021 and reaches approximately 28,000 at the end of August 2023. Note the last three months of data are subject to revision as extra deaths are reported.

These results indicate that the model does not fit the actual data very well during the reference period 2013 to 2019. It is therefore unlikely that it will make accurate predictions.

We now look at the ABS data for the period of the pandemic from 2020. This is reproduced in Figure 15 below from the ABS report.

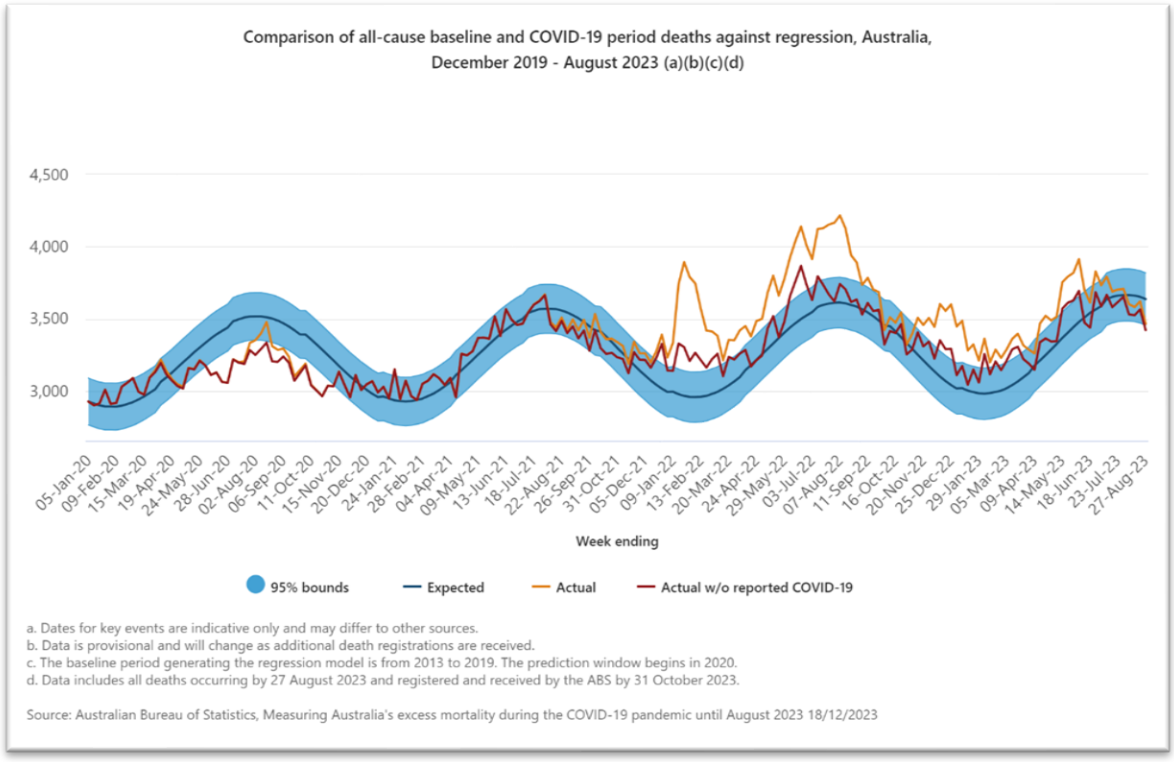


Figure 15. ABS mortality model 2020-2023.

Figure 15 shows in orange the actual number of deaths, and, in red, deaths with all COVID-19 deaths subtracted. For 2021 up till October 2021, the data appear to fit the model reasonably well. However, this is strange as there was minimal influenza and COVID-19 in 2021 and so we should not expect to see the typical seasonal pattern. Data for 2020 show the suppression of the typical seasonal variation and a similar suppression in 2021 would be expected. With respect to total numbers for the year, the annual value for the year 2020 is not so different from the expected annual value (see Section 6) based on the existing trend. From the government website reporting on influenza in 2021:

https://www.health.gov.au/resources/collections/australian-influenza-surveillance-reports-2021

data shows that there was relatively low Influenza Like Illness (ILI) cases compared to usual.

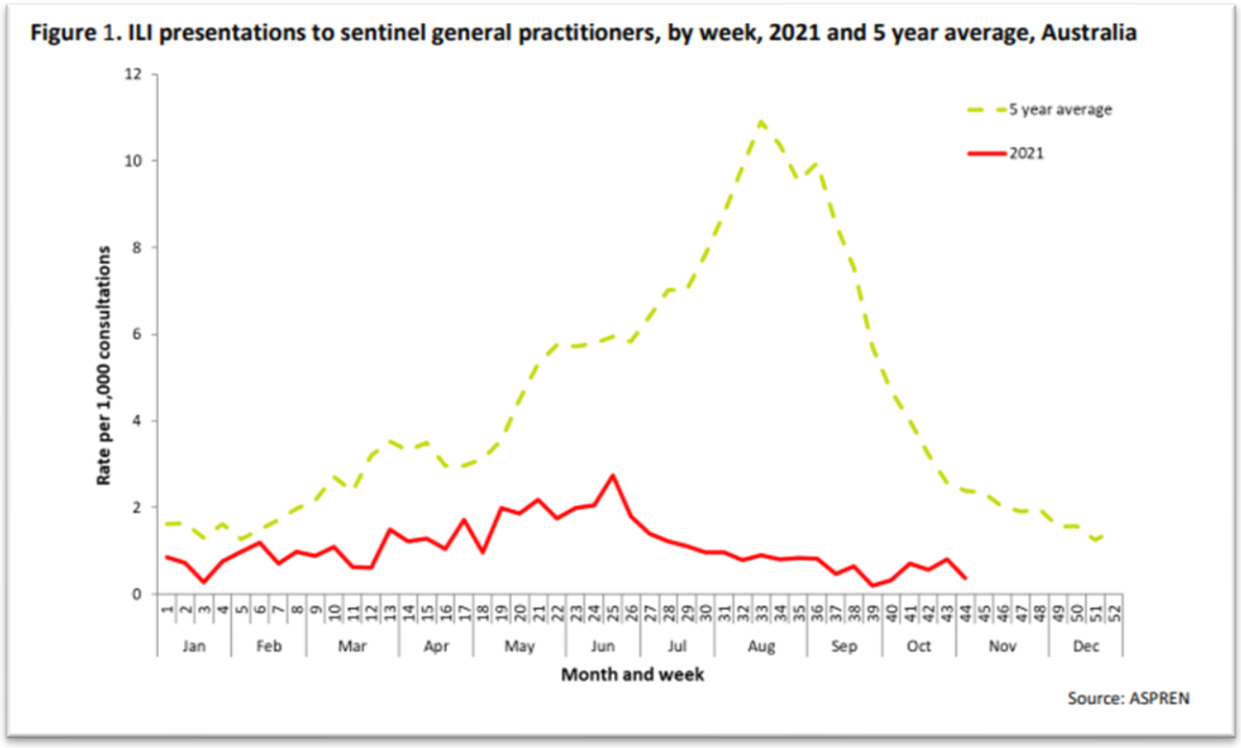


Figure 16. 2021 Influenza Like Illness (ILI) rate per 1,000 consultations.

From:

https://www.health.gov.au/resources/publications/aisr-2021-national-influenza-season-summary

The above message is vague stating that numbers may be inaccurate because of pandemic measures but at the same time that social distancing measures "are likely having an effect on transmission of acute respiratory infections, including influenza".

In any case it does seem clear there was minimal influenza in 2021, yet the official model appears to track the 2021 data well as if it was a normal influenza season. The ABS model fits two seasons particularly well. They are 2013 and 2021. It is asserted in this analysis that the reason this fit for 2021 appears to be good is because of the trend being tipped upwards in the official model by reaching back to 2013 and using a linear fit only for trend.

We will see the actual distortion of the actual data for 2021 from what we should expect of the typical pattern (see for example Figure 26).

5.2 Discussion on Years used for the Baseline

The official model uses a reference period from 2013 to 2019. We see from the raw mortality data in Figure 12 that 2013 is lower than subsequent years.

It is instructive to look at what was happening over a longer period of time. The Australian Institute of Health and Welfare (AIHW) publishes data on mortality and rates. From report "Deaths in Australia" (last updated: 11 Jul 2023), found at:

https://www.aihw.gov.au/reports/life-expectancy-deaths/deaths-in-australia/data

data over the period 1907 to 2021 are published. The following graphs are produced from this data. Figure 17 shows the raw death counts over the period 2002 to 2020.

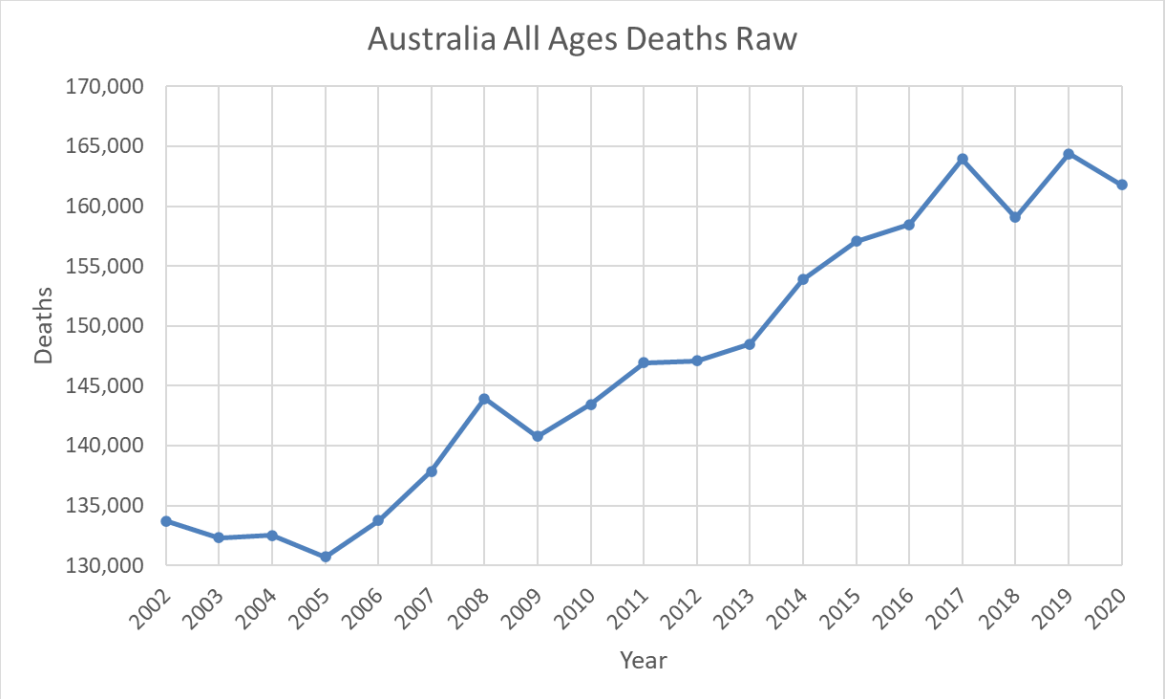


Figure 17. Australia all ages deaths count from AIHW report.

While it can be seen that there is a general trend upwards, driven by population growth, there are some complexities in the pattern. 2013 is a local minimum with respect to the trend at that time. The year 2008, like 2017, is a year of higher mortality than trend suggests. If anything, there is a curvature, flattening out at the right of the graph. To look at the Australia population over this time, see Figure 18.

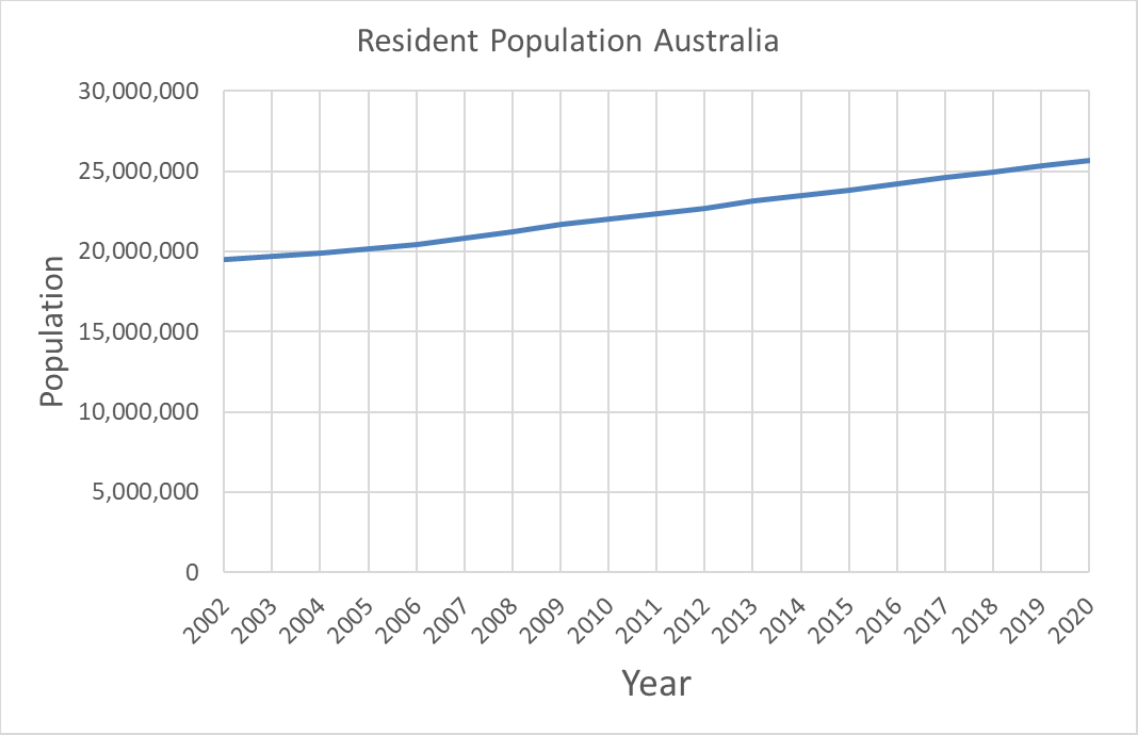


Figure 18. Australia population 2002-2020.

This varies smoothly, gradually increasing over the period. The crude death rate, which is simply dividing the number of deaths by the population, is shown in Figure 19.

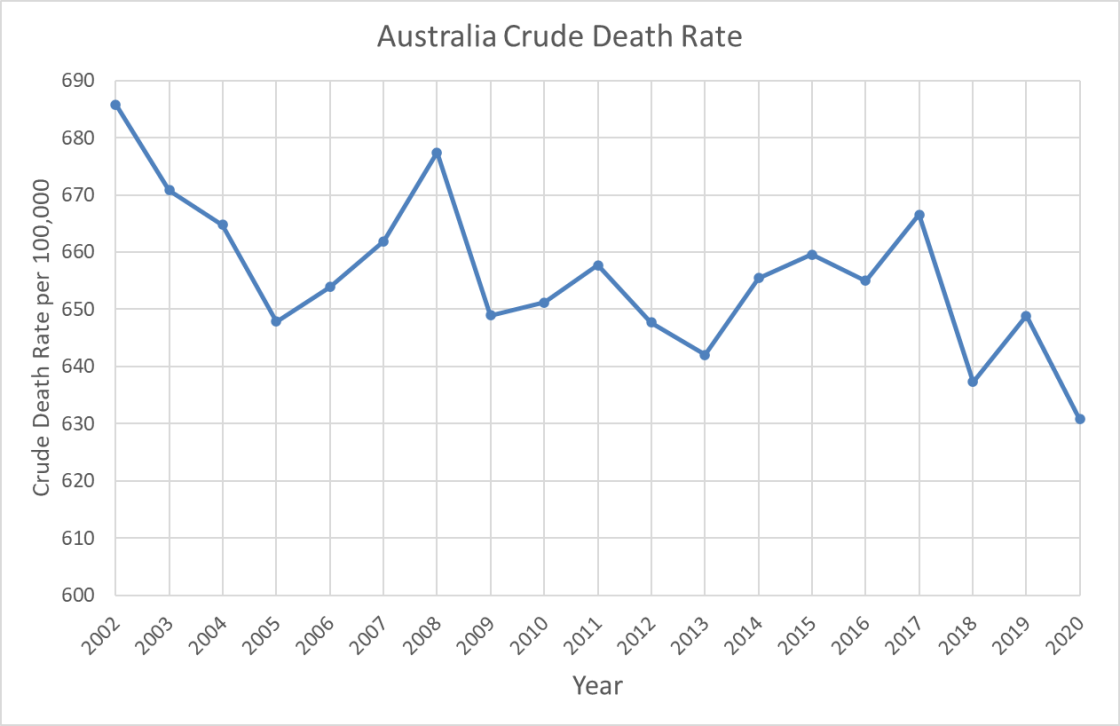


Figure 19. Crude all ages death rate.

It is noted that the crude death rate can be misleading because it does not take into account the size of different age groups in the population. For example, the population could be dominated by growth of young people but most of the mortality occurs in older ages.

However, we expect the changes from year to year to be minimal and short-term local changes observed can be relevant. We see both in the death count and crude all ages death rate that 2013 was a distinct trough.

A method called age standardisation references the rates of death in different age groups to a pre-specified population distribution. Age standardisation has limited usefulness as it provides one number for what can be complex underlying dynamics. However, it can still be instructive. The Age Standardised Rate (ASR) of mortality, taken from AIHW data, is shown in Figure 20.

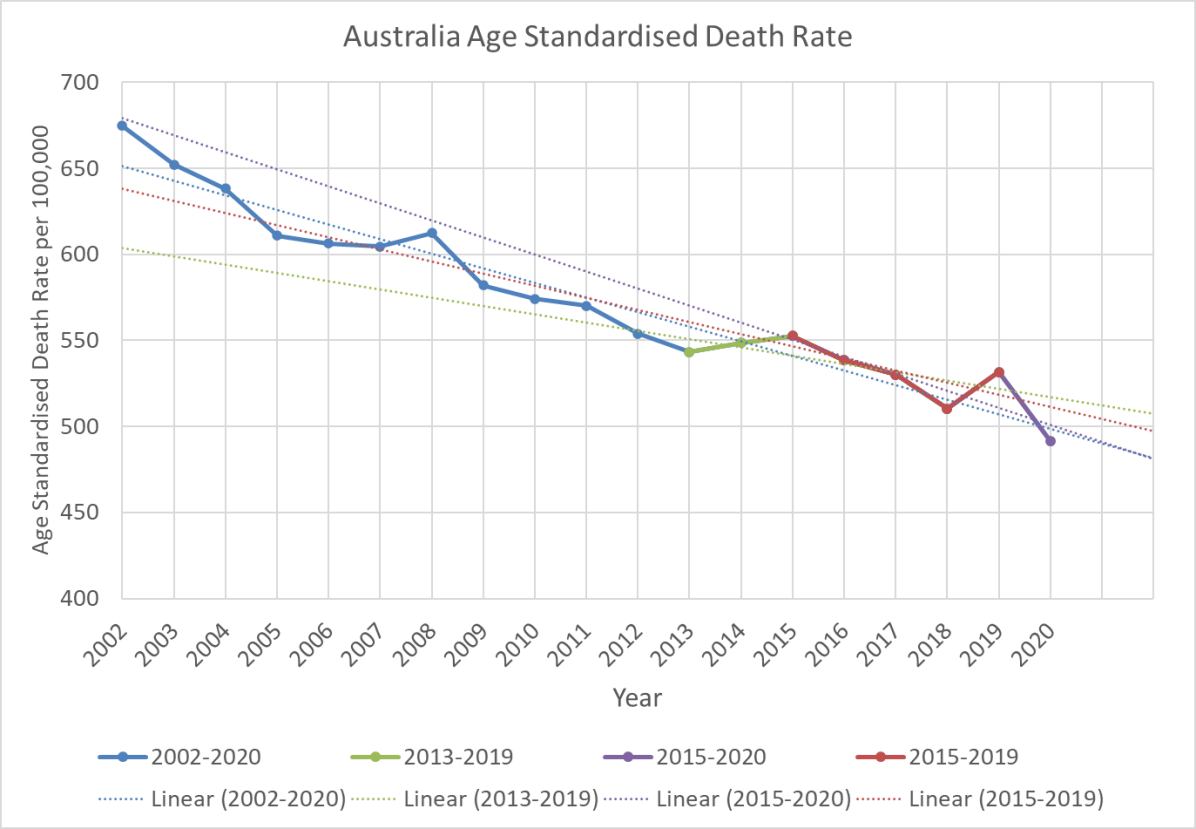


Figure 20. Age Standardised Rate of mortality. Linear trendlines shown for selected year ranges.

Four ranges have been selected and a linear trendline fitted to each. They are:

- 2002-2020
- 2013-2019 (the ABS model uses)
- 2015-2019 (the PMS reference period)
- 2015-2020 (for comparison)

2020 is included in some example ranges as the annual value for mortality for that year is not far off trend (see Section 6). Looking at the different coloured trendlines, fitted to the age specific rates, the right end of the graph shows the effect of the different fits. It can be clearly seen that the 2013 to 2019 period (used in the official model) provides the highest baseline possible in years post 2020.

If we assume that the true underlying trend should be taken as that over a longer period, and all the lumps and bumps in between are noise, then we have the blue dashed line. This gives a much lower baseline over the years post 2020 than the official model does.

Over the years 2021-2023, the long-term trend (blue line) appears to agree well with the fit from 2015 to 2020 (the purple line). However, it can be seen over the longer term the purple line will diverge because it is steeper. The 2015-2019 trendline is higher than the long-term trend but is less than the 2013-2019.

This raises the question why would a reference period be chosen that generates the highest possible baseline in the forecast period of 2021 to 2023?

This discussion also indicates that there is justification for including mortality in the year 2020 in some circumstances. While this is not logical in other countries around the world, where the pandemic had a major effect on mortality in 2020, in Australia deaths from COVID-19 disease were limited through border closures. Any changes to mortality patterns in 2020 in Australia are due to local measures implemented. In some of the modelling in this report the year 2020 is included. This will be specified. In particular for some age bands the year 2020 was consistent with previous years. In other age bands 2020 was lower than trend.

5.3 Seasonal Pattern

It is instructive to compare the typical seasonal pattern of mortality with the sine wave curve of the official model. The seasonal patterns, with linear trend subtracted, are shown in Figure 21 below for years 2015-2019. The average of the five seasonal patterns is shown for reference (in dark grey).

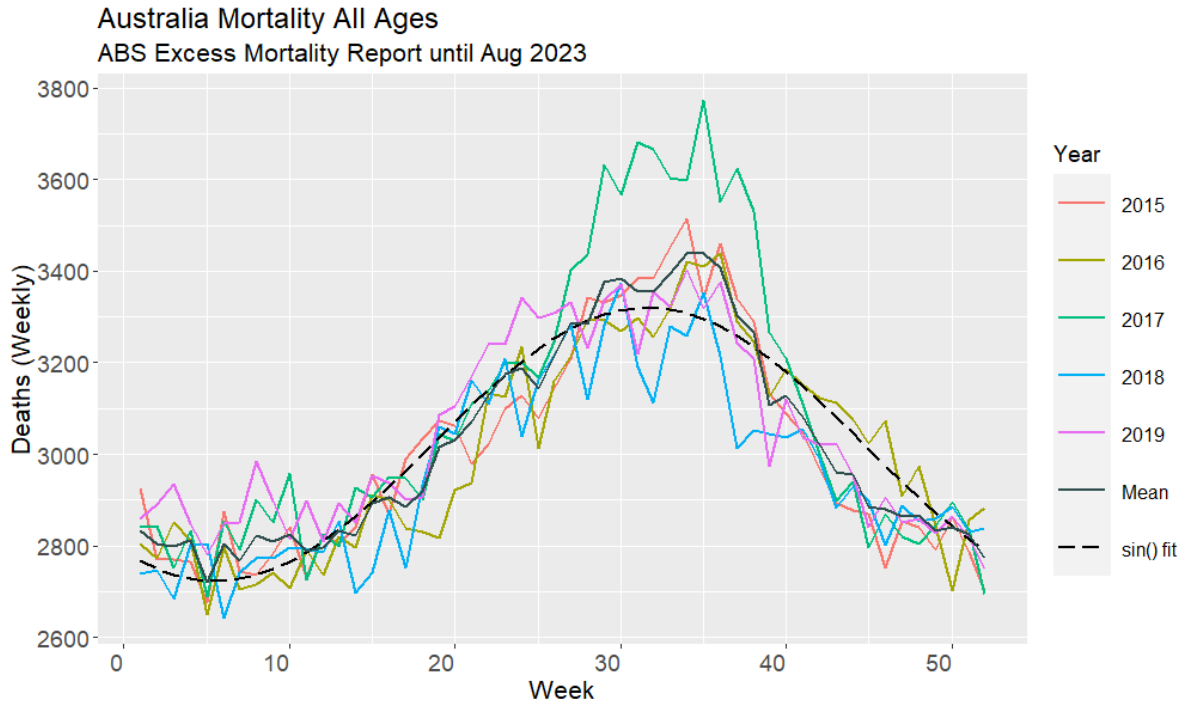


Figure 21. Seasonal patterns overlaid together with mean of 2015-2019 and the sine wave pattern fit.

It can be observed that the sine wave pattern does not accurately capture the peakiness of the typical seasonal mortality. The average line shows that the actual mortality typically lies below the rising edge of the sine wave, leading in to Winter. It lies below the falling edge of the sine wave.

While the Serfling model is not very useful for general mortality prediction, it may be useful if one wants to detect when the peak of an influenza season is occurring. This is because it underestimates the peak of the typical seasonal pattern and therefore it can be used as a detector of excess at the peak of the influenza season. On the lead-in to the influenza season the actual data typically fall below the sine curve and so excursions above the sine wave are unusual, until near the crest, potentially alerting to the onset of excess influenza.

The raw mortality data for the years used in the ABS baseline calculation are shown in Figure 22 below.

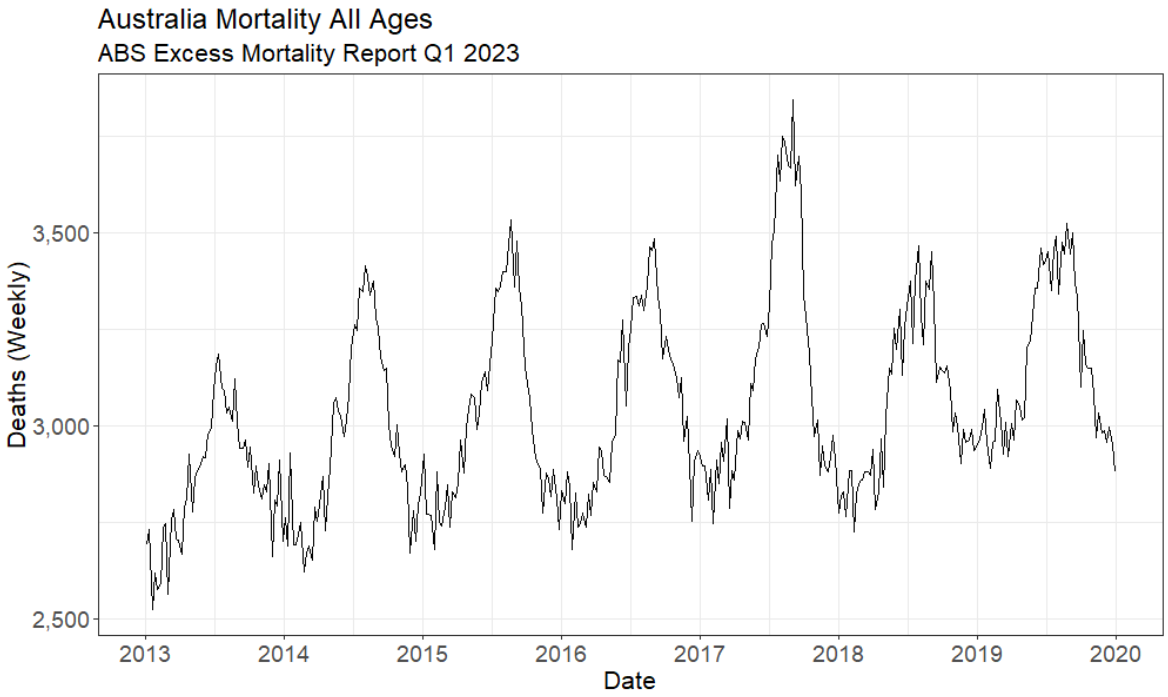


Figure 22. Australia mortality all ages 2013 – 2019, the reference years in ABS model.

Clearly 2013 was a low mortality year, very different to years 2014 to 2019 (Figure 22). This is also seen in the mortality rates discussed in Section 5.2 and in Figure 20. Note that population is not accounted for and may be contributing to mortality numbers.

Now we apply the cyclic regression model fit from years 2015 to 2019 only, and compare the model generated with actual mortality to see whether it gives a better fit than the model used by the ABS. See Figure 23 below. Note that this is based on the raw mortality data. It is assumed that the official model has been developed based on age-specific mortality rates and then converted back to raw numbers by multiplying by population. Generating the model on raw numbers is still valid as it is taking into account population in the trend term.

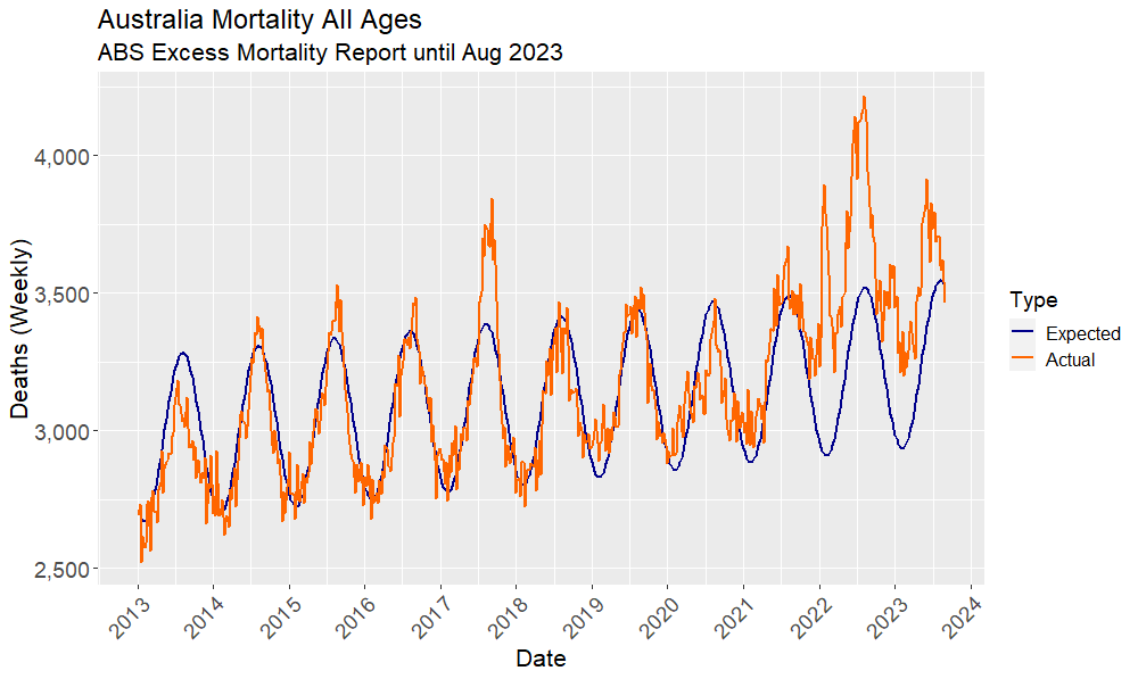


Figure 23. Cyclic regression fit to all ages mortality data based on a reference period 2015-2019.

We observe the fit is better for years 2014 to 2020 compared to that in Figure 8. 2013 is below the fit, as we would expect given that a simple linear trend only was used and the fact it was a low year (see Figure 22). We see a distinct divergence in the 2021 mortality pattern, with respect to the sine wave, when using the 2015-2019 modelling window.

We see the increased deviation of the 2015-2019 fit with the actual (2013-2019) ABS model in Figure 24 below. This can be compared with Figure 9 where the same reference window was used. The ABS fit (black sine wave) is clearly on a steeper slope compared to the blue line (using 2015-2019 reference window).

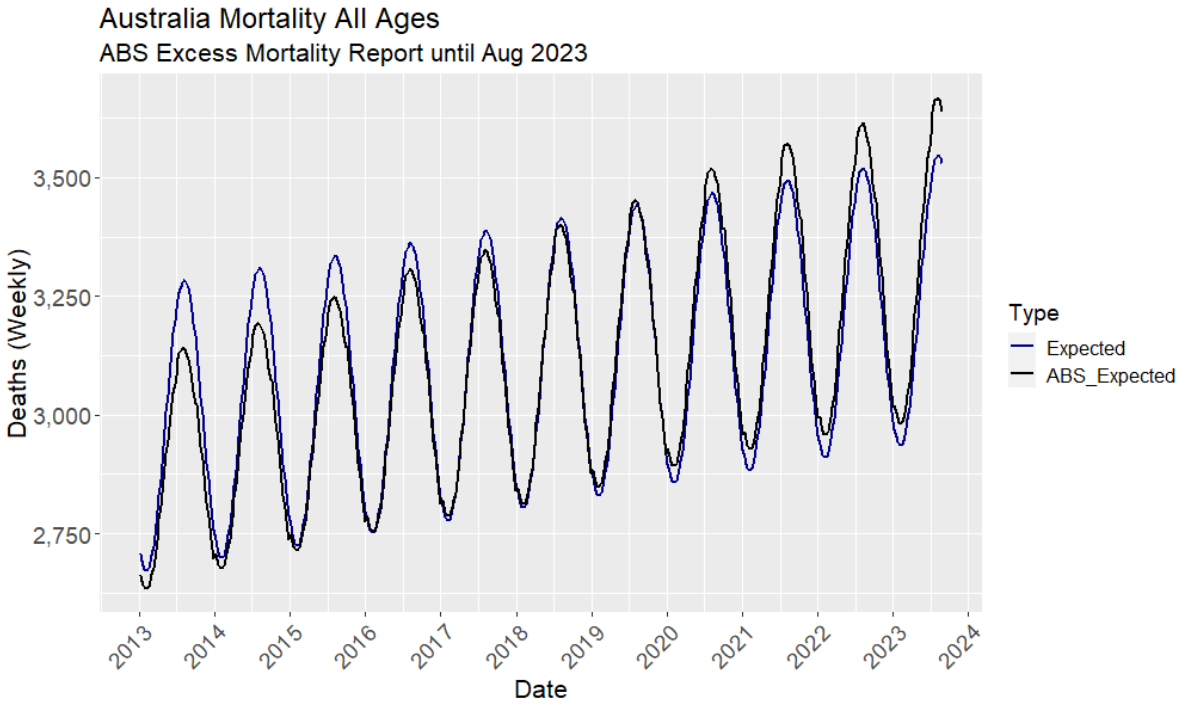


Figure 24. Comparison of the ABS model fit using 2013-2019 reference window (ABS Expected) with a fit using 2015-2019 reference window (Expected).

The inclusion of 2013 in the model fit clearly has a large effect on the model prediction. The sensitivity analysis that is purported to have been undertaken should have reported the actual sensitivity of excess numbers with respect to the various assumptions.

Subtracting out the linear trend from the 2015-2019 fit we get the graph shown in Figure 25 below.

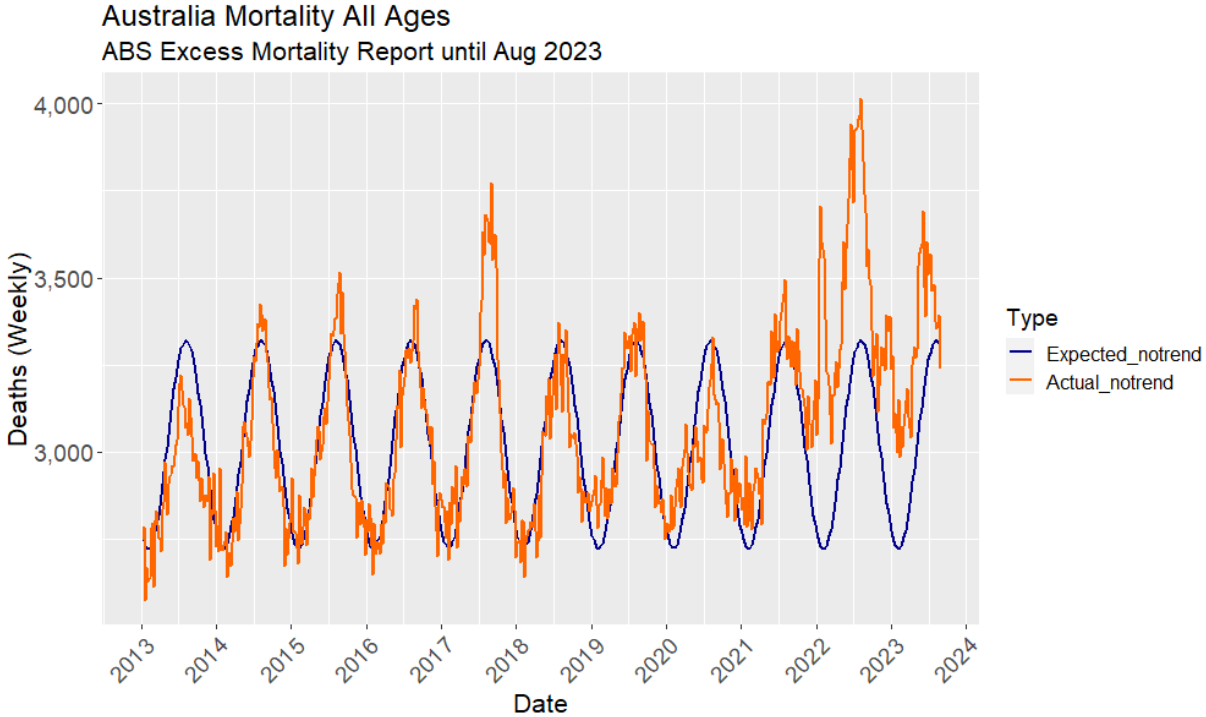


Figure 25. Subtraction of linear trend from data in Figure 23 using 2015-2019 reference window.

Now looking at just the years 2019 to 2021 in Figure 26 below.

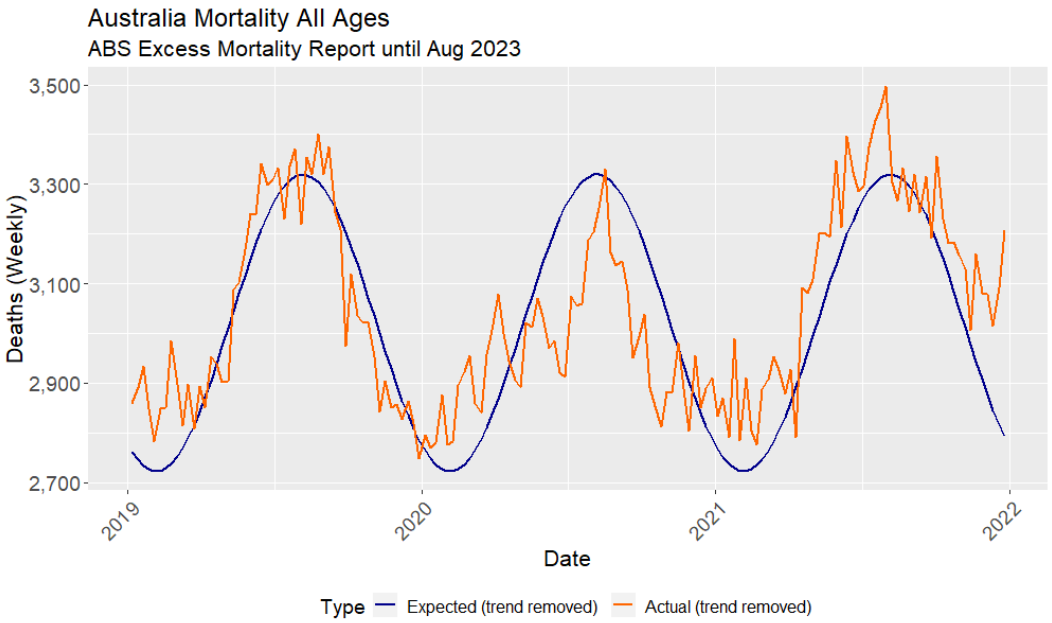


Figure 26. Comparison of years 2019 -2021 with expected value based on years 2015-2019. Trend removed for comparison.

In 2020 the seasonal pattern is still present but is distorted from the typical pattern with a sharp rise at the peak of the Winter season and elevated levels at either end of the year.

In 2021 there is a seasonal pattern that is also unusual (see Figure 21). For 2021 we observe a pattern not seen before in any of the years from 2013, where it rises suddenly in Q2 of 2021 and consistently tracks above the sine wave curve as if it is a bad influenza season starting early in the year. We have noted previously (see Figure 4) there was minimal influenza in the community in Australia in 2021.

An observation is that there is a sharp, distinct rise observed in April 2021 and this is investigated further in Section 7.1.

5.4 Error Modelling

It is important to clarify what the blue shaded uncertainty regions mean in the official ABS model. The graph in Figure 27 below is taken from the ABS Mortality report up till the first quarter of 2023:

https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-first-quarter-2023

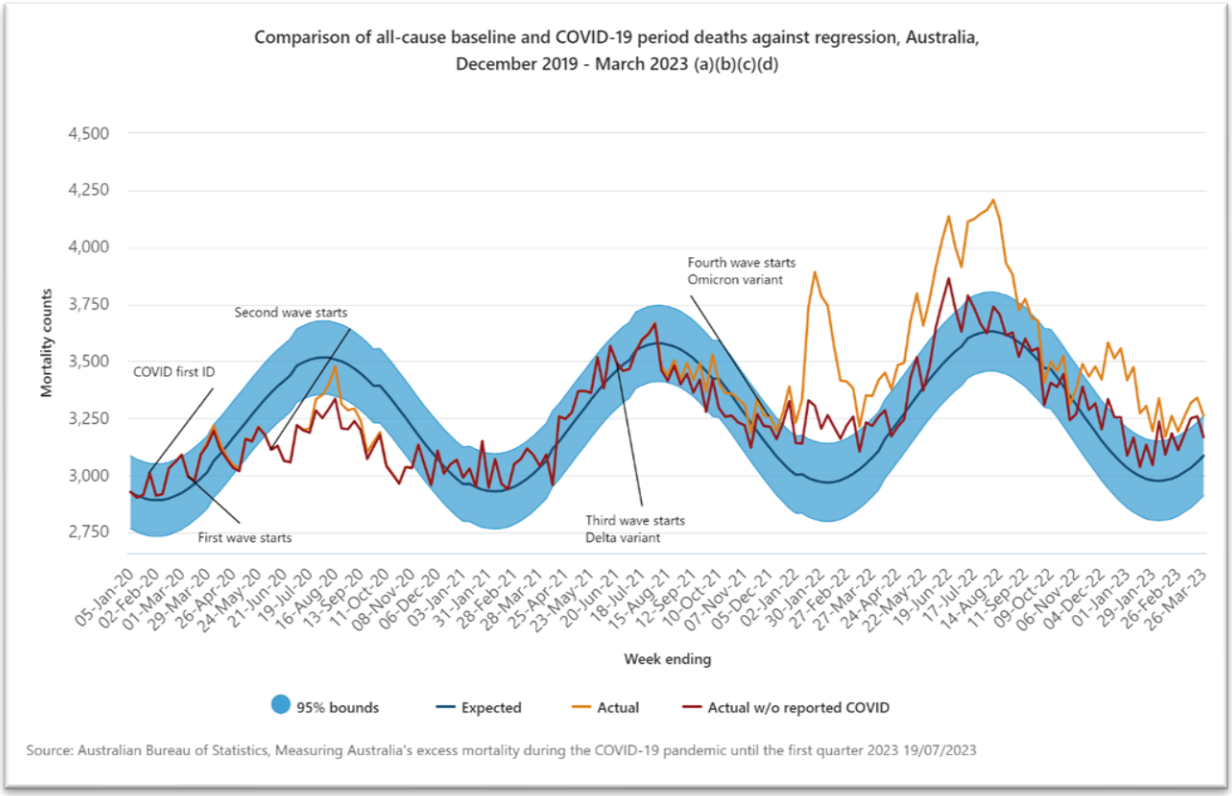


Figure 27. ABS comparison or mortality with baseline estimate for data till March 2023.

The orange line is the actual all-cause mortality. The red line is mortality with deaths both from and with COVID-19 subtracted. The blue shaded region is the 95% confidence interval around baseline estimates which is the solid blue line.

In response to a question from Senator Malcolm Roberts on excess mortality in a Senate estimates hearing – found here: https://www.youtube.com/watch?v=7V_DJLxsD_4 – a reply was provided by a Moderna representative that misinterprets this data. The following is a transcript of the Moderna representative's response:

> *I noted that in 2020, 2021 ummm excess mortality was either within the normal range or slightly below. In 2022 we do see that there is an increase in excess mortality outside the normal range but in fact it does appear actually to be due to the SARS CoV-2 infections because the period in which excess mortality do correlate with spikes in disease activity and the ABS did do an initial analysis where they subtracted the number of COVID deaths from the total number of deaths and when they did that the urrr mortality rate is actually within the expected range, so it suggests very clearly that the excess mortality that we have been observing in 2022 is due to the virus.*

There are many problems with this response to Senator Roberts as well as a lack of understanding of the relevant quantities.

By 2022 the Australian population was highly vaccinated. In older age bands close to 100% coverage was reported. In the answer "the virus" is offered as the complete cause of the excess mortality. Clearly vaccination failed to deliver the promised result and has to be factored in to understanding the causes of the excess mortality. A question for further inquiry

is deaths from COVID-19 in setting of vaccination. This is discussed in Annexure B of this submission.

In the response to Senator Roberts, Figure 27 has been used to suggest that periods of excess non-COVID mortality coincide with peaks of COVID waves and that this implies these "unexplained non-COVID deaths" are in fact related to COVID.

Firstly, the blue bands in the graph represent a confidence interval for **one particular week's mortality**. A good model will fit the underlying trend and the difference between actual values and the estimated value should be a noise signal which has minimal correlation within itself. In other words, the difference of actual values from the model estimates should look like random noise. The noise is up sometimes and down other times, with respect to the expected value. The average of the noise values over time should be zero. The noise should stay within confidence limits to the specified degree (eg 95% confidence).

However, while we may not observe weekly values consistently above the confidence limits, they may still be consistently above the baseline estimate. Even though it is clear from Section 5.2 that the baseline estimate shown in Figure 27 is not accurate (being an overestimate of the true baseline) we still observe a run above the baseline estimate in Figure 27 for a 4 month stretch in 2021 starting in April and then from November 2021 onwards.

It is cumulative excess mortality that is relevant, rather than week to week excess mortality.

What we want to know is how does the total number of deaths over a period compare with what was expected for the same period? We are also interested in periods of the order of one year. The bands for the confidence interval shown in the ABS report do not apply to a cumulative sum.

In simple terms when n multiple values with a certain random error σ are added, the error of the sum value is not n times the error but rather the square root of n times the individual error. Therefore, the error for the summed values is relatively smaller than for individual weeks. To calculate limits for cumulative values one approach is to look to the theory of statistical process control, to determine when a process has gone out of control. In any case if the number of deaths remains above the estimate, that means there is a cumulative excess building up. The error band that applies to the cumulative number is different to the error for one week.

We have also shown that the Serfling model, used in Figure 27, to predict the baseline, is a poor model with an unrealistic trend implemented and not matching the true shape of the seasonal variation.

The other incorrect statement provided to Senator Roberts is that "the excess mortality that we have been observing in 2022 is due to the virus", implying it is all due to the virus. It is clear that there is significant non-COVID excess mortality. This will be demonstrated further in following sections.

Even in the ABS official report it is stated, with respect to data for 2023 up to the end of August 2023, that:

COVID-19 associated deaths were still a key contributor to excess mortality in Australia in 2023. The number of deaths excluding deaths "from" or "with" COVID-19 for 2023 has been largely within normal bounds.

Being largely within bounds and at the same time consistently above the estimate does not mean everything is okay. It is alarming that such a lack of understanding of the data abounds.

5.5 Summary of Review of the "Official" Model

It may be asserted that the review provided in this section is limited as it does not reflect exactly what has been done in the official model. Replication of the "official" model was not possible because the underlying age bands have not been specified and the data for mortality in individual states and narrow age bands is not freely available to the public. However, the implementation provided here, using all age data, provides results close to what is predicted in the official model and the differences are noted.

In any case mortality is driven by deaths in older ages so it is not surprising that the simple implementation provided here is not too different. Our review shows that there are fundamental limitations of the "official" approach.

The sine wave model is not a good representation of the seasonal variation. It may have some utility for detecting peaks of influenza seasons but other than that it is not a first-line approach for mortality modelling. The limitations of the Serfling model have been listed.

A linear fit for the trend, together with reaching further back in time, from the 2015-2019 reference period to the year 2013, does not appear to give the best-fitting model available based on the data. If it was considered important to include 2013 in the reference period a second order or other curve fit should have been used. Figure 20 provides some insight into the sensitivity of the baseline to the choice of the reference period.

While it is stated that a sensitivity analysis was performed, no indication is given of what the different assumptions made mean to a derived excess. Indeed, it appears that all the assumptions chosen lead to a minimisation of the excess mortality in the years 2021-2023. A sensitivity analysis is not meant to be a minimisation process.

This author asserts that more accurate and representative models for mortality modelling are available. The following sections of the report will provide such modelling.

6 Top Level Annual Mortality Model

6.1 All-Ages

When performing modelling it is useful to generate a top level "simple model." If more complex models are in agreement with the simple model, then this is an indication that models are good and we understand the underlying factors. This section provides a top-level look at the Australian annual mortality numbers.

Using the PMS we look at annual deaths, for all ages, in Australia, see Figure 28. below.

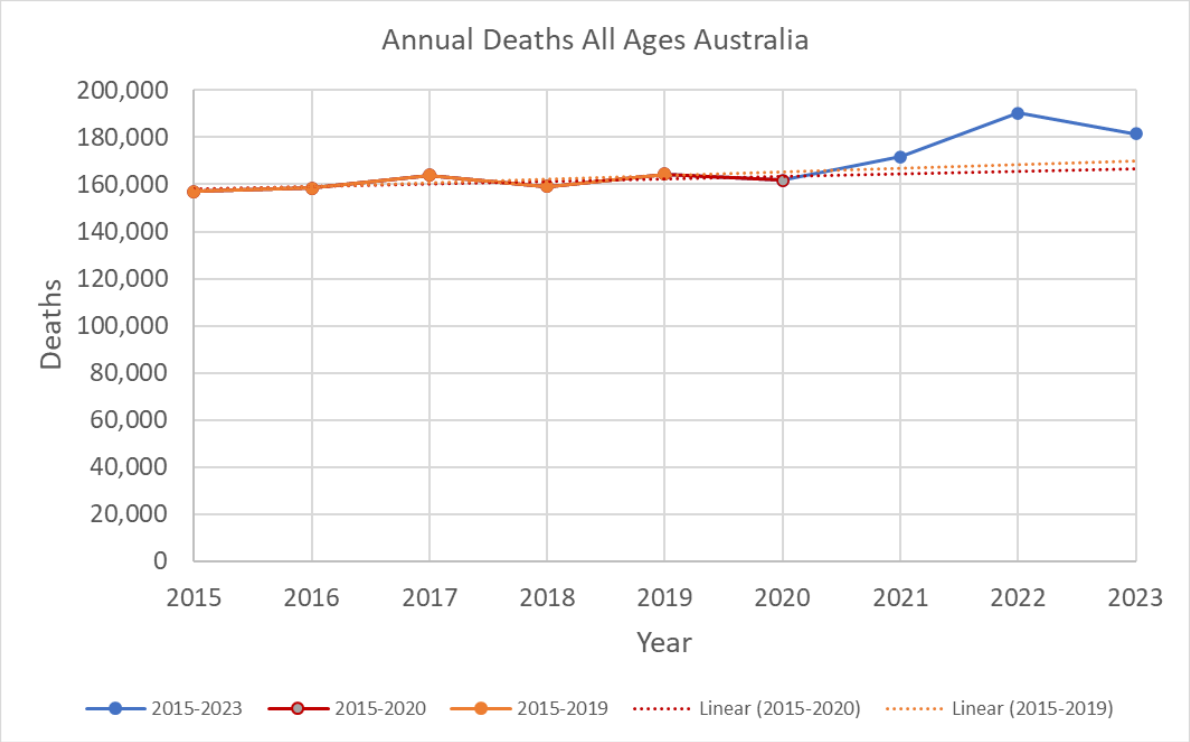


Figure 28. Annual, all ages, deaths in Australia 2015-2023.

Linear regression lines are fit to the years 2015-2020 and 2015-2019. There is a small difference with the trend tipping upwards for the fit to 2019 (the orange dashed line) compared with the fit to 2020 (the red dashed line).

Australia kept COVID-19 largely out of the community until the end of 2021. There were 1,356 deaths from COVID-19, according to the PMS January 2024 dataset. We see however a distinct increase in deaths from trend in 2021, greater than can be accounted for by COVID-19. The increase from trend is 5,035 or 7,275 extra deaths for the 2015-2019 or 2015-2020 reference period respectively. We will be conservative and choose the higher 2015-2019 baseline and estimate 5,025 excess deaths in 2021.

The number of deaths above the trend for years 2022 is 22,119 and for 2023 is 11,787. This is a total of 38,941 excess deaths, ie approximately 40,000 extra deaths. The number of COVID-19 deaths for the same period 2020-2023, from the latest PMS dataset found here:

https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/jan-2024

- 17,111 deaths “from COVID-19” and
- 4,511 “with COVID-19”.

This is a total of 21,622 COVID deaths, approximately half of the total estimated excess deaths. It is noted that the deaths with COVID are likely to have occurred as a result of other conditions (see Section 4.3) and may not be valid to be considered as COVID excess.

There is a large jump in mortality in 2022 driven by COVID-19, when vaccinated travellers were allowed into Australia in late 2021 without quarantine and the Omicron variant spread rapidly in the community.

In some analyses it is important to adjust for population. However, when looking at raw death counts, we can see in Figure 28 that there was a consistent mortality trend in the normal times. Therefore, the simple all ages calculation does not necessarily need to be adjusted for population. We assume that the underlying age specific population and mortality rate trends continue the same. If they are linear then this is valid.

Population adjusting the all-ages mortality will not be accurate because of the different properties of mortality for different ages. Most of the population is in younger ages, where there are smaller numbers of deaths, and most of the deaths are in a smaller population of older ages.

Australian population from 2015 to 2023 is shown in Figure 29 below.

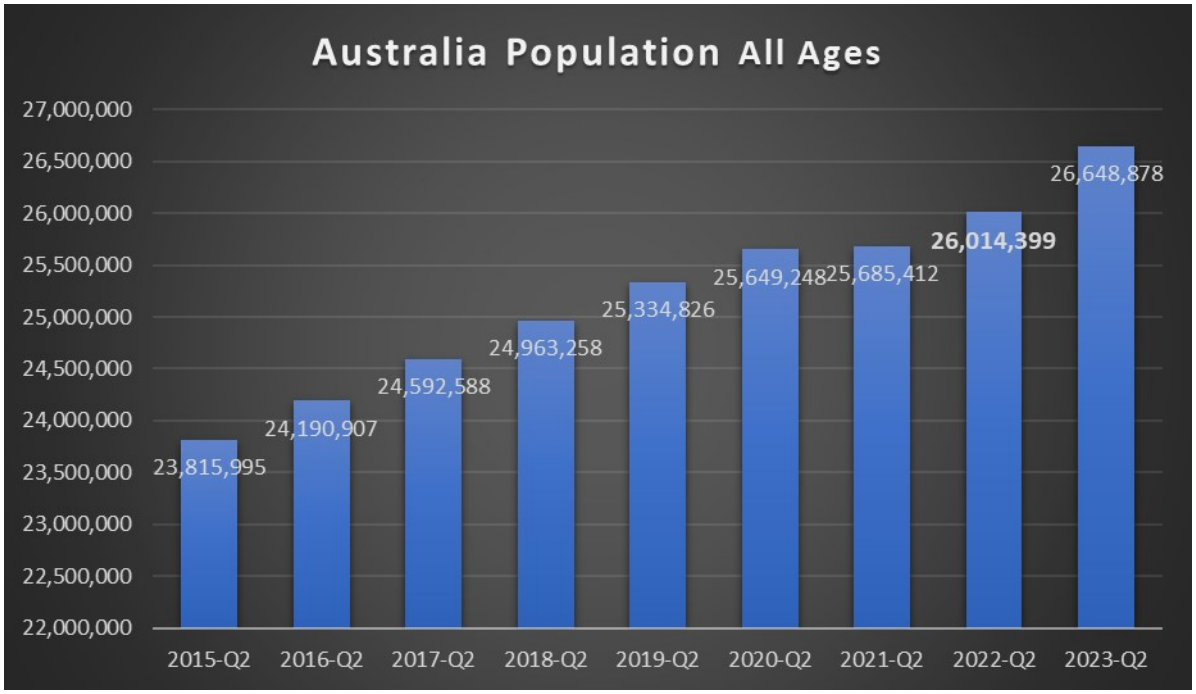


Figure 29. Population Australia all ages. Population as at 30 June each year.

Population growth in Australia stagnated from 2020 to 2021 from border closure and expats returning overseas. For comparison if we look at an older age group there is no such stagnation. See Figure 30 for ages 75-84.

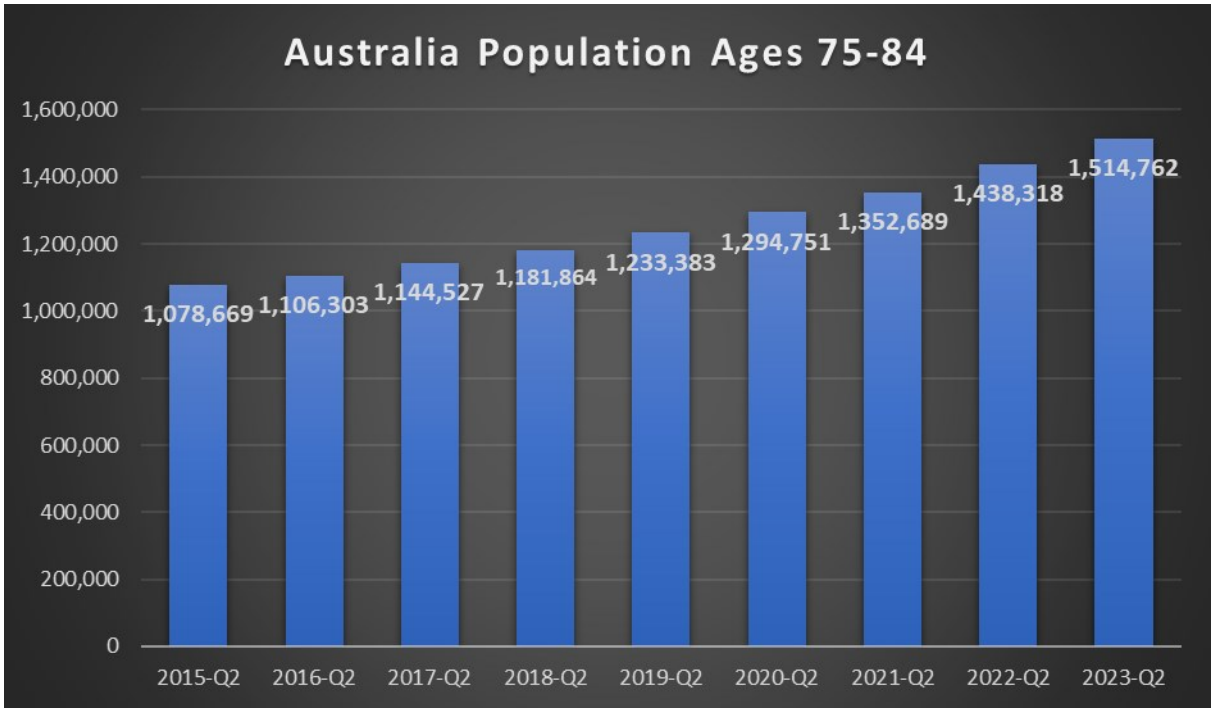


Figure 30. Population for ages 75-84. Population as at June 30 each year.

Adjusting for population will be effective for narrower age bands. For all ages it may be misleading.

6.2 Is Year 2020 a Representative Year?

A question arises as to whether 2020 should be considered a normal year. It can be seen above that the mortality for the total year 2020 is within what could be expected to be typical deviation (ie less than one standard deviation). We do know from previous work (see Figure 4) that the typical seasonal pattern in 2020 was different to other years probably because of low effects from influenza in Winter of 2022. But overall, the annual number for 2020 appears to be on trend. A lower than trend number for 2020 was expected as 2019 was a worse influenza season, particularly in some states (see Figure 4).

Annual mortality for 2021 is calculated to be approximately three standard deviations above the 2015-2019 trend according to the data above (Figure 28). However, COVID-19 was not spreading widely in the community in Australia in 2021. There were 1,121 COVID-19 deaths in Australia in 2021 according to the AIHW report:

https://www.aihw.gov.au/reports/life-expectancy-deaths/deaths-in-australia/contents/covid-10-deaths

This leaves approximately 4,000 unexplained excess deaths in 2021.

At a Senate Estimates hearing in March 2024 Senator Rennick suggested to Health Department officials that the increase in mortality in 2021 was three standard deviations. The interaction is found in Hansard here:

https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=committees/estimate/27723/&sid=0013

and video on youtube here: https://www.youtube.com/watch?v=zvA012sqxog

The Health Department seemed to be unaware of this increase in 2021.

6.3 Individual Age Bands

Care has to be taken with aggregated data, such as mortality for all ages. We can see too that the population of Australia stagnated in 2021 when there was no travel allowed. This stagnation was mainly due to young people not coming to Australia to work or study. We know the majority of deaths occur in older ages and so that demographic drives the mortality. Underlying trends for each individual age band (both population and mortality rate) are not expected to change dramatically year to year, so estimates based on all ages should still be reasonably reliable when projecting forward. In particular, if mortality rates and population vary consistently, eg monotonically, from year to year, within individual age bands, then the prediction for the following year using the aggregated data should still be accurate. We do expect accuracy to decrease the further out we forecast on account of changes in individual trends in the sub-bands.

We therefore look at individual age bands for the best accuracy. With the ABS public data, we have coarse age-band data available for the ages:

- 0-44
- 45-64
- 65-74
- 75-84
- 85+

We now analyse each of the age bands in the following section. Data are taken from the latest ABS PMS data up till end of 2023. Annual deaths were taken as 52 weeks. Years 2015 and 2020 have 53 weeks using the ISO convention. Using 52 weeks avoids any bias in those years. We fit a linear regression over the years 2015-219 and project forward to 2023. The standard error range is shown. Calculation is done for both raw death counts and an age specific rate. While this may be accurate at the narrower older age bands, there will be inaccuracy in the younger age bands 0-44 and 45-64 where there will be different dynamics in sub-bands.

6.3.1 Age 85 Plus

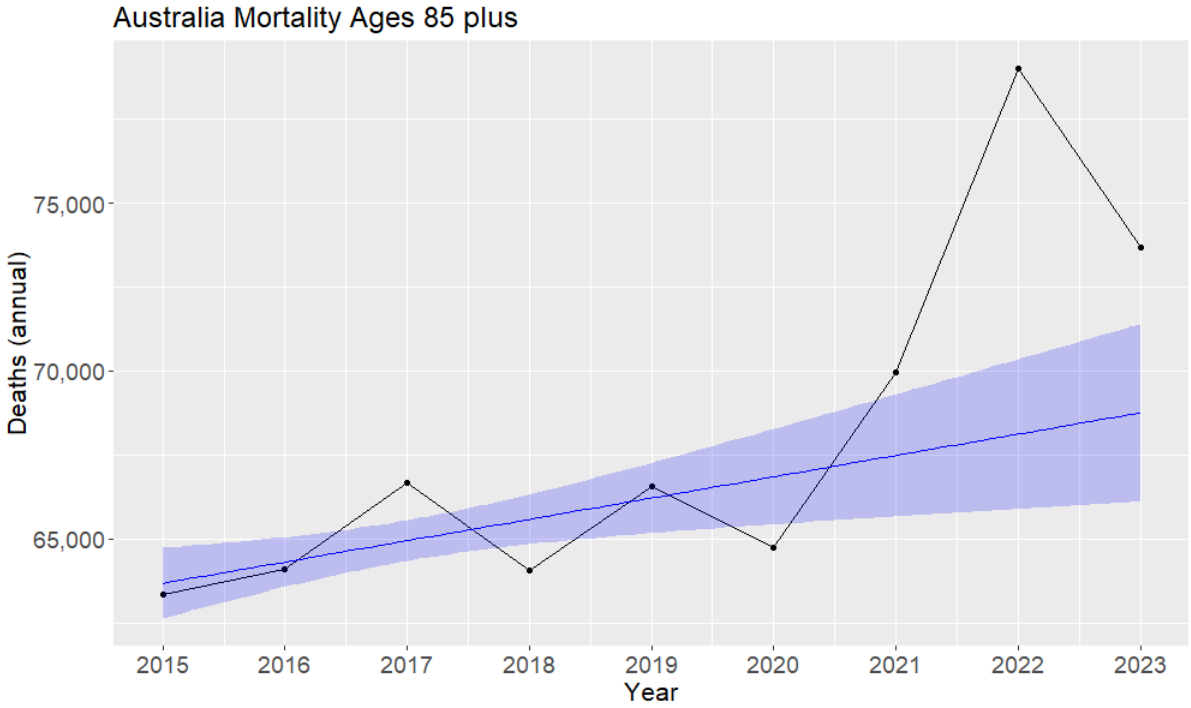


Figure 31. Annual mortality ages 85 plus

Excess for 2021: 2,466.8; 2021-2023 Excess total: 16,172.

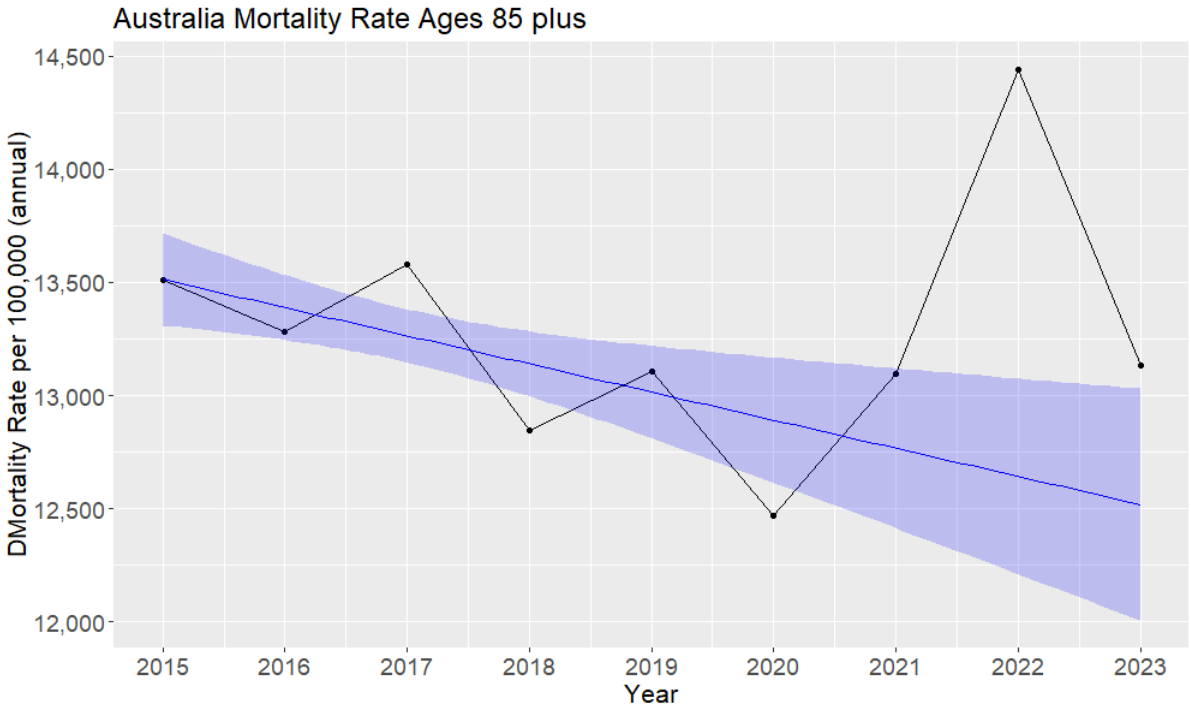


Figure 32. Annual age specific mortality rate ages 85 plus.

Excess for 2021: 1743; 2021-2023 Excess total: 12,832.

6.3.2 Ages 75-84

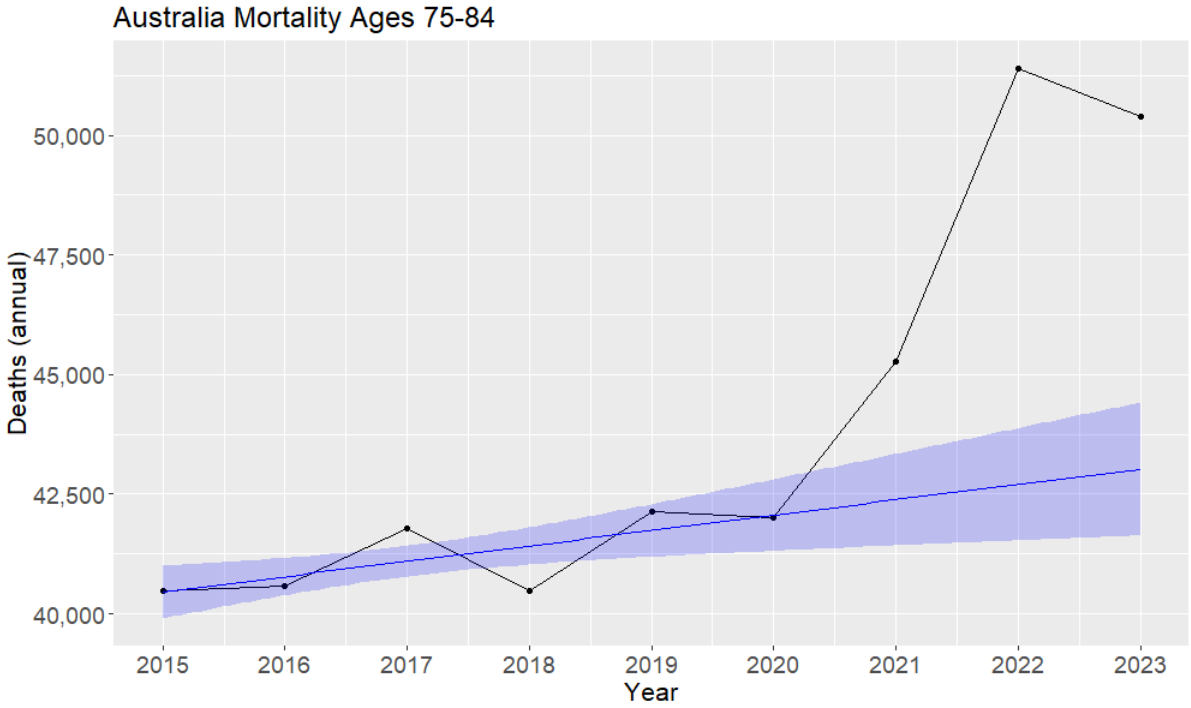


Figure 33. Annual mortality ages 75-84.

Excess for 2021: 2,900; 2021-2023 Excess total: 18,960. When baseline fit to 2020 Excess total:18,910. The similarity is indication that 2020 was consistent with previous years.

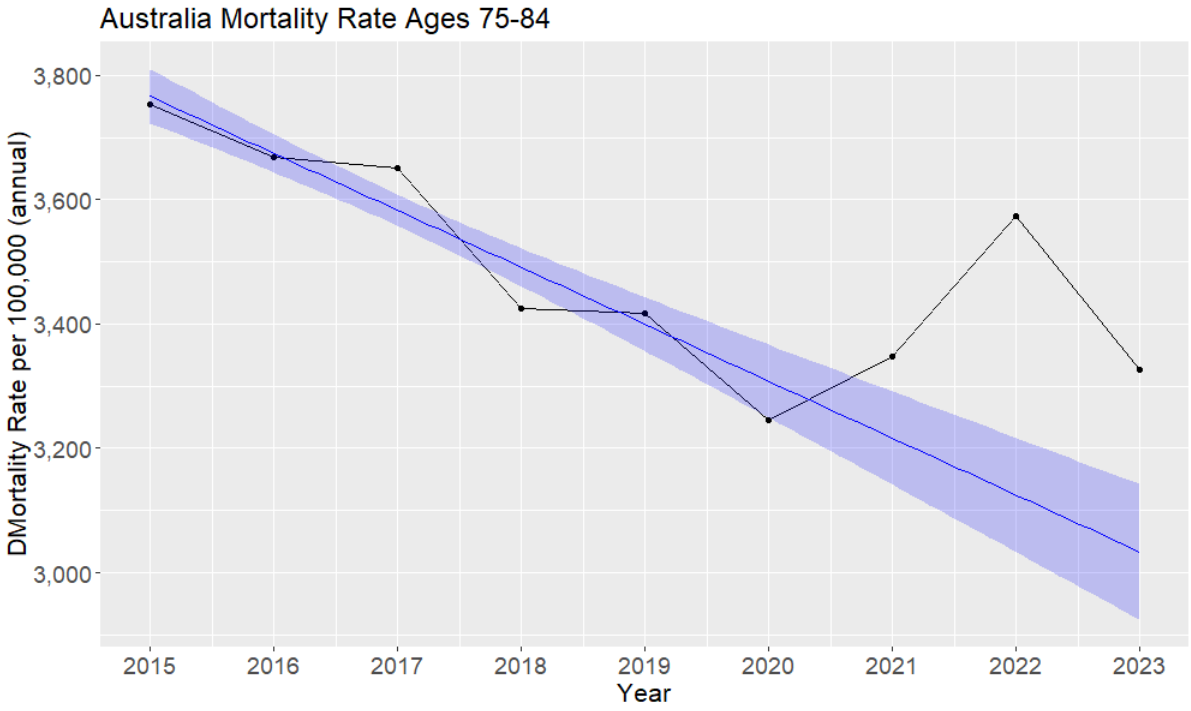


Figure 34. Annual age specific mortality rate ages 75-84.

Excess for 2021: 1,771; 2021-2023 Excess total: 12,661. When baseline fit to 2020 Excess total: 11,838. The similarity is indication that 2020 was consistent with previous years.

6.3.3 Ages 65-74

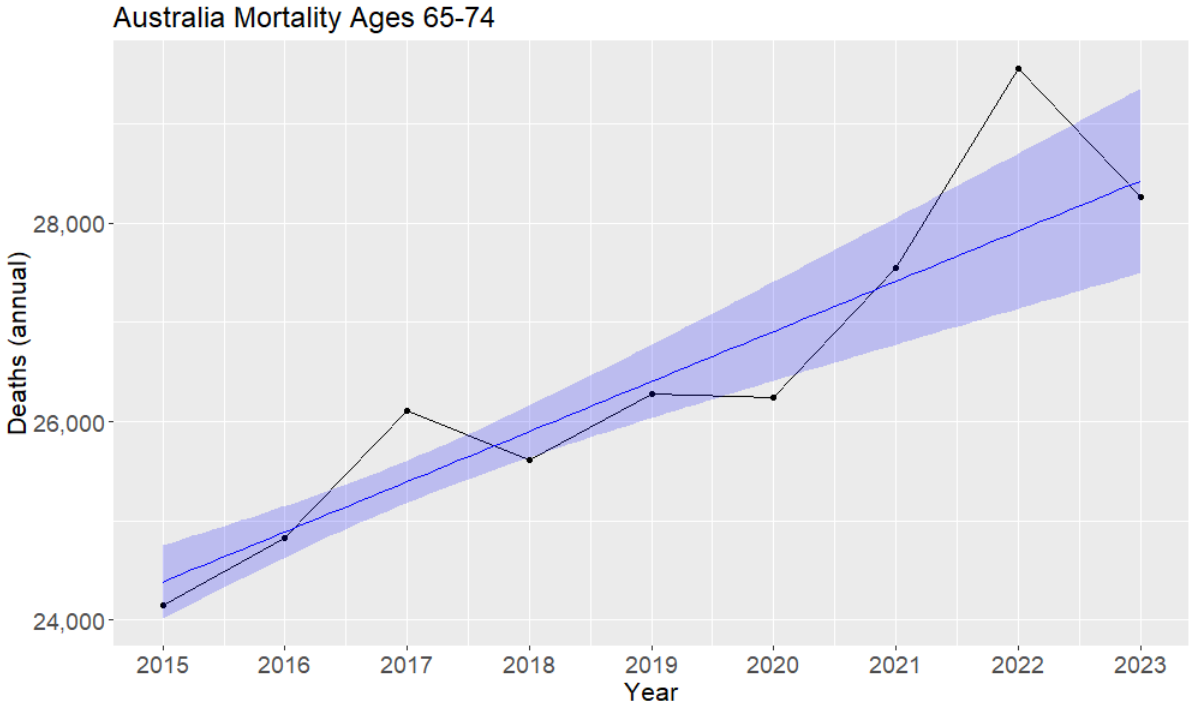


Figure 35. Annual mortality ages 65-74.

Excess for 2021: 139; 2021-2023 Excess total: 1,624.

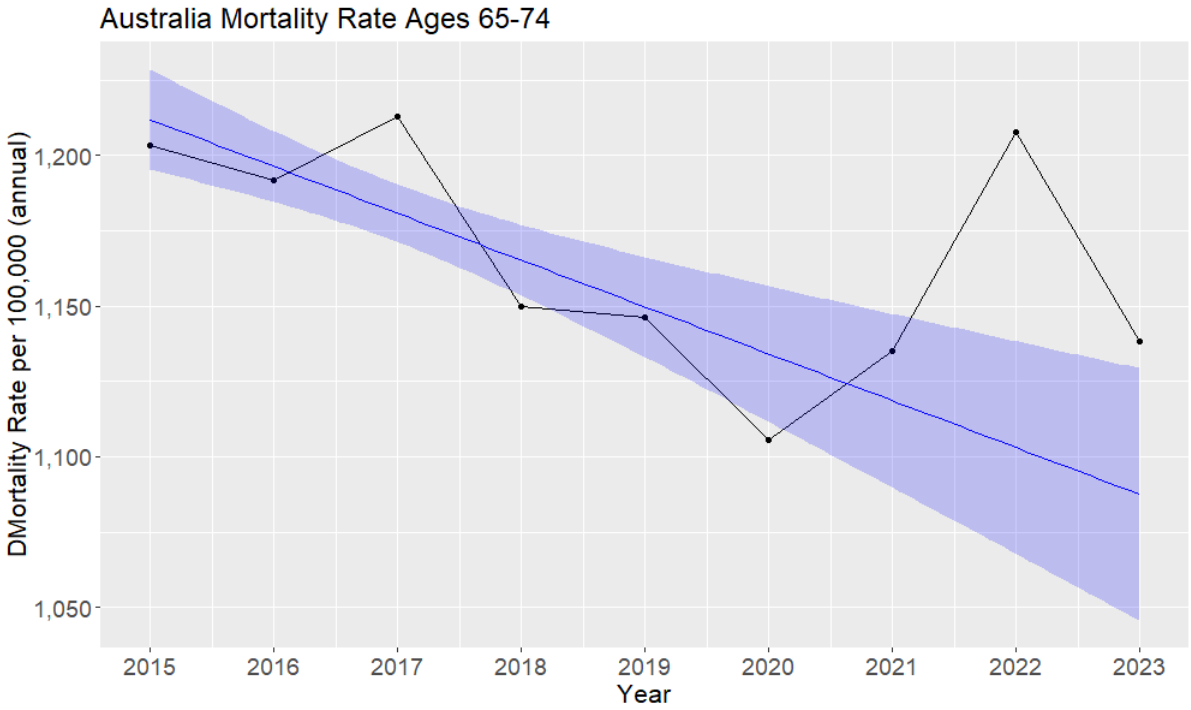


Figure 36. Annual age-specific mortality rate ages 65-74.

Excess for 2021: 401; 2021-2023 Excess total: 4,216.

6.3.4 Ages 45-64

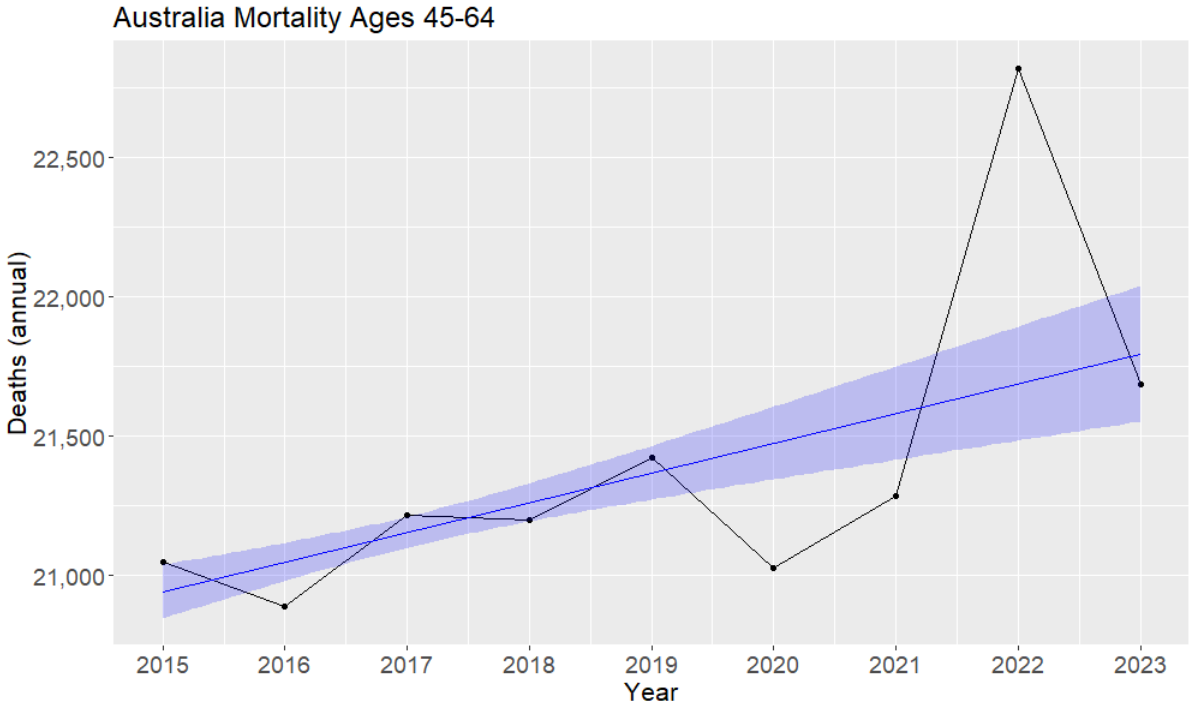


Figure 37. Annual mortality ages 45-64.

Excess for 2021: -299; 2021-2023 Excess total: 724.

There is a distinct dip in mortality in the age group in 2020. No excess is seen in 2021.

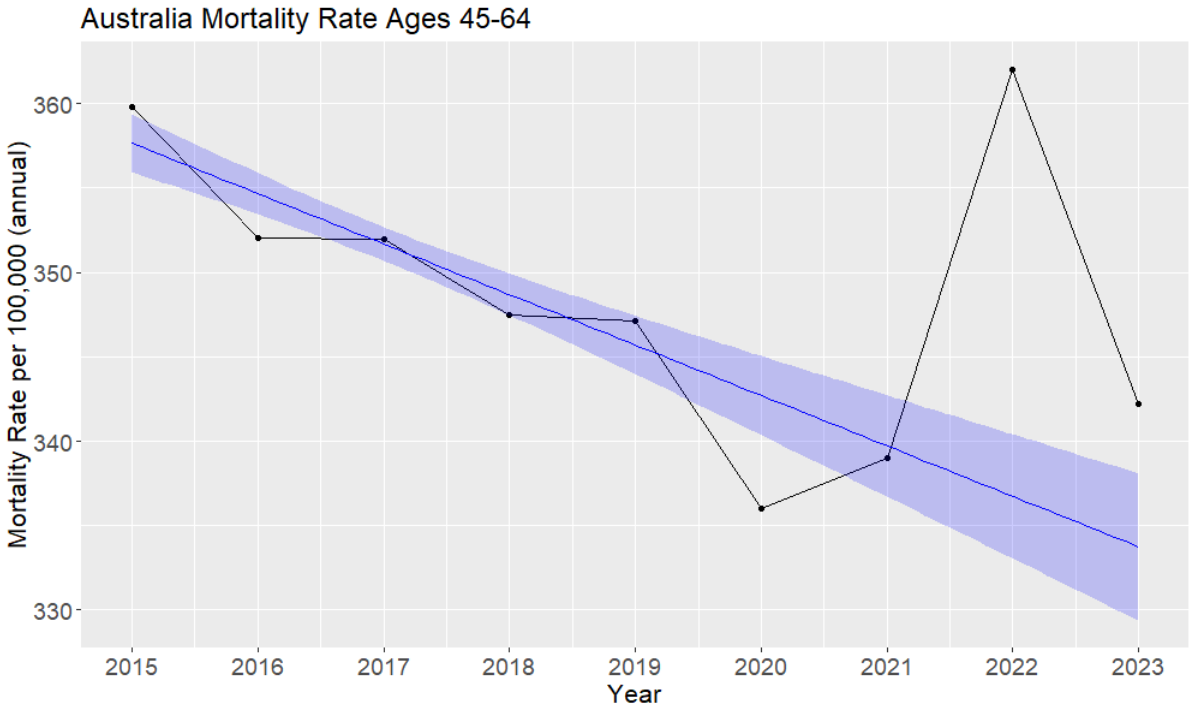


Figure 38. Annual age specific mortality rate ages 45-64.

Excess for 2021: -43; 2021-2023 Excess total: 2,088.

6.3.5 Ages 0-44

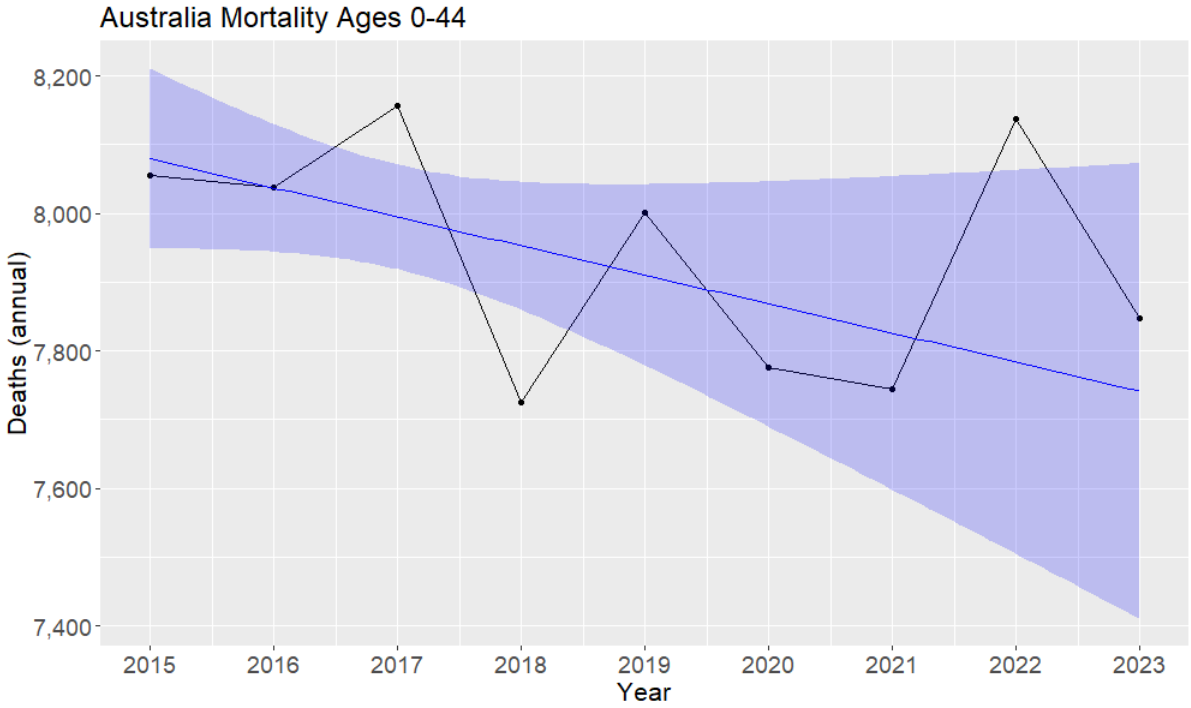


Figure 39. Annual mortality ages 0-44

Excess for 2021: -82; 2021-2023 Excess total: 377.

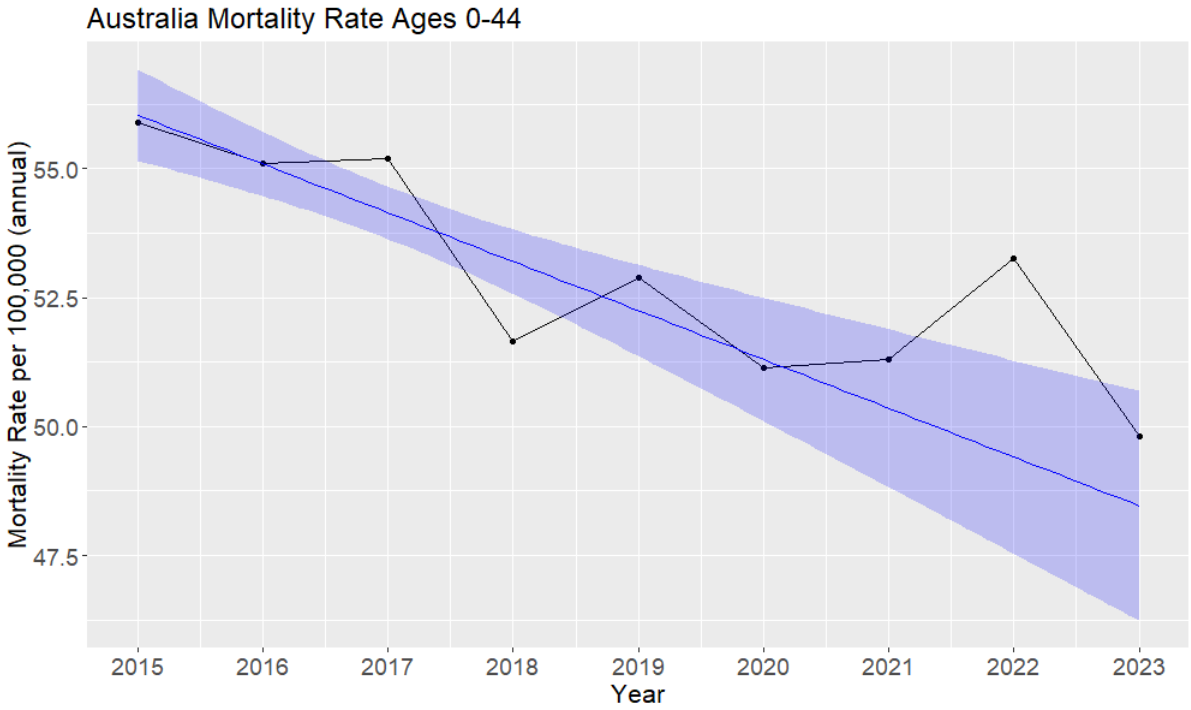


Figure 40. Annual age specific mortality rate ages 0-44.

Excess for 2021: 143; 2021-2023 Excess total: 946.

A summary of these top-level estimates is provided in Table 1 below.

Age Band	Annual Raw Data Method	Annual Rate Method
85 Plus	16,172	12,832
75-84	18,960	12,661
65-74	1,624	4,216
45-64	724	2,088
0-44	377	946
SUM	37,857	32,743

Table 1. Estimates of excess mortality using simple annual method.

We observe that the estimates using the rate method are lower for the two oldest age bands. We expect that the population adjustment is valid for the 75-84 age band which is the narrowest band available. For the three lowest age band 65-74, 45-64 and 0-44 the rate method is a higher estimate.

Summing all bands for each method gives a rough estimate of 33,000 to 38,000. We estimated 38,941 using all ages data without population adjustment. This is consistent with the sum of the individual bands.

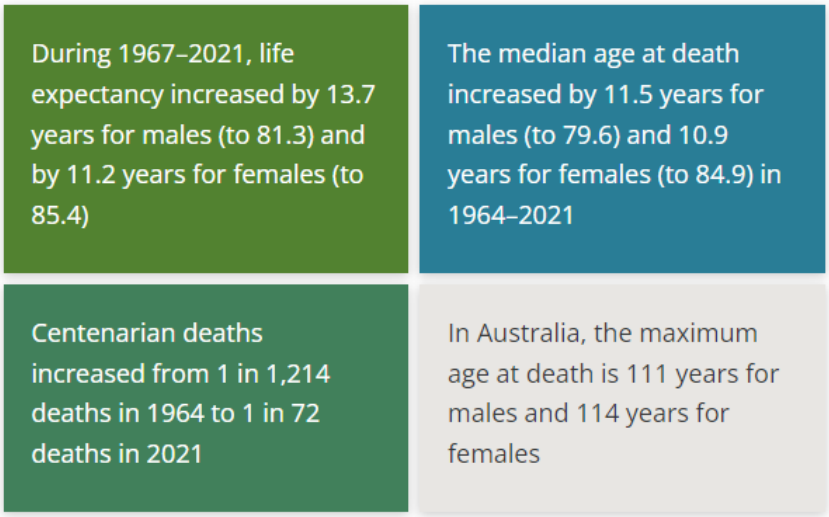
While this simple method is crude it provides some insight. The excess from 2021 to 2023 is in the ball-park of 30-40,000 excess deaths. The excess is primarily in the ages above 75. But there is still significant excess in younger ages, given the relatively lower rate of deaths expected in younger ages.

In 2021 we see a distinct jump above the error bands in the 75-84 and 85 plus ages. In the 45-64 age band we see a large deficit in 2020 and a deficit still in 2021. Then there is a large jump in 2022 of over 1,000 deaths. This will be contributed to by COVID deaths. Data in Figure 73, for COVID-19 deaths by age band, have deaths in 10-year age bands, and unfortunately these are offset by 5 years from the mortality data. We can make a rough estimate by halving the adjacent bands and get approximately 650 COVID-19 deaths.

6.3.6 Age Specific Rate Trend

We see from 2015 till 2020 the trend was decreasing for all age bands. This is equivalent to the rate of deaths decreasing. This is what we expect. People in Australia were living longer up till 2021. Australian Institute of Heath Welfare data show us this. See the following graphic from webpage:

https://www.aihw.gov.au/reports/life-expectancy-deaths/how-long-can-australians-live/summary



It is noted that while life expectancy was slowly improving up till 2021 the highest ages of death do not increase. This is a fact of life, that there is a hard stop, and very few reach past a certain maximum age.

7 Patterns in the Mortality Data

In this section, before we launch into implementation of models for mortality, we investigate certain unusual patterns in the data that have been observed.

7.1 Differencing

Numbers of deaths vary up and down from week to week. This random variation, or noise, sits on top of the seasonal variation and the underlying trend. That trend is upwards in the all-ages actual mortality dataset, mainly from increasing population. In terms of a rate, for older age groups, this was gently trending downwards as shown in the previous section.

If we have a good model then this noise, being the difference from actual values and our model, should be what is known as random noise, with no correlation in the week-to-week variation. There are methods to assess this. The noise component will typically stay within specified bounds. An example of such bounds is those represented by the blue shaded bands in the ABS graphs for that model, noting these bounds apply to individual data samples for a week. Of course, with random noise we do expect occasional wide excursions. A single exceedance could be that. A successive exceedance is more unlikely to be random noise.

We will be using the ARIMA model with seasonal adjustments as one of our modelling methods in the following sections. One of the steps in analysing time series using ARIMA modelling is taking differences of time sample values. The first difference, d=1, is the subtracting of successive values. This is the week-to-week difference in deaths. A reason for applying differencing in the ARIMA model is that it can be used to remove linear trend in the data. A linear trend is removed by first differencing values. The trend then turns into a constant average value.

For all-age mortality first differencing is shown in Figure 41 below.

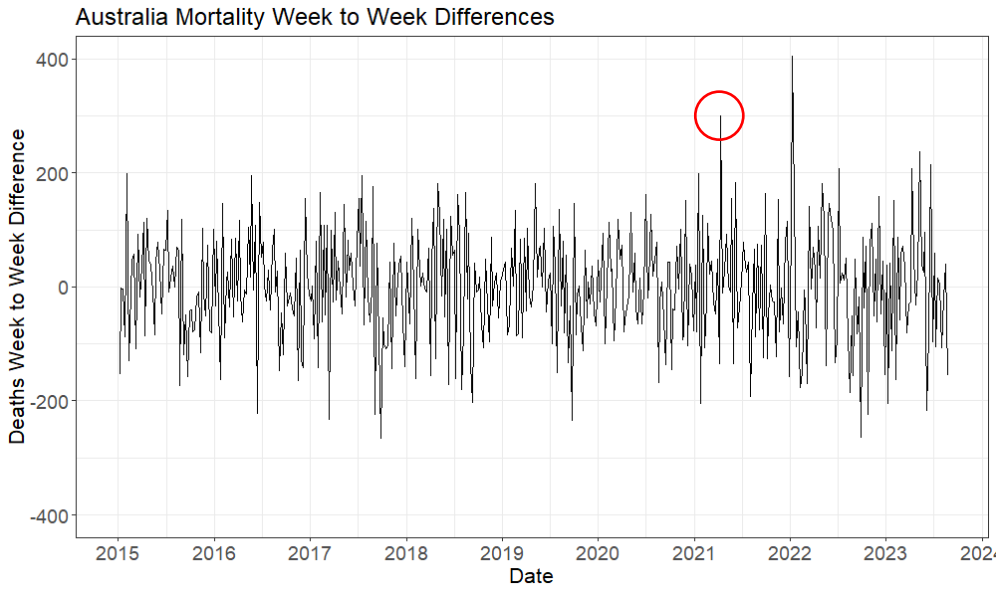


Figure 41. All age mortality week to week differences, 2015-2023.

Close inspection shows that prior to 2021 there is a seasonal variation embedded in this series, but in general the week-to-week variation remains within ±200 deaths. Because of the seasonal effect in the series the differences will tend to be a little bigger on the upslope of the season.

We see a large excursion at the start of 2022. This is known to be the onset of the Omicron wave in Australia. We expected a large jump in deaths at that time through the volume of deaths attributed to COVID-19 Omicron across this period.

There is a second wide excursion in these data observed in mid-April 2021 (the week ending 11 April 2021), circled in red. There was no COVID-19 in Australia at this time. Now while this does occur on the upslope of the seasonal variation, the difference is still unusually large compared to all preceding years, even at the seasonal peaks.

In graphs below we show other types of differencing used in ARIMA modelling. Note the x axis time scale is only up till the end of 2021 now, as we are interested in the time before COVID-19 was prevalent in the community in Australia. Seasonal differences (52 weeks apart) can be taken and this is shown in Figure 42. Seasonal differencing uncovers an annual alternating pattern of mortality. After a year of high mortality from a bad influenza season, for example, the next year is typically less. 2017 is up, 2018 down; 2019 up, 2020 down.

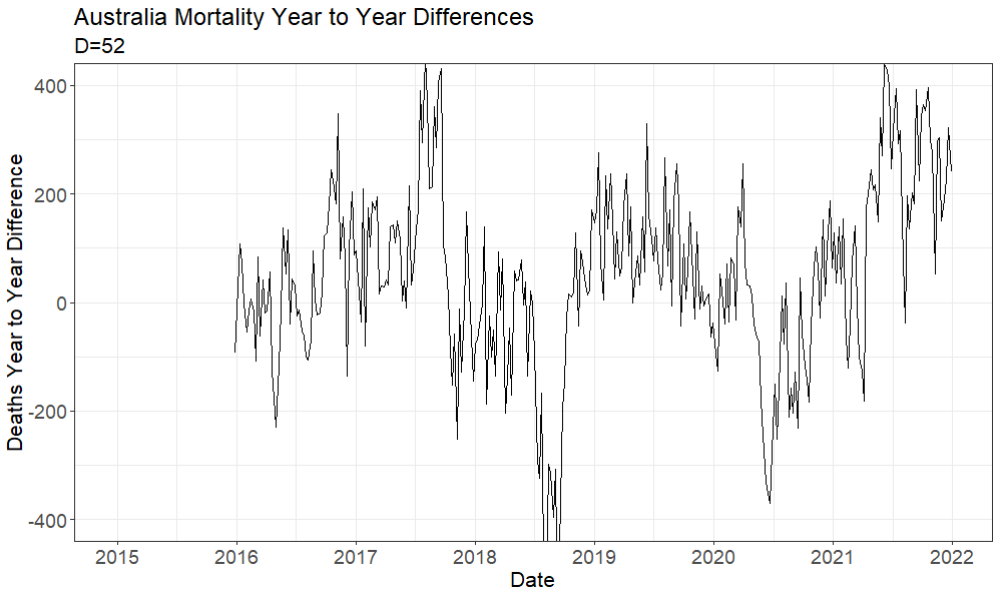


Figure 42. All-age mortality seasonal (ie 52 week) differences, 2015-2023.

We have noted that the 2020 seasonal pattern was different to previous years and was affected by government COVID-19 measures. Consequently, 2021 seasonal differences may also not be expected to be consistent with the normal years.

In ARIMA modelling both seasonal and inter-sample differencing may be used. Figure 43 below includes seasonal differencing, ie subtracting year to year values as well as differencing week to week values. This looks more like true random noise but the large difference in April 2021 is still seen.

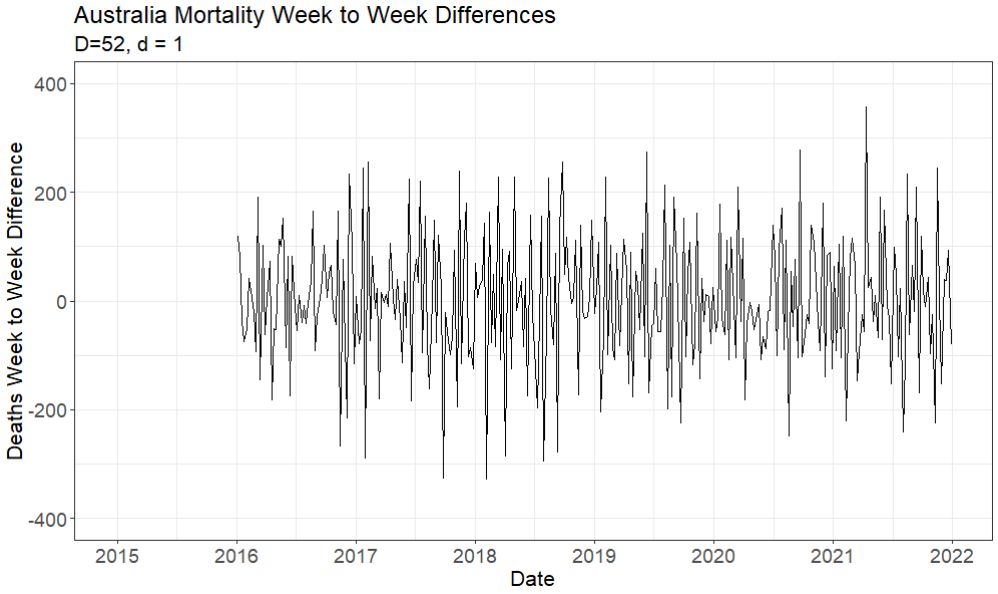


Figure 43. All age mortality week to week and seasonal differences, 2015-2023.

Note the double differenced value in 2021 is affected by the unusual 2020 seasonal pattern so we have to be careful interpreting the 2021 double difference.

This unusual jump in mortality in mid-April 2021 warrants further investigation. See Figure 44 below for the mortality for Victoria from the ABS report.

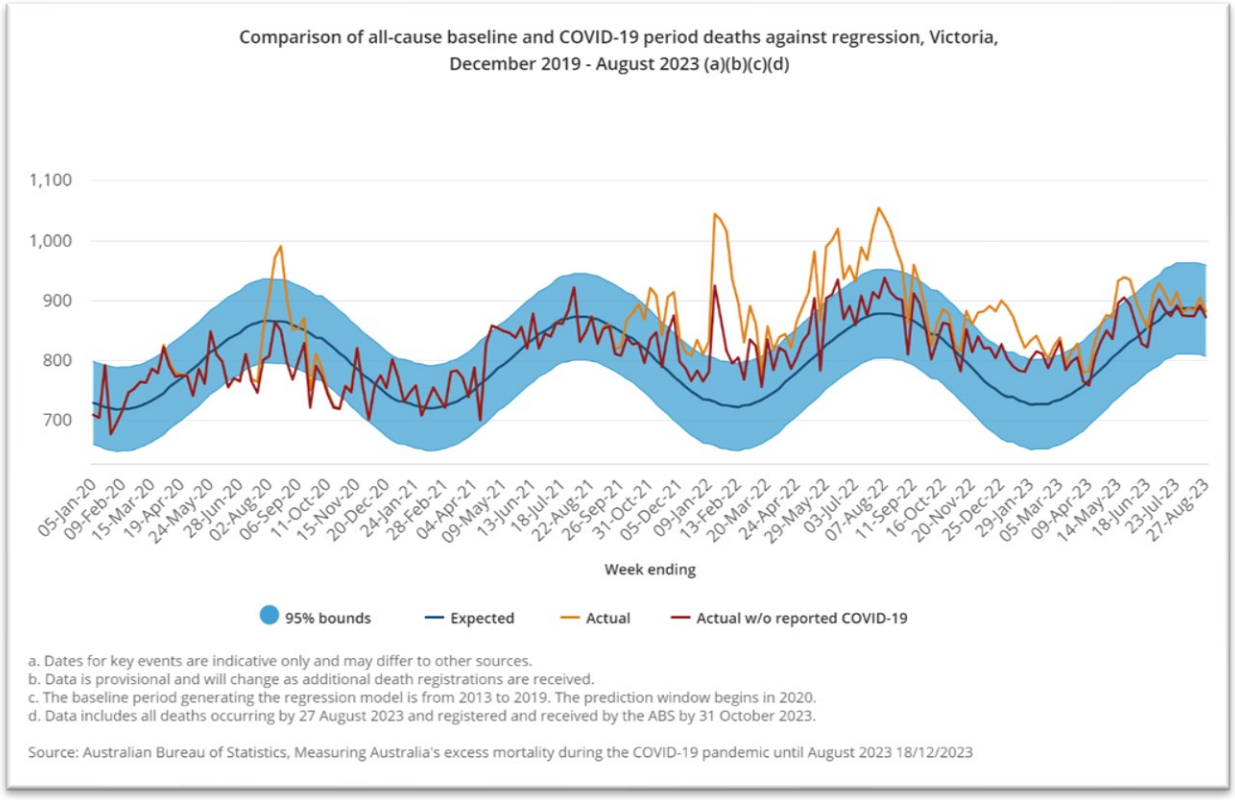


Figure 44. ABS modelling report graphic for pandemic years 2020 to 2023.

A distinct jump is observed to occur between the 11th and 25th April. We can investigate what was occurring at that time in the community that might lead to a sudden increase in mortality. We know influenza was minimal and that there was no COVID-19 in Australia at that time (see Figure 45 below).

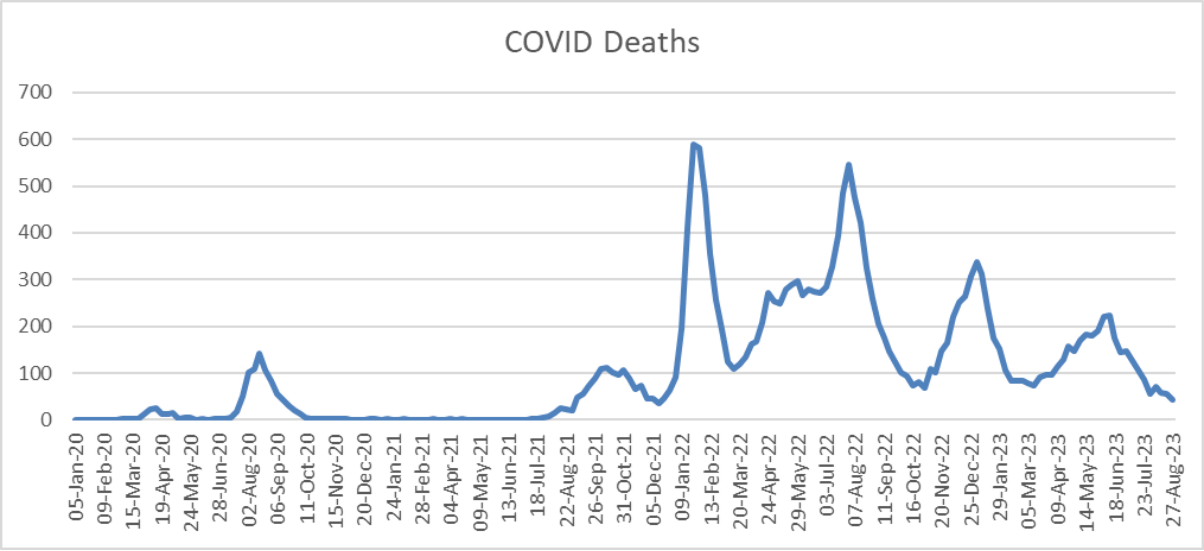


Figure 45. Weekly COVID-19 deaths taken from ABS mortality modelling report.

Introduction of new medicines must be considered. To plot the COVID-19 vaccination roll-out, we take data from aggregator site covidlive.com.au, which collects data from government health websites. We see the vaccine doses delivered in Victoria in Figure 46 below.

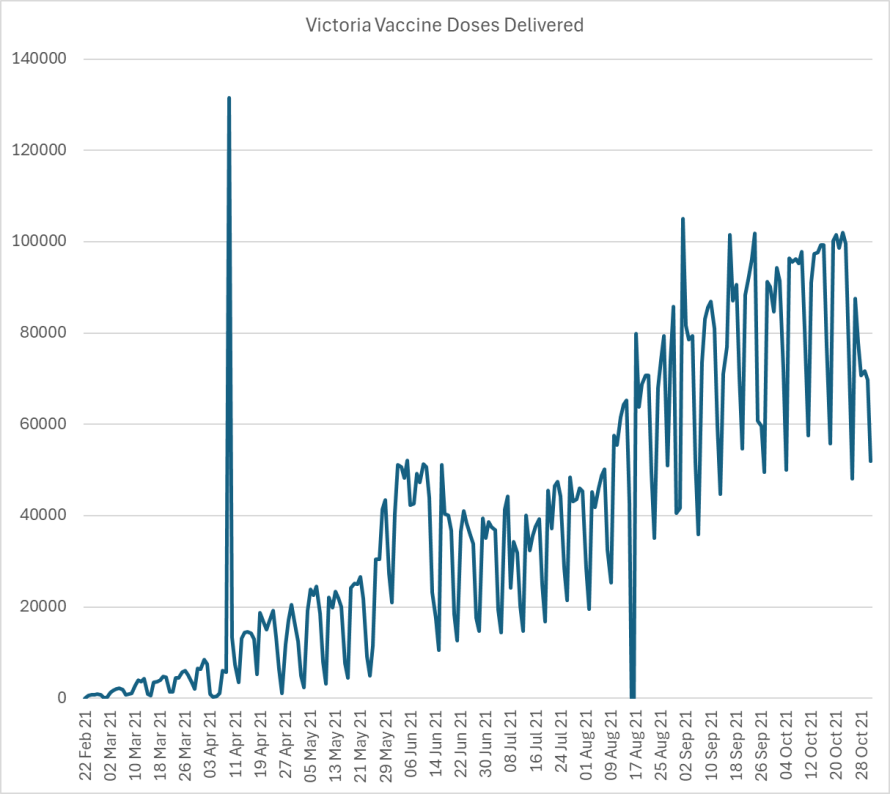


Figure 46. Victorian vaccine doses delivered according to covidlive.com.au.

9th April 2021 has an unusual large number of doses delivered. This is a Friday. This may be doses added retrospectively to the data. This timing does however coincide with opening of mass vaccination centres. Searching news articles, we find Victoria opened its high-volume vaccination centres in April to older ages. From the Herald Sun:

https://www.heraldsun.com.au/coronavirus/victorias-vaccine-program-off-to-a-flying-start/news-story/27bc572036f89df60f40407b68a3f01c

> *Sunday 21 March 2021: Australia is preparing to ramp up the vaccination rollout on Monday with the start of Phase 1B, which allows those over 70 and people with underlying health conditions to be vaccinated at GP clinics.*

From: https://www.premier.vic.gov.au/vaccine-rollout-ramps-across-victoria

> *To help achieve this, from Wednesday 21 April, Victorians eligible under phases 1a and 1b of the rollout will be able to receive the AstraZeneca vaccine at three of Victoria's high-volume vaccination centres.*

Initially health workers were prioritised for vaccination, followed by the elderly. It could be a coincidence that delivery to the elderly of the Astra Zeneca vaccine was commencing at the end of March 2021.

In section 3.3 we observed the high number of reported deaths in the DAEN following vaccination in older ages in April 2021 (see Figure 5 in Section 3.3). Coincidentally we observe an unexpected high increase (statistically significant) in week-to-week mortality in April 2021. These correlations warrant further investigation. Temporally mass vaccination of the elderly starts, mortality increases with a pattern not seen in previous years and adverse events including deaths are reported to the DAEN. This occurs at a time when there was no COVID-19 or influenza affecting the population.

The way to further investigate this is to obtain record level data of those that unfortunately passed away at this time, recording date of vaccination and date of death. Section 10 will provide details of data necessary to investigate this further.

8 Modelling Cumulative Excess Mortality

In this section we use a method of modelling the Cumulative Excess Deaths. This is an alternative method to modelling the time series of the weekly deaths. If we are able to generate a model that faithfully represents the dynamics of mortality over the reference modelling period, we have confidence that the model can be used to forecast forward using the same model parameters. An advantage is that this method provides the cumulative excess directly.

8.1 All-Ages Analysis

Note we have used the PMS data available up to the end of 2023 for this analysis. We accumulated deaths from the start of the reference period 2015. This in effect is counting week to week the total number of deaths in Australia. With approximately 160,000 deaths per year from 2015-2019 this means that at the end of 2019 there are approximately 800,000 deaths. This is shown below in Figure 47.

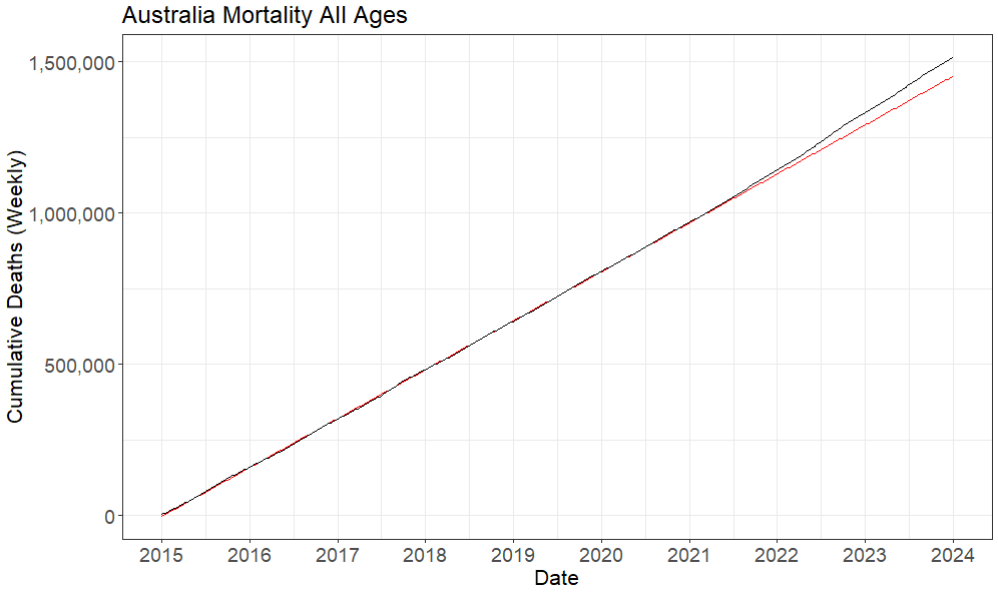


Figure 47. Cumulative mortality for all ages from 2015. Black line raw data. Red line is linear fit to period 2015 to 2020.

In Figure 47 the black line shows the actual accumulated deaths for all ages. It looks remarkably straight up till 2021. A linear fit is made to this data for the reference period, where we consider annual mortality patterns normal. It was found there was minimal difference whether 2019 or 2020 was used as the end of the reference period. We use up to the end of 2020 for this analysis. A red line is shown according to the model fitted right up to the end of 2023. There is a clear divergence of the actual data and the linear fit somewhere in 2021. We subtract the line of fit to see the difference from trend and the result is in Figure 48 below.

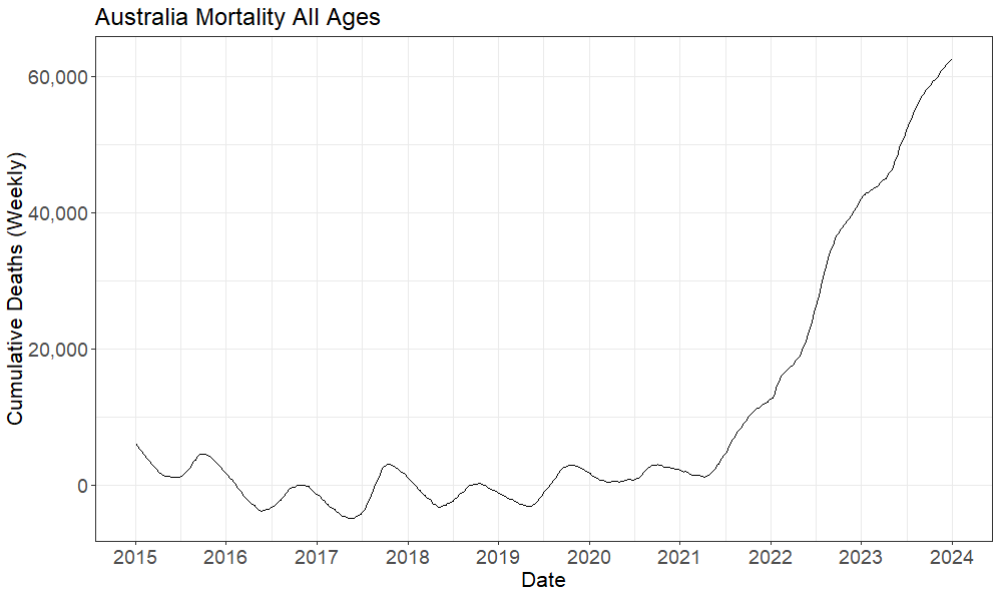


Figure 48. Excess computed using a linear fit to the reference period.

What we see is an oscillating pattern about the zero line that takes off in 2021. However, prior to 2021 there appears to be an underlying bowl shape. This implies that the linear fit is not the best and that a second order fit may be more appropriate. This is not surprising given that the cumulative deaths has built into it both population and mortality rate changes.

We apply a second order fit with the result in Figure 49 below.

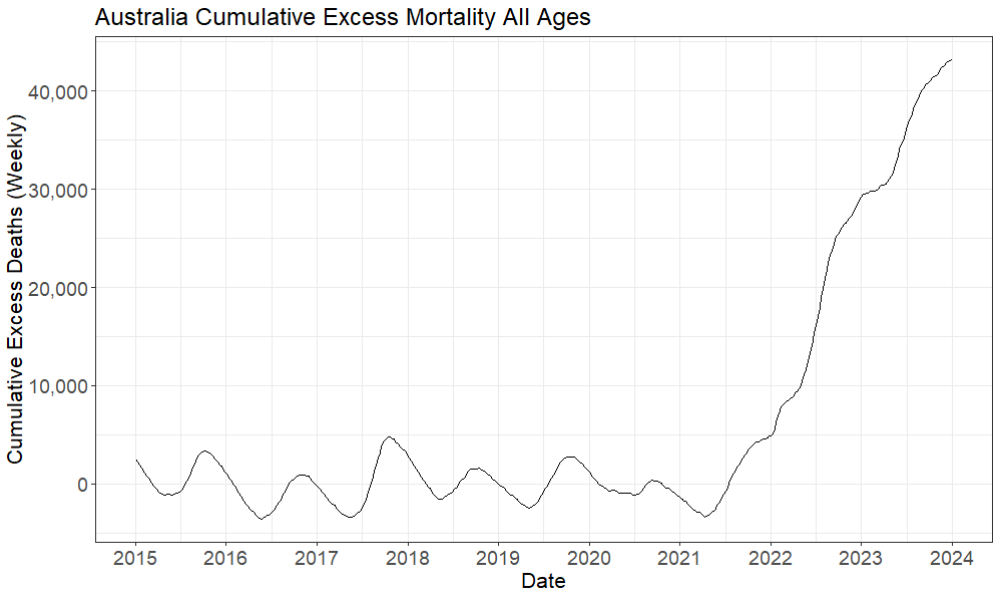


Figure 49. Excess computed using a second order fit to the reference period.

This appears to be an appropriate fit to the data. In the period from 2015 to the end of 2020 the pattern is remarkably consistent. The take-off is still mid-2021.

In the consistent period, prior to 2021, troughs in the pattern occur consistently in mid-May and peaks occur in mid-October. Note that the location of these cumulative troughs and peaks is offset from the troughs and peaks of the weekly mortality. They occur in early February

and late August respectively. The cumulative values are lagged by about 3 months. Mathematically this is because integration of a sine wave gives a negative cosine wave which is effectively phase shifted by one quarter of one cycle, ie 3 months. The location of the minima and maxima are shown in Table 2 below.

Year	Minima	Maxima
2015	03-May-15	11-Oct-15
2016	22-May-16	13-Nov-16
2017	07-May-17	15-Oct-17
2018	06-May-18	14-Oct-18
2019	05-May-19	27-Oct-19
2020	03-May-20 28-Jun-20*	13-Sep-20
2021	11-Apr-21**	NA

* 2020 has a flat trough with two local minima; ** 2021 minimum occurs early.

Table 2. Location of minima and maxima in cumulative excess pattern.

The location of minima and maxima are consistent to within a month. The 2020 maximum is a month early because of the unusual seasonal pattern. The 2021 minimum is a month early on account of the sudden rise in 2021. 2021 does not have a local maximum. The pattern never turns downwards as it should, based on what occurs in all previous years not influenced by COVID-19.

Another pattern observed is that a larger amplitude wave is followed by a smaller amplitude wave. This is a reflection of what is called the pull forward effect (also called mortality displacement) as discussed in Section 2.4. A bad influenza season is typically followed by lower number of deaths the next year. Similarly, when there is a low influenza season some people get through that season only to be more vulnerable the next year. The cumulative method handles this behaviour appropriately. Overall, the trajectory of cumulative mortality follows a smooth trend line. It may be curved, but still monotonic, ie always curving either up or down.

This cumulative excess, according to this method, at any time sits within approximately ±3,000 deaths from our predicted line. In a bad influenza season, such as 2017, it is almost 5,000. The pattern stays within the typical bounds up until the last quarter of 2021.

2020 is unusual in that the winter peak is lower than other peaks. However, it is does not make the cumulative excess stay low as if lives were miraculously saved that year; it predicably turns upwards again towards zero excess.

Looking into the forecast region from 2021 onwards, where we assume the trendline continues, the change in regime appears to be occurring prior to October 2021. By October we expected, according to the pattern of previous years shown in Table 2, that the line would have started turning downwards. Prior to this it should be flattening out. However, there is no such flattening. There is no downturn in 2021.

This timing coincides with the Delta wave in Australia. The weekly COVID-19 deaths are shown in Figure 50 below.

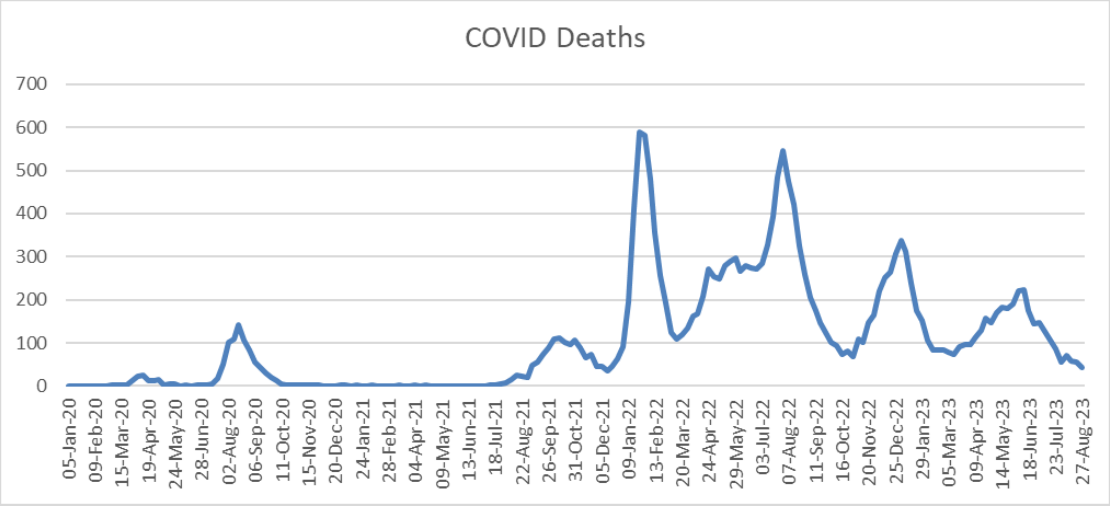


Figure 50. Weekly COVID-19 deaths Australia.

However, the Delta wave was largely contained and led to a small number of deaths in Australia. The Delta wave commenced with first deaths in mid-July 2021. For the data shown in Figure 50 it is noted that the numbers for weekly COVID-19 deaths from the ABS modelling report, for data till end August 2023, used COVID-19 deaths "from and with" COVID. The "with" deaths are also called COVID-related deaths where people died primarily of other causes but had COVID-19 recorded on the death certificate. The COVID from and with deaths till August 2023 add to a total of 20,095 according to the dataset.

From mid-July to the trough in mid-December (which was before the rise of the Omicron wave), there were approximately 1,200 COVID-19 deaths. There were 1,356 COVID-19 deaths for the whole year 2021. It is important to recognise this is a small percentage for the annual mortality in 2021 of approximately 172,000 (0.8%). It is also not large enough to cause the distortion to the cumulative excess pattern for 2021 from the expected behaviour, considering there were minimal deaths from influenza in 2021, which would be expected to offset the distortion. By October 2021 the curve should have turned downwards even with the contribution of the order of 1,000 COVID-19 deaths of mainly elderly people.

By the end of 2021 the cumulative excess is greater that the peak of the 2017 influenza season, despite the lack of influenza cases. While the onset of COVID is an upwards driving factor the pattern should have still turned downwards in 2021.

To confirm this, we can subtract out all COVID-19 deaths. Those data are available weekly for all ages. We do not have in the publicly available data for COVID-19 deaths by age bands on a weekly basis. Using the ABS mortality report data we get the result shown in Figure 51 below.

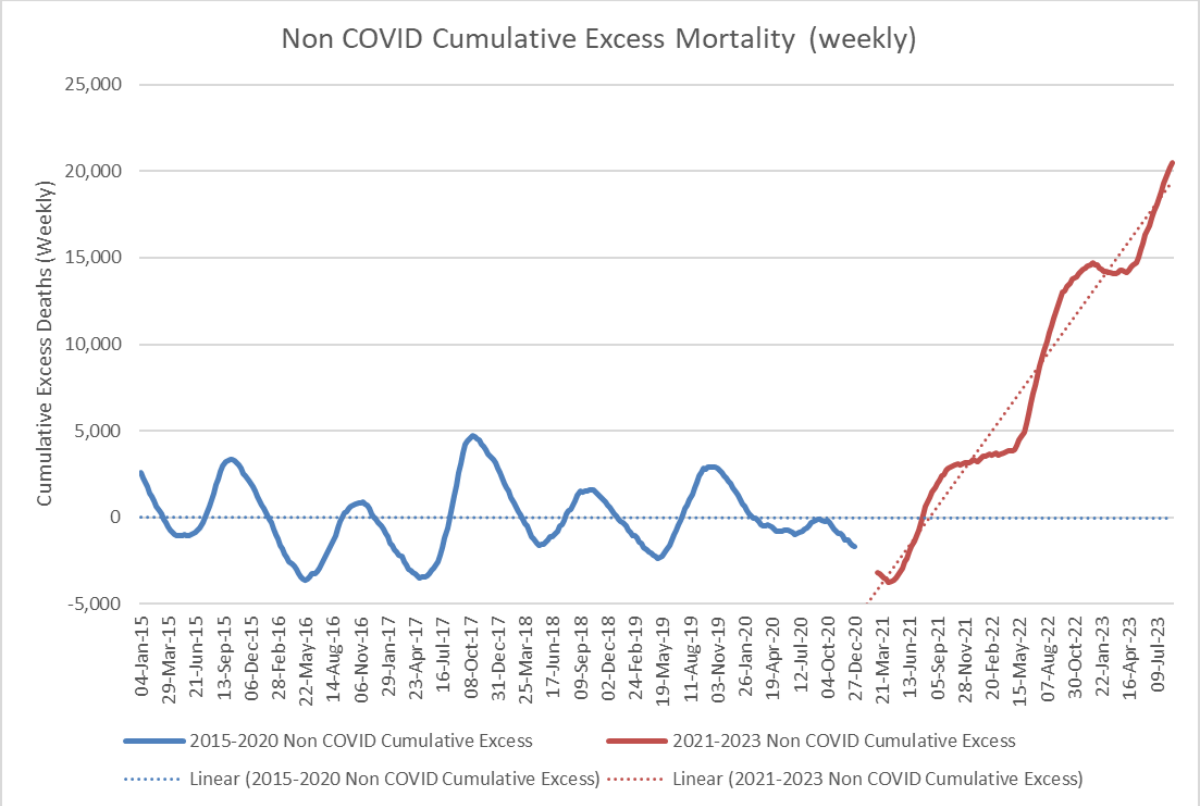


Figure 51. Non-COVID-19 cumulative excess.

It can be seen that a mortality regime change is occurring somewhere in 2021. Data from March 2021 are shown in red. A linear trendline (red dashed line) is fitted to data from 2021. A linear trendline (blue dashed) is shown fitted to data prior to 2021. The location where there is a distinct change in trend is called a changepoint. The changepoint will be in the region of the intersection of the two dashed trendlines shown. This is Q2 to Q3 2021. Methods know as changepoint detection can accurately determine the timing of this turning point. An example of this is shown in the chapter written for the AMPS publication *Too Many Dead*, attached to this submission. See Part 4, Figure 22, p299.

Certainly, COVID-19 attributed deaths started contributing to mortality in Australia in 2021, with the Delta wave, but all COVID-19 deaths have already been subtracted in Figure 51 above. Given the extensive COVID-19 testing going on in 2021 it is unlikely that COVID-19 deaths were missed. On the contrary, the high rates of testing and the application of the ICD-10 codes may have inflated counts.

In the non-COVID-19 cumulative excess curve from 2021 (red line) we still see the predictable winter waves, with peaks relative to the red trendline occurring at the expected times of October (Figure 51). These are timed the same as waves we expect to result from seasonal variation. However, they appear to be smaller in amplitude than in the previous normal years. This suggests that a proportion of the COVID-19 deaths, that are occurring in the winter waves, are replacing the typical seasonal influenza deaths.

This linear fit to the non-COVID-19 cumulative excess from 2021 corresponds to a fixed “extra” number of deaths week by week, above what we should expect in Australia.

Another observation is that there is no pattern to suggest that this non-COVID excess is correlated with COVID waves, as was suggested to Australian Senators in the Senate hearing referenced in Section 5.4. The pattern of non-COVID cumulative excess follows the typical pattern around the fitted trendline of Winter waves, albeit lower in amplitude, suggesting COVID-19 is replacing some typical respiratory virus deaths that were not occurring at the same rate as in the normal years.

8.1.1 The Curve Should Be Turning Downwards

COVID-19 will have brought some deaths forward. The deaths from COVID-19 (see Section 4.3) are typically of people with poor health (with 4.2 comorbidities on average), and older than the median age of death from all causes. When this occurs, we expect that this drives a deficit in excess deaths in later times. This pattern has been seen in some Eastern European countries where frail elderly died early on in the pandemic from COVID-19. There should be a driving force to bring the cumulative excess curve back downwards. The question is how long it will take? Perhaps if life expectancy has been permanently disrupted it will not turn back? But there is no sign of this downturn by the end of 2023.

It appears that there is another factor (or factors) causing excess mortality.

8.2 Age-band Analysis

We now use the publicly available mortality data for age groups in the PMS. We do not have COVID-19 deaths on a weekly basis for the age bands so we can only estimate total excess. These age bands are:

- 85 plus
- 75-84
- 65-74
- 45-64
- 0-44

We will analyse these individually and then compare with the all-age results.

8.2.1 Age 85 plus

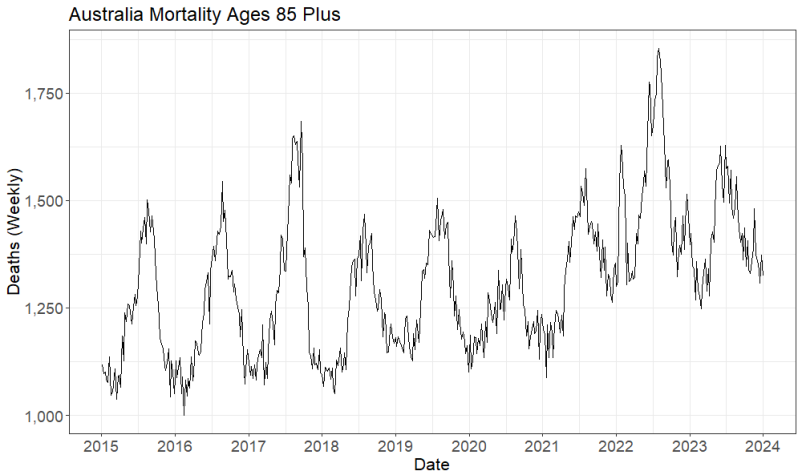


Figure 52. Raw mortality ages 85 plus.

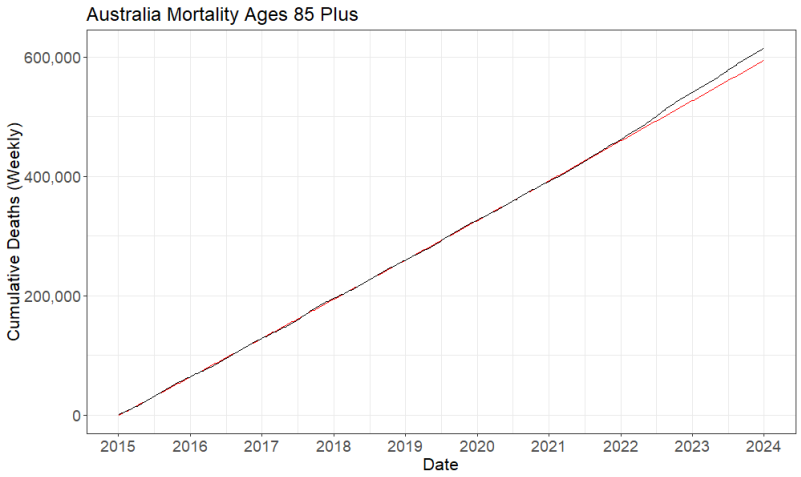


Figure 53. Cumulative sum ages 85 plus. Red line is baseline fit.

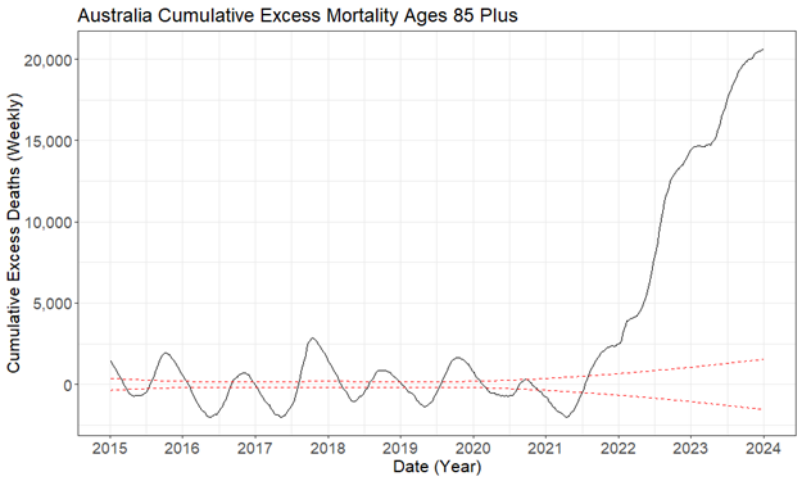


Figure 54. Cumulative excess ages 85 plus. Red dotted lines are 95% confidence intervals for trendline fit line.

Cumulative excess at end 2023 is 20,604.

8.2.2 Age 75-84

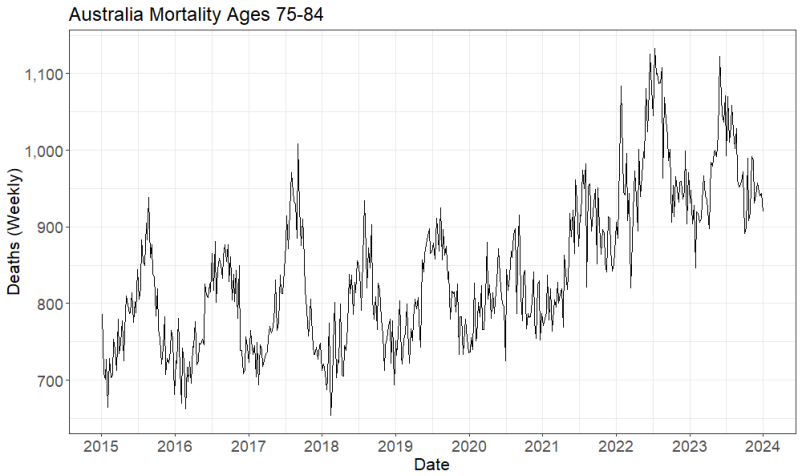


Figure 55. Raw mortality ages 75-84.

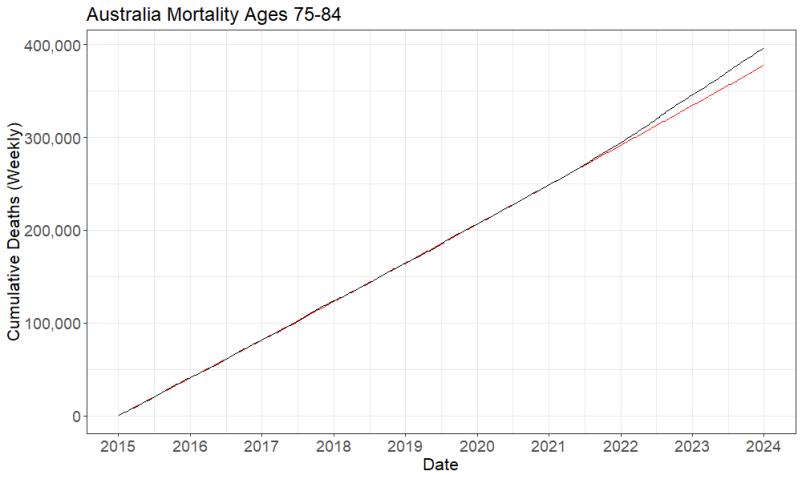


Figure 56. Cumulative sum ages 75-84. Red line is baseline fit.

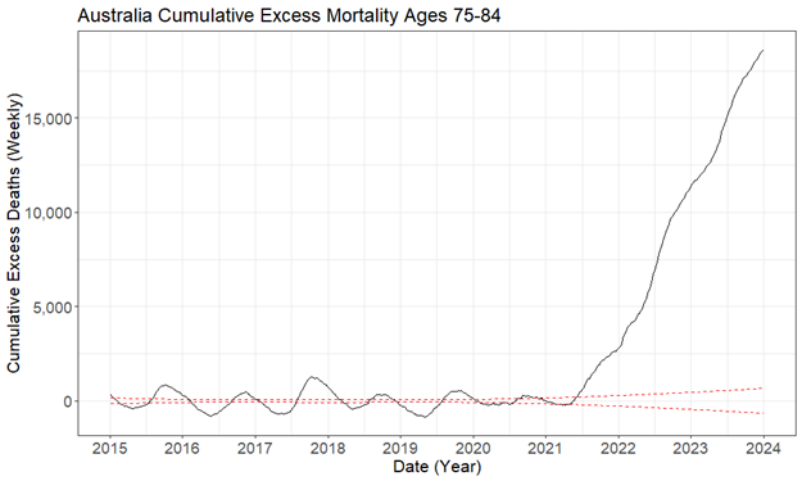


Figure 57. Cumulative excess ages 75-84. Red dotted lines are 95% confidence intervals for trendline fit line.

Cumulative excess at end 2023 is 18,645.

8.2.3 Age 65-74

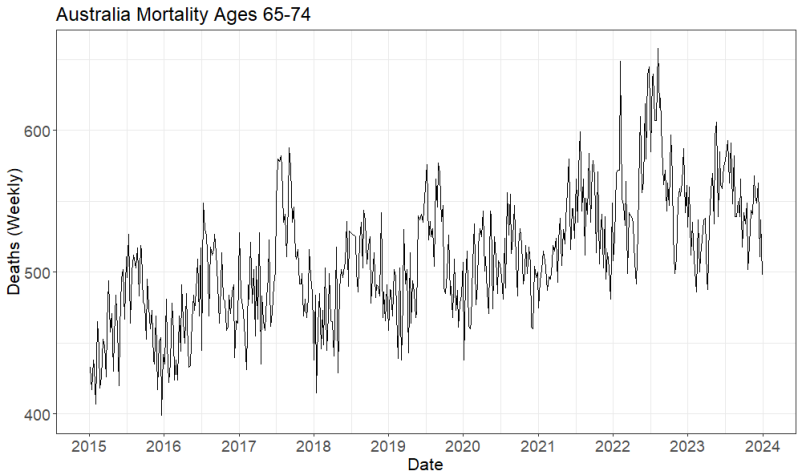


Figure 58. Raw mortality ages 65-74.

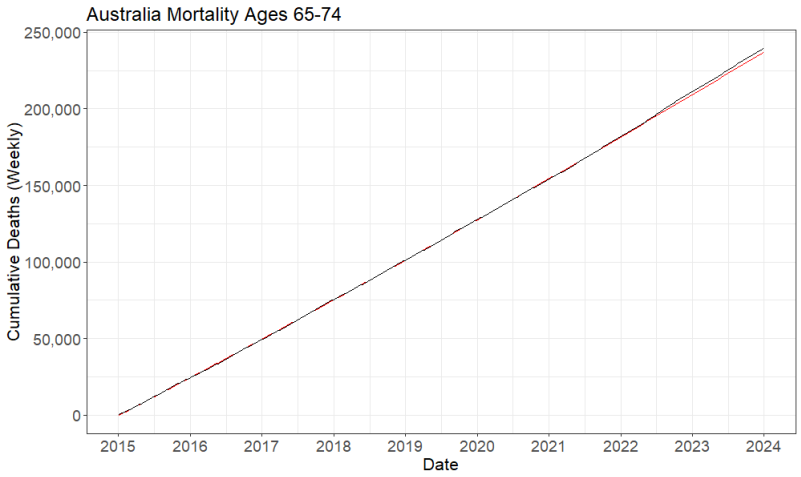


Figure 59. Cumulative sum ages 75-84. Red line is baseline fit.

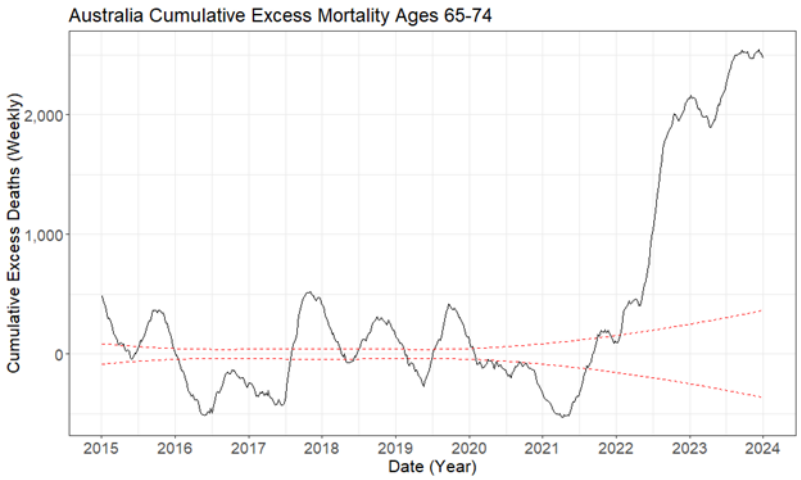


Figure 60. Cumulative excess ages 75-84. Red dotted lines are 95% confidence intervals for trendline fit line.

Cumulative excess at end 2023 is 2,471.

8.2.4 Age 45-64

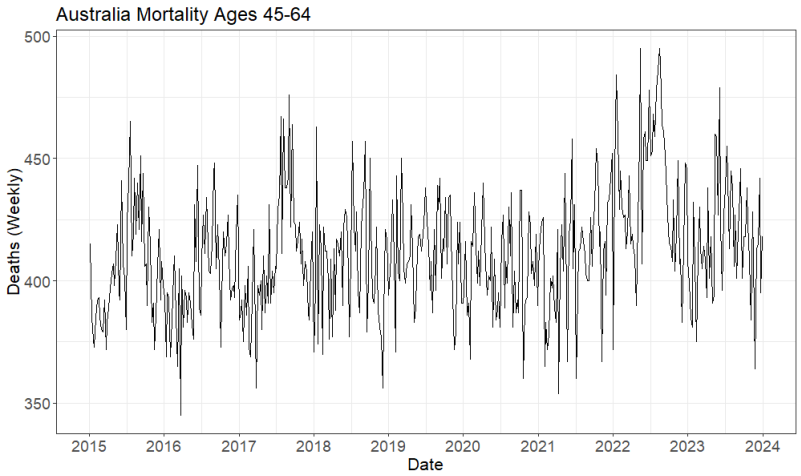


Figure 61. Raw mortality ages 45-64.

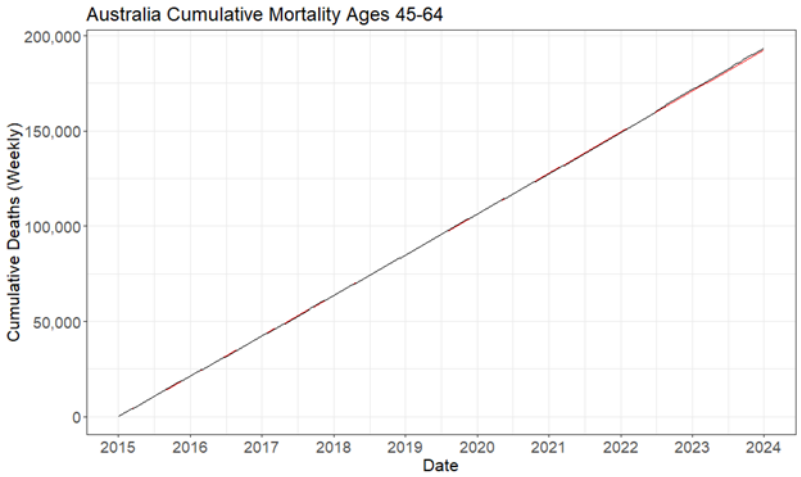


Figure 62. Cumulative sum ages 45-64. Red line is baseline fit.

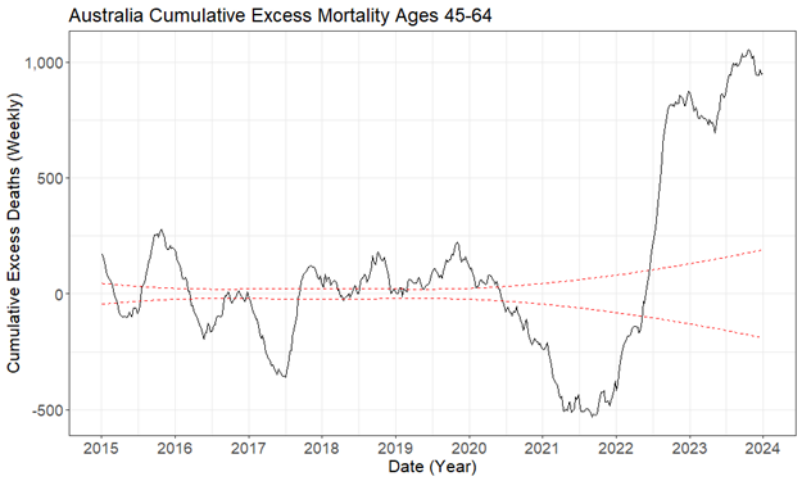


Figure 63. Cumulative excess ages 45-64. Red dotted lines are 95% confidence intervals for trendline fit line.

Cumulative excess at the end of 2023 is 949.

8.2.5 Age 0-44

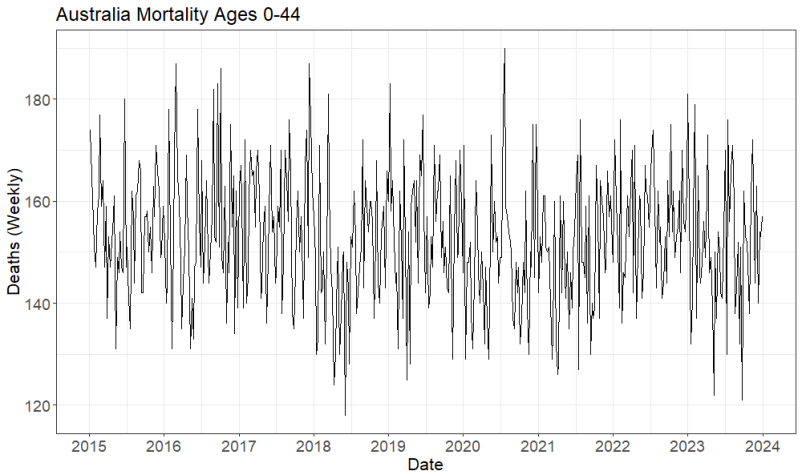


Figure 64. Raw mortality ages 0-44.

An observation of the raw mortality data 0-44 is that a spike appears in mid-2020.

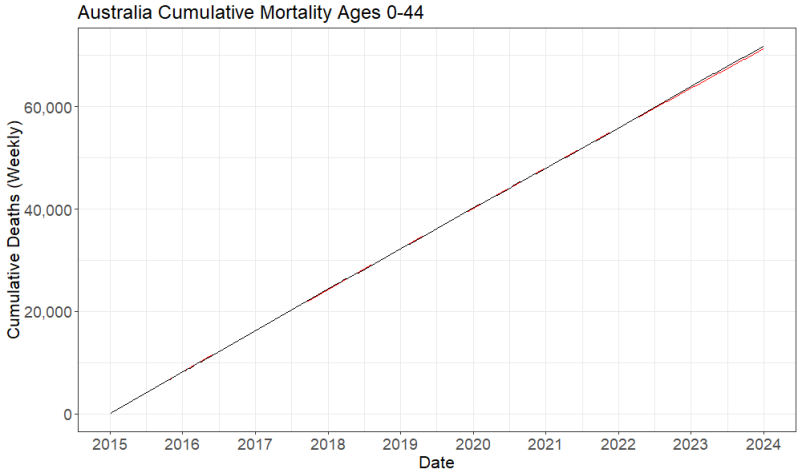


Figure 65. Cumulative sum ages 0-44. Red line is baseline fit.

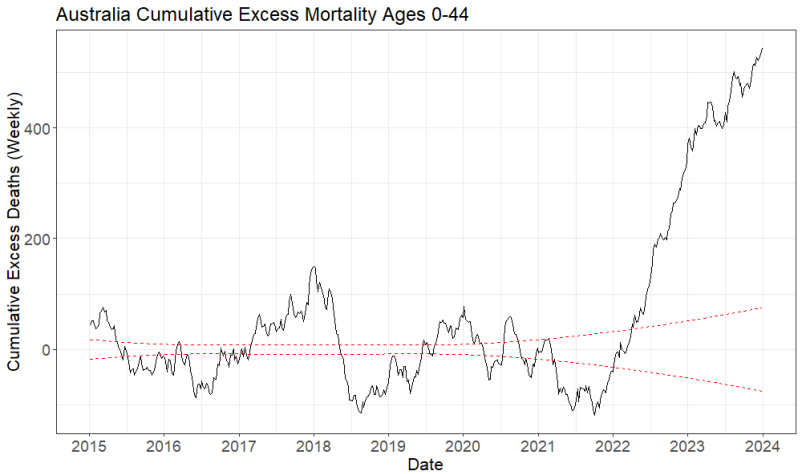


Figure 66. Cumulative excess ages 0-44. Red dotted lines are 95% confidence intervals for trendline fit line.

Cumulative excess at end of 2023 is 521.

Mortality for younger ages does not exhibit the characteristic seasonal pattern as it does for older people. The deaths appear to be relatively flat, around 150 deaths per week over the period. We expect a slight decrease in age-specific death rate based on Figure 40 for the annual data. We find narrower age-band age-specific death rates from ABS:

https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022

See Figure 67 for ages 25-44.

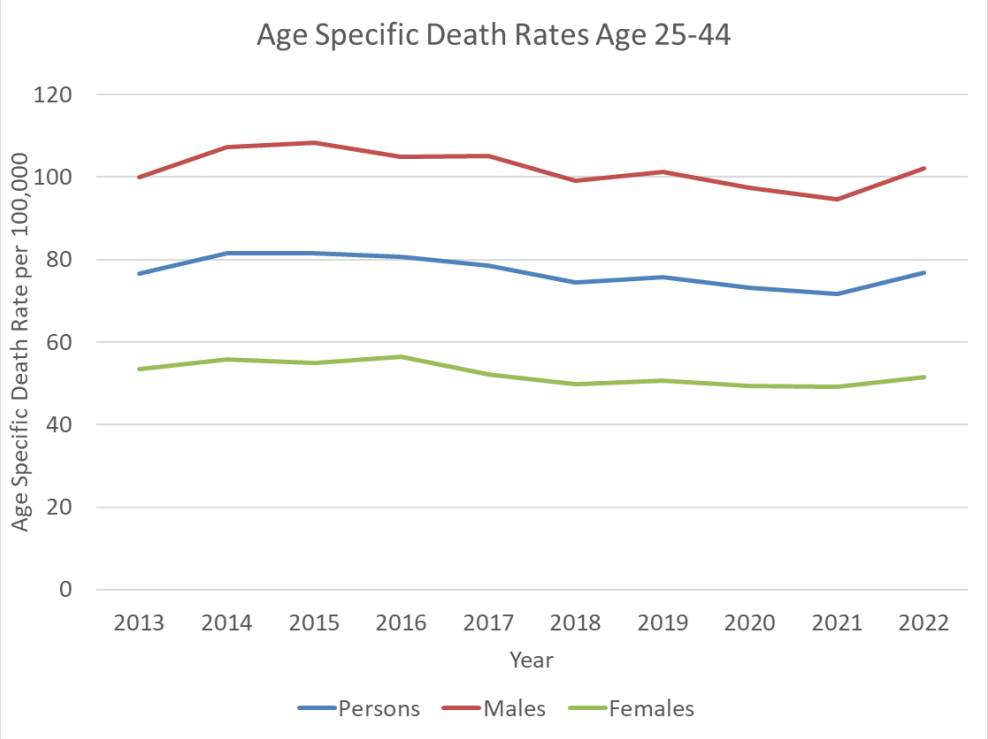


Figure 67. Age specific death rates for ages 25-44, 2013 to 2022. Male, female and persons shown.

The ABS states these rates are calculated at June 30 each year. We can see the distinct increase in rate in 2022. It is driven by mortality in males.

Looking closer at the mortality of this young age group we take the one-year running average; see Figure 68 below.

Figure 68. One-year running average of mortality for ages 0-44. Red dashed line is linear fit pre-2021.

The dashed red line is a linear fit pre-2021. There appears to be a small downwards trend. Looking at the population of this group in Figure 69 below.

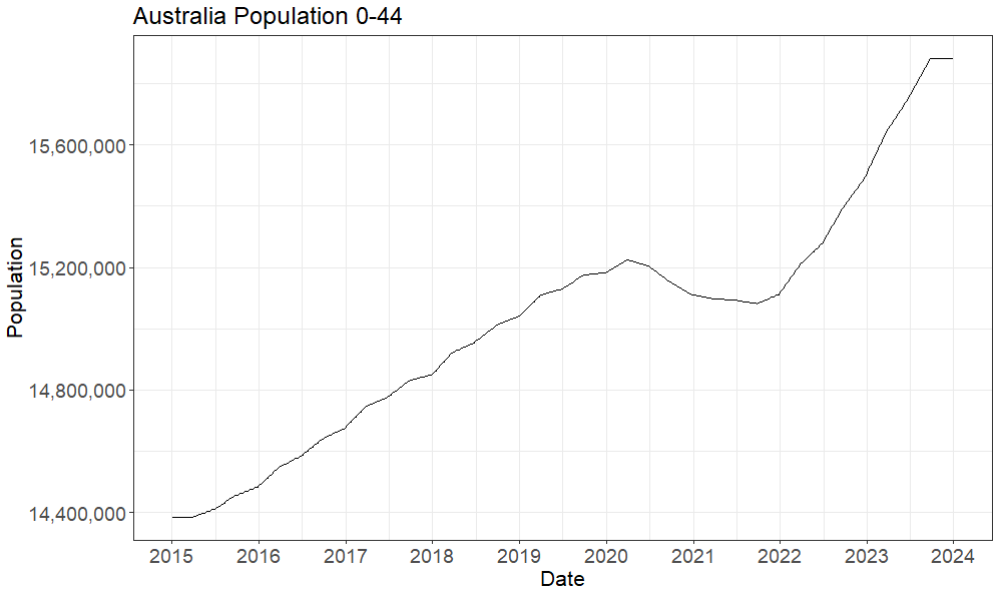


Figure 69. Population ages 0-44.

We see the distinct change in the normal population growth trend in 2020, when the country was blocked to international travel and many people of working and student age returned overseas. Calculating the mortality rate, based on the one year running average, for ages 0-44 is shown in Figure 70 below.

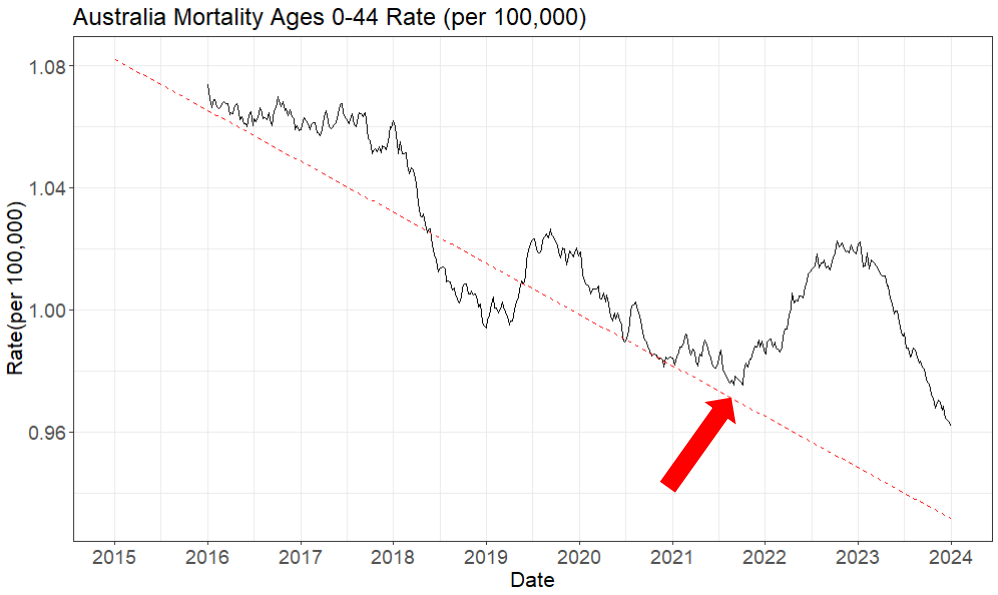


Figure 70. Mortality rate (weekly) for ages 0-44.

We can compare this with the annual rate from Section 6.3.5, reproduced below in Figure 71.

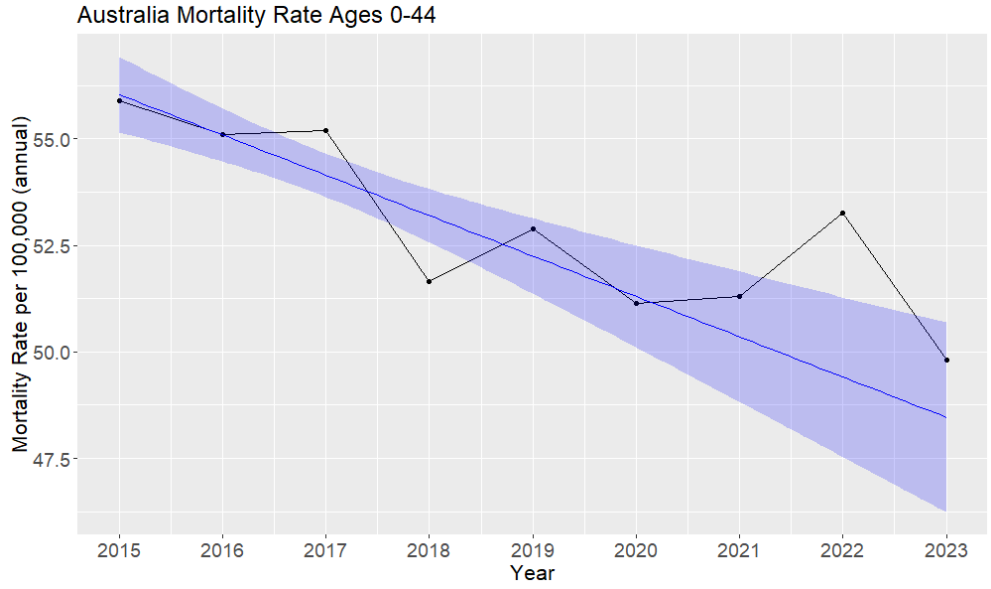


Figure 71. Mortality rate (annual) for ages 0-44.

It is interesting to see the pattern observed in the annual data filled out with the weekly calculated trend value in Figure 70. The annual data has coarsely captured the shape of the waves in the pattern. We see a gentle trend downwards for mortality rate up to 2021 as was shown for annual ABS age specific death rate data in Figure 67. From the third quarter of 2021, however, the behaviour is different with a turn upwards away from trend. The area under the curve and above the red dashed trend line in Figure 70 is related to the number of excess deaths. To get the number of deaths we multiply the population at each week by the difference in rate from trend to get that excess.

In Figure 70 above the rate was calculated based on the one-year running average of the previous year. We should use the raw weekly rate number rather than one-year average for the

purpose of calculating an excess. The population adjustment is then applied to the relevant week. This is shown in Figure 72 below.

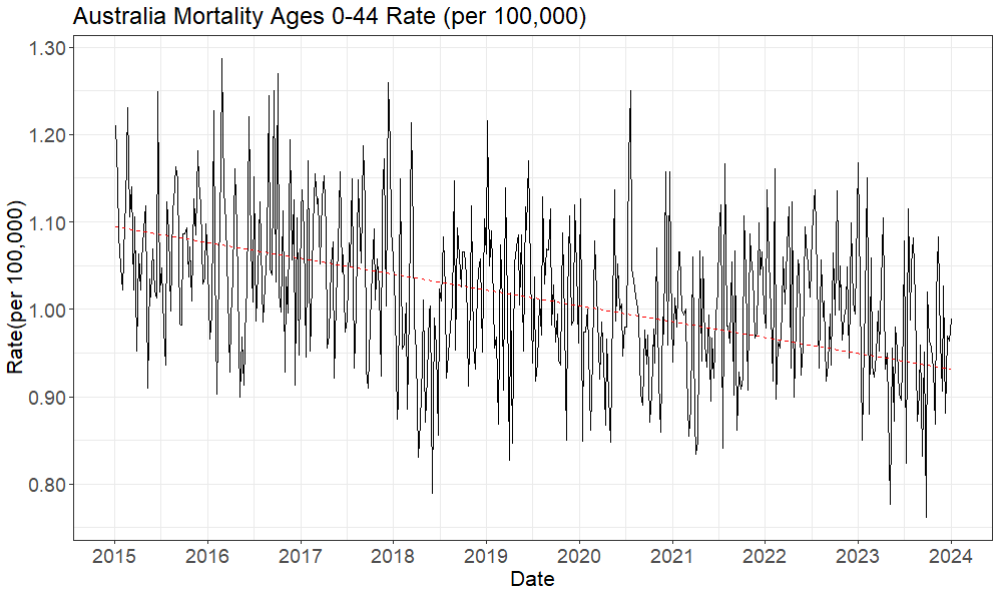


Figure 72. Mortality rate (weekly) for ages 0-44.

Because of the noise of the raw data signal, compared with the one-year previous average value, it is harder to see the pattern but the variation is consistently above trend.

However, the consistency of values above the trendline can still be observed in the raw data from 2021 onwards. We multiply the rate by the population from 2021-2023. The sum is 721 extra deaths. This is compared with 544 calculated previously using the cumulative method. In this rate method we directly compensate for population. In the cumulative method the population is compensated for as part of the process. That works well when the population varies in a smooth way. We know this is the case for older ages. Border closures did not change the population trends of these older age bands. In the case of students and young working age people it is different, and population adjustment may be important for accuracy.

Another point is that age band 0-44 is too broad an age category. It is expected that there are different mortality dynamics within this band. For example, it includes infant mortality.

8.2.6 COVID-19 Deaths for Ages 0-44

We calculated 544 and 721 excess deaths for the ages 0-44 using two different methods. The uncertainty is assessed in section 8.5. We know that the effect of COVID-19 on mortality was low in this young age group. While we do not have weekly data for COVID-19 deaths in age bands we can compare with the total number of COVID-19 deaths in the age band over the years 2021-2023. From this ABS report:

https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-30-september-2023#deaths-due-to-covid-19-age-and-sex

the following graphic, Figure 73, shows annual COVID-19 deaths in 10-year age bands.

COVID-19 deaths by age and sex, 2020-23

Download

	2020	2021	2022	2023	Total
Males					
0-19 years	0	2	10	2	14
20-29 years	0	5	9	2	16
30-39 years	1	10	27	5	43
40-49 years	3	28	53	10	94
50-59 years	11	70	164	34	279
60-69 years	26	138	425	121	710
70-79 years	102	207	1,269	370	1,948
80-89 years	178	250	2,237	760	3,425
90+ years	119	93	1,500	489	2,201
All	440	803	5,694	1,793	8,730
Females					
0-19 years	0	1	8	0	9
20-29 years	0	3	10	1	14
30-39 years	0	8	15	6	29
40-49 years	0	16	36	5	57
50-59 years	6	39	102	15	162
60-69 years	15	64	260	79	418
70-79 years	53	132	671	229	1085
80-89 years	198	164	1,633	585	2,580
90+ years	194	125	1,855	662	2,836
All	466	552	4,590	1,582	7,190

Figure 73. ABS COVID-19 deaths by age band.

According to the ABS, up till the end of September 2023 there was a total of 73 COVID deaths in ages 0-40. It will be slightly larger because four extra years 41-44 are not included. It is difficult to estimate this from the neighbouring band because of the large age gradient.

We compare that with the approximate 700 excess deaths we estimated using the population adjusted method based on the trend. The 700 deaths number may be relatively small but in this age group the number of deaths per week is typically around 150 (from inspection of Figure 64). The upturn in mortality appears to start in the last quarter of 2021. 700 divided by 2 years divided by 52 weeks equates to approximately 7 extra deaths per week.

Clearly there is an unexplained excess of deaths of young people where COVID-19 mortality has the lowest effect.

8.3 Summary of Age Band Analysis

The all-ages analysis in Section 8.1 found approximately 43,000 excess deaths from 2021 till 2023. We then performed the same analysis on mortality broken down into five age bands. The excess for each of these age bands is summarised in Table 3 below.

Age Band	Cumulative Sum Estimated Excess Method	Annual Raw Data Method	Annual Rate Method	SARIMA method
All Ages	42,000	38,941	NC	42,000
85 Plus	20,604	16,172	12,832	NC
75-84	18,645	18,960	12,661	NC
65-74	2,471	1,624	4,216	NC
45-64	949	724	2088	NC
0-44	544	377	949	NC
Checksum of age bands	43,213	37,857	32,746	NC

Table 3. Summary of different excess estimate methods for the period 2021 to 2023. Individual age band calculations Not Calculated (NC) for SARIMA method.

It is seen that the sum of excess deaths estimated for individual age bands is in reasonable agreement with that for the all-ages calculation. This means that we have confidence that the all-ages calculation is effectively capturing the underlying trends. Calculation using the age specific rate provides slightly lower estimates.

For reference the ABS mortality model results are summarised in Figure 74 below. Note that these estimates are only up to the end of August 2023 rather than end of 2023 as for other results.

Excess mortality by year, Australia, 2020-23 — Download

	Expected	Observed	Excess	% Excess	Reported deaths from or with COVID-19
2020	170,045	164,795	-5,250	-3.1	916
2021	169,048	171,799	2,751	1.6	1,448
2022	170,911	190,856	19,945	11.7	13,287
2023	112,714	119,619	6,905	6.1	4,444

a. Data is provisional and subject to change.
b. Years are based on a sum of ISO weeks derived from the weekly modelling. There are 53 weeks in 2020. There are 52 weeks in 2021 and 2022. Excess mortality has been estimated for the first 34 weeks of 2023.
c. Reported deaths 'from' or 'with' COVID-19 are as recorded on the death certificate.
d. Deaths in 2023 are deaths that occurred by 27 August and were registered and received by the ABS by 31 October 2023.

Figure 74. ABS Serfling model estimates of excess mortality.

There are a total 20,095 from and with COVID-19 deaths reported up till the end of August 2023. So even with the official model, with a biased baseline (see Section 5 for details), there are 29,601 – 20,095 = 9,506 unexplained excess deaths.

This is a non-trivial excess mortality.

8.4 Calculation by Gender Ages 75-84

The age band 75-84 is one which has been hit hard by excess deaths. This age band brackets the median age of death for both males and females in Australia. We now look at data for each gender individually using the cumulative method.

8.4.1 Males

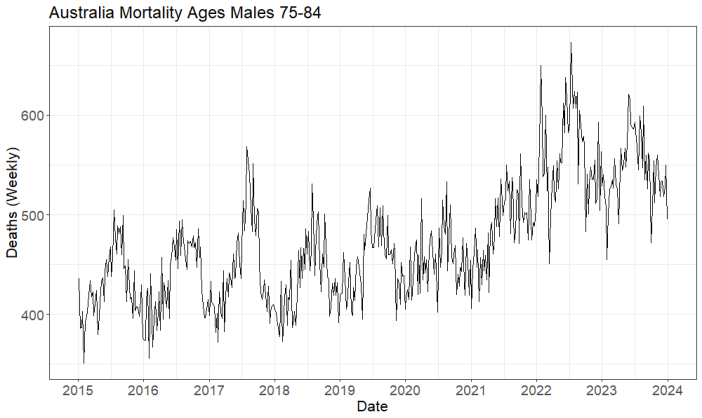


Figure 75. Raw mortality for males ages 75-84.

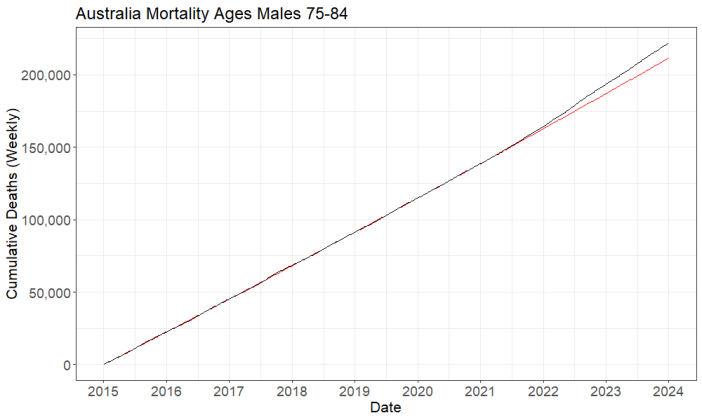


Figure 76 Cumulative mortality for males ages 75-84.

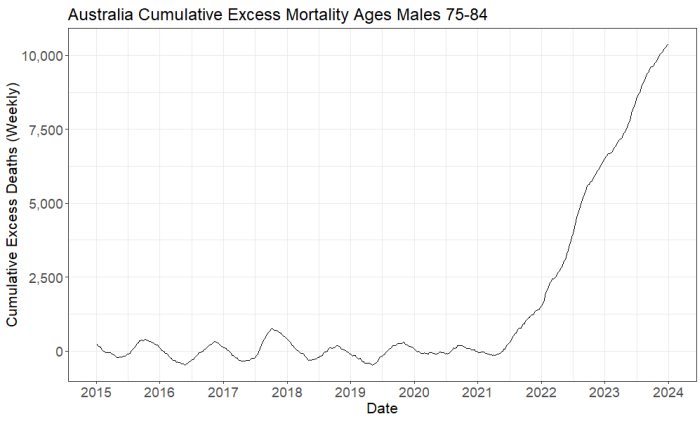


Figure 77. Excess mortality for males ages 75-84.

Excess at end of 2023 is 10,382 for Males age 75-84.

8.4.2 Females

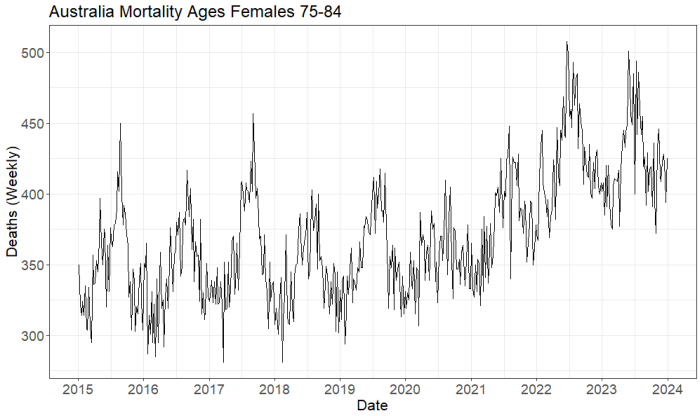


Figure 78. Raw mortality for females ages 75-84.

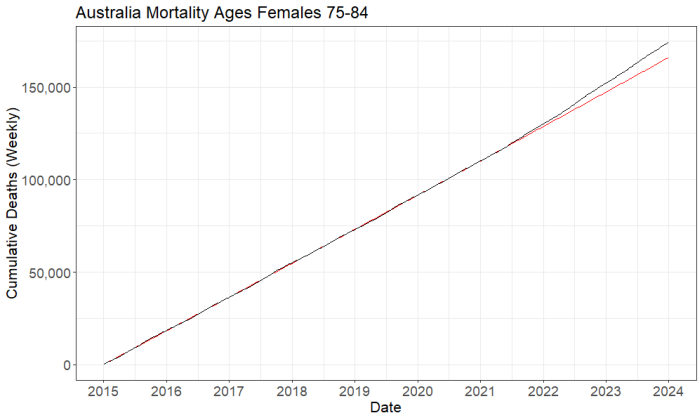


Figure 79. Cumulative mortality for females ages 75-84.

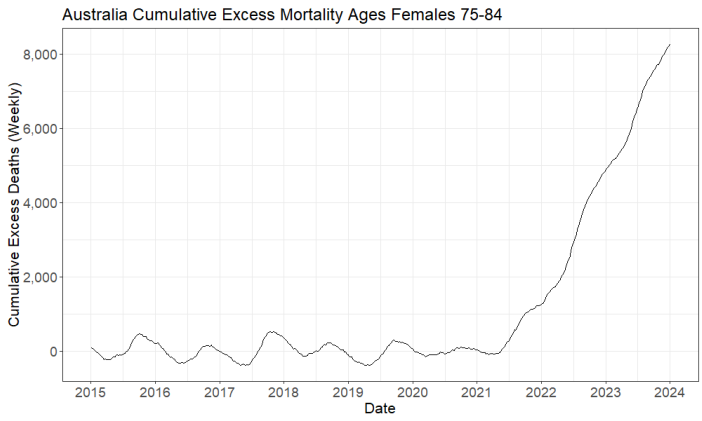


Figure 80. Excess mortality for females ages 75-84.

Excess at the end of 2023 is 8,263 for females ages 75-84. The total for males and females is therefore 19,005. Comparing with the combined gender estimate of 18,362, this is in reasonable agreement. There are some subtle differences observed by inspection of the time domain data but in general the patterns are similar.

8.5 Uncertainty Estimates

We can calculate the uncertainty of the trendline fit to all the cumulative mortality curves. This is shown in Figure 81 below for the data for ages 0-44. Note this is the error on the trend fit. There is still expected seasonal variation about this trend.

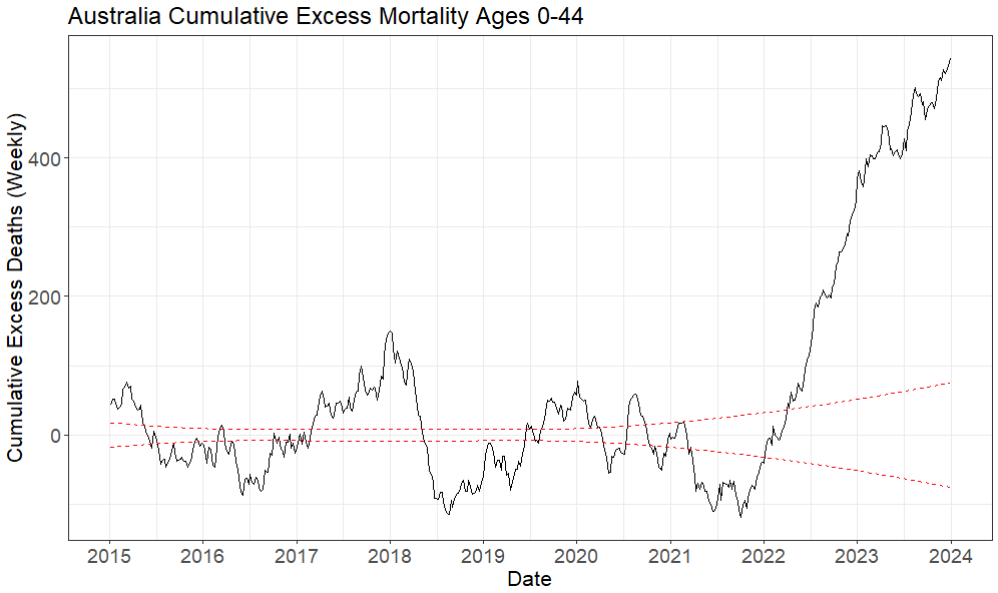


Figure 81. Excess mortality ages 0-44 with uncertainty estimate (95% confidence interval) for the trendline fit shown in red dotted line.

According to the cumulative excess analysis there were 544 excess deaths at end of 2023 for ages 0-44. We can say the actual number of deaths is the actual number with no uncertainty. The uncertainty exists in the baseline fit we have estimated, based on the data for the chosen reference period. 95% Confidence Intervals on the baseline fit are shown in red dotted lines in Figure 81 above. The Confidence interval at the end of 2023 is ±75.

9 ARIMA Modelling

ARIMA is one of the classical time-series modelling methods. It provides good estimates and generally performs well even compared with more modern methods. It has the useful feature that it provides some understanding of the underlying process generating the time series.

9.1 All Ages Model

An ARIMA model with seasonal adjustment (also known as SARIMA) was fitted to the all-age mortality data. The forecast, using that model, is shown in a blue line below in Figure 82, with the black line being the raw actual data. Note in this example the data from the ABS mortality modelling report have been used, which is only up till the end of August 2023. Note also that the last few months of the published data typically revise upwards as death reports are received.

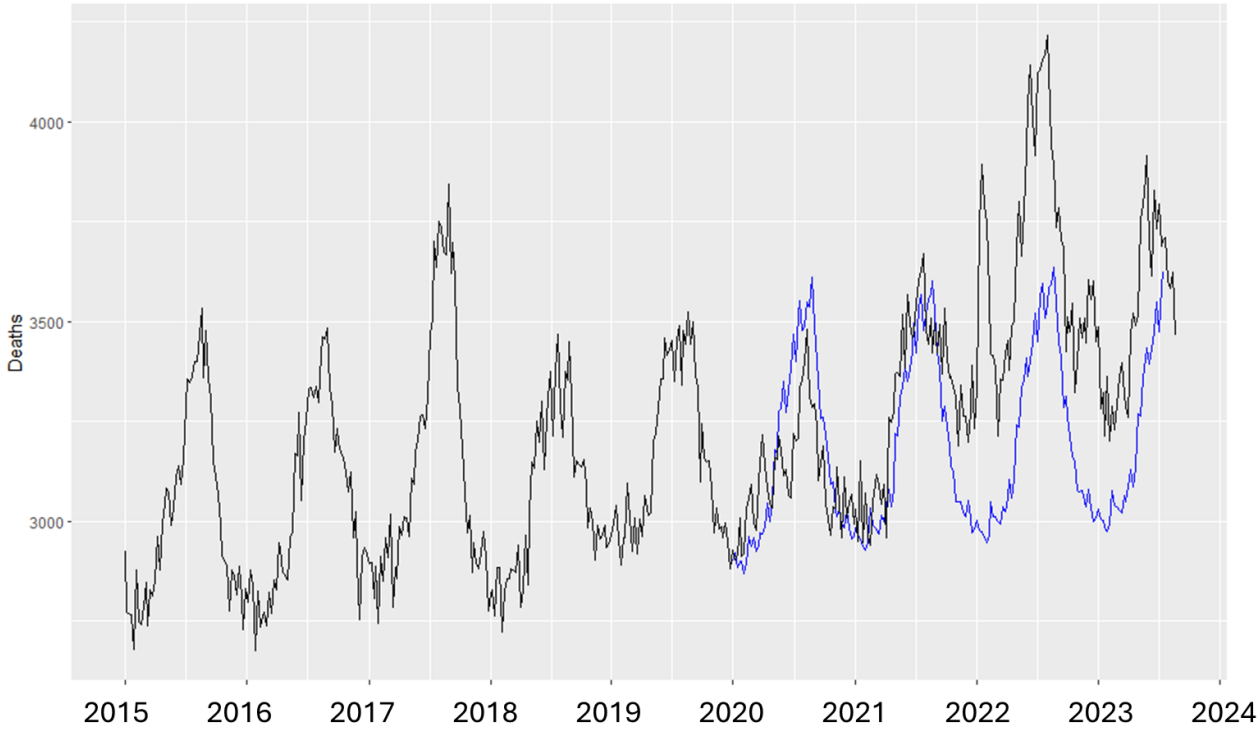


Figure 82. SARIMA model forecast for all age data.

We can see that the seasonal pattern of the forecast is more representative of the true seasonal pattern as compared to a sine wave used in the official model. The model errors are shown in Figure 83 below and meet the desirable criteria for the error, ie Gaussian random variation with no correlation.

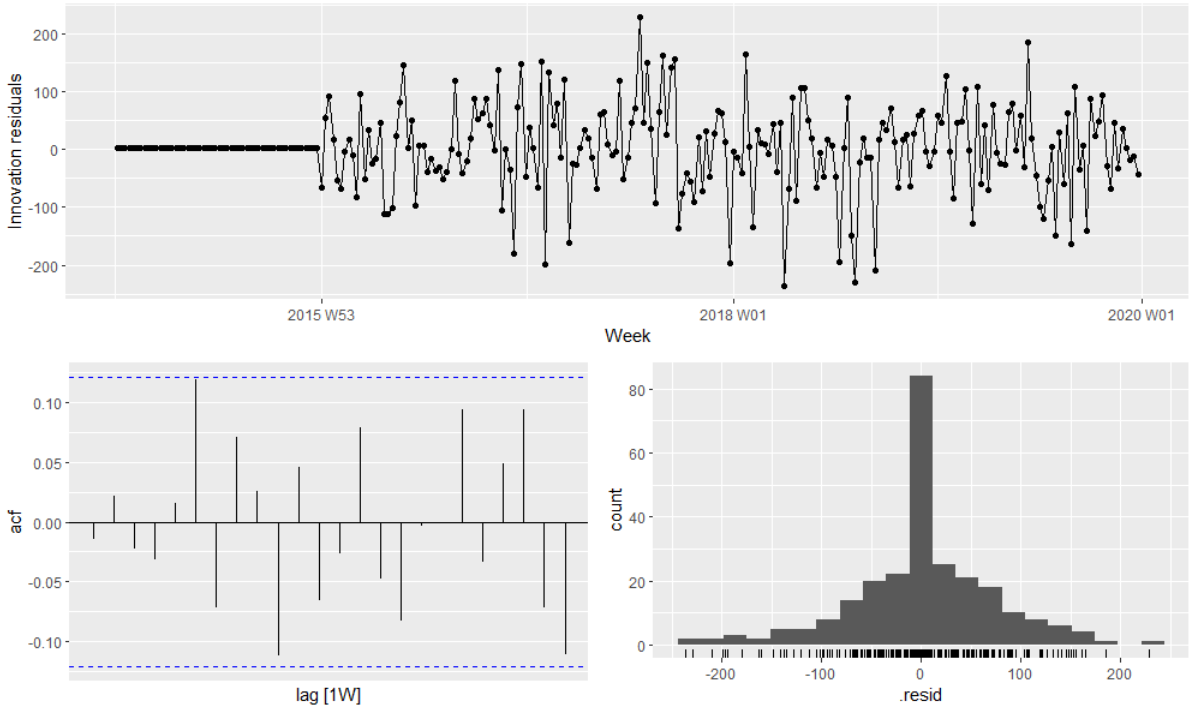


Figure 83. ARIMA model error.

The weekly excess over the forecast, over the years 2020 -2023, is shown in Figure 84 below.

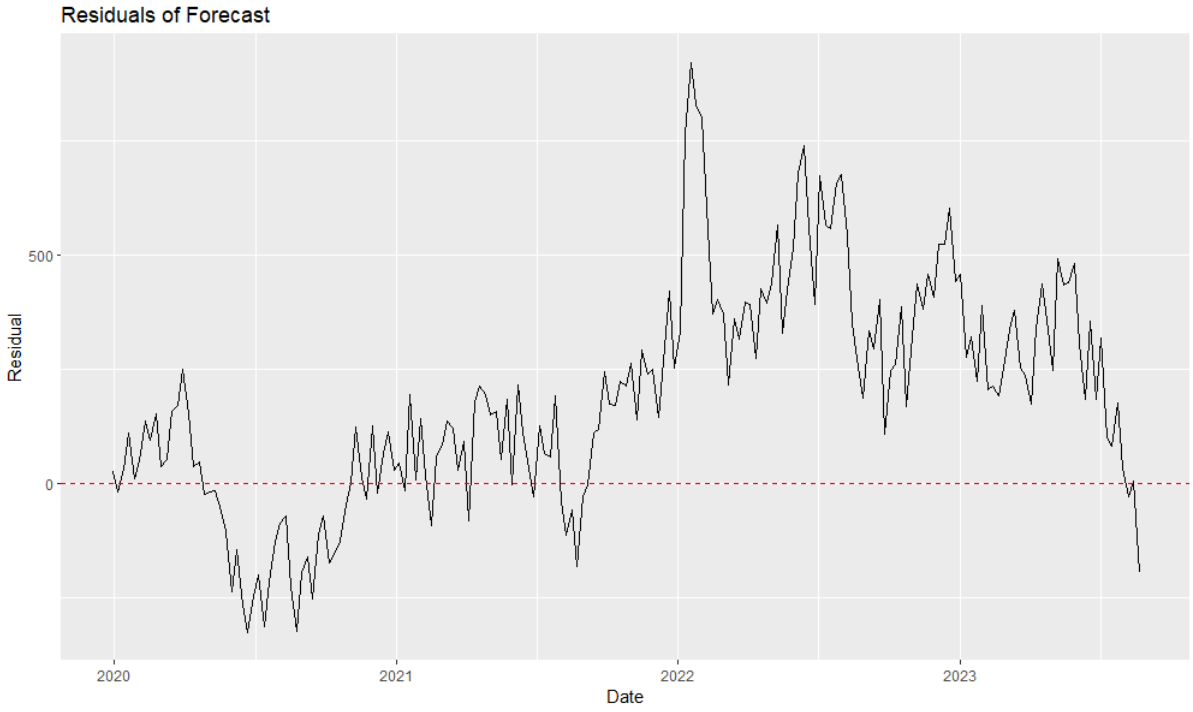


Figure 84. Difference of actual mortality and ARIMA modelled mortality for years 2020-2023.

There is a small, accumulated deficit at the end of 2020 of approximately 2,000. This is consistent with the deviation trend from annual modelling (see Figure 28). In Figure 85 the excess, shown in Figure 84, is accumulated starting from 2021.

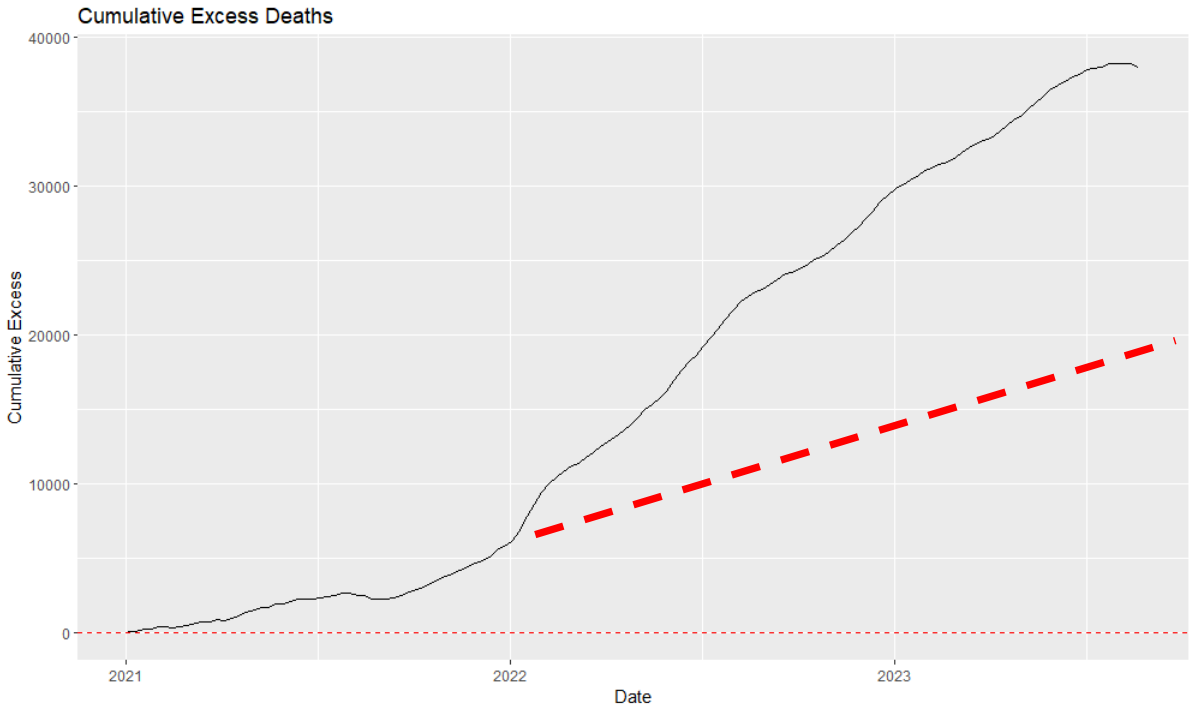


Figure 85. Cumulative excess from 2021 using the SARIMA model based on 2015-2019.

The cumulative excess increases consistently, except for a small dip around August 2021. This is where prediction and actual values are very close in the raw data (see Figure 82). A dashed red line is drawn at the approximate rate of increase of the 2021 accumulated excess, assuming it continues. We can see that the cumulative excess rate of increase tips up from the start of 2022 as the Omicron wave hits Australia.

There are approximately 6,000 excess deaths above prediction at the end of 2021. In Section 6.1 we estimated between 5,000 and 7,000 excess for 2021 based on annual data and the baseline chosen. Only 1,000 may be attributed to COVID-19 in 2021.

An important point is that the accumulated excess should have turned downwards before the end of 2021, even considering the COVID-19 Delta wave at the end of 2021.

Why the rate continued to grow in the leadup to the onset of Omicron must be considered by the Inquiry.

In Section 3 we confirmed this uncharacteristic increase is not caused by COVID-19, as the same upward trend is seen in mortality data from Queensland where there was zero COVID-19 right up till the last weeks of 2021.

To confirm what the non-COVID-19 excess deaths are in the period from 2021 onwards, we subtract the weekly COVID-19 deaths provided in data from the ABS Mortality modelling report available up to the end of August 2023. This is shown in Figure 86 below.

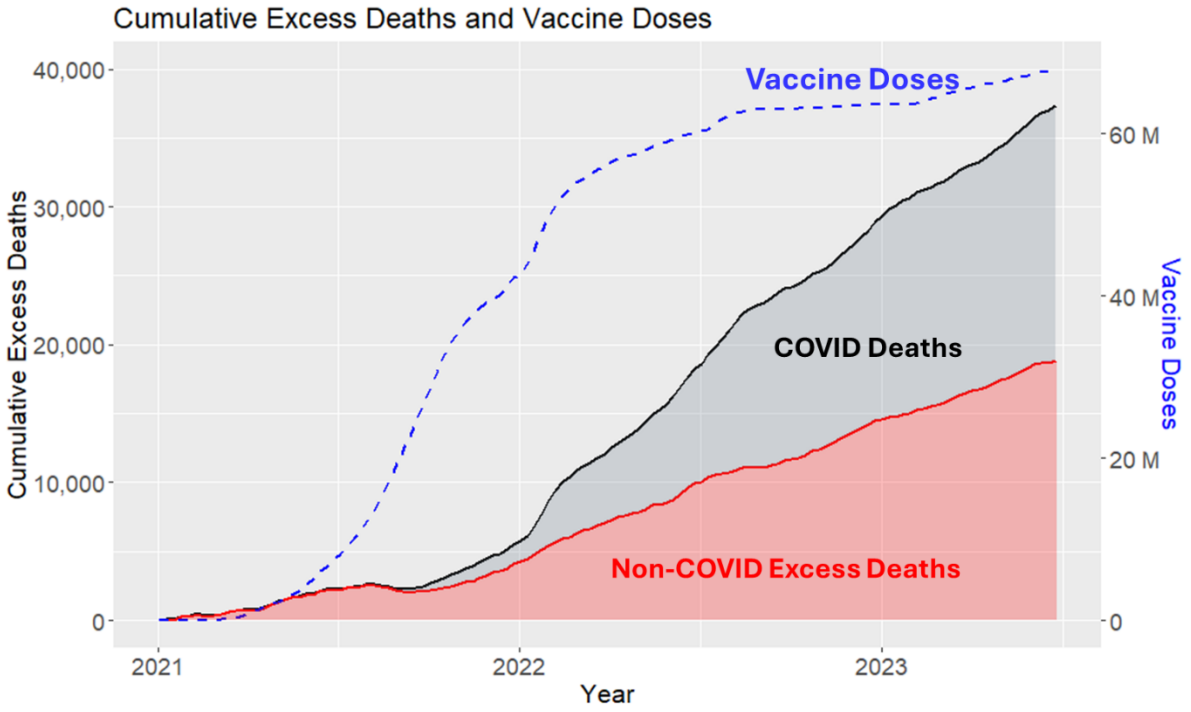


Figure 86. Cumulative excess deaths from 2021 calculated from ARIMA model. Vaccination doses delivered are shown for reference.

It is seen that the increase in accumulated non-COVID deaths (red line) does continue upwards approximately linearly. The data in Figure 84 have been truncated by the last two months as these data are subject to revision as deaths are reported in late. It looks as though the value at the end of 2023 will be approximately 20,000. 20,000 deaths over the 3 years of 52 weeks equates to 128 extra deaths in Australia per week. The average number of deaths in Australia is around 3,000 per week (visually from Figure 22). The 128 represents an extra 4% on what should be expected.

This excess depends critically on the assumed underlying trend of mortality. Much of this report has been dealing with estimation of the underlying trend and considering the variations based on different assumptions. It is clear that this is a challenge because we never know what the true underlying trend is. We can only make estimates based on previous years. If using a linear trend and we have that trend tipping too far downwards we would expect an excess that increases week to week over time. This would lead to a cumulative excess that curves upwards (exponentially). Similarly, if the trend is tipped upwards from what the actual is, therefore underestimating excess, we would see diminishing excess eventually becoming a deficit, with a cumulative excess with curvature downwards. What we see here is a non-COVID cumulative excess that appears to be neither turning upwards nor downwards.

10 Data Transparency

From the analysis provided with this submission it is clear that there are unexplained deaths occurring in Australia over the period 2021-2023. The trend in mortality turns upwards in 2021 at a time when mortality was minimally influenced by COVID-19. It affected older people first. Later in 2021 the trend change is observed in younger ages.

Given the temporal correlation of the change in trend occurring shortly following introduction of new medicines, further inquiry is required. In this section data are specified which will facilitate further investigation.

10.1 Record Level Data

One dataset ideally required is death certificate data suitably anonymised. This would have ICD10 codes for cause of death. It is sometimes asserted that date of death can be used to identify a person. The actual dates can be dithered so as to anonymise.

In addition, date of COVID-19 vaccinations is required with the date of death. This can be achieved by joining different government datasets. This will allow an analysis of the distribution of times to death to determine if there are unusual patterns. The time to death should be evenly distributed over time. Date of vaccination should be independent of date of death.

t is expected that there would be a “healthy vaccinee effect” where there are very few deaths close to date of vaccination as those close to death may typically not be offered COVID-19 vaccination.

The data should cover the whole population, both vaccinated and unvaccinated.

It is understood that data in this format have been shared with COVID-19 manufacturers for their safety surveillance. There is no reason the public should not also be provided these data. Professor Carl Henegan, Director for the Centre for Evidence Based Medicine at Oxford University has written about the need to provide these data:

https://trusttheevidence.substack.com/p/why-would-mortality-data-by-vaccine

10.2 New Zealand Freedom of Information Request

A FOI request in New Zealand (found here)

https://fyi.org.nz/request/25882-injury-events-from-covid-19-vaccine-by-age-month-and-dose#outgoing-42836

requested aggregated data relating date of vaccination and date of death. New Zealand Health (Te Whatu Ora) released data showing mortality counts against vaccination categories. This was provided on a monthly basis, for 20-year age bands. An extract of the dataset, screen captured in Excel to show the column headers, is shown in Figure 87.

	A	B	C	D	E
1	Month of Death	Age at death	Last COVID-19 dose number	Days between last vaccination and death	Count
158	2021-05	81 to 100	2	<= 30	27
159	2021-05	81 to 100	2	<= 90	<5
160	2021-06	0 to 20	0	N/A	94
161	2021-06	0 to 20	2	<= 30	<5
162	2021-06	100+	0	N/A	14
163	2021-06	100+	1	<= 30	<5
164	2021-06	100+	1	<= 90	<5
165	2021-06	100+	2	<= 30	<5
166	2021-06	21 to 40	0	N/A	77
167	2021-06	21 to 40	1	<= 90	<5
168	2021-06	21 to 40	2	<= 90	<5
169	2021-06	41 to 60	0	N/A	279
170	2021-06	41 to 60	1	<= 30	<5
171	2021-06	41 to 60	1	<= 90	<5
172	2021-06	41 to 60	2	<= 30	<5
173	2021-06	61 to 80	0	N/A	855
174	2021-06	61 to 80	1	<= 180	<5
175	2021-06	61 to 80	1	<= 30	111
176	2021-06	61 to 80	1	<= 90	22
177	2021-06	61 to 80	2	<= 180	<5
178	2021-06	61 to 80	2	<= 30	75
179	2021-06	61 to 80	2	<= 90	14
180	2021-06	81 to 100	0	N/A	901
181	2021-06	81 to 100	1	<= 30	258
182	2021-06	81 to 100	1	<= 90	50
183	2021-06	81 to 100	2	<= 30	212
184	2021-06	81 to 100	2	<= 90	41
185	2021-07	0 to 20	0	N/A	95
186	2021-07	0 to 20	2	<= 90	<5
187	2021-07	100+	0	N/A	7
188	2021-07	100+	1	<= 30	<5
189	2021-07	100+	2	<= 30	9
190	2021-07	100+	2	<= 90	7
191	2021-07	21 to 40	0	N/A	72

Figure 87. Extract of New Zealand FOI.

These data are useful with 20-year age bands (ideally narrower bands) and an indication of time since last vaccination. These same data should be made available in Australia. However, they do not provide population sizes to allow rate comparisons, and these should be provided as well.

10.3 Aggregated Data

Data on deaths by vaccination status for England can be found at “Deaths by Vaccination status, England”:

https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland

A recent dataset is: “Deaths occurring between 1 April 2021 and 31 May 2023 edition of this dataset”. This provides counts of deaths in vaccination categories and computed age standardised mortality rates. Politicians in the United Kingdom have requested further aggregated data be released.

In the interests of transparency in Australia, there should be made available similar data that will unambiguously allow an evaluation of mortality in the current regime of continuing excess mortality to be further investigated.

In the New Zealand dataset the last COVID-19 dose number was provided as well as broad categories for days between last vaccination and death (≤30, 30<..≤60, 60<..≤90, 90<..≤180, 180<.. ≤365 and 366+ days). With respect to computed values, such as age standardisation, it is preferable to provide crude/raw numbers in the age bands that make up those statistics in the interest of transparency.

Table 4 lists the column names and descriptions of data required.

Column Name	Resolution	Description
Observation year	2019 – end 2023 by single year	Noting that from 2019 till end February 2021 there will only be an unvaccinated (0 dose) category.
Observation Week	ISO Week 1 to 52 (1 to 53 for 2020)	England originally provided weekly data as requested here. Monthly data only are provided in later England datasets, as it is for New Zealand. Weekly data are preferable.
Dose Number	0 to 10+ by 1	0 is unvaccinated. 10 is an assumed maximum dose number. If dose number is unknown please make this a separate category. Do not combine unknown with 0 dose. Similar to Age this is the last dose number at the week of the record.
Days between last vaccination and death	Suggested broad categories as provided by NZ Health with intervals: ≤30, 30<..≤60, 60<..≤90, 90<..≤180, 180<.. ≤365 and 366+ days	This field is provided in New Zealand data.
Sex	Male and Female separately. Other category if necessary.	For categories other than Male, Female include an “other” category if sufficient numbers require it.
Age	Single year ages bands from 5 to 100. Single category for ages 101+	Single year ages bands are required to unambiguously compute standardised rates. Age is the age of the person at the week of death.

Column Name	Resolution	Description
Number of deaths from all causes.	Exact count except where privacy rules apply to weekly counts for a category with fewer than 5 counts. If count is zero it remains zero.	Use dithering rules, as applied in Australian statistics, for small counts <5. In those cases indicate that count is less than 5.
Number of deaths from COVID	As per Number of deaths from all causes.	
Population alive	Exact count of living population for this category	The population alive for each category is a crucial quantity. If the population is not known accurately this must be indicated.

Table 4. Format of data requested to allow further investigation into unexplained excess mortality.

These data will not expose anyone's private health information.

11 Summary

While this report provides a detailed analysis it still only scratches the surface of what is required to robustly and exhaustively analyse excess mortality in Australia. Any estimation of excess mortality is based on assumptions. It has to be acknowledged that those assumptions may be wrong. In the context of the health of Australians the risk of assumptions being wrong needs to be considered. There is an unexplained excess of deaths whose causes need to be thoroughly investigated, looking beyond raw mortality statistics.

In summary:

- A range of modelling methods have been implemented in this report.
- 35-40,000 excess deaths are estimated to have occurred in Australia from 2021 to 2023.
- Official modelling estimates 29,601 excess deaths from 2021-2023 up to the end of August 2023.
- Approximately 20,000 deaths are attributed to COVID-19 (both from and with) over the 2020 – 2023 period.
- It is shown that the baseline reference period in the official model has been chosen to minimise the excess in later years, by tipping up the trendline of the predicted baseline. The official model implemented is not one that is useful for time series predictions of mortality data.
- Unusual patterns are identified in the raw mortality time series. These include a sudden jump in deaths in April 2021. At the same time the seasonal pattern rose more steeply than in previous years, in a year with minimal influenza or COVID. These patterns are not seen elsewhere in the reference period.
- The rise in excess occurs in older ages earlier in 2021 as compared to younger ages.
- The cumulative excess mortality, with all COVID-19 deaths subtracted, shows a distinct trend upwards from midway in 2021.
- The effect of COVID-19 has been primarily on the older population and those with multiple comorbidities. At the end of 2023 there is no indication of the cumulative excess turning downwards, as should be expected from mortality displacement effects.
- Further transparency of data is required to allow independent analysts to dig deeper into what may be causing the “unexplained” excess.

Chapter 6

Factors for consideration in the review of excess deaths in Australia:

An evaluation of adverse event reports associated with Covid-19 vaccines

Dr Suzanne Niblett
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Abstract

There is general agreement that excess deaths have occurred during the pandemic. What is still a matter of debate are the details regarding the number of excess deaths, the temporal profile of excess deaths, and the factors that may be contributing to excess deaths.

In this report, five models of excess death are reviewed. Estimates of excess death for the period from January 2021 to December 2023 were calculated to range between approximately 30,000 and 60,000.

The potential contribution of Covid-19 infection to excess deaths is examined and limitations of the diagnostic criteria for Covid-19 are discussed.

The potential role of Covid-19 vaccines to excess deaths is also reviewed through an evaluation of adverse event reports submitted to the Therapeutic Goods Administration Database of Adverse Event Notifications (DAEN) and the AusVaxSafety Program. Unprecedented numbers and rates of adverse event reports, including over one thousand deaths, have been associated with Covid-19 vaccines. A broad range of adverse events was noted that included adverse event terms from all MedDRA system organ classes, and over 400 adverse events not previously reported over the 52-year history of the DAEN. The data collectively indicate that Covid-19 vaccines may be contributing to ill health and excess death in the population. Additional research is needed.

Introduction

Excess deaths have been reported during the pandemic years across many countries, including Australia (https://ourworldindata.org/excess-mortality-covid). Whether excess deaths have occurred is not in dispute. What is argued, however, is the number of excess deaths, the time period over which they have occurred, and the factors that may have contribute to the excess deaths.

Core to evaluating excess deaths is an understanding of the how excess deaths are defined and calculated.

Definition of Excess Deaths

As defined in the Parliament of Australia document "Excess Deaths in Australia: Frequently Asked Questions", reported excess mortality is defined as "the deaths from all diagnosed causes (including Covid-19) which are greater than might be expected when compared with a modelled estimate based on recent historical experience" https://www.aph.gov.au/About_Parliament/Parliamentary_departments/Parliamentary_Library/pubs/rp/rp2324/ExcessDeathsAustraliaFAQ#:~:text=Excess%20mortality%20is%20defined%20as,%2C%20COVID%2D19%20pandemic).

Calculation of Excess Deaths

Excess deaths are calculated as the difference between actual deaths and expected deaths. While the number of actual deaths does vary slightly over time, due to factors such as time lags in reporting, the actual deaths figure is relatively static and reporting lag does not contribute substantially to variations in excess death estimations. What does contribute to variation, however, is the method used to calculate the expected deaths. Calculations that result in lower expected death rates will increase excess death estimates, while calculations that increase expected death rates will reduce excess deaths estimates. Adjusting the formulae used to calculate expected deaths can, therefore, have a significant impact on the final estimation of excess deaths, both in terms of the of excess deaths and their temporal profile.

Estimates of Excess Deaths in Australia

Excess deaths in Australia have been calculated using several different methods.

Method 1: Provisional Mortality Method

As part of the ABS provisional mortality data releases, the ABS have traditionally examined excess death by comparing current death rates to the weekly, monthly, or yearly averages calculated from the previous 5 years. In the 2020 and 2021 releases, the ABS compared the data to the average of the 2015 to 2019 years (https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics). In 2022, the ABS switched to comparing the provisional death data to the average of 2017 to 2019 and 2021. The 2020 year was excluded from the baseline for the evaluation of the 2021 and 2022 data because the ABS believed that "mortality during 2020 had periods where deaths were significantly lower than expected". This view is subject to debate but will not be addressed here. For the current analysis, it is

agreed that the 2020 year should be excluded from establishing the expected death baseline due to it being a pandemic year. It is uncertain why 2016 was excluded from the 2022 ABS evaluations as it reduced the baseline to a four-year average. It is also uncertain why, if 2020 was excluded for its 'low' death rates, 2017 was not excluded also for its substantially higher mortality rate (Figure 1). What is certain is that the exclusion of the 2020 death data, and inclusion of the 2017, data would have resulted in higher weekly, monthly and yearly averages and would have increased the expected death rates, and reduced the excess death estimates, across 2022.

For the purposes of this discussion, and to address the question "how does the number of deaths which have occurred during the Covid-19 pandemic (2020 to 2023) compare to what would have been expected had there not been a pandemic", the Provisional Mortality Method has been applied to the ABS current provisional mortality data using the 5 years preceding 2020, that being 2015 to 2019 *(https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release: release date 30 April 2024; data cube "Deaths by month of occurrence, 2015-2023")*. The monthly deaths, and the calculated expected averages and excess deaths are summarised in Table 1. The 2015 to 2019 profiles of monthly deaths are presented and compared in Figure 1. The higher rates of death in 2017 are evident. The monthly reported death rates from 2020 to 2023 are presented in Figure 2, together with the calculated monthly average expected death data. The monthly excess death counts are presented in Figure 3.

Using the provisional mortality method to estimate the number of excess deaths provides a crude and potentially inflated estimation that does not correct for changes in population or age structure. As such, it would be expected that this method would provide an "upper range" computation of the excess death estimate that would be partially offset by the inclusion of the 2017 data in the calculation of the expected average.

The excess deaths calculated across the pandemic years using the Provisional Mortality Method with expected death rates based on the 2015 to 2019 averages were: 1,621 for 2020; 11,068 for 2021; 30,317 for 2022; and 15,237 to August 2023 or 21,316 to December 2023. For the purpose of comparison, the overall excess death rates were calculated for the periods:

(1) January 2020 to December 2023: 64,322
(2) January 2020 to August 2023: 58,243
(3) January 2021 to December 2023: 62,701
(4) January 2021 to August 2023: 56,622

Examination of the profile of excess deaths calculated using the Provisional Mortality Method (Figures 2 and 3) indicated that death rates exceeded the average from November 2020 onward with a sharp increase evident in the period from February 2021 to May 2021, and then again from August 2021 to January 2022.

TABLE 1: Monthly death rates (persons, all ages) reported by the Australian Bureau of Statistics*

	January	February	March	April	May	June	July	August	September	October	November	December
Baseline years												
2015	12,237	11,172	12,439	12,603	13,488	13,415	14,754	15,260	14,114	13,301	12,197	12,468
2016	12,401	11,477	12,397	12,443	13,198	13,680	14,727	15,114	14,064	13,992	13,000	12,738
2017	12,691	11,529	12,755	12,832	13,662	13,945	15,849	16,480	15,432	13,818	12,556	12,813
2018	12,518	11,262	12,815	12,264	13,953	13,912	14,799	14,817	13,666	13,671	12,773	13,034
2019	13,194	11,973	13,176	12,995	14,185	14,659	15,183	15,286	14,270	14,010	12,847	13,047
Average	12,608	11,483	12,716	12,627	13,697	13,922	15,062	15,391	14,309	13,758	12,675	12,820
Pandemic years												
2020	12,999	12,513	13,549	13,301	14,027	13,270	14,482	14,862	13,696	13,439	13,040	13,513
2021	13,370	12,028	13,629	13,581	15,044	14,883	15,916	15,417	14,775	14,996	14,052	14,447
2022	16,275	14,093	14,748	14,864	16,493	17,182	18,329	17,765	15,783	15,357	14,802	15,696
2023	14,813	13,028	14,840	14,738	16,627	16,118	16,590	15,991	14,887	14,985	14,827	14,942
Calculated excess												
2020	391	1,030	833	674	330	-652	-580	-529	-613	-319	365	693
2021	762	545	913	954	1,347	961	854	26	466	1,238	1,377	1,627
2022	3,667	2,610	2,032	2,237	2,796	3,260	3,267	2,374	1,474	1,599	2,127	2,876
2023	2,205	1,545	2,124	2,111	2,930	2,196	1,528	600	578	1,227	2,152	2,122
Total Excess Deaths January 2020- December 2023												
Monthly	7,024	5,732	5,900	5,974	7,402	5,764	5,067	2,469	1,904	3,743	6,023	7,318
Overall	64,322											
Total Excess Deaths January 2020- August 2023												
Monthly	7,024	5,732	5,900	5,974	7,402	5,764	5,067	2,469	1,326	2,517	3,870	5,196
Overall	58,243											
Total Excess Deaths January 2021- December 2023												
Monthly	6,633	4,701	5,068	5,301	7,072	6,416	5,648	2,999	2,517	4,063	5,657	6,625
Overall	62,701											
Total Excess Deaths January 2021- August 2023												
Monthly	6,633	4,701	5,068	5,301	7,072	6,416	5,648	2,999	1,940	2,836	3,505	4,503
Overall	56,622											

**Source:* "Deaths by month of occurrence, 2015-2023" data cube downloaded from https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release on 13 May 2024, document release date 30 April 2024.

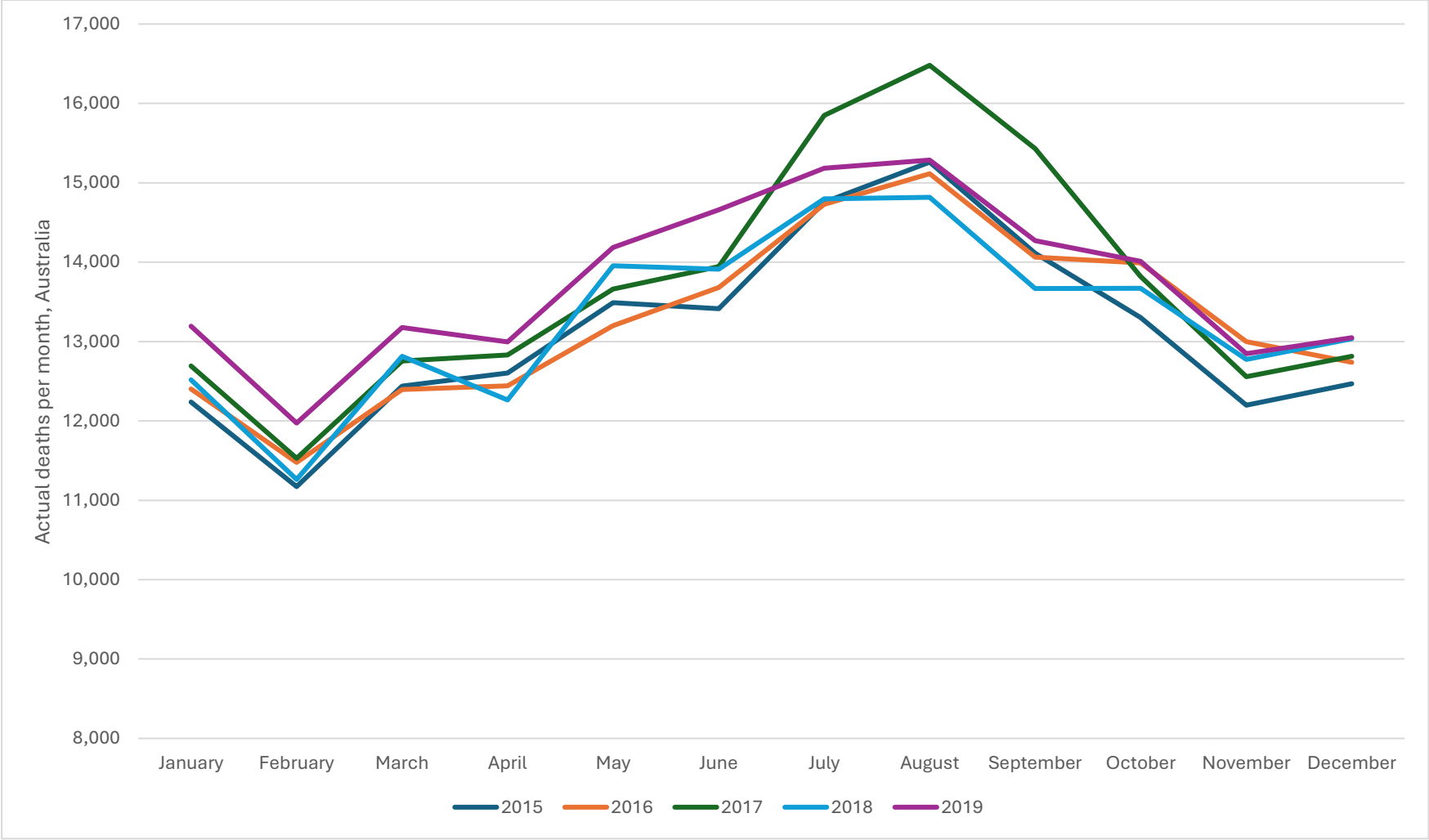


FIGURE 1: Monthly deaths in Australia from 2015 to 2019. *Source:* "Deaths by month of occurrence, 2015-2023" data cube downloaded from https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release on 13 May 2024, document release date 30 April 2024.

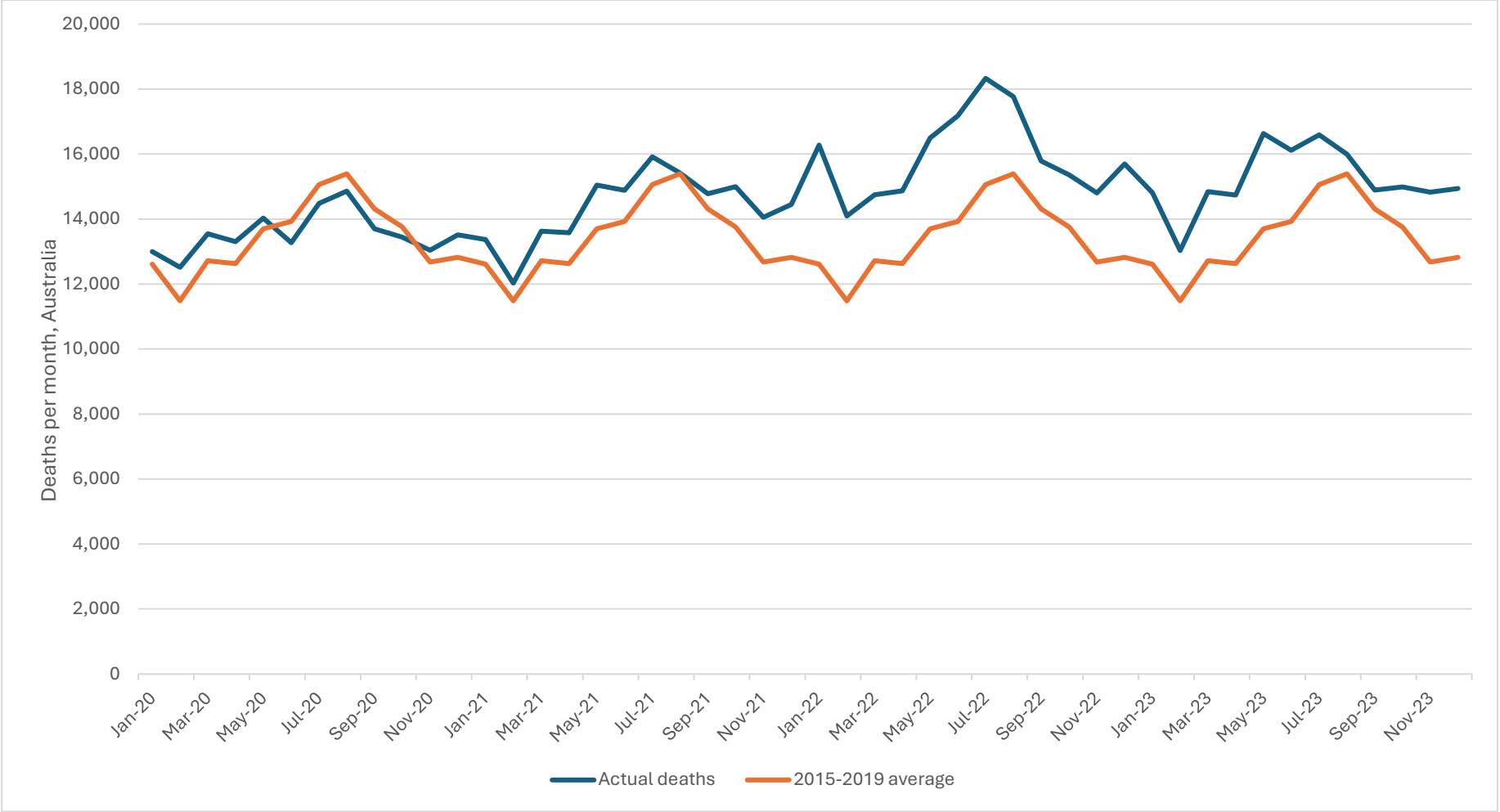


FIGURE 2: Monthly deaths (actual and expected average) in Australia from 2020 to 2023. *Source*: "Deaths by month of occurrence, 2015-2023" data cube downloaded from https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release on 13 May 2024, document release date 30 April 2024.

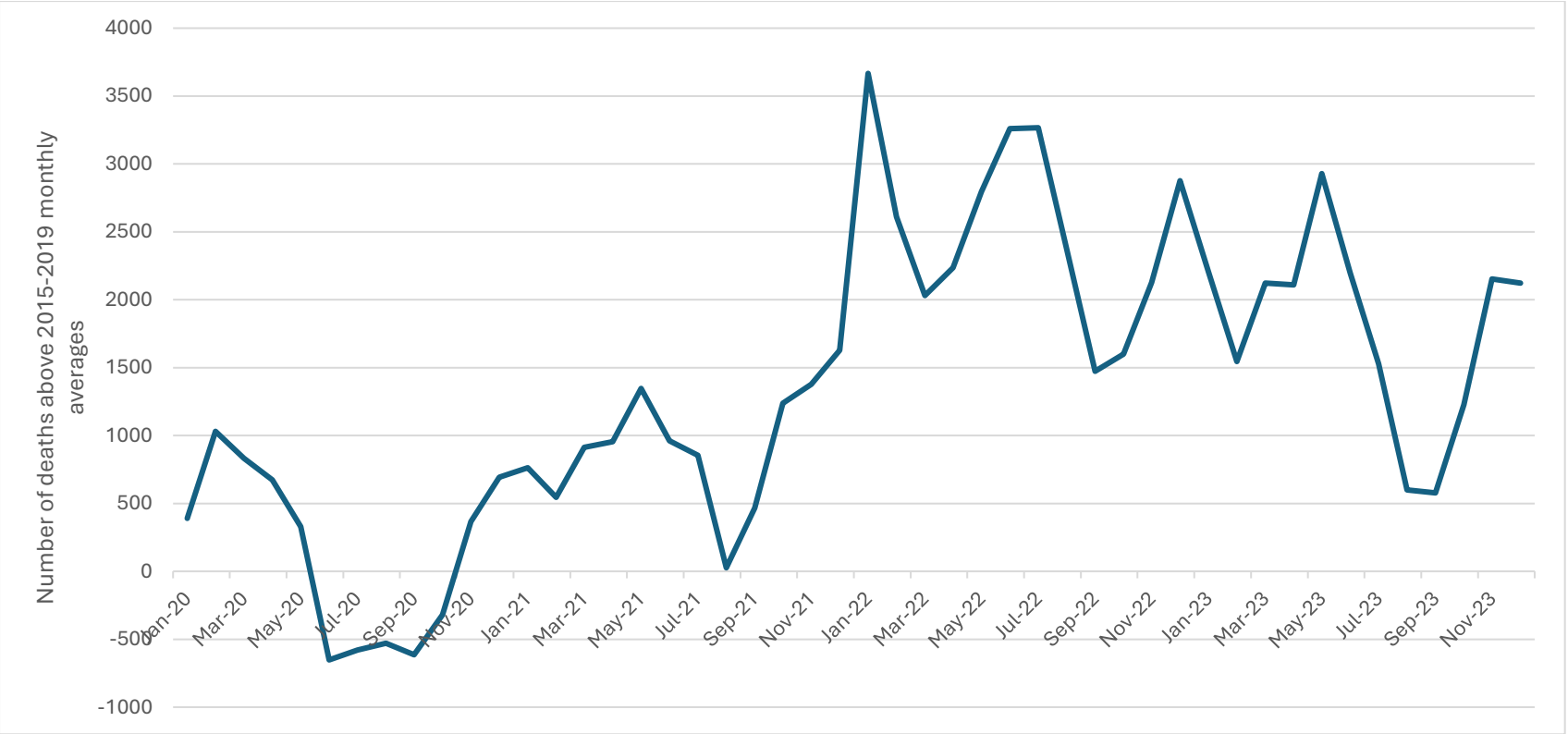


FIGURE 3: Monthly excess deaths in Australia from 2020 to 2023 calculated using the provisional mortality method. *Source*: "Deaths by month of occurrence, 2015-2023" data cube downloaded from https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release on 13 May 2024, document release date 30 April 2024.

Method 2: The ABS Serfling Model

The ABS has recently released an alternate analyses of excess deaths calculated using a model of the number of expected deaths based on "*a model developed by Serfling and later adapted by the Centre for Disease Control (CDC) and New South Wales (NSW) Health"* (https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023). This model applies a cyclic linear regression to calculate an expected number of deaths and a range of expected deaths. The ABS describes that it has "*applied this model to estimate age specific death rates for certain age groups and converted the expected death rates into an expected number of deaths for each age group. These are then added across age groups to obtain an expected count for the total population*". Dr Andrew Madry has discussed this method in substantial detail elsewhere in this document. Of significance here are the results of the modelling which show a substantially altered profile of excess deaths compared to that shown using the Provisional Mortality Method. Figure 4 provides a screenshot of the relevant figures from the ABS article. These are compared to the figures calculated using the Provisional Mortality Method in Table 2. Figure 5 shows the data for actual deaths verses expected deaths calculated using the ABS Serfling model. The blue shaded regions are the models expected ranges.

Excess mortality by year, Australia, 2020-23 Download

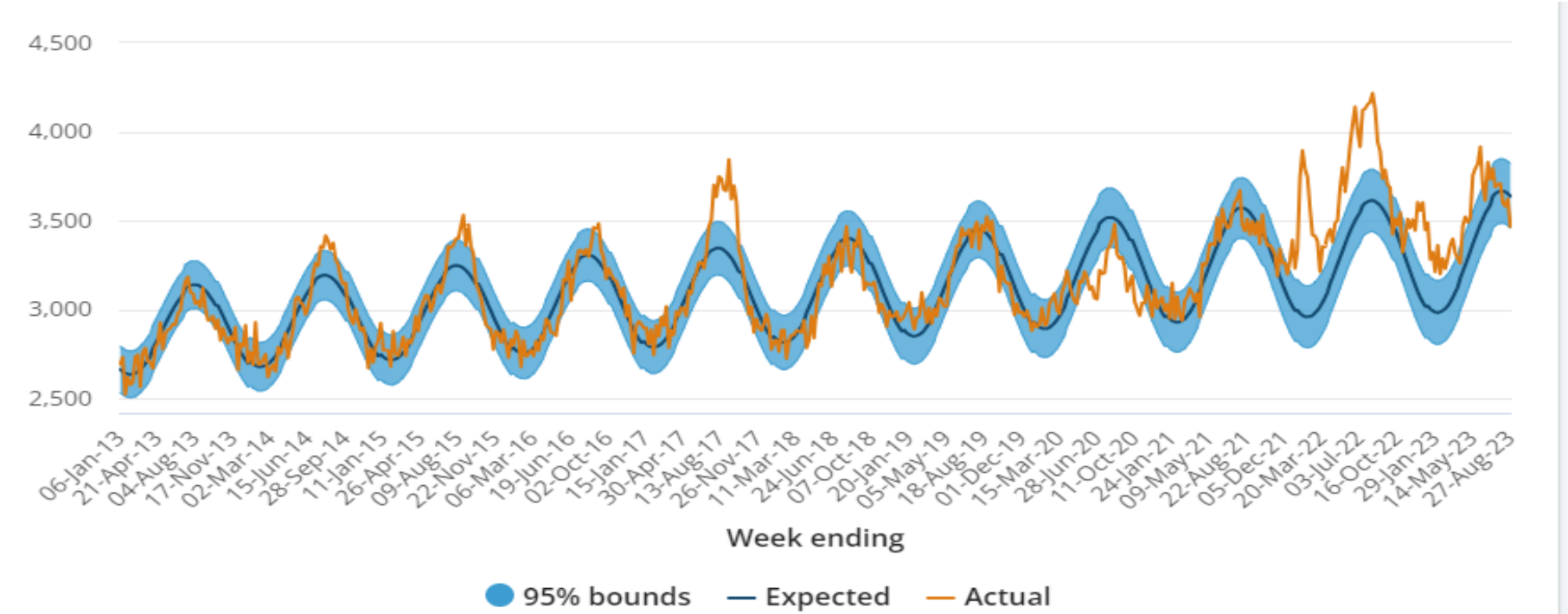
	Expected	Observed	Excess	% Excess	Reported deaths from or with COVID-19
2020	170,045	164,795	-5,250	-3.1	916
2021	169,048	171,799	2,751	1.6	1,448
2022	170,911	190,856	19,945	11.7	13,287
2023	112,714	119,619	6,905	6.1	4,444

a. Data is provisional and subject to change.
b. Years are based on a sum of ISO weeks derived from the weekly modelling. There are 53 weeks in 2020. There are 52 weeks in 2021 and 2022. Excess mortality has been estimated for the first 34 weeks of 2023.
c. Reported deaths 'from' or 'with' COVID-19 are as recorded on the death certificate.
d. Deaths in 2023 are deaths that occurred by 27 August and were registered and received by the ABS by 31 October 2023.

FIGURE 4: Screenshot showing estimates of excess deaths from January 2020 to 27 August 2023 as calculated using the ABS Serfling Model.

TABLE 2: Difference in excess deaths calculated using the Provisional Mortality Method versus the ABS Serfling Model.

	Provisional Mortality Method	ABS Serfling Model	Difference
Jan-Dec 2020	1,621	-5,250	6,871
Jan-Dec 2021	11,068	2,751	8,317
Jan-Dec 2022	30,317	19,945	10,372
Jan-Aug 2023	15,237	6,905	14,411
Total 2020 to Aug 2023	58,243	24,351	33,892
Total 2021 to Aug 2023	56,622	29,601	27,021



a. Dates for key events are indicative only and may differ to other sources.

b. Data is provisional and will change as additional death registrations are received.

c. The baseline period generating the regression model is from 2013 to 2019. The prediction window begins in 2020.

d. Data includes all deaths occurring by 27 August 2023 and registered and received by the ABS by 31 October 2023.

FIGURE 5: Actual versus expected deaths calculated using the ABS Serfling Model. https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023

Table 2 shows that the ABS Serfling model estimates the excess deaths for the January 2020 to August 2023 at 24,351 and the January 2021 to August 2021 period as 29,601. These estimates are 33,892 and 27,021 deaths lower, respectively, that those calculated using the Provisional Mortality Method. These differences reflect differences in the calculation of the expected deaths. As mentioned previously, the Provisional Mortality Method would be expected to provide an inflated estimate of excess deaths given that it has not accounted for changes in population and age structure. However, as reviewed by Dr Madry, the incorporation of a sine curve into the ABS Serfling model, together with the way the sensitivity analysis was conducted and the resultant choice of years for inclusion in the model's baseline, may have bias the model to higher predictions of expected deaths, and thus lower estimates of excess death, across the pandemic years. As argued by Dr Madry, the sine curve that the prediction equation is based on is not a good fit to the peaks of seasonal variations (Figure 5). Furthermore, the incorporation of 2013 at the lower extreme of the predictive baseline seems excessive and potentially biases the model towards an underestimation of excess deaths. This year has a reduced seasonal amplitude compared to other years (Figure 5) and its inclusion in the model baseline would be expected to increase the positive gradient of the predictive trendline and thus increase the predicted expected deaths and reduce the calculate excess. With these factors in mind, it could thus be argued that the excess deaths estimations calculated using the ABS Serfling model would represent the lower extreme of the estimations of excess deaths.

Other Methods

Dr Andrew Madry has employed several alternative models to calculate expected deaths and excess mortality for the period from January 2021 to December 2023. A summary of these is presented in Section 8.3 of his report. Of relevance here is that the Cumulative Sum Estimate and SARIMA method both estimated the cumulative excess death across the 2021, 2022 and 2023 years at 42,000 while the Annual Raw Data Method estimated the cumulative excess death at approximately 39,000. These figures are comparable to each other and sit between the estimates of 29,601 and 62,701 calculated using the ABS Serfling Model (Table 2) and the Provisional Mortality Method (Table 1), respectively.

It is noted that the ABS Serfling model is to 27 August 2023. Extrapolation of the ABS Serfling Model weekly death data to 31 December 2023 using the weekly data provided in the most recently released Provisional Mortality data release (https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release; Data cube: *Deaths by week of occurrence, 2015-23*; Weeks 35 to 52) against the expected figures for the September to December 2022 period (https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023 ; Data cube: *Excess mortality, Australia by state, Jan 2013 – Aug 2023*; Weeks 5 September 2022 to 1 January 2023) estimated an additional 1,900 additional excess deaths. Correcting this for the graduated increase in the expected deaths across years calculated an additional 692 deaths as expected from September to December 2022 compared to September to December 2021 period. If a comparable change in expected deaths for the September to December period between 2022 and 2023 is assumed, it can be estimated that

the additional excess deaths from September 2023 to December 2023 would be approximately 1,200 which would give a final excess deaths estimate for the ABS Serfling model of approx. 30,800 deaths for the January 2021 to December 2023 period.

In summary, based on the above models, it is evident that the excess deaths in Australia from January 2021 to December 2023 count are somewhere between 30,000 and 60,000 and most likely around approximately 40,000.

Regarding the temporal profile of excess deaths, the Provisional Mortality Model and Dr Andrew Madry's models indicate that excess deaths begin in early 2021 and continue across 2022 and 2023. In contrast, the ABS Serfling model absorbs the 2021 excess deaths into the 2021 seasonal peak, and suggests the excess deaths begin in early 2022. The absorption of the 2021 deaths into the seasonal influenza peak, when there were no influenza deaths reported in 2021, is questionable. That the actual death curve did not drop below the expected death curve across the April 2021 to September 2021 period raises the question - what was replacing the influenza deaths through this period?

Potential Causes of Excess Deaths: Deaths from Covid-19 Infection

Several factors have been proposed as potential contributors to the observed excess deaths, but most prominent among them is the claim that Covid-19 infection either directly or indirectly account for most of the deaths.

In a recent ABS article, estimates of the number of deaths from Covid-19 infection, and the number of deaths associated with Covid-19 infection, were provided for the years 2020 to 2023 (https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-january-2024). The findings are summarised in Table 3.

According to these estimates, 17,087 individuals died from Covid-19 between January 2020 and 31 December 2023. Of these, 16,181 deaths were reported between January 2021 and 31 December 2023. These figures represent 38.5% of Dr Madry's 42,000 estimate calculated to 31 December 2023 and 53% of the 30,800 estimated using the ABS Serfling model.

Notable is that according to these estimations there were an additional 4,488 individuals who died between January 2020 and 31 December 2023 where Covid-19 was listed on the death certificate as an associated cause (Table 3). Of these, 4,479 deaths were reported between January 2021 and 31 December 2023. Caution needs to be taken when including these in estimations of the contribution of Covid-19 infection to deaths, particularly when one considers the issues around diagnosing Covid-19 infection. The ABS have included these in their paper when they have assessed the role of Covid-19 infection in explaining the excess deaths (https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023). This is arguably incorrect.

TABLE 3: Estimates of deaths from Covid-19 infection, and associated with Covid-19 infection, for the years 2020 to 2023.

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
(a) Deaths due to COVID-19 by year and month of occurrence													
2020	0	0	23	79	12	3	145	473	146	16	8	1	906
2021	2	1	1	2	0	0	13	98	316	443	260	219	1,355
2022	1646	1034	425	716	929	889	1408	1129	447	254	456	968	10,301
2023	753	232	268	433	633	598	335	161	153	202	395	362	4,525
												Total	17,087
												Total January 2021 to 31 December2023	16,181
												Total January 2021 to 31 August 2023	15,069
(b) COVID-19 related deaths by year and month of occurrence													
2020	0	0	0	1	0	1	0	5	2	0	0	0	9
2021	0	0	0	0	0	0	1	1	4	15	19	25	65
2022	231	208	125	216	298	283	466	446	186	97	139	275	2,970
2023	221	108	112	147	187	191	92	74	49	53	94	116	1,444
												Total	4,488
												Total January 2021 to 31 December2023	4,479
												Total January 2021 to 31 August 2023	4,167
(a) + (b)													
2020	0	0	23	80	12	4	145	478	148	16	8	1	915
2021	2	1	1	2	0	0	14	99	320	458	279	244	1,420
2022	1877	1242	550	932	1227	1172	1874	1575	633	351	595	1243	13,271
2023	974	340	380	580	820	789	427	235	202	255	489	478	5,969
												Total	21,575
												Total January 2021 to 31 December2023	20,660
												Total January 2021 to 31 August 2023	19,236

Source: https://www.abs.gov.au/articles/covid-19-mortality-australia-deaths-registered-until-31-january-2024

Proportion of Excess Deaths due to Covid-19 Infection

As stated above, it is currently estimated that approximately half to two thirds of the excess deaths that have occurred between January 2021 and December 2023 are due to Covid-19 infection, with further claims that this is under-reported and that, in fact, the majority of excess deaths may be attributed to the direct and/or indirect impacts of Covid-19 infection. This argument is often used to dismiss the need to further investigate excess deaths. However, there are also arguments that estimates of the contribution of Covid-19 infection to excess deaths across 2021 to 2023 may be substantially less than these figures suggest. As raised elsewhere in this document by Clare Pain and Dr Andrew Madry, the average age of deaths, in those listed as dying from Covid-19 infection, is older than the overall average age of death. This indicates that a proportion of Covid-19 deaths would have most likely have occurred anyway, and been attributed to another cause, and thus would really be considered as expected deaths, based on age. Care needs to be taken when interpreting data presented by Health Departments and the ABS regarding Covid-19 infection cases and deaths with many figures providing estimations of death from and with Covid-19 and not distinguishing between deaths where Covid-19 is assigned as the underlying cause versus deaths where it is an associated cause. Figure 6 provides a screenshot of the Australian Institute of Health and Welfare definition of "underlying cause", "associated causes" and multiple causes" of death.

Box 1: Terminology used to describe causes of death

The **underlying cause of death** is the disease or injury that initiated the train of events leading directly to death, or the circumstances of the accident or violence that produced the fatal injury. Deaths are referred to here as 'due to' the *underlying cause of death*.

Associated causes of death are all causes listed on the death certificate, other than the *underlying cause of death*. They include the immediate cause, any intervening causes, and conditions which contributed to the death but were not related to the disease or condition causing the death.

Multiple causes of death are defined here as all causes listed on the death certificate. This includes the *underlying cause of death* and all *associated causes of death*. This information is useful for describing the role of all diseases involved in deaths especially for chronic diseases, where there is usually more than one disease contributing to the death.

FIGURE 6: Definitions of the underlying causes of death, associated cause of death and multiple causes of death by Australian Institute of Health and Welfare. *Source:* https://www.aihw.gov.au/reports/life-expectancy-deaths/deaths-in-australia/contents/multiple-causes-of-death

Regardless of whether cases where Covid-19 infection is the underlying cause of death are distinguished from cases where Covid-19 is an associated cause of death, the accuracy and clinical significance of coroners and/or doctor determinations of deaths is still limited by the reliability, validity and accuracy of the criteria used to classify Covid-19 cases. This factor must be considered when evaluating the role of Covid-19 infection in excess deaths.

Issues with the Classification of Covid-19 Infection

The classification of Covid-19 infection in Australia has involved both laboratory testing using a test such as the polymerase chain reaction (PCR) test developed for the detection of segments of the Covid-19 virus's genetic material, together with the application of the ICD-10 codes recommended by the WHO – U07.1 and U07.2. Both components of diagnosis are subject to inconsistencies and potential inaccuracies in classification.

The PCR Test

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 standardisation 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 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, 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-19 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 code 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-19 infection at all and be classified as a Covid-19 case or a Covid-19 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 may inflate case and death 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 infection have 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 for its employment of additional amplification cycles beyond that considered to give a valid result, a factor that is exacerbated when the test is used with asymptomatic individuals. The PCR test has also been criticised because it cannot ascertain whether a person is infected with the disease or not. Having a segment of viral material does not mean an individual has an active infection but could result in the attribution of death to Covid-19 according to this code.

The U07.2 code is also potentially problematic. The U07.2 code classifies individuals as Covid-19 cases/deaths if they are suspected of having Covid-19 but laboratory testing for Covid-19 infection 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 the number of deaths attributed to Covid-19 infection, through mis categorisation of underlying and associated causes.

While doctors, coroners and the ABS may review deaths to determine whether obvious alternative causes are present, the diagnosis of Covid-19 infection is still reliant on the above diagnostic protocols, and as such is subject to their diagnostic limitations.

Review of the multiple cause data support the possibility that attributions of Covid-19 infection as the underlying cause of so many excess deaths may be over-stated.

Covid-19 Infections – Underlying Cause, Associated Causes and Multiple Causes
Cause of death data released annually by the ABS include data that outline the underlying causes of death together with the associated causes (https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia).

Table 4 presents a summary of the number of associated causes listed on death certificates where Covid-19 infection has been listed as the underlying cause of death. The numbers and percentages of deaths where the underlying cause was listed alone, together with the numbers and percentages of deaths where 1, 2, 3 or ≥4 associated causes have been listed on the death certificate are provided, together with the mean number of causes for 2020 to 2022.

From Table 4, it is evident that Covid-19 was reported as the underlying cause of death for 898, 1122 and 9856 individuals in 2020, 2021 and 2022 respectively, giving a total of 11,879 across this period. However, only 527 (4.4%) of these deaths listed covid-19 infection alone as the causative agent. The remaining 95.4% were reported one or more other causes, with a mean of 3.4, 3.8 and 4.2 other causes reported for 2020, 2021 and 2022 respectively.

Table 5 provides a summary of the number of deaths for 2020 to 2022 where Covid-19 infection was (a) listed on the death certificate as the underlying cause of death, together with the number of deaths where Covid-19 was (b) listed on the death certificate as either the underlying cause or an associated cause. The ratios of (b)/(a) are also presented. A lower ratio indicates a higher proportion of deaths where, for example, Covid-19 infection has been listed on the death certificate and that death certificate has also listed Covid-19 infection as the underlying cause. For deaths where Covid-19 infection was listed on the death certificate, the ratio was between 1.0 and 1.3 with an average of 1.2. *This suggests that almost all cases where Covid-19 infection was mentioned on the death certificate, it was also listed as the underlying cause.* This is incongruent with the questionable reliability and validity of the Covid-19 diagnostic criteria and contrasts the ratios of 5.7 to 6.7 observed for influenza and pneumonia infection (Table 5).

TABLE 4: Summary of the number of associated causes listed on the death certificates of individuals where Covid-19 infection has been listed as the underlying cause of death.

	2020[1]		2021[2]		2022[3]		2020-2022	
	No.	*(%)*	No.	*(%)*	No.	*(%)*	No.	*(%)*
Total deaths	898	*(100)*	1,122	*(100)*	9,856	*(100)*	11,879	*(100)*
Reported alone	103	*(11.5)*	78	*(7.0)*	346	*(3.5)*	527	*(4.4)*
Reported with								
One other cause	217	*(24.2)*	243	*(21.7)*	1,551	*(15.7)*	2011	*(16.9)*
Two other causes	210	*(23.4)*	237	*(21.1)*	2,182	*(22.1)*	2629	*(22.1)*
Three other causes	161	*(17.9)*	215	*(19.2)*	2,055	*(20.9)*	2431	*(20.5)*
Four or more other causes	207	*(23.1)*	349	*(31.1)*	3,722	*(37.8)*	4278	*(36.0)*
Mean number of causes	3.4		3.8		4.2			

[1] COVID-19 (U07). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2020, Data cube: 3303_10 Multiple causes of death (Australia).xlsx, Table 10.1.
[2] COVID-19 (U07). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2021, Data cube 2021_10 Multiple causes of death (Australia).xlsx, Table 10.1.
[3] COVID-19 (U07.1-U07.2). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022#revisions-to-causes-of-death, Data cube: 2022_10 Multiple Causes of Death (Australia) Table 10.1

TABLE 5: Summary of the number of deaths where Covid-19 infection, and Influenza and Pneumonia infection, were listed on the death certificate as the underlying cause of death, together with the number of deaths where these infections were listed on the death certificate overall (mentions), across the years 2020 to 2022.

	Covid-19 Infection (U07.1 & U07.2)			Influenza and Pneumonia (J09-J18)		
	Underlying cause	Multiple cause	Ratio	Underlying cause	Multiple cause	Ratio
2020[1]	898	906	1.0	2,287	12,948	5.7
2021[2]	1,122	1,153	1.0	2,073	13,292	6.4
2022[3]	9,856	12,643	1.3	2,762	18,580	6.7
2020-2022	11,876	14,702	1.2	7,122	44,820	6.3

[1] COVID-19 (U07). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2020, Data cube: 3303_10 Multiple causes of death (Australia).xlsx, Table 10.2.
[2] COVID-19 (U07). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2021, Data cube 2021_10 Multiple causes of death (Australia).xlsx, Table 10.2.
[3] COVID-19 (U07.1-U07.2). Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022#revisions-to-causes-of-death, Data cube: 2022_10 Multiple Causes of Death (Australia) Table 10.2

In the 2022 data, the ABS also provided a breakdown of some of the most frequently reported associated conditions reported on death certificates where the underlying cause of death had been listed as Covid-19 infection. This data is reproduced below in Table 6.

Consistent with Table 4, only 3.5 % of deaths listing Covid-19 infection as the underlying cause of death reported this cause alone on the death certificate. Influenza and pneumonia were the most commonly reported associated conditions, being reported for 4,122 of the 9,859 (42%) Covid-19 deaths. Ischaemic heart diseases, and heart failure, were also listed as associated causes on a further 1,695 (17.2%) and 1,501 (15.2%) of Covid-19 deaths.

TABLE 6: Summary the most frequently reported associated conditions reported on death certificates where the underlying cause death was listed as Covid-19 infection in 2022.

Underlying cause / associated cause and ICD-10 code	Males		Females		Persons	
	No.	*(%)*	No.	*(%)*	No.	*(%)*
COVID-19 (U07.1, U07.2, U10.9)	5,484	*(100.0)*	4,375	*(100.0)*	9,859	*(100.0)*
Reported alone	184	*(3.4)*	162	*(3.7)*	346	*(3.5)*
Reported with:						
Influenza and pneumonia (J09-J18)	2,511	*(45.8)*	1,611	*(36.8)*	4,122	*(41.8)*
Dementia, including Alzheimer's disease (F01, F03, G30)	1,144	*(20.9)*	1,209	*(27.6)*	2,353	*(23.9)*
Diseases of the urinary system (N00-N39)	1,054	*(19.2)*	759	*(17.3)*	1,813	*(18.4)*
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	906	*(16.5)*	861	*(19.7)*	1,767	*(17.9)*
Ischaemic heart diseases (I20-I25)	1,133	*(20.7)*	562	*(12.8)*	1,695	*(17.2)*
Heart failure and complications and ill-defined descriptions of heart disease (I50-I51)	784	*(14.3)*	717	*(16.4)*	1,501	*(15.2)*

Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/2022#revisions-to-causes-of-death. Data cube: 2022_10 Multiple Causes of Death (Australia).xlsx, Table 10.4.

Interestingly, the report of influenza and pneumonia, and ischaemic heart disease, as underlying illnesses was reduced in 2020, 2021 and 2022 compared to the 2015-2019 average (Table 7). This raises the question, could these reductions in report for other conditions with over-lapping symptomatology reflect a shift in diagnoses of these conditions as the underlying causes of death to Covid-19 infection? If so, it could be argued that not only are these deaths not all the direct result of Covid-19 infection but that they may also not be excess deaths either.

TABLE 7: Change in the number of deaths attributed various respiratory and circulatory causes in 2020, 2021, 2022 and 2023 compared to the average for 2015 to 2019.

	2020 change	2021 change	2022	2020-2022 Total
Influenza and pneumonia (J09-J18)	-508	-1,315	-777	-2,600
Influenza due to certain identified influenza virus (J09)	-4	-7	-7	-18
Influenza due to other identified influenza virus (J10)	-178	-455	-198	-831
Influenza, virus not identified (J11)	-73	-191	-145	-409
Viral pneumonia, not elsewhere classified (J12)	-11	2	-4	-13
Pneumonia due to Streptococcus pneumoniae (J13)	-7	-10	-8	-25
Pneumonia due to Haemophilus influenzae (J14)	-2	-5	-3	-10
Bacterial pneumonia, not elsewhere classified (J15)	-8	-8	-5	-21
Pneumonia due to other infectious organisms, not elsewhere classified (J16)	0	0	0	0
Pneumonia, organism unspecified (J18)	-225	-641	-407	-1,273
Other acute lower respiratory infections (J20-J22)	-139	-185	-201	-524
Acute bronchitis (J20)	-6	-11	-11	-29
Acute bronchiolitis (J21)	-4	-2	-3	-9
Unspecified acute lower respiratory infection (J22)	-128	-171	-186	-486
Chronic lower respiratory diseases (J40-J47)	-984	-379	-124	-1,488
Bronchitis, not specified as acute or chronic (J40)	-14	-13	-13	-41
Simple and mucopurulent chronic bronchitis (J41)	0	0	0	-1
Unspecified chronic bronchitis (J42)	-6	-5	-5	-17
Emphysema (J43)	-114	-69	-22	-206
Other chronic obstructive pulmonary disease (J44)	-801	-251	-80	-1,133
Asthma (J45)	-13	-76	0	-88
Status asthmaticus (J46)	-3	-4	1	-7
Bronchiectasis (J47)	-32	40	-4	4
Ischaemic heart diseases (I20-I25)	-1,789	-1,373	-1,371	-4,533
Acute myocardial infarction (I21)	-1,089	-1,195	-1,332	-3,616
Other acute ischaemic heart diseases (I24)	19	-2	-15	2
Chronic ischaemic heart disease (I25)	-726	-176	-20	-922
Cerebrovascular diseases (I60-I69)	-689	-451	-1,010	-2,151
Stroke, not specified as haemorrhage or infarction (I64)	-354	-344	-596	-1,295
Sequelae of cerebrovascular disease (I69)	-678	-647	-642	-1,968

Source: https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/latest-release. Data cube: 2022_14 Causes of death by year of occurrence (Australia).

Table 7 shows also some of the other causes of death that were reported as the underlying cause less frequently in 2020, 2021 and 2022 compared to the 2015-2019 average. These include "Other acute lower respiratory infections", several "chronic lower respiratory diseases", and "cerebrovascular diseases". A thorough examination of deaths attributed to Covid-19 infection is warranted to investigate whether reductions in these causes reflect a shift in diagnoses from these conditions to Covid-19.

Other Factors that May be Contributing to Excess Deaths

Regardless, of whether all or only a portion of deaths attributed to Covid-19 infection have genuinely contributed to death, at least two thirds to a half of excess deaths remain unexplained.

As already mentioned, many documents claim that undiagnosed Covid-19 infection may explain a solid portion of the remaining deaths.

In stark contrast, almost invariably, the potential that Covid-19 vaccine injuries are contributing to the unexplained excess deaths is not considered. This is perplexing for reasons including the following:

Firstly, scientific process requires consideration of ALL variables that are temporally or otherwise related to a variable that is under investigation. The roll-out of millions of doses of experimental Covid-19 vaccines was sufficiently temporally related to the profile of excess deaths that it should have prompted an open and transparent review, especially when one considers that both short-term and long-term adverse events may occur which may impact the temporal relationship between vaccination and death.

Secondly, Covid-19 vaccines were released under a provisional registration and as such have a recognized lack of safety data and a requirement for a higher standard of pharmacovigilance.

Thirdly, deaths from Covid-19 vaccines have been reported worldwide and are accepted to occur. In Australia, the Covid-19 vaccines have been linked to 14 deaths by the TGA and 16 deaths in the ABS all cause mortality data.

Finally, authorities accept that Covid-19 infection causes severe illness and deaths in individuals and that much of the pathology of Covid-19 infection is mediated by the Covid-19 spike protein but completely ignore or discount the possibility that exposure of individuals to vaccine spike protein, which has been genetically modified to resist degradation and packaged in such a way as to have potentially greater mobility in the body, may have similar pathogenic consequences.

Covid-19 Vaccines as Potential Contributors to Excess Deaths

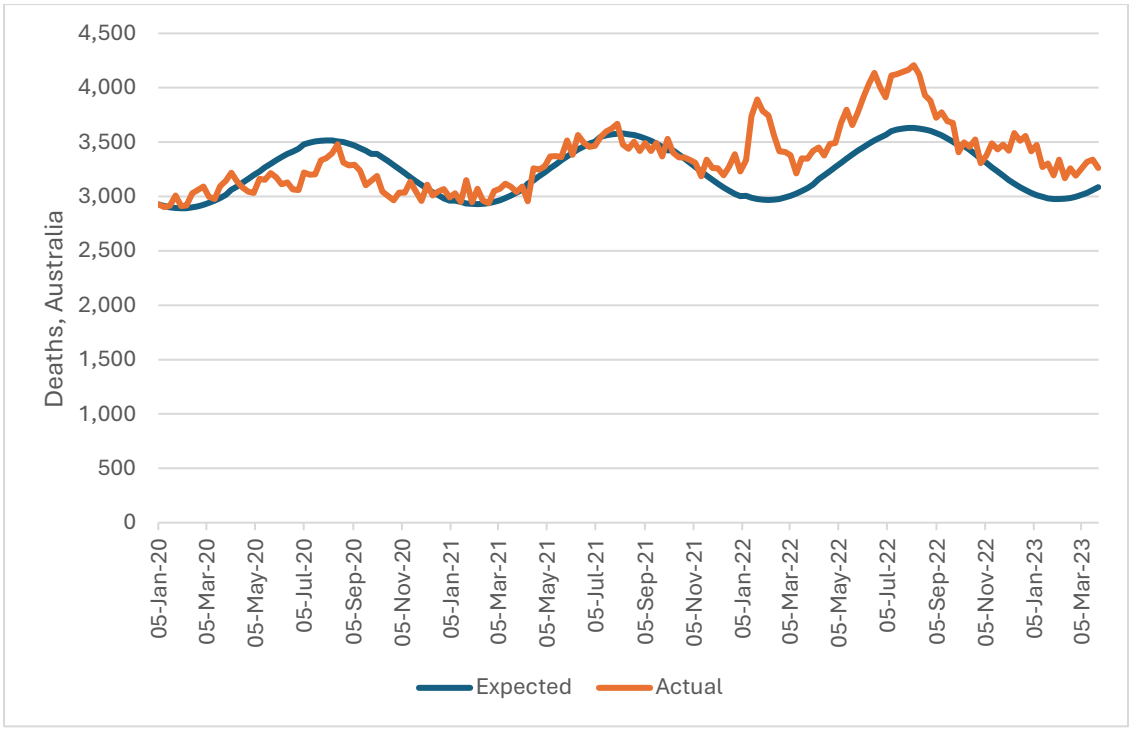
Temporal Relationship between Excess Deaths and Covid-19 Vaccine Roll-out
Much has been made of the temporal relationship between covid-19 infection and excess deaths, but the vaccine roll-out is also temporally related to the profile of excess deaths.

Figure 7 presents the profile of actual deaths verses the expected deaths calculated using the Serfling model. Figure 8 provides the profile for Covid-19 vaccine doses administered.

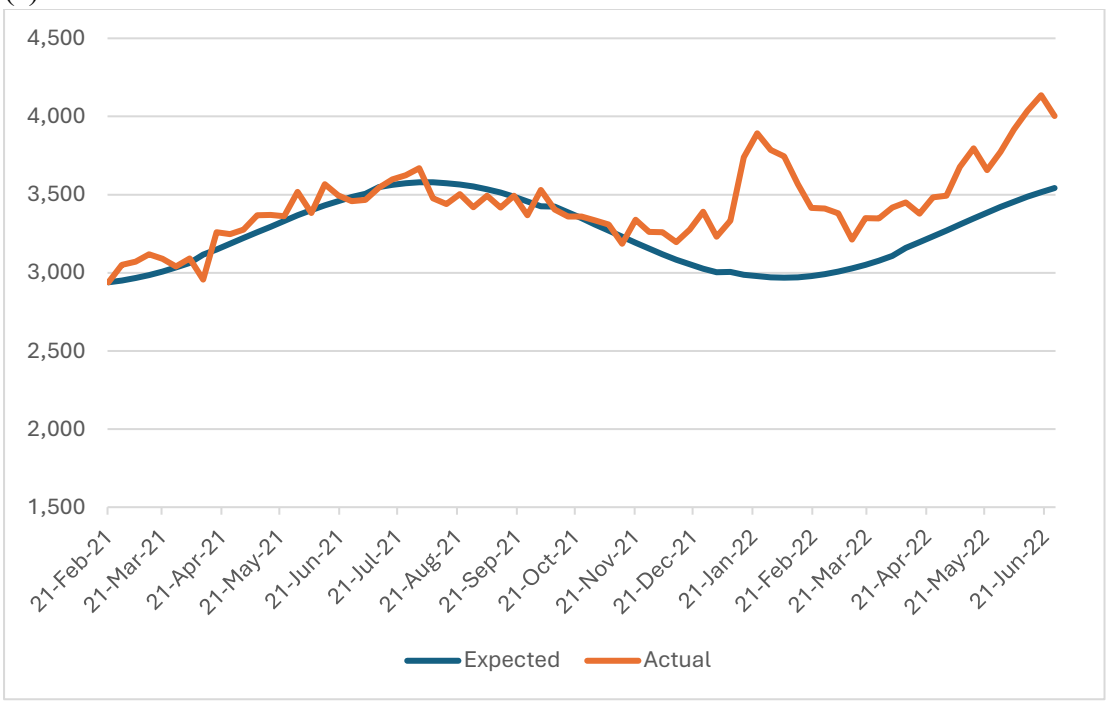
Figure 7 shows a definitive sharp rise in deaths occurring between April 11th and April 18th 2021 that coincides with the commencement of the vaccine roll out and the initial surge of vaccine doses being administered between March 27th and April 22nd 2021 (Figure 8).

There are also two peaks in excess deaths commencing at (a) 12th December 2021 and peaking on 26th December 2021, and (b) from 2nd January to 23rd January (Figure 7). These coincide with vaccination surges that start at (a) December 12th 2021 and peaking at 23rd December 2021, and (b) starting at 31st December 2021 and peaking at 21st January 2022 (Figure 8).

The continuation of excess deaths past the vaccination surge does not rule out the potential role of vaccines in causing excess deaths. As mentioned above, vaccines may have medium- and long-term consequences. Adding to this is the potential impact of sequential doses of vaccine and the possible overlap of vaccination with Covid-19 infection which may have dose dependent pathophysiological consequences.



(a)



(b)

FIGURE 7: Actual deaths (orange) verses expected deaths as calculated using the ABS Serfling Model for the periods (a) January 2020-March 2023 and (b) 21 February 2022 to 30 June 2022. Source: https://www.abs.gov.au/articles/measuring-australias-excess-mortality-during-covid-19-pandemic-until-august-2023 . Data cube "Excess mortality, Australia and by state, Jan 2013 - Aug 2023".

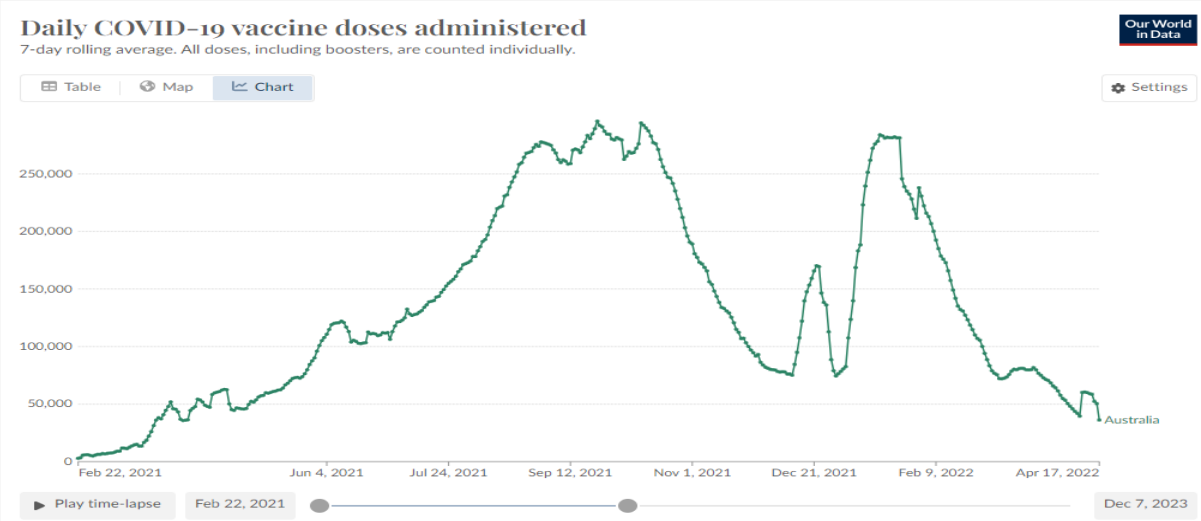


FIGURE 8: Daily Covid-19 vaccine doses administered between February 2021 and April 2022 in Australia. Source: https://ourworldindata.org/covid-vaccinations

Evaluating the Safety of Covid-19 Vaccines

All drugs have the potential to cause side effects including death. Clinical trials do not identify all side effects and some effects may not be seen until after drug approval & release. For this reason, side effects are generally tracked after drug release to examine for safety concerns. This process is referred to as post-marketing pharmacovigilance.

In Australia, the TGA registers and monitors the safety, efficacy and quality of medicines, vaccines and therapeutics. As part of this process the TGA manages a passive spontaneous system where reports of adverse events are made to the TGA, reviewed and published to the Database of Adverse Event Notifications – Medicines (DAEN – medicines)

The TGA also reviews information from state level adverse event management programs and from the national active reporting system, AusVaxSafety.

In the following section, the adverse event reports associated with Covid-19 vaccines will be reviewed to assess whether safety signals exist and whether Covid-19 vaccines may be contributing to excess deaths.

Safety signals may be indicated by:

1) the increased frequency of report of existing or known adverse events;
2) report of new adverse events; and
3) changes in proportionality (Proportional Reporting Ratio).

Overview of TGA DAEN Data

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 TGA DAEN is a passive surveillance system that relies on the spontaneous, voluntary report of adverse events by a reporter. An advantage of this systems is that anyone can submit a report 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 (see below).

Review of the overall profile of reports made to the DAEN across its 52-year history revealed a significant change following the rollout of the Covid-19 vaccines.

Figure 9 presents the total number of adverse event reports (AERs) added to the TGA DAEN between 1 January 1971 (the inception of the DAEN – medicines) and 1 November 2023 for all medicines, vaccines and biological therapies ("all medicines"). As shown in Figure 9, the number of AERs listed in the TGA DAEN has risen steadily from 1 January 1971 reaching 414,217 AERs by 31 December 2020. The rate of AERs then increased dramatically following the introduction of the four covid-19 vaccines, with 199,105 additional AERs added from 1 January 2021 to 1 Nov 2023. Over 70% of these adverse event reports were in relation to covid-19 vaccines and for 97% of those cases, the covid-19 vaccine was listed as the only suspected medicine.

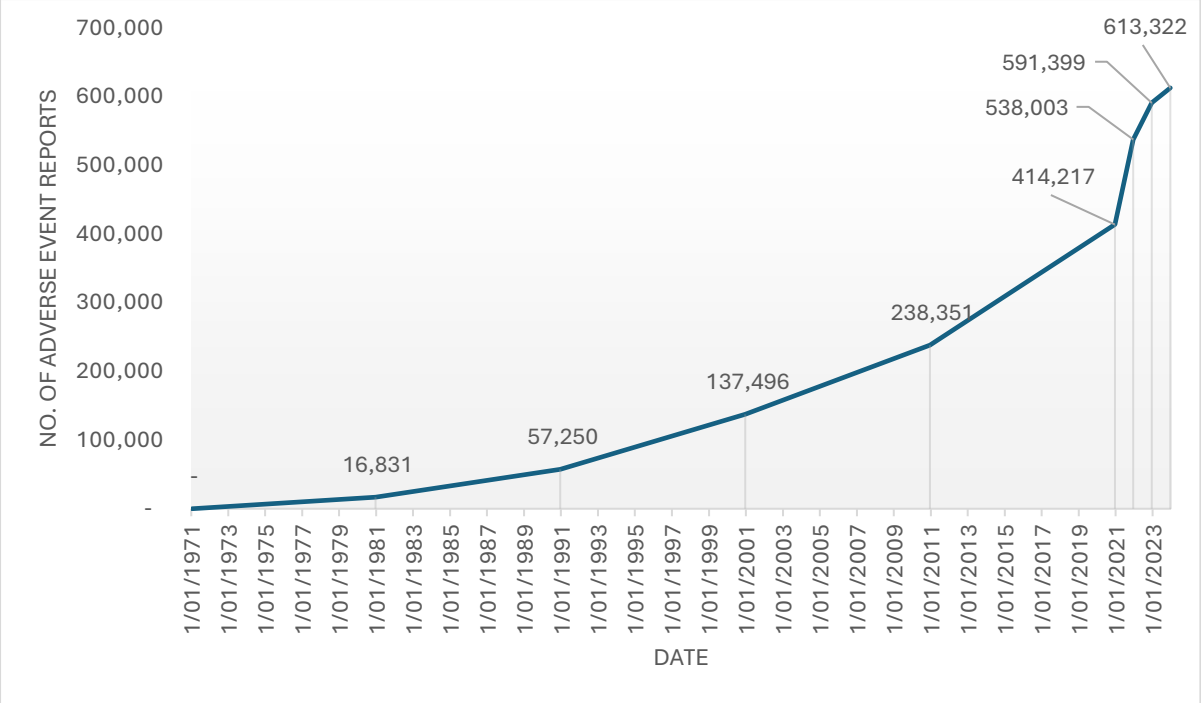


FIGURE 9: Number of adverse event reports submitted to the TGA DAEN between 1 January 1971 and 1 November 2023. *Source:* TGA DAEN extracted 1 May 2024.

Figure 10 presents the number of AERs submitted to TGA DAEN each year from 1 January 2009 to 31 December 2022. Consistent with the data presented in Figure 9, the number of AERs submitted in 2021 and 2022, following the roll-out of the Covid-19 vaccines, were substantially higher than in previous years. In particular, the 2021 annual report rate was approximately 6 times higher than the number of reports reported for 2018, 2019 and 2020.

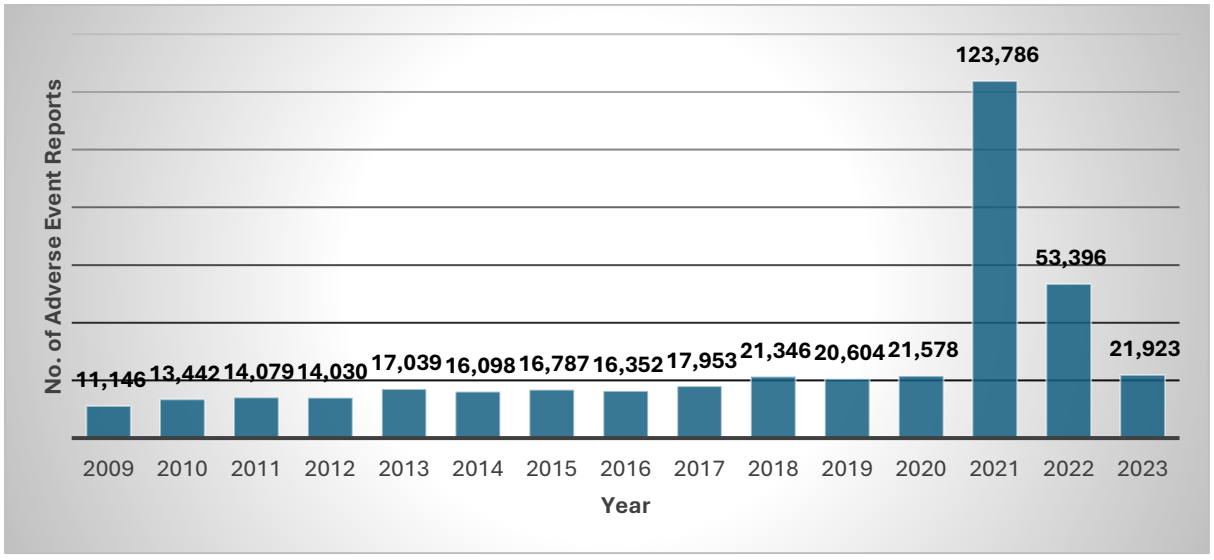


FIGURE 10: Number of adverse event reports submitted each year to the TGA DAEN from 1 January 2009 to 31 Dec 2022. *Source:* TGA DAEN extracted 1 May 2024

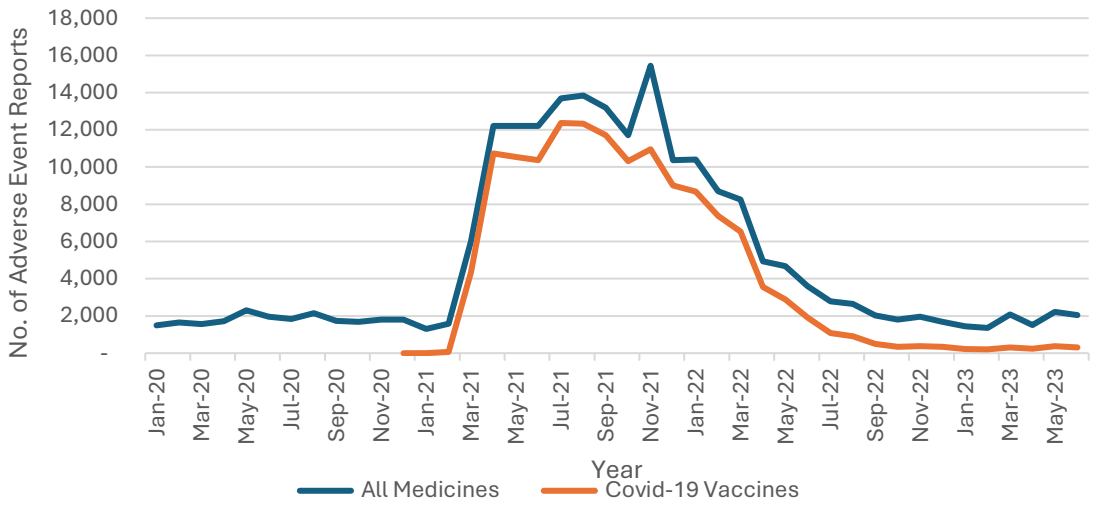


FIGURE 11: The number of adverse event reports submitted to the TGA DAEN monthly in relation to (a) one or more of the covid-19 vaccines between 1 January 2020 to 31 June 2023 and (b) all medicines, vaccines and therapies used in Australia ("All Medicines").

Figure 11 presents the relationship between the number of AERs submitted to the TGA DAEN from 1 January 2020 to 31 June 2023 overall for all medicines, vaccines and therapies ("All medicines") and AERs related to the covid-19 vaccines. The graph clearly shows that the AERs related to covid-19 vaccines constituted the majority of AERs across this period. Importantly, over 70% of the cases and deaths associated with Covid-19 vaccines 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.

Figure 12 presents the number of AERs with an outcome of death submitted to TGA DAEN between 1 January 1971 and 31 December 2022 and annualised across 5-year increments from 1971 to 2020 and the 2-year increment for 2021 and 2022. As shown in Figure 12, the number of AERs that reported death as an outcome was 61% higher in 2021 and 2022 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 a suspected medicine.

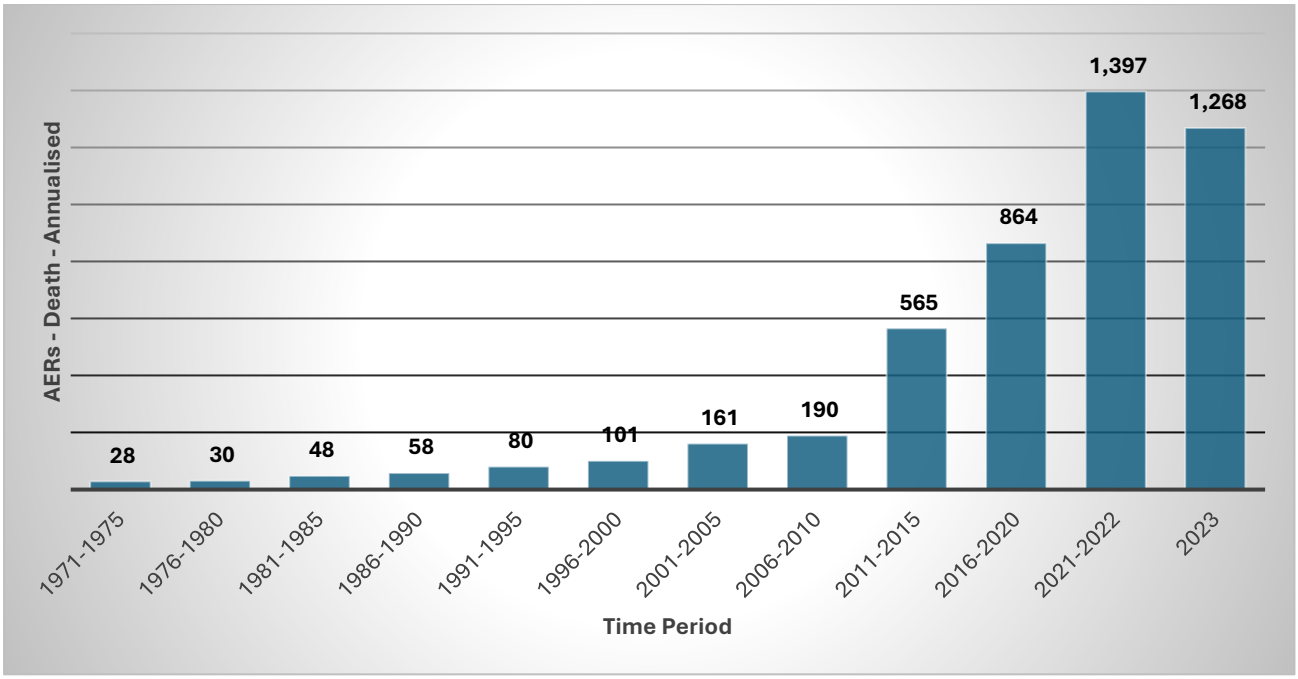
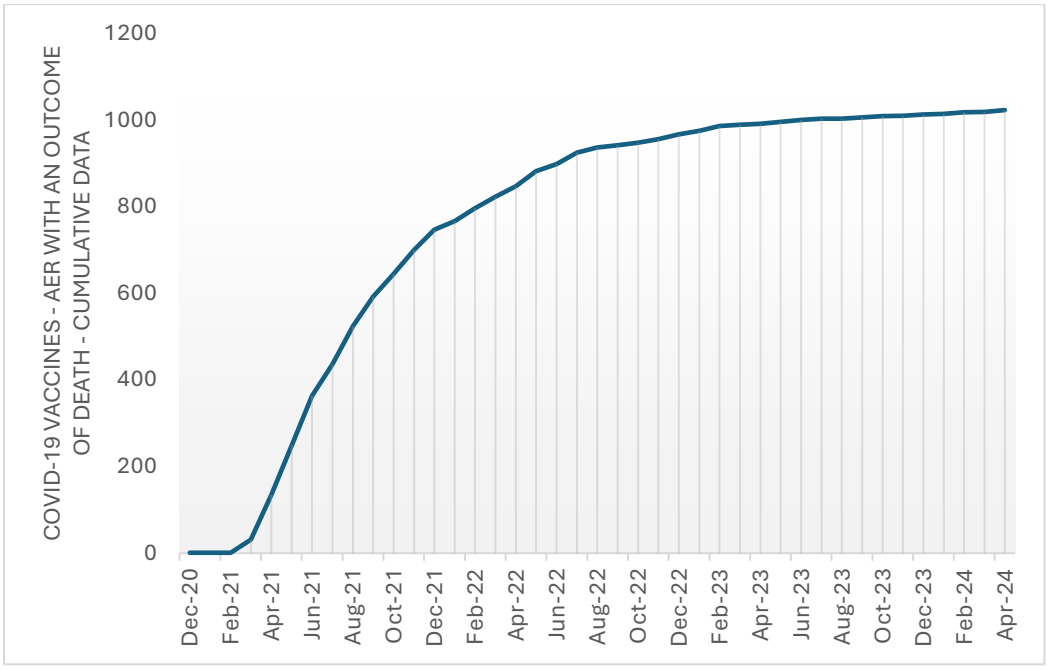


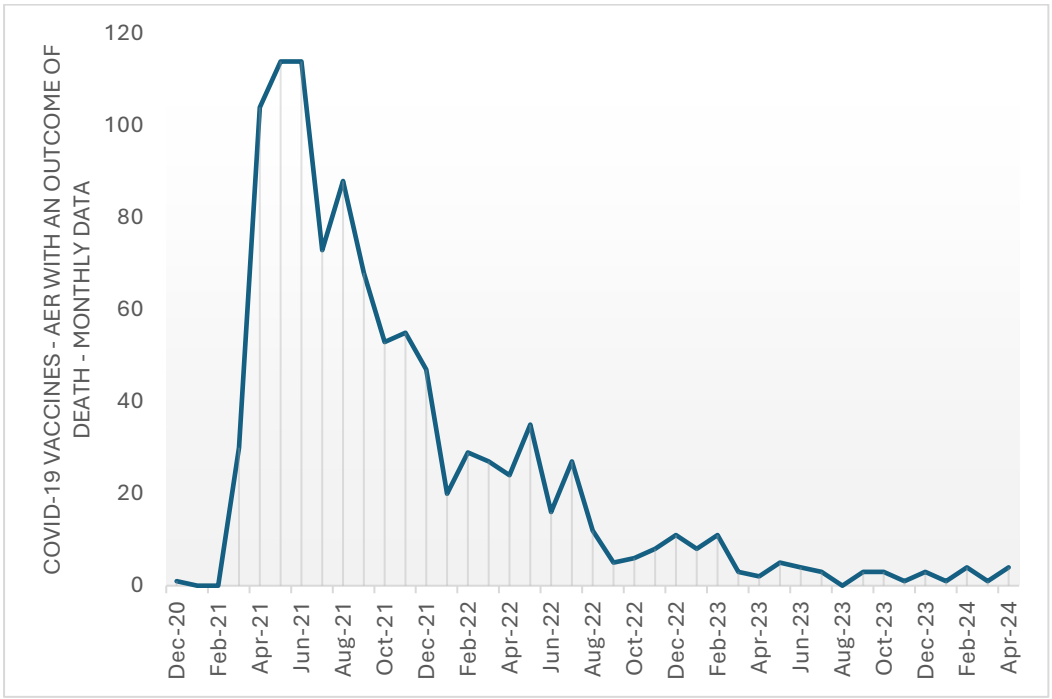
FIGURE 12: Number of adverse event reports (AERs) with an outcome of death submitted to TGA DAEN between 1 January 1971 and 1 November 2023 - annualised AER data reported in 5-year increments from 1971 to 2020, the 2-year increment for 2021 and 2022, and for 2023. *Source:* TGA DAEN extracted 1 May 2024.

TGA DAEN: Reports of Adverse Events Associated with the Covid-19 Vaccines on the
A search of the TGA DAEN (https://daen.tga.gov.au/medicines-search/; 15 May 2024) found that, as of 30 April 2024, 140,385 adverse event reports had been submitted to the TGA and published to the DAEN where one or more Covid-19 vaccines were listed as the suspected medicine. Of these, 97.3% listed a Covid-19 vaccines as the only suspected medicine. For 1,023 of the reports, death was reported as an outcome.

Figure 13 presents the profile of death reports from December 2020 to April 2023. Figure 13(a) presents the cumulative report profile while Figure 13(b) presents the death reports per month. As is shown by the profiles, the rate of report of deaths was highest at the start of the rollout, increasing rapidly to over 110 deaths per month and peaking in June 2021 and decreasing over time.



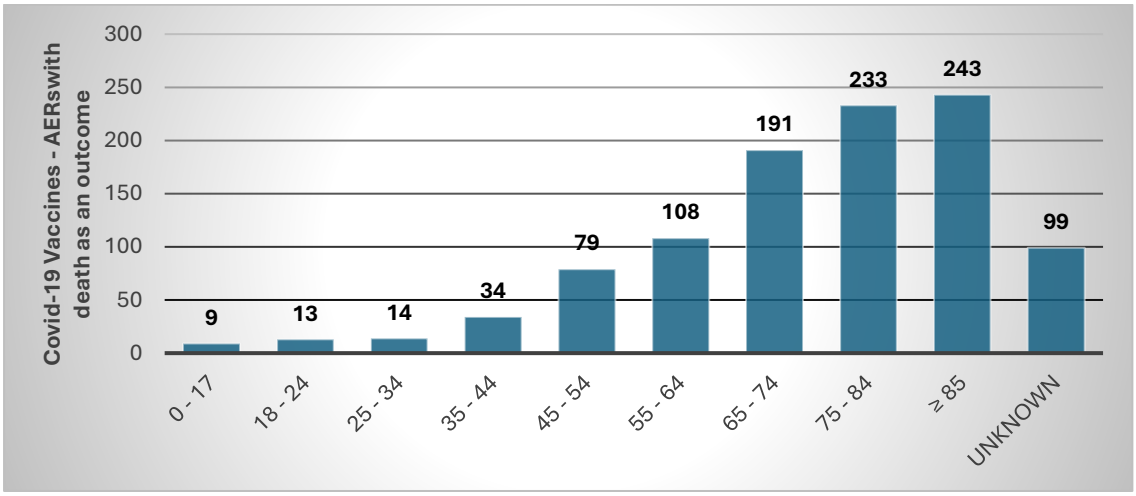
(a)



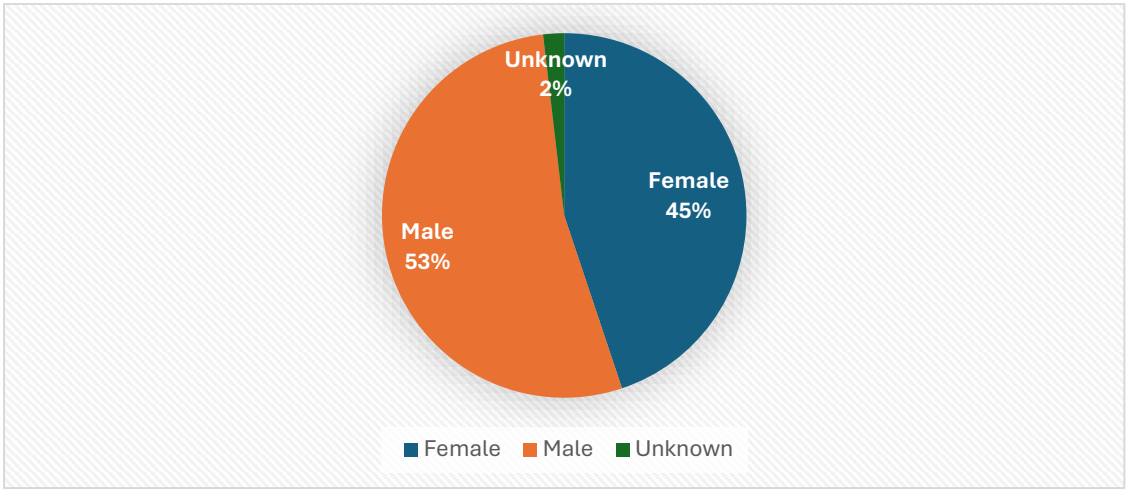
(b)

FIGURE 13: Number of adverse event reports (AER) where Covid-19 vaccines were reported as a suspected medicine with an outcome of death submitted to TGA DAEN between December 2020 and April 2024: (a) cumulative data; and (b) monthly data. *Source:* TGA DAEN extracted 15 May 2024.

Figure 14 presents the age and sex demographics of the 1,023 reports of death. Nine deaths were reported to be aged 5 to 17 years, 248 deaths were among the 18- to 64-year-old, or working age group, and 667 deaths were reported to be 65 years of age and older. For 99 deaths, age was unknown. A slightly higher portion of deaths were among men compared with women (53% vs 45%) and for 2% of cases, gender was unknown (Figure 13).



(a)



(b)

FIGURE 14: Age and sex demographics of adverse event reports (AER) where Covid-19 vaccines were reported as a suspected medicine with an outcome of death submitted to TGA DAEN between December 2020 and April 2024: (a) cumulative data; and (b) monthly data. *Source:* TGA DAEN extracted 15 May 2024 and TGA FOI 5044.

Review of the adverse event profiles of the 1,023 adverse event reports with an outcome of death identified 604 MedDRA reaction terms that were associated with deaths. Sixty-two of these were associated with 10 deaths or more. These are presented in Table 8, sorted into MedDRA System Organ Class. Adverse events from a range of MedDRA System Organ Classes (SOCS) were associated with deaths (Table 8). The MedDRA reaction term with the highest numbers of deaths reported was "adverse event following immunisation" with 210 deaths listed. For the majority of these cases, no further adverse event information was

provided. Cardiac arrest was associated with the second highest number of deaths (102). Myocardial infarction (47 deaths) and acute myocardial infarction (27 deaths) were also frequently reported as was dyspnoea (89 deaths), chest pain (50 deaths), pulmonary embolism (81 deaths), deep vein thrombosis (40 deaths), cerebrovascular accident (71 deaths) and multiple organ dysfunction syndrome (27 deaths).

TABLE 8: MedDRA reaction terms associated with 10 or more deaths where Covid-19 vaccines are listed as the suspected medicine. Source: TGA DAEN, extracted 15 May 2024.

MedDRA SOC	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases - death reported outcome
Blood and lymphatic system disorders				
	Thrombocytopenia	836	797	52
Cardiac disorders				
	Cardiac arrest	164	154	102
	Myocardial infarction	390	380	47
	Myocardial ischaemia	44	41	28
	Acute myocardial infarction	158	153	27
	Cardiac failure	111	104	20
	Myocarditis	1,353	1,302	20
	Atrial fibrillation	504	482	17
	Arteriosclerosis coronary artery	16	15	15
	Arrhythmia	318	308	10
	Cardiogenic shock	20	20	10
	Tachycardia	2,995	2,927	10
Gastrointestinal disorders				
	Vomiting	6,586	6,443	59
	Nausea	15,867	15,591	27
	Abdominal pain	5,545	5,453	22
	Diarrhoea	5,392	5,279	18
General disorders and administration site conditions				
	Concomitant disease progression	112	104	69
	Malaise	4,668	4,505	59
	Concomitant disease aggravated	2,490	2,381	51
	Chest pain	15,531	15,052	50
	Pyrexia	18,383	18,036	41
	Fatigue	16,296	15,906	34
	Multiple organ dysfunction syndrome	39	35	27
	Asthenia	1,866	1,792	15
	General physical health deterioration	20	19	13
	Pain	2,592	2,492	10
Infections and infestations				
	Pneumonia	538	519	44
	Sepsis	120	116	33
	Pneumonia aspiration	32	30	20
Injury, poisoning and procedural complications				
	Adverse event following immunisation	1,046	1,022	210
	Fall	259	244	25

TABLE 8 *cont'd:*

MedDRA SOC	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases - death reported outcome
Investigations				
	Fibrin D dimer increased	1,711	1,629	46
	Troponin increased	940	897	18
	C-reactive protein increased	431	392	11
Metabolism and nutrition disorders				
	Decreased appetite	2,167	2,122	22
Musculoskeletal and connective tissue disorders				
	Myalgia	20,825	20,479	16
	Pain in extremity	5,925	5,728	14
	Arthralgia	13,477	13,207	12
Nervous system disorders				
	Cerebrovascular accident	553	526	71
	Headache	33,412	32,803	48
	Lethargy	13,730	13,537	28
	Syncope	4,025	3,954	17
	Unresponsive to stimuli	84	81	17
	Dizziness	13,908	13,659	16
	Cerebral haemorrhage	54	50	14
	Cerebral infarction	50	47	14
	Loss of consciousness	418	405	14
	Haemorrhage intracranial	31	30	13
	Subarachnoid haemorrhage	30	30	11
	Seizure	852	821	10
	Somnolence	481	469	10
Psychiatric disorders				
	Confusional state	1,373	1,332	13
Renal and urinary disorders				
	Acute kidney injury	91	81	10
Respiratory, thoracic and mediastinal disorders				
	Dyspnoea	11,827	11,466	89
	Pulmonary embolism	1,617	1,547	81
	Respiratory failure	39	35	24
	Cough	2,900	2,816	10
	Hyperhidrosis	3,157	3,079	13
Vascular disorders				
	Deep vein thrombosis	1,498	1,435	40
	Hypotension	741	720	23
	Thrombosis	528	498	20
	Hypertension	1,987	1,948	11

Temporal Relationship Between Vaccination and Death

The TGA DAEN does not provide information regarding the timeframe between vaccination and the onset of adverse events, such as death. Efforts are currently underway to obtain this data via Freedom of Information. In the interim, the TGA have provided the below table in response to a senate estimates question (Table 9). The table summarises the data for reports submitted up to February 2023 regarding the time between vaccination and death for adverse event reports where a covid-19 vaccine was the suspected medicine.

Approximately 983 deaths had been reported to the TGA and published to the DAEN as of 16 February 2023. Onset data was available for approximately three quarters of these. Of the deaths where onset data was known, almost 40% died within a week of vaccination while just under 60% died within 2 weeks of vaccination.

TABLE 9: Timeframe between vaccination and death for deaths to February 2023.

Timeframe between vaccination and death*	% of reports	% of known reports
Deaths that occurred within 1 week of vaccination	30	39.5
Deaths that occurred between 1 and 2 weeks of vaccination	15	19.7
Deaths that occurred between 2 and 6 weeks of vaccination	21	27.6
Deaths that occurred more than 6 weeks after vaccination	10	13.2
Data not available to determine timeframe	24	

*In cases where an adverse event report includes multiple doses of a COVID-19 vaccine, the time interval between vaccination and death is calculated from the most recently administered COVID-19 vaccine.
Source: Question on notice no. 250 Portfolio question number: SQ23-000281 2022-23 Supplementary Budget estimates Community Affairs Committee, Health and Aged Care Portfolio. Senator Gerard Rennick: asked of the Department of Health and Aged Care on 16 February 2023 *Question 84*

Under-Reporting Factor

It is generally accepted that adverse events are under-reported to spontaneous reporting systems such as the DAEN (https://www.tga.gov.au/news/media-releases/new-web-service-helps-consumer-reporting-side-effects). A systematic review of the rates of under-reporting examined 37 studies that had employed a range of surveillance methods across 12 countries providing 43 estimates of under-reporting rates (Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: A systematic review Drug Saf 2006:29(5);385-396). The review found that between 90 to 95% of adverse events, including serious or severe ADRs, are not reported to regulators. This suggests that possibly only 1 in 10 to 1 in 20 cases of adverse events, including deaths, following Covid-19 vaccines are reported. If that were the case, the number of deaths from Covid vaccines may be as high as 10,000 to 20,000 and may explain a significant proportion of excess deaths.

It has been proposed that adverse events may not be under-reported to the DAEN for Covid-19 vaccines due to the profiling Covid-19 and the Covid-19 vaccines. However other factors, such as the AHPRA Position Statement March 2021 (https://www.ahpra.gov.au/Search.aspx?q=covid-19+position+statement) which may have impacted health professionals willingness to make reports, the sheer number of reports, the

constant exposure to the "safe and effective" mantra, together with the government and media campaign to silence any conversation that may threaten public confidence in the vaccines, could have had the opposite effect and magnified the under-reporting rate.

Supporting substantial under-reporting is a comparison of the number of adverse event reports submitted to the DAEN against the number of adverse event reports made through the AusVaxSafety system. As of 19th February 2024, 43.7% of 6,796,084 safety surveys completed and returned to AusVaxSafety reported one or more adverse events (Figure 15). This is approximately 2,969,889 surveys reporting adverse events which is 21.2 x as many adverse event reports as had been submitted to the TGA and published on the DAEN by 19th February 2024 (140,119 cases). This is an under-estimation of the under-reporting rate given that not all vaccinees are invited to participate in the AusVaxSafety survey. Comparison of actual rates of reports suggest an under-reporting factor an order of magnitude higher (see the AusVaxSafety section below).

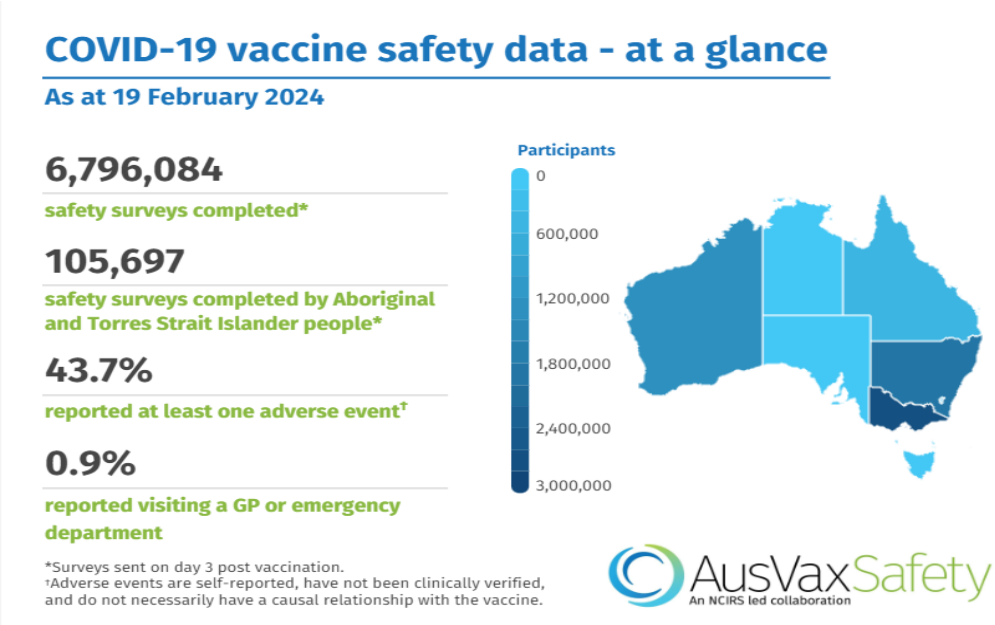


FIGURE 15: Screenshot of AusVaxSafety summary data for Covid-19 vaccines. *Source:* https://ausvaxsafety.org.au/vaccine-safety-data/covid-19-vaccines.

Breakdown of Reporters of Adverse Event Reports Related

Table 10 provides a breakdown of the sources of notifications of adverse reports for Covid-19 vaccines received between 1 January 2020 and 31 December 2023, obtained via freedom of information.

As shown in Table 10, 73% of all spontaneous reports of adverse events made to the DAEN were made by health professionals (including medical practitioners, pharmacists, and nurses) or State and Territory health departments. A further 1.3% were made by pharmaceutical companies and 25.6% were made by patients and/or consumers.

Similarly, 73.2% of all spontaneous reports of adverse events made to the DAEN where death was an outcome were made by health professionals (including medical practitioners,

pharmacists, and nurses) or State and Territory health departments. A further 5.0% were made by pharmaceutical companies and 8.9% were made by other sources. Only 12.3% of reports of death were made by patients and/or consumers.

TABLE 10: Breakdown of the sources of notifications of adverse reports for COVID vaccines received between 1 January 2020 and 31 December 2023*.

	All COVID-19 vaccine adverse events in DAEN – medicines		**All COVID-19 vaccine adverse events in DAEN – medicines with an outcome of death**	
	No. of reports	(% of all reports)	No. of reports	(% of all reports)
Reports by health professionals (total)	12,607	(9.0)	125	(12.3)
Medical practitioners	*5,586*	(4.0)	*44*	(4.3)
Pharmacists	*1,366*	(1.0)	*6*	(0.6)
Nurses	*3,421*	(2.4)	*19*	(1.9)
Others	*656*	(0.5)	*26*	(2.6)
Unknown	*1,578*	(1.1)	*30*	(3.0)
Patients/consumers	35,765	(25.6)	130	(12.8)
Pharmaceutical companies	1,801	(1.3)	51	(5.0)
State and Territory health departments	89,531	(64.0)	618	(60.9)
Other source	116	(0.1)	90	(8.9)
Total	**139,820**	100.0%	**1014**	100.0%

*Source: TGA Freedom of Information document FOI 4910, Part 2. (https://www.tga.gov.au/sites/default/files/2024-04/FOI%204910.pdf)

It should be emphasised here that spontaneous reports are made by health and other professionals when there is a genuine suspicion that the adverse event and the drug are linked. In a recent article spontaneous reports are described as "reports of genuine, general clinical concerns about a drug and suspected reaction. All must be treated as 'valid', in fact they should be labelled 'clinical concerns' rather than 'spontaneous reports' because the label is descriptively more explicit." (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2014296/).

TGA links Vaccine to only 14 Deaths

To date the TGA has identified 14 reports where the cause of death was linked to vaccination from the reports received https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-02-11-23. While the TGA generally claims it has reviewed the remaining reports of death, the extent of these reviews is unclear. What is clear is that the TGA is not a coroner and is not able to decide the cause of death in individuals. The TGA "does not undertake autopsies, request coronial investigations or make formal determinations. In Australia, coroners and treating doctors perform this role" (https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-weekly-safety-report-02-12-2021). In a recent document released under TGA Freedom of Information, FOI 4910, the TGA states 'adverse event reports with a fatal outcome are almost always accepted with a decision of 'causality possible', even where the case does not have sufficient information to be eligible for further causality assessment or when a Coroner has

determined that a death was not related to vaccination".' Therefore, while the TGA has linked 14 deaths to the vaccines, the remaining 1009 remain causality possible. Also, as mentioned in the section above, it is possible that many deaths caused by the vaccines have not been reported to the TGA to review. Given that there is some over-lapping symptomology between vaccine injury and Covid-19 infections, owing to the pathogenic role of spike protein in both conditions, it is possible that at least some vaccine injuries may have been mistakenly attributed to Covid-19 infection.

Further Review of Adverse Event Reports Made to DAEN in Relation to Covid-19 Vaccines

A principal role of post-marketing pharmacovigilance is the assessment of adverse event profiles for safety signals. As mentioned earlier, safety signals may include one or more of the following:

(1) An increased report of specific adverse events relative to other medications/therapeutics.
(2) Reports of new adverse events.
(3) Profiles of adverse events that are distinct to the background report of adverse events for other medicines, and that which may be expected to occur by chance. This is assessed by comparing the relative proportion of reports of particular adverse events using proportional reporting ratios (PRRs) and other statistical methods.

In the following section, some of the preliminary findings from the results of a larger extensive evaluation of the adverse event reports related to Covid-19 vaccines will be presented. This evaluation has generally examined adverse event reports made to the DAEN up to 31 March 2023, with a few exceptions. The Covid-19 vaccine adverse event data is compared to all medicines, to influenza virus vaccines and all non-covid vaccines.

Table 11 presents the number of adverse event reports made to TGA DAEN between 1 January 1971 to 31 March 2023 for all medicines and where influenza vaccines, covid-19 vaccines, and non-covid-19 vaccines were listed as suspected medicines. Figure 16 presents the influenza vaccines, covid-19 vaccines, and non-covid-19 vaccines data graphically.

As at the 31 March 2023, there had been a total of 596,254 adverse event reports (AERs) submitted to the TGA DAEN across the 52-year period with a total of 9,845 different medicine terms listed as suspected medicines (Table 11). Of these, 138,046 (23.2%) 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 (data not shown here). This is almost eight times the total number of AER submissions ever made to the DAEN in relation to influenza vaccines (17,474) across 52 years (2.9% of all AERs) and almost double the total number of AERs ever reported in relation to all non-covid vaccines (71,644) across 52 years (12.0% of all AERs) (Table 11, Figure 16a).

As of 31 March 2023, there had been 13,654 AERs made to the TGA DAEN across the 52-year period that had an outcome of death (Table 11). Of these, 990 (7.3%) listed one or more of the Covid-19 vaccines as suspected medicines. This is 14 times higher than the number of

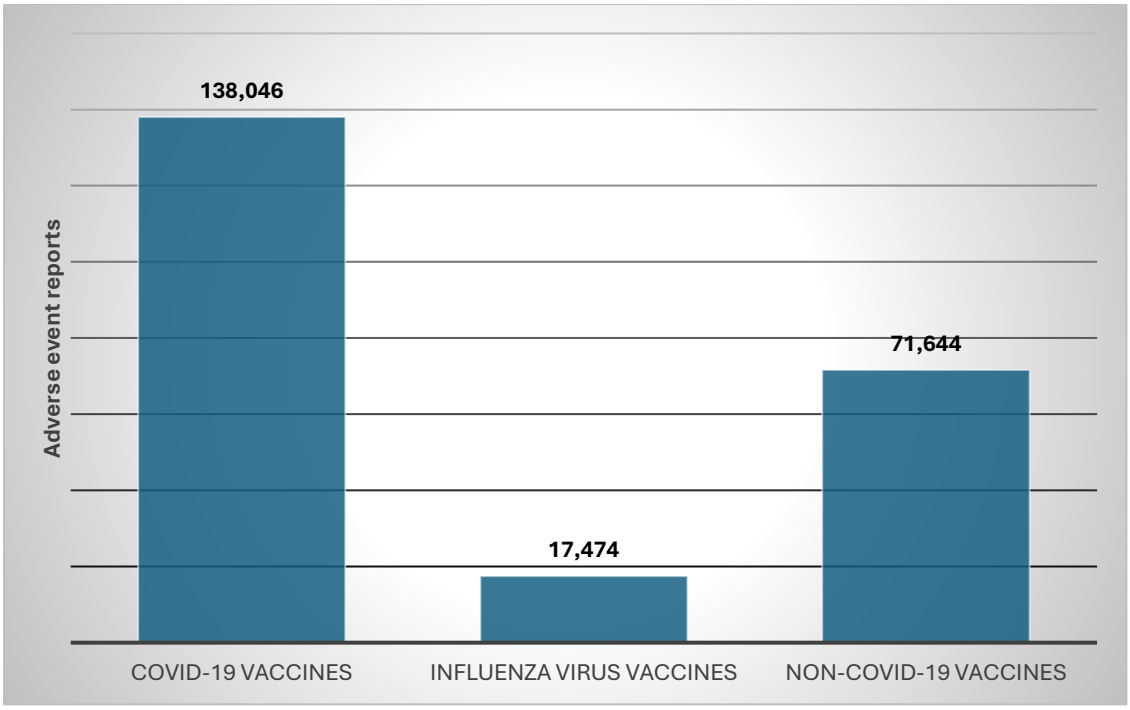
deaths reported in association with influenza virus vaccines (70) and 6 times greater than the number of deaths reported across all non-covid vaccines combined (Table 11, Figure 16b).

TABLE 11: Number of adverse event reports made to TGA DAEN between 1 January 1971 to 31 March 2023 for all medicines and where influenza vaccines, covid-19 vaccines, and non-covid-19 vaccines were listed as suspected medicines.

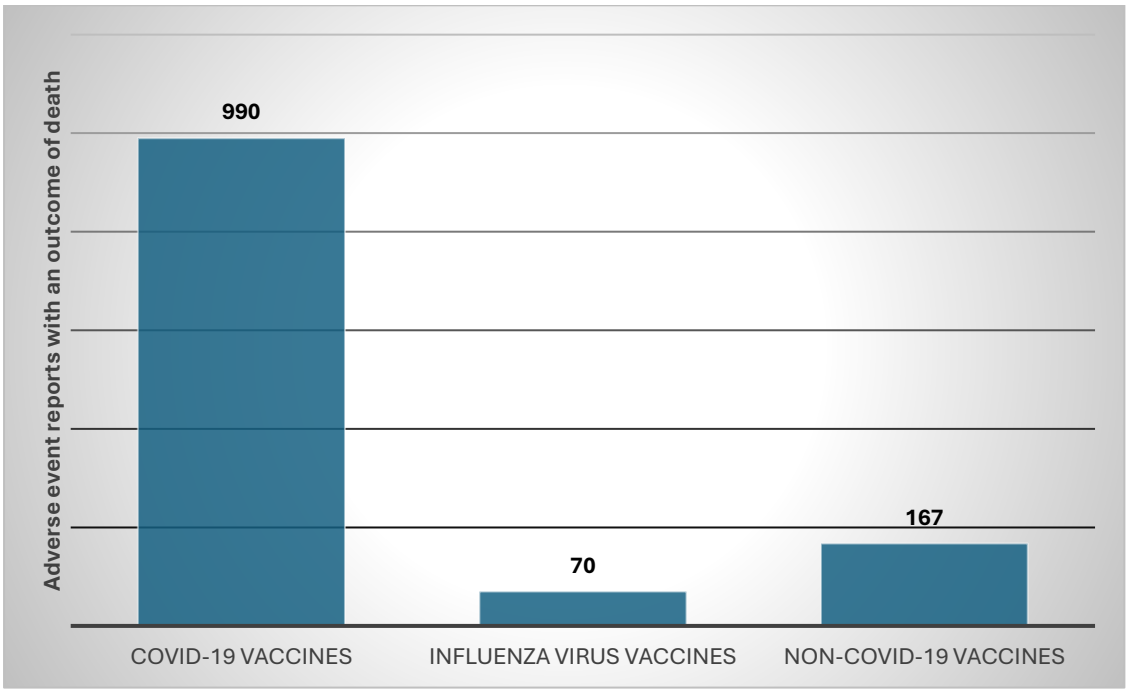
	No. of cases reporting adverse events	(% of all DAEN cases)	No. of cases where death is a reported outcome	(% of all DAEN deaths)
ALL ADVERSE EVENT REPORTS				
All medicines *(9,845 medicine terms)*	596,254		13,654	
Covid-19 vaccines (*11 medicine terms)*	138,046	(23.2)	990	(7.3)
Pfizer	*81,162*	*(13.6)*	*440*	*(3.2)*
Moderna	*7,618*	*(1.3)*	*38*	*(0.3)*
AstraZeneca	*48,179*	*(8.1)*	*482*	*(3.5)*
Novavax	*987*	*(0.2)*	*3*	*(0.02)*
Type not specified	*701*	*(0.1)*	*28*	*(0.2)*
Influenza virus vaccines *(27 medicine terms)*	17,474[1]	(2.9)	70[2]	(0.5)
All non-covid-19 vaccines *(197 medicine terms)*	71,644[3]	(12.0)	167[4]	(1.2)

Cases = Reports of adverse events.
Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 30 April and 1 May 2024.
[1]251 of these cases reported both an influenza virus vaccine as a 'suspected' medicine and one or more covid vaccines as a 'suspected' (231 cases) or 'not-suspected' medicine (20 cases).
[2]19 of these cases reported both an influenza vaccine as a 'suspected' medicine and one or more covid vaccines as a 'suspected' (18 cases) or 'not-suspected' medicine (1 case)
[3]302 of these cases reported both an influenza vaccine as a 'suspected' medicine and one or more covid vaccines as a 'suspected' (268 cases) or 'not-suspected' medicine (34 cases).
[4]19 of these cases reported both a non-Covid-19 vaccine as a 'suspected' medicine and one or more covid vaccines as a 'suspected' (18 cases) or 'not-suspected' medicine (1 case).

Figures 17 and 18 present the number of adverse event reports (Figure 17) and adverse event reports with an outcome of death (Figure 18) reported in association with all of the non-covid vaccines collectively compared to the reports related to Covid-19 vaccines. It is clear that Covid-19 vaccines were associated with a substantially greater number of AERs than influenza vaccines or all non-covid vaccines combined.



(a)



(b)

FIGURE 16: Comparison of the number of adverse event reports made to TGA DAEN between 1 January 1971 to 31 March 2023 where influenza vaccines, covid-19 vaccines, and non-covid-19 vaccines were listed as suspected medicines (a) overall and (b) where death was an outcome. *Source:* TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 30 April and 1 May 2024.

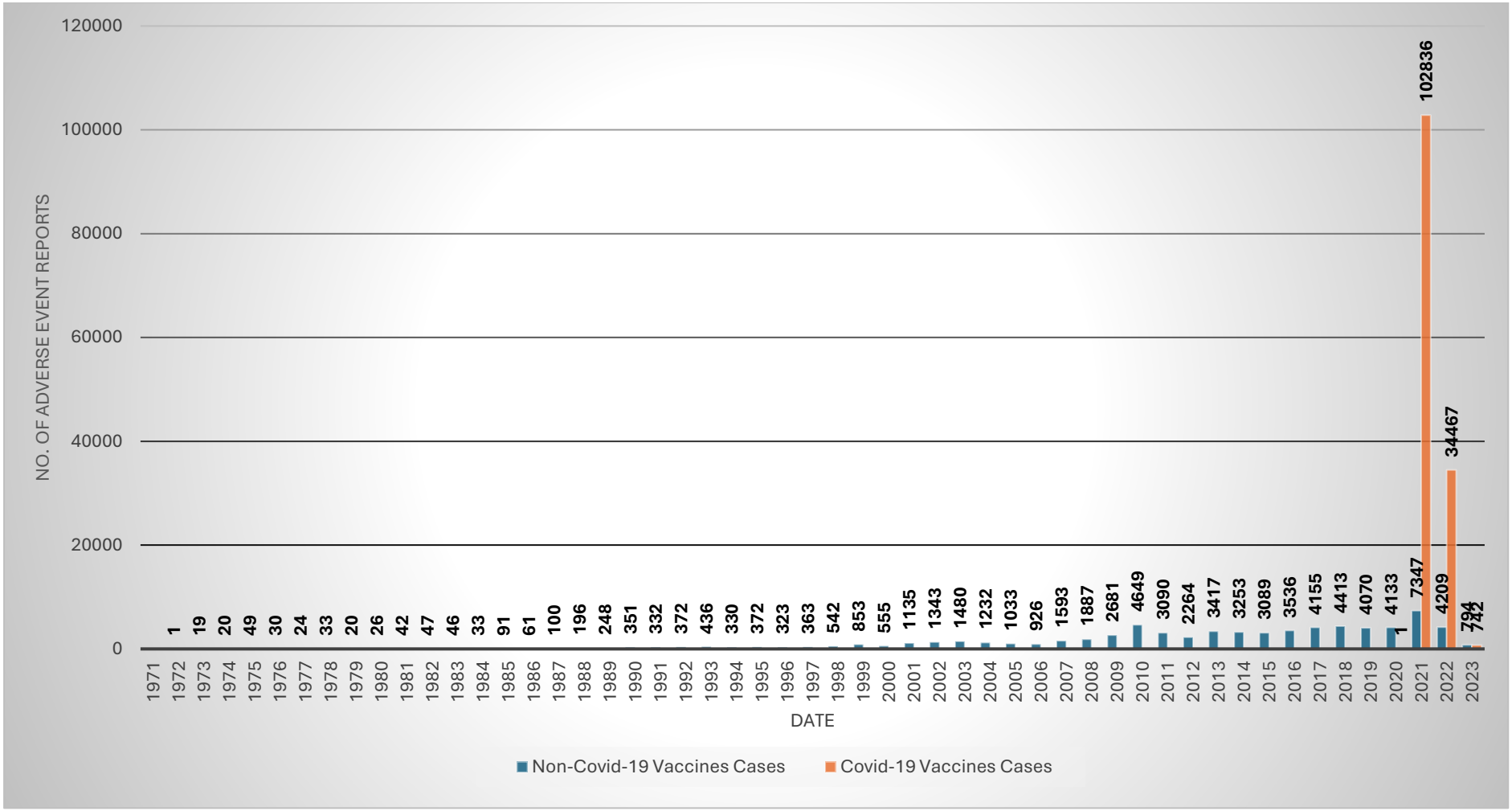


FIGURE 17: Number of adverse event reports (AER) submitted to TGA DAEN between 1 January 1971 and 1 November 2023 where covid-19 vaccines, and non-covid-19 vaccines were listed as suspected medicines. *Source:* TGA DAEN extracted 1 May 2024.

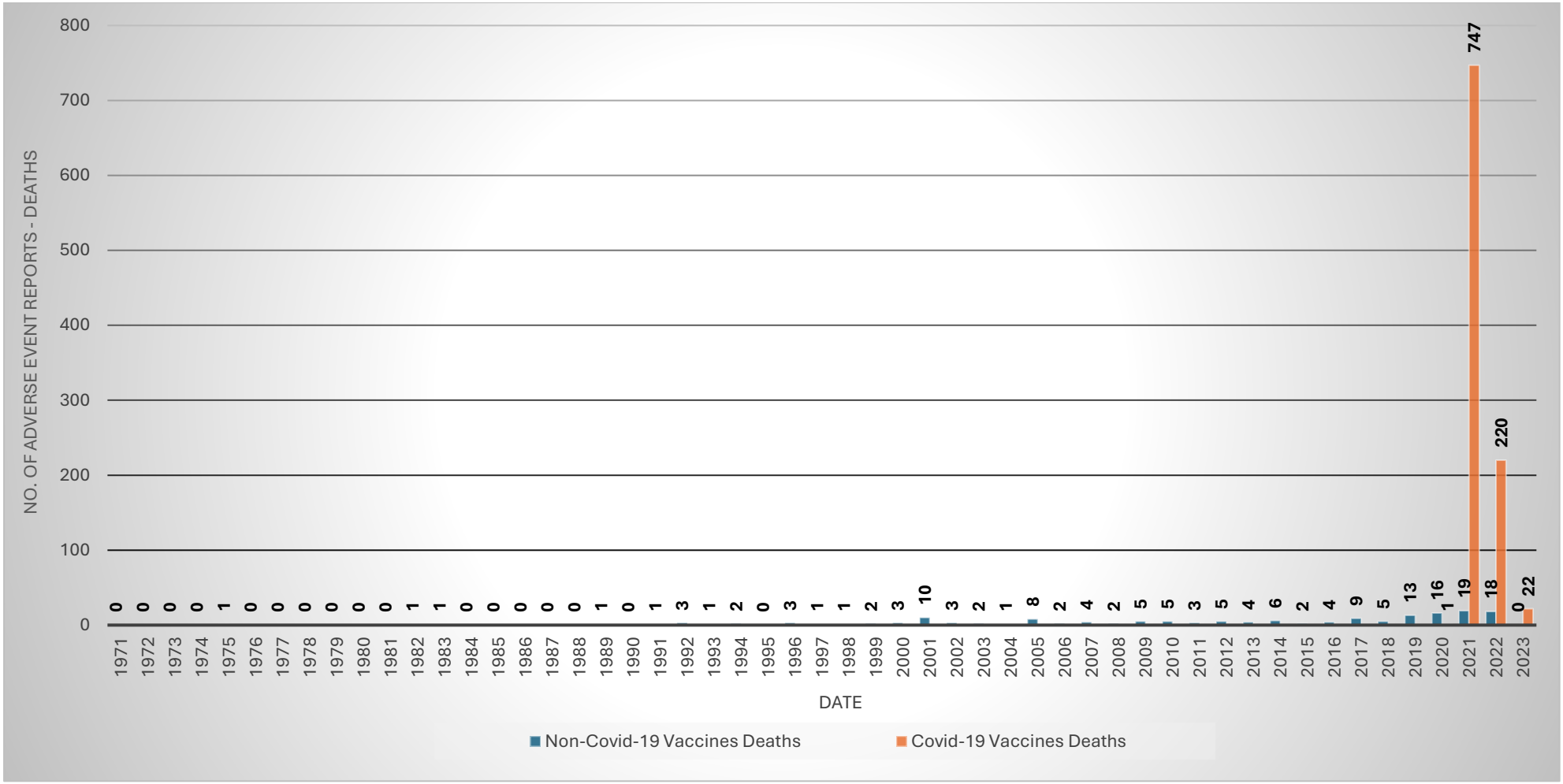


FIGURE 18: Number of adverse event reports (AER) submitted to TGA DAEN between 1 January 1971 and 1 November 2023 where covid-19 vaccines, and non-covid-19 vaccines were listed as suspected medicines, *and where death was an outcome*. *Source:* TGA DAEN extracted 1 May 2024.

While mass vaccination would be expected to contribute somewhat to the surges in adverse event reports that are clearly evident in Figures 10, 12, 17 and 18, 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 medication 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, vaccines and therapies are not remarkable. The level of negative adverse responses to those dosages, however, is.

To further review the issue of dose, Table 12 presents the results of an analysis comparing the absolute risk of adverse events per 100,000 doses of covid-19 vaccines against influenza vaccines. 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 12, the absolute risk of an adverse event report was calculated as 189.5 per 100,000 doses of covid-19 vaccine compared to 9.6 per 100,000 doses of influenza virus vaccines. This converts to a relative risk of 19.8 indicating that AERs were reported almost 20 times more frequently following covid vaccination than influenza vaccination across this period. The number of AERs with an outcome of death through this period was 1.6 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 17. 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 32.7.

Figure 19 shows the changes in the absolute risk of an AER (a) overall and (b) where death was an outcome following a Covid-19 vaccination over time. Absolute risk of AERs calculated from the TGA DAEN data varied considerably over time with values as high as 648.6 and 709.5 per 100,000 doses evident across the March to April 2021 period (Figure 19(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 19(b)). It is noteworthy that 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 12: 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	189.5	19.8 (18.2-21.5)	136	1.6	17.0 (7.3-39.5)
Pfizer	*12,023*					
Moderna	*1,993*					
AstraZeneca	*1,724*					
Novavax	*821*					
Type not specified	*161*					
Influenza vaccines	1,039*	9.6		10**	0.09	

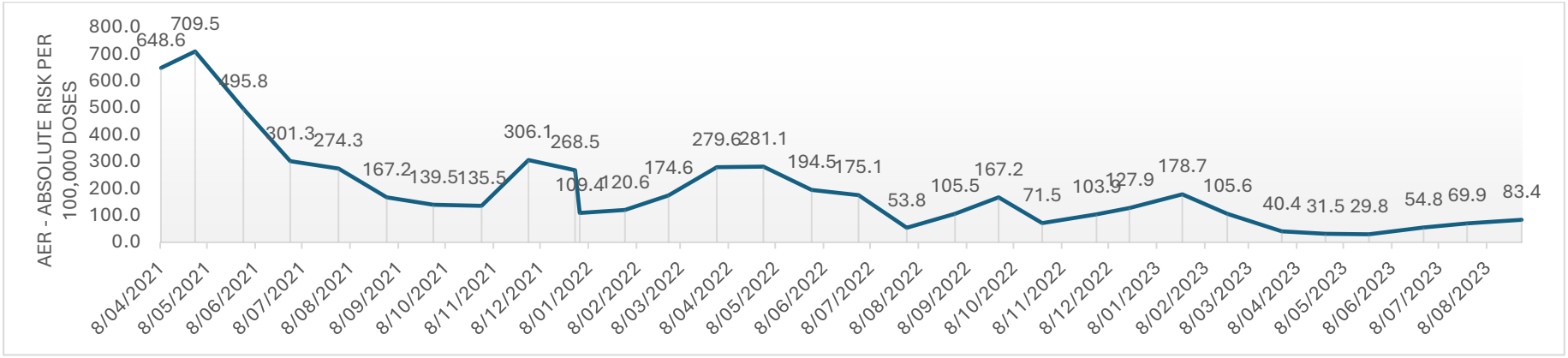
Cases = Reports of adverse events

Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/), extracted 2 May 2024.

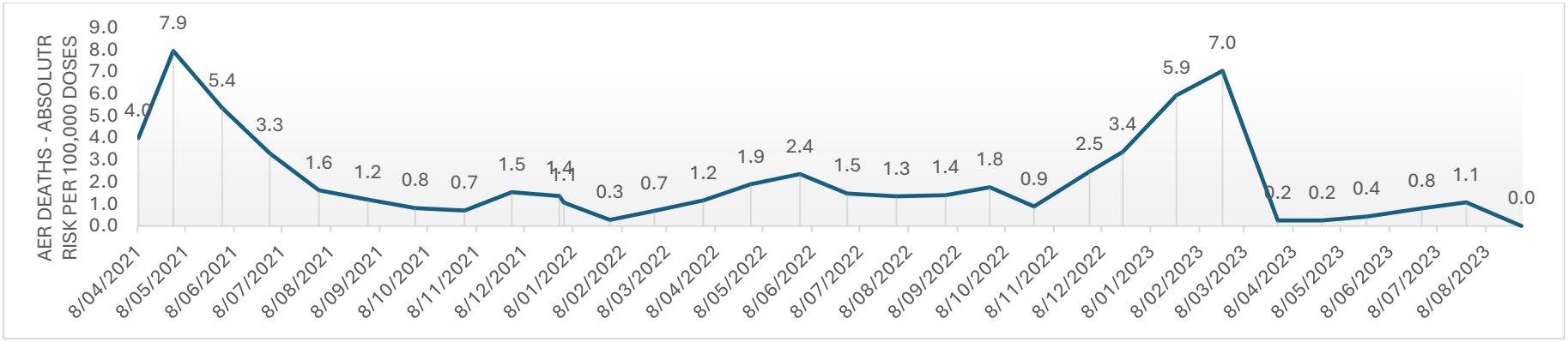
Doses: Influenza vaccines 10,846,430 (https://www.health.gov.au/sites/default/files/documents/2022/08/influenza-flu-immunisation-data-1-march-2022-to-14-august-2022.pdf); Covid-19 vaccines 8,691,619 (https://www.health.gov.au/sites/default/files/documents/2022/03/covid-19-vaccine-rollout-update-1-march-2022.pdf, 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. If the 95 with dual suspected medicines are removed from both sides of the analyses, the number of cases associated with covid-19 and influenza vaccines becomes 16,373 vs 944 respectively and the absolute risk becomes 188.4 vs 8.7 per 100,000 doses. This translates to a relative risk of 21.6 (19.9-23.6).

**5 of the influenza deaths also reported a covid-19 vaccine as a suspected medicine. Four of these were verifiable to FOI 3845. If the 5 with dual suspected medicines are removed from both sides of the analyses, the number of cases of deaths associated with covid-19 and influenza vaccines becomes 131 vs 5 respectively and the absolute risk of death becomes 1.5 vs 0.05 per 100,000 doses. This translates to a relative risk of 32.7 (10.1-105.9).



(a)



(b)

FIGURE 19: Number of adverse event reports submitted to the TGA DAEN for various time periods from 8 April 2021 to 30 August 2023 converted to Absolute Risk per 100,000 doses (a) overall and (b) for adverse events where death was an outcome. *Source:* TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 2 May 2024; Doses - vaccine rollout updates for dates *9/04/2021, 1/05/2021, 1/06/2021, 1/07/2021, 1/08/2021, 1/09/2021, 1/10/2021, 1/11/2021, 1/12/2021, 31/12/2021, 2/01/2022, 1/02/2022, 1/03/2022, 1/04/2022, 1/05/2022, 1/06/2022, 1/07/2022, 1/08/2022, 1/09/2022, 29/09/2022, 27/10/2022, 1/12/2022, 22/12/2023, 25/01/2023, 23/02/2023, 31/03/2023, 28/04/2023, 26/05/2023, 29/06/2023, 27/07/2023, 1/09/2023 (https://www.health.gov.au/resources/collections/covid-19-vaccination-rollout-update)*

The number of different adverse event *terms* among AERs submitted to the TGA DAEN overall for all medicines and where influenza vaccines, covid-19 vaccines or all non-covid vaccines were listed as suspected medicines, for the period from 1 January 1971 to 31 March 2023, is summarised in Figure 20.

Overall, there were 10,030 MedDRA reaction terms within the DAEN database as of 31 March 2023. Of these, 3,863 were reported in association with Covid-19 vaccines compared to 1428 and 2370 for influenza virus and non-covid vaccines, respectively. These data illustrate the broad spectrum of adverse events being reported with Covid-19 vaccines, a factor that potentially reflects the physiological mechanisms underlying these vaccines.

Noteworthy was that Covid-19 vaccines contributed 410 new adverse event terms to the DAEN. These included: thrombosis with thrombocytopenia syndrome (184 cases); splenic thrombosis (7 cases); splenic artery thrombosis (2 cases); visceral venous thrombosis (14 cases); artery dissection (4 cases); aortic dissection rupture (2 cases); and multisystem inflammatory syndrome in adults (5 cases).

For a further 650 terms, 50% or more of DAEN cases reporting the MedDRA term, reported a covid-19 vaccine as the suspected medicine. Of the 1060 MedDRA terms that represented 50% or more of the DAEN AERs, 117 were reported for 70 or more cases. These are summarised in Table 13.

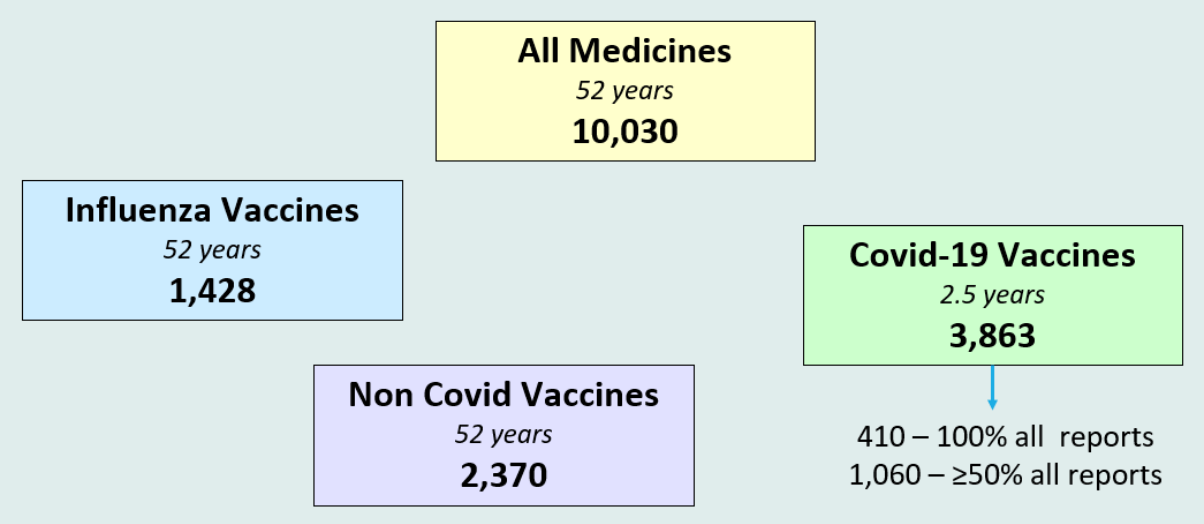


FIGURE 20: The number of different adverse event *terms* among AERs submitted to the TGA DAEN overall for all medicines and where influenza vaccines, covid-19 vaccines or all non-covid vaccines were listed as suspected medicines, for the period from 1 January 1971 to 31 March 2023. *Source:* TGA DAEN, extracted 30 April 2024 and 1 May 2024.

TABLE 13: Adverse events reports made to DAEN from 1 January 1971 to 30 March 2023 where covid-19 vaccines were suspected medicines, and where the number of cases reporting the adverse event represented 50% or more of all the cases in the DAEN database.

SOC	MedDRA reaction term	No. of cases	% All _cases	No. of deaths	% All _deaths
Blood and lymphatic system disorders					
	Lymphadenopathy	5,852	*(76.9)*	2	*(8.3)*
	Lymph node pain	260	*(88.1)*	0	*NA*
	Thrombosis with thrombocytopenia syndrome	184	*(100.0)*	9	*(100.0)*
Cardiac disorders					
	Palpitations	6,843	*(62.8)*	4	*(30.8)*
	Pericarditis	3,796	*(92.5)*	6	*(50.0)*
	Myopericarditis	466	*(91.4)*	1	*(100.0)*
	Cardiac flutter	224	*(81.2)*	0	*NA*
	Carditis	142	*(97.9)*	0	*NA*
	Atrial flutter	104	*(53.9)*	1	*(11.1)*
	Postural orthostatic tachycardia syndrome	94	*(83.2)*	0	*NA*
Ear and labyrinth disorders					
	Tinnitus	1,707	*(54.2)*	2	*(50.0)*
	Vertigo	1,671	*(51.2)*	1	*(20.0)*
	Ear pain	475	*(62.4)*	0	*NA*
	Hypoacusis	199	*(52.4)*	0	*NA*
	Ear discomfort	165	*(60.2)*	0	*NA*
	Ear congestion	107	*(73.3)*	0	*NA*
Eye disorders					
	Blepharospasm	94	*(56.6)*	0	*NA*
	Ocular discomfort	94	*(50.8)*	0	*NA*
Gastrointestinal disorders					
	Paraesthesia oral	1,035	*(50.1)*	0	*NA*
General disorders and administration site conditions					
	Fatigue	16,022	*(61.1)*	32	*(18.7)*
	Chest pain	15,331	*(69.6)*	48	*(31.6)*
	Chills	10,957	*(65.9)*	6	*(15.0)*
	Injection site pain	5,741	*(69.2)*	4	*(33.3)*
	Chest discomfort	4,983	*(61.7)*	5	*(31.3)*
	Influenza like illness	4,442	*(64.3)*	8	*(27.6)*
	Concomitant disease aggravated	2,452	*(79.9)*	51	*(81.0)*
	Feeling cold	595	*(51.2)*	1	*(14.3)*
	Axillary pain	480	*(87.0)*	0	*NA*
	Local reaction	443	*(81.4)*	0	*NA*
	Feeling of body temperature change	383	*(57.9)*	0	*NA*
	Injection site rash	352	*(52.9)*	0	*NA*
	Injection site discomfort	309	*(70.4)*	0	*NA*
	Injection site pruritus	283	*(64.2)*	0	*NA*
	Shoulder injury related to vaccine administration	252	*(88.1)*	0	*NA*
	Exercise tolerance decreased	217	*(65.6)*	1	*(12.5)*
	Injection site hypersensitivity	193	*(88.1)*	0	*NA*
	Facial pain	127	*(53.4)*	0	*NA*
	Vaccination site reaction	80	*(60.6)*	0	*NA*
	Non-cardiac chest pain	70	*(64.2)*	0	*NA*

TABLE 13 *cont'd*

SOC	MedDRA reaction term	No. of cases	% All _cases	No. of deaths	% All _deaths
Infections and infestations					
	Herpes zoster	1,452	*(54.5)*	3	*(20.0)*
	Appendicitis	254	*(74.7)*	1	*(33.3)*
	Oral herpes	178	*(59.9)*	0	*NA*
	Vaccine breakthrough infection	146	*(97.3)*	1	*(100.0)*
	Tonsillitis	143	*(54.0)*	0	*NA*
Injury, poisoning and procedural complications					
	Vaccination error	2,726	*(60.9)*	3	*(37.5)*
	Adverse event following immunisation	1,037	*(98.0)*	206	*(97.6)*
	Contusion	941	*(50.4)*	5	*(20.8)*
	Expired product administered	529	*(72.3)*	0	*NA*
	Product administered to patient of inappropriate age	456	*(76.3)*	0	*NA*
	Product administered at inappropriate site	104	*(54.2)*	0	*NA*
Investigations					
	Fibrin D dimer increased	1,705	*(98.3)*	46	*(97.9)*
	Heart rate increased	1,409	*(58.9)*	2	*(40.0)*
	Electrocardiogram abnormal	711	*(56.3)*	3	*(27.3)*
	Heart rate irregular	412	*(61.2)*	0	*NA*
	Electrocardiogram	320	*(99.1)*	3	*(100.0)*
	SARS-CoV-2 test positive	266	*(81.8)*	4	*(36.4)*
	Troponin	264	*(97.1)*	0	*NA*
	Electrocardiogram ST segment elevation	232	*(66.7)*	1	*(33.3)*
	Echocardiogram	182	*(99.5)*	1	*(100.0)*
	Echocardiogram abnormal	140	*(50.2)*	2	*(100.0)*
	Fibrin D dimer	96	*(100.0)*	2	*(100.0)*
	Electrocardiogram normal	80	*(100.0)*	0	*NA*
	Heart rate abnormal	79	*(69.3)*	0	*NA*
	Chest X-ray	78	*(100.0)*	0	*NA*
Musculoskeletal and connective tissue disorders					
	Myalgia	20,585	*(72.2)*	14	*(28.6)*
	Arthralgia	13,294	*(67.2)*	10	*(26.3)*
	Pain in extremity	5,788	*(63.4)*	13	*(36.1)*
	Neck pain	1,298	*(65.0)*	3	*(42.9)*
	Limb discomfort	621	*(65.1)*	1	*(33.3)*
	Pain in jaw	327	*(51.7)*	1	*(14.3)*
	Costochondritis	297	*(92.2)*	1	*(100.0)*
	Musculoskeletal chest pain	272	*(63.1)*	0	*NA*
	Bursitis	236	*(53.6)*	0	*NA*
	Groin pain	152	*(59.8)*	1	*(20.0)*
	Musculoskeletal discomfort	111	*(55.2)*	0	*NA*
	Periarthritis	89	*(69.0)*	0	*NA*
Nervous system disorders					
	Headache	33,092	*(64.4)*	45	*(37.2)*
	Lethargy	13,597	*(75.4)*	28	*(33.7)*
	Paraesthesia	7,759	*(54.4)*	6	*(37.5)*
	Presyncope	3,094	*(72.2)*	2	*(25.0)*

TABLE 13 *cont'd*

SOC	MedDRA reaction term	No. of cases	% All _cases	No. of deaths	% All _deaths
Nervous system disorders (cont'd)					
	Hypoaesthesia	2,506	*(52.5)*	3	*(27.3)*
	Migraine	2,073	*(62.1)*	4	*(66.7)*
	Brain fog	926	*(79.7)*	1	*(50.0)*
	Bell's palsy	713	*(84.0)*	0	*NA*
	Neuralgia	580	*(62.6)*	0	*NA*
	Facial paralysis	513	*(76.2)*	3	*(60.0)*
	Taste disorder	403	*(51.5)*	1	*(33.3)*
	Head discomfort	352	*(64.6)*	0	*NA*
	Guillain-Barre syndrome	275	*(51.7)*	8	*(61.5)*
	Anosmia	197	*(64.0)*	1	*(100.0)*
	Demyelination	108	*(53.2)*	1	*(50.0)*
	Cerebral venous sinus thrombosis	81	*(87.1)*	6	*(100.0)*
Reproductive system and breast disorders					
	Menstrual disorder	2,709	*(92.1)*	0	*NA*
	Heavy menstrual bleeding	1,118	*(70.6)*	0	*NA*
	Menstruation irregular	830	*(89.8)*	0	*NA*
	Dysmenorrhoea	486	*(84.2)*	0	*NA*
	Intermenstrual bleeding	360	*(57.1)*	0	*NA*
	Menstruation delayed	215	*(90.0)*	0	*NA*
	Polymenorrhoea	202	*(87.8)*	0	*NA*
	Postmenopausal haemorrhage	149	*(75.3)*	0	*NA*
	Oligomenorrhoea	141	*(89.2)*	0	*NA*
	Breast swelling	113	*(76.9)*	0	*NA*
Respiratory, thoracic and mediastinal disorders					
	Oropharyngeal pain	1,930	*(57.6)*	1	*(10.0)*
	Pulmonary embolism	1,582	*(51.4)*	78	*(32.4)*
	Rhinorrhoea	848	*(51.7)*	1	*(25.0)*
	Oropharyngeal discomfort	354	*(74.8)*	0	*NA*
	Pleuritic pain	263	*(66.9)*	1	*(14.3)*
	Sinus pain	101	*(69.2)*	0	*NA*
	Pleurisy	90	*(50.6)*	0	*NA*
	Sinus congestion	89	*(52.4)*	0	*NA*
Skin and subcutaneous tissue disorders					
	Night sweats	348	*(50.4)*	2	*(50.0)*
	Sensitive skin	136	*(86.6)*	0	*NA*
	Pain of skin	105	*(55.0)*	0	*NA*
Social circumstances					
	Bedridden	112	*(53.6)*	0	*NA*
Vascular disorders					
	Deep vein thrombosis	1,473	*(57.7)*	39	*(44.3)*
	Superficial vein thrombosis	267	*(76.5)*	0	*NA*
	Peripheral coldness	234	*(59.7)*	2	*(100.0)*

Source: TGA DAEN, extracted 30 April 2024.

Examination of the data presented in Table 13 shows that adverse events reports where Covid-19 vaccines are a suspected medicine contribute over 90% of reports of pericarditis (3,796 cases), myopericarditis (466 cases), carditis (142 cases), Fibrin D dimer increased (1,705), and troponin (264) that have ever been submitted to the DAEN, together with 60% of all reports of palpitations (6,843 cases), and over 80% of cases of cardiac flutter (224 cases) and postural orthostatic tachycardia syndrome (94 cases)(Table 13). AERs related to covid-19 vaccines have also contributed: over 50% of cases of pulmonary embolism (1,582 cases), deep vein thrombosis (1,473 cases), herpes zoster (1452) and oral herpes (178 cases); 75% of cases of appendicitis (254 cases); and between 57.1% and 92.1% of cases of menstrual disorder (2,709 cases), heavy menstrual bleeding (1,118), menstruation irregular (830 cases), dysmenorrhoea (486 cases), intermenstrual bleeding (360 cases), menstruation delayed (250 cases), polymenorrhoea (202 cased), postmenopausal haemorrhage (149 cases), oligomenorrhoea (141 cases) and breast swelling (113 cases) ever reported on the DAEN (Table 13).

The high contribution of covid vaccines to the report of these cardiovascular, infectious and reproductive symptoms is alarming given the number of other medications and therapeutics that would be thought to be more likely to impact these adverse event rates.

As shown above, AERs where covid-19 vaccines are a suspected medicine have contributed both a large number and a broad range of adverse events submitted to the TGA DAEN. As shown in Table 13, these adverse events are spread across all of the MedDRA system organ classes.

MedDRA Standard System Organ Classes Analyses

To further assess the adverse event profiles of covid-19 vaccines, the number of cases reporting one or more adverse events from each of the MedDRA system organ classes was evaluated and compared across all medicines, covid-19 vaccines, influenza vaccines, and non-covid vaccines.

The results of the 52-year analysis are presented in Tables 14 and 15 for all adverse events and for adverse events with an outcome of death, respectively. The case numbers expressed as percentages of the all-medicines data, are then visually compared in Figures 21 and 22.

The results of the six-month analysis, from 1 March 2022 to 14 August 2022, are presented in Tables 16 and 17, and Figures 23 and 24 together with the calculated absolute risk and relative risk values.

Table 14 and Figure 21 shows that Covid-19 vaccines were suspected medicines for a considerably higher number of AERs for every one of the 27 MedDRA system organ classes, when compared to influenza vaccines and all non-covid-19 vaccines combined. Covid-19 vaccines were associated with 38.1% of all AERs ever reported to the DAEN across the 52 year period (1 January 1971 to 31 March 2023) that included adverse events categorised as “cardiac disorders”, 47.9 % of all AERs that included adverse events categorised as “ear and

labyrinth disorders", 51.4% of AERs that included adverse events categorised as "musculoskeletal and connective tissue disorder", 42% of AERs that included adverse events categorised as "nervous system disorders", 33.8% of AERs that included adverse events categorised as "respiratory, thoracic and mediastinal disorders", and 35.5% of AERs that included adverse events categorised as "reproductive system and breast disorders". These percentages contrasted those for all other vaccines combined (Table 14 and 21).

Similarly to the overall AER data, Table 15 and Figure 22 demonstrate that Covid-19 vaccines were also associated with a considerably higher number of AERs with an outcome of death that reported adverse events from the various MedDRA system organ classes, when compared to influenza vaccines and the combined non-covid-19 vaccines. Covid-19 vaccines were associated with greater than 10% of all AERs ever submitted to the DAEN that had an outcome of death and that reported adverse events categorised as "cardiac disorder", "ear and labyrinth disorders", "eye disorders", "musculoskeletal and connective tissue disorder", "nervous system disorders", or "respiratory, thoracic and mediastinal disorders" (Table 15 and Figure 22).

When the Covid-19 vaccine AER data was corrected for vaccine dose and compared to influenza vaccines, it was evident that covid-19 vaccine recipients had a greater absolute risk of reporting adverse events from all SOCs (Table 17). The relative risk of reporting adverse events from each of the SOCs for Covid-19 vaccines compared to influenza vaccines ranged from 8.6 for "injury, poisons and procedural complications" to 304.1 for "reproductive and breast disorders" (Figure 23). The relative risk of reporting a cardiac disorder was 55.9.

Where the absolute risk and relative risk of reporting an adverse event with an outcome of death was calculated for each of the SOCs, the Covid-19 vaccines again displayed the higher absolute risk (Table 17). The relative risk of reporting adverse events with an outcome of death from each of the SOCs ranged from 2.6 for "ear and labyrinth disorders" to 38.7 for "injury, poisons and procedural complications" (Figure 24). The relative risk of reporting a cardiac disorder was 27.5.

TABLE 14: Reports of adverse events made to TGA DAEN from 1 January 1971 to 31 March 2023 that included adverse event terms categorised into the various MedDRA system organ classes for all medicines and where influenza vaccines, covid-19 vaccines, and non-covid vaccines were listed as suspected medicines.

	All Medicines	Covid-19 Vaccines	Influenza Vaccines	Non-Covid Vaccines
	No. of cases	No. of cases *(% All)*	No. of cases *(% All)*	No. of cases *(% All)*
Blood and lymphatic system disorders	28,538	7,428 *(26.0)*	423 *(1.5)*	1,422 *(5.0)*
Cardiac disorders	43,052	16,398 *(38.1)*	465 *(1.1)*	1,193 *(2.8)*
Congenital, familial and genetic disorders	1,474	59 *(4.0)*	8 *(0.5)*	51 *(3.5)*
Ear and labyrinth disorders	8,948	4,283 *(47.9)*	237 *(2.6)*	492 *(5.5)*
Endocrine disorders	2,900	250 *(8.6)*	16 *(0.6)*	30 *(1.0)*
Eye disorders	24,436	5,714 *(23.4)*	615 *(2.5)*	1,764 *(7.2)*
Gastrointestinal disorders	114,884	30,836 *(26.8)*	4,397 *(3.8)*	12,862 *(11.2)*
General disorders and administration site conditions	202,968	71,629 *(35.3)*	10,539 *(5.2)*	42,933 *(21.2)*
Hepatobiliary disorders	13,668	427 *(3.1)*	35 *(0.3)*	168 *(1.2)*
Immune system disorders	17,800	2,600 *(14.6)*	476 *(2.7)*	1,104 *(6.2)*
Infections and infestations	40,190	7,519 *(18.7)*	829 *(2.1)*	7,539 *(18.8)*
Injury, poisoning and procedural complications	36,535	5,830 *(16.0)*	641 *(1.8)*	2,551 *(7.0)*
Investigations	43,310	9,397 *(21.7)*	399 *(0.9)*	1,336 *(3.1)*
Metabolism and nutrition disorders	21,449	2,884 *(13.4)*	362 *(1.7)*	1,773 *(8.3)*
Musculoskeletal and connective tissue disorders	70,849	36,390 *(51.4)*	2,852 *(4.0)*	6,548 *(9.2)*
Neoplasms benign, malignant, unspecified (incl cysts, polyps)	10,514	403 *(3.8)*	10 *(0.1)*	59 *(0.6)*
Nervous system disorders	157,182	65,992 *(42.0)*	5,654 *(3.6)*	17,894 *(11.4)*
Pregnancy, puerperium and perinatal conditions	4,917	437 *(8.9)*	42 *(0.9)*	90 *(1.8)*
Product issues	4,825	149 *(3.1)*	8 *(0.2)*	35 *(0.7)*
Psychiatric disorders	49,456	6,413 *(13.0)*	859 *(1.7)*	3,967 *(8.0)*
Renal and urinary disorders	16,284	1,375 *(8.4)*	91 *(0.6)*	261 *(1.6)*
Reproductive system and breast disorders	11,648	4,135 *(35.5)*	35 *(0.3)*	176 *(1.5)*
Respiratory, thoracic and mediastinal disorders	62,604	21,189 *(33.8)*	2,048 *(3.3)*	4,968 *(7.9)*
Skin and subcutaneous tissue disorders	120,422	18,249 *(15.2)*	3,589 *(3.0)*	16,503 *(13.7)*
Social circumstances	1,188	217 *(18.3)*	21 *(1.8)*	65 *(5.5)*
Surgical and medical procedures	2,792	295 *(10.6)*	22 *(0.8)*	64 *(2.3)*
Vascular disorders	40,071	8,633 *(21.5)*	822 *(2.1)*	2,868 *(7.2)*

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 30 April 2024.

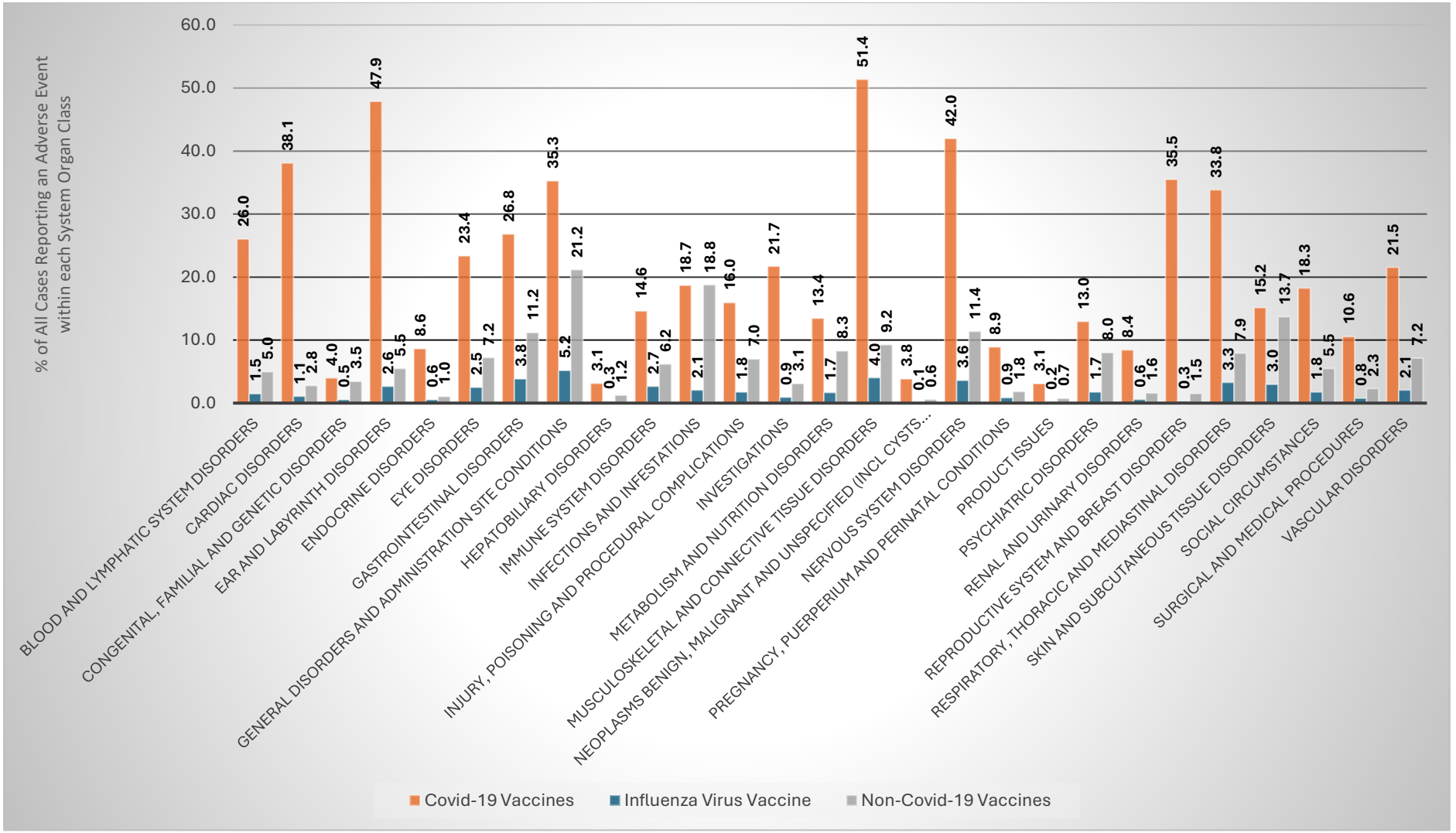


FIGURE 21: Percentage of all reports of adverse events made to TGA DAEN from 1 January 1971 to 31 March 2023 that included adverse event terms categorised into the various MedDRA system organ classes for influenza vaccines, covid-19 vaccines, and non-covid vaccines.

TABLE 15: Reports of adverse events *with an outcome of death* made to TGA DAEN from 1 January 1971 to 31 March 2023 that included adverse event terms categorised into the various MedDRA system organ classes for all medicines and where influenza vaccines, covid-19 vaccines, and non-covid vaccines were listed as suspected medicines.

	All Medicines	Covid-19 Vaccines	Influenza Vaccines	Non-Covid Vaccines
	No. of cases - death	No. of cases - death *(% All)*	No. of cases - death *(% All)*	No. of cases - death *(% All)*
Blood and lymphatic system disorders	1,016	70 *(6.9)*	2 *(0.2)*	6 *(0.6)*
Cardiac disorders	2,173	293 *(13.5)*	12 *(0.6)*	27 *(1.2)*
Congenital, familial and genetic disorders	86	2 *(2.3)*	1 *(1.2)*	4 *(4.7)*
Ear and labyrinth disorders	19	3 *(15.8)*	0 *(0.0)*	- *(0.0)*
Endocrine disorders	73	0 *(0.0)*	0 *(0.0)*	- *(0.0)*
Eye disorders	100	10 *(10.0)*	1 *(1.0)*	2 *(2.0)*
Gastrointestinal disorders	1,551	137 *(8.8)*	5 *(0.3)*	18 *(1.2)*
General disorders and administration site conditions	3,660	312 *(8.5)*	24 *(0.7)*	78 *(2.1)*
Hepatobiliary disorders	636	19 *(3.0)*	0 *(0.0)*	1 *(0.2)*
Immune system disorders	309	9 *(2.9)*	2 *(0.6)*	5 *(1.6)*
Infections and infestations	1,997	143 *(7.2)*	19 *(1.0)*	57 *(2.9)*
Injury, poisoning and procedural complications	2,826	251 *(8.9)*	9 *(0.3)*	21 *(0.7)*
Investigations	946	125 *(13.2)*	5 *(0.5)*	13 *(1.4)*
Metabolism and nutrition disorders	667	44 *(6.6)*	4 *(0.6)*	10 *(1.5)*
Musculoskeletal and connective tissue disorders	394	51 *(12.9)*	4 *(1.0)*	8 *(2.0)*
Neoplasms benign, malignant, unspecified (incl cysts, polyps)	1,445	16 *(1.1)*	1 *(0.1)*	3 *(0.2)*
Nervous system disorders	2,362	281 *(11.9)*	21 *(0.9)*	49 *(2.1)*
Pregnancy, puerperium and perinatal conditions	83	0 *(0.0)*	3 *(3.6)*	3 *(3.6)*
Product issues	46	0 *(0.0)*	0 *(0.0)*	1 *(2.2)*
Psychiatric disorders	1,058	27 *(2.6)*	1 *(0.1)*	3 *(0.3)*
Renal and urinary disorders	798	30 *(3.8)*	5 *(0.6)*	11 *(1.4)*
Reproductive system and breast disorders	32	1 *(3.1)*	0 *(0.0)*	- *(0.0)*
Respiratory, thoracic and mediastinal disorders	1,950	226 *(11.6)*	17 *(0.9)*	30 *(1.5)*
Skin and subcutaneous tissue disorders	510	33 *(6.5)*	0 *(0.0)*	7 *(1.4)*
Social circumstances	38	0 *(0.0)*	0 *(0.0)*	- *(0.0)*
Surgical and medical procedures	85	1 *(1.2)*	0 *(0.0)*	- *(0.0)*
Vascular disorders	992	129 *(13.0)*	5 *(0.5)*	9 *(0.6)*

Cases = Reports of adverse events. Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 30 April 2024.

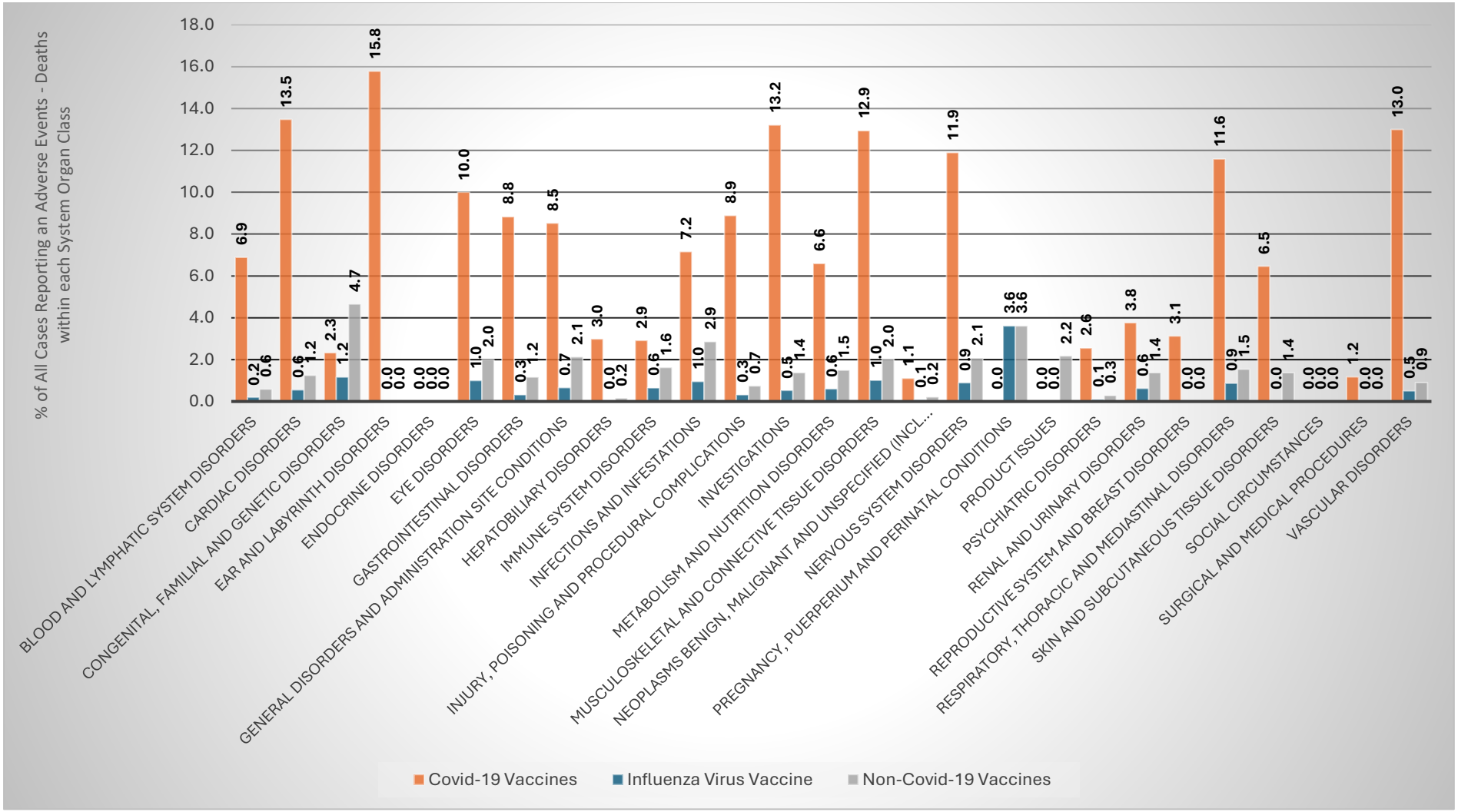


FIGURE 22: Percentage of all reports of adverse events *with an outcome of death* made to TGA DAEN from 1 January 1971 to 31 March 2023 that included adverse event terms categorised into the various MedDRA system organ classes for influenza vaccines, covid-19 vaccines, and non-covid vaccines.

TABLE 16: Reports of adverse events made to TGA DAEN from 1 March 2022 to 14 August 2022 that included adverse event terms categorised into the various MedDRA system organ classes for covid-19 vaccines and/or influenza vaccines.

MedDRA system organ class	Covid-19 vaccines			Influenza vaccines		
	No. of cases reporting AEs	Cases - single suspected	No. of cases - death outcome	No. of cases reporting AEs	Cases - single suspected	No. of cases - death outcome
Blood and lymphatic system disorders	988	949	5	21	16	-
Cardiac disorders	2,600	2,494	44	58	48	2
Congenital, familial and genetic disorders	9	8	-	1	-	-
Ear and labyrinth disorders	614	590	2	15	15	-
Endocrine disorders	54	49	-	-	-	-
Eye disorders	688	649	2	30	25	-
Gastrointestinal disorders	3,026	2,907	15	203	164	1
General disorders and administration site conditions	7,990	7,452	32	520	410	2
Hepatobiliary disorders	79	74	3	-	-	-
Immune system disorders	302	278	3	31	27	-
Infections and infestations	1,430	1,180	22	60	40	3
Injury, poisoning and procedural complications	1,358	1,302	62	197	170	2
Investigations	1,269	1,134	17	40	28	-
Metabolism and nutrition disorders	324	302	5	31	21	-
Musculoskeletal and connective tissue disorders	3,833	3,663	11	164	134	-
Neoplasms benign, malignant, unspecified (incl cysts, polyps)	114	109	6	2	2	-
Nervous system disorders	6,458	6,176	28	319	254	3
Pregnancy, puerperium and perinatal conditions	66	65	-	-	-	-
Product issues	10	10	-	-	-	-
Psychiatric disorders	879	838	3	37	30	-
Renal and urinary disorders	233	218	8	13	8	1
Reproductive system and breast disorders	731	699	-	3	3	-
Respiratory, thoracic and mediastinal disorders	2,647	2,527	23	161	127	3
Skin and subcutaneous tissue disorders	2,259	2,135	8	221	172	-
Social circumstances	58	52	-	5	3	-
Surgical and medical procedures	60	47	-	4	2	-
Vascular disorders	839	802	13	52	42	1

Cases = Reports of adverse events. Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 7 May 2024.

TABLE 17: Reports of adverse events made to TGA DAEN from 1 March 2022 to 14 August 2022 that included adverse event terms categorised into the various MedDRA system organ classes. Absolute Risk (AR) per 100,000 doses and Relative Risk (to influenza vaccine; RR)

	Cases			Deaths		
	Covid – AR per 100,000	Flu – AR per 100,000	RR (99% CI)	Covid – AR per 100,000	Flu – AR per 100,000	RR (99% CI)
Blood and lymphatic system disorders	11.4	0.2	58.7 (33.2-103.7)	0.06	0.00	6.2 (0.4-105.3)[1]
Cardiac disorders	29.9	0.5	55.9 (39.7-78.8)	0.51	0.02	27.5 (4.3-177.3)
Congenital, familial and genetic disorders	0.1	0.0	11.2 (0.7-170.4)	0.00	0.00	-
Ear and labyrinth disorders	7.1	0.1	51.1 (26.0-100.2)	0.02	0.00	2.5 (0.1-58.8)[1]
Endocrine disorders	0.6	-	67.4 (5.0-910.7)[1]	0.00	0.00	-
Eye disorders	7.9	0.3	28.6 (17.7-46.3)	0.02	0.00	2.5 (0.1-58.8)[1]
Gastrointestinal disorders	34.8	1.9	18.6 (15.4-22.4)	0.17	0.01	18.7 (1.3-268.8)
General disorders and administration site conditions	91.9	4.8	19.2 (17.1-21.5)	0.37	0.02	20.0 (3.0-130.9)
Hepatobiliary disorders	0.9	-	98.6 (7.3-1322.4)[1]	0.03	0.00	3.7 (0.2-73.6))[1]
Immune system disorders	3.5	0.3	12.2 (7.5-19.8)	0.03	0.00	3.7 (0.2-73.6))[1]
Infections and infestations	16.5	0.6	29.7 (21.2-41.8)	0.25	0.03	9.2 (1.9-44.8)
Injury, poisoning and procedural complications	15.6	1.8	8.6 (7.1-10.5)	0.71	0.02	38.7 (6.1-246.9)
Investigations	14.6	0.4	39.6 (26.2-59.9)	0.20	0.00	21.2 (1.5-301.7)[1]
Metabolism and nutrition disorders	3.7	0.3	13.0 (8.0-21.2)	0.06	0.00	6.2 (0.4-105.3)[1]
Musculoskeletal and connective tissue disorders	44.1	1.5	29.2 (23.7-35.8)	0.13	0.00	13.7 (0.9-203.2)[1]
Neoplasms benign, malignant, unspecified (incl cysts, polyps)	1.3	0.0	71.1 (11.3-448.0)	0.07	0.00	7.5 (0.5-121.5)[1]
Nervous system disorders	74.3	2.9	25.3 (21.8-29.3)	0.32	0.03	11.6 (2.4-55.8)
Pregnancy, puerperium and perinatal conditions	0.8	-	82.4 (6.1-1108.3)[1]	0.00	0.00	-
Product issues	0.1	-	12.5 (0.8-186.8)[1]	0.00	0.00	-
Psychiatric disorders	10.1	0.3	29.6 (19.2-45.7)	0.03	0.00	3.7 (0.2-73.6)[1]
Renal and urinary disorders	2.7	0.1	22.4 (10.7-46.7)	0.09	0.01	10.0 (0.6-154.1)
Reproductive system and breast disorders	8.4	0.0	304.1 (68.4-1352.7)	0.00	0.00	-
Respiratory, thoracic and mediastinal disorders	30.5	1.5	20.5 (16.6-25.3)	0.26	0.03	9.6 (2.0-46.6)
Skin and subcutaneous tissue disorders	26.0	2.0	12.8 (10.6-15.3)	0.09	0.00	10.0 (0.6-154.1)[1]
Social circumstances	0.7	0.0	14.5 (4.3-48.2)	0.00	0.00	-
Surgical and medical procedures	0.7	0.0	18.7 (4.9-70.9)	0.00	0.00	-
Vascular disorders	9.7	0.5	20.1 (13.9-29.1)	0.15	0.01	16.2 (1.1-236.0)

Cases = Reports of Adverse Events. Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 7 May 2024. 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. [1] The reference group (influenza vaccine listed as a suspected medicine) recoded 0 adverse events. The relative risk ratio was estimated by moving one case from the no event group into the event group.

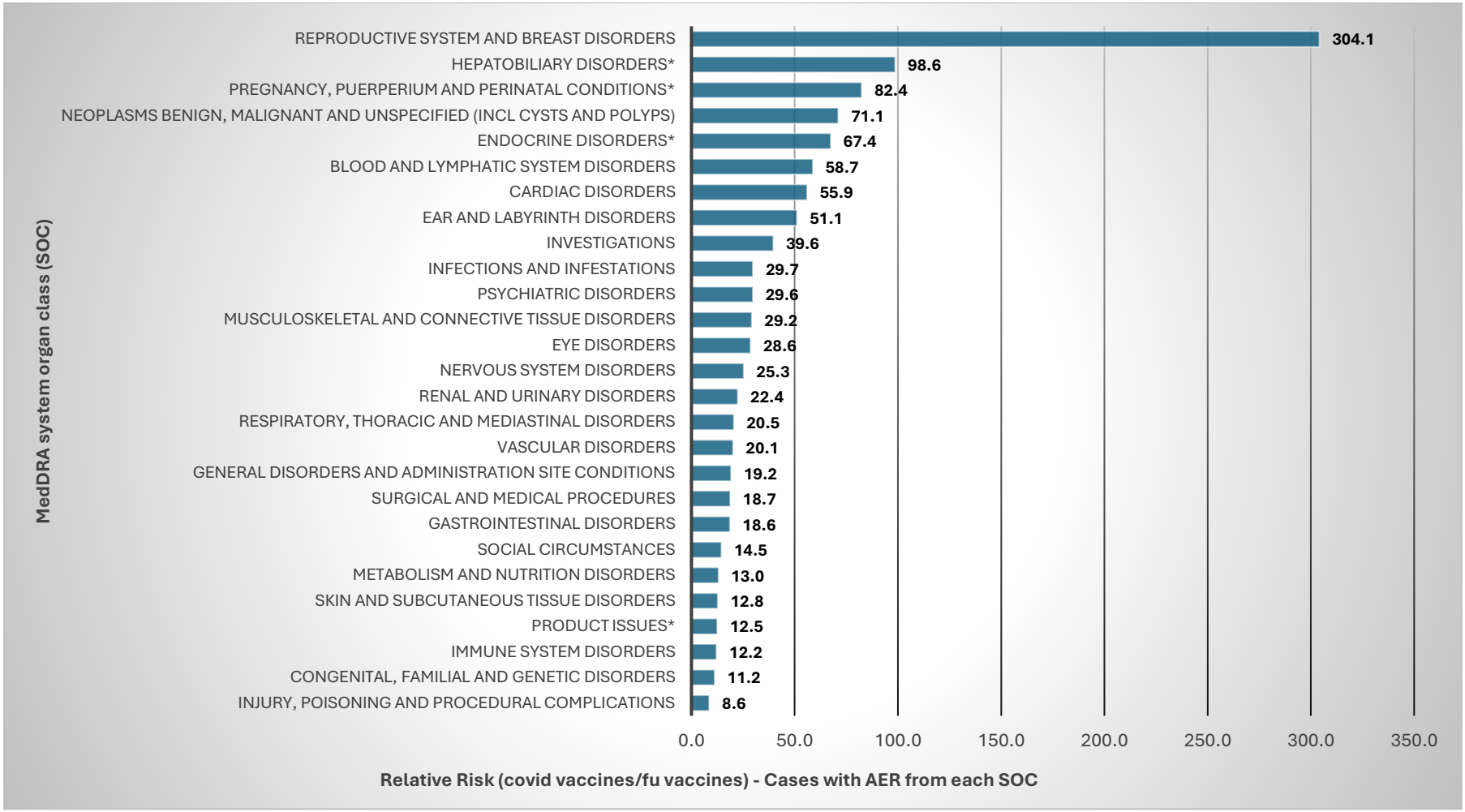


FIGURE 23: Relative risk of reports of adverse events made to TGA DAEN between 1 March 2022 to 14 August 2022 that included adverse event terms categorised into the various MedDRA system organ classes and where covid-19 vaccines and/or influenza vaccines were listed as suspected medicines. Relative risk is calculated for the covid-19 vaccine referenced to the influenza vaccine. *Source:* TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 7 May 2024 July 2023. *Reference group (influenza vaccine listed as a suspected medicine) recoded 0 adverse events. The relative risk ratio was estimated by moving one case from the no event group into the event group.

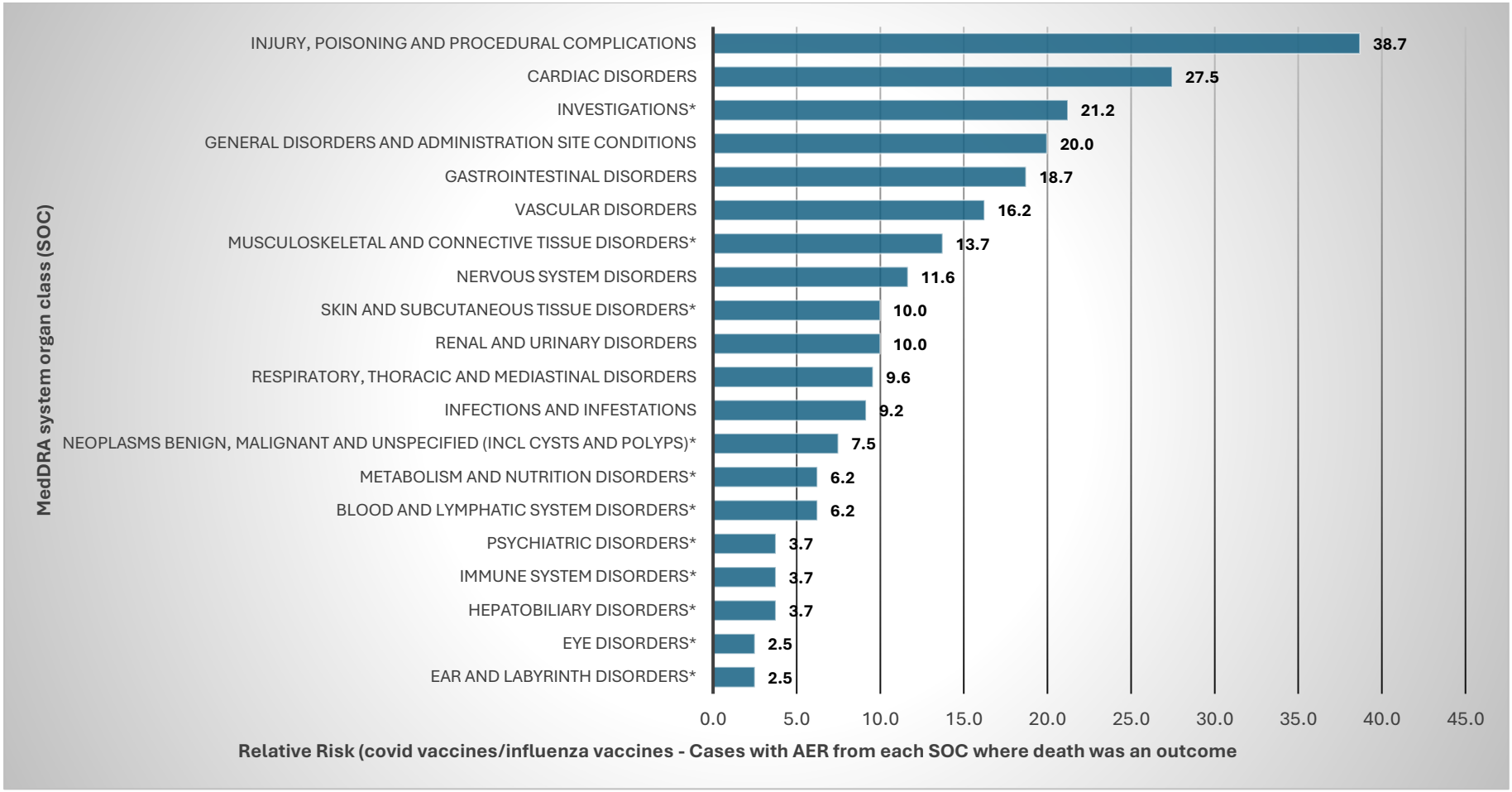


FIGURE 24: Relative risk of reports of adverse events made to TGA DAEN between 1 March 2022 to 14 August 2022 that included adverse event terms where death was a reported outcome, that were categorised into the various MedDRA system organ classes, and where covid-19 vaccines and/or influenza vaccines were listed as a suspected medicine. Relative risk is calculated for the covid-19 vaccine with the influenza vaccine as the reference. *Source:* TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 7 May 2024. *Reference group (influenza vaccine listed as a suspected medicine) recoded 0 adverse events. The relative risk ratio was estimated by moving one case from the no event group into the event group.

Serious Adverse Reactions

In addition to the large number of AERs incorporating adverse events from all MedDRA system organ classes, and the substantial number of deaths associated with Covid-19 vaccines, there have also been a substantial number of reports that were classified as "suspected serious adverse event reports" by the reporter.

In 2023, the TGA released a document under Freedom of Information that provided a list of the "TGA case numbers for suspected serious adverse events in people who received Covid-19 vaccines" (https://www.tga.gov.au/sites/default/files/2023-11/FOI%204769.pdf). The TGA noted that the assessment of seriousness was the view of the reporter and was not assigned by the TGA.

Table 18 summarises the number of AERs up to 31 March 2023 that were classified as serious by the reporter. As shown in Table 18, 21,821 of the 138,046 AERs (15.8%) were classified as suspected serious by the reporter.

TABLE 18: Number of adverse event reports made to TGA DAEN between 1 January 1971 to 31 March 2023 where covid-19 vaccines were listed as suspected medicines and cases were classified as suspected serious by the reporter*.

	No. of cases reporting adverse events	No. of cases reporting adverse events that were classified as serious by reporter	% of cases reporting adverse events that were classified as serious by reporter
Covid-19 vaccines (*11 medicine terms)*	138,046	21,821	15.8%
Pfizer	*81,162*	*12,440*	*15.3%*
Moderna	*7,618*	*1,178*	*15.5%*
AstraZeneca	*48,179*	*8,107*	*16.8%*
Novavax	*987*	*145*	*14.7%*
Type not specified	*701*	*162*	*23.1%*

Cases = Reports of adverse events.
* As per the list provided in TGA Freedom of Information document FOI 4769 (https://www.tga.gov.au/sites/default/files/2023-11/FOI%204769.pdf)
Source: TGA DAEN (https://daen.tga.gov.au/medicines-search/) extracted 30 April and 1 May 2024

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The absolute risk of reporting an adverse event that was classified as suspected serious was calculated using monthly vaccination figures and is presented in Figure 25. Of note is that the absolute risk of an AER being submitted to the DAEN that was considered serious varied over time, from 9.6 to as high as 87.7 AERs per 100,000 doses. Importantly, one of the highest points was observed immediately after the vaccine roll-out and raises the question as to why this was NOT considered a safety signal.

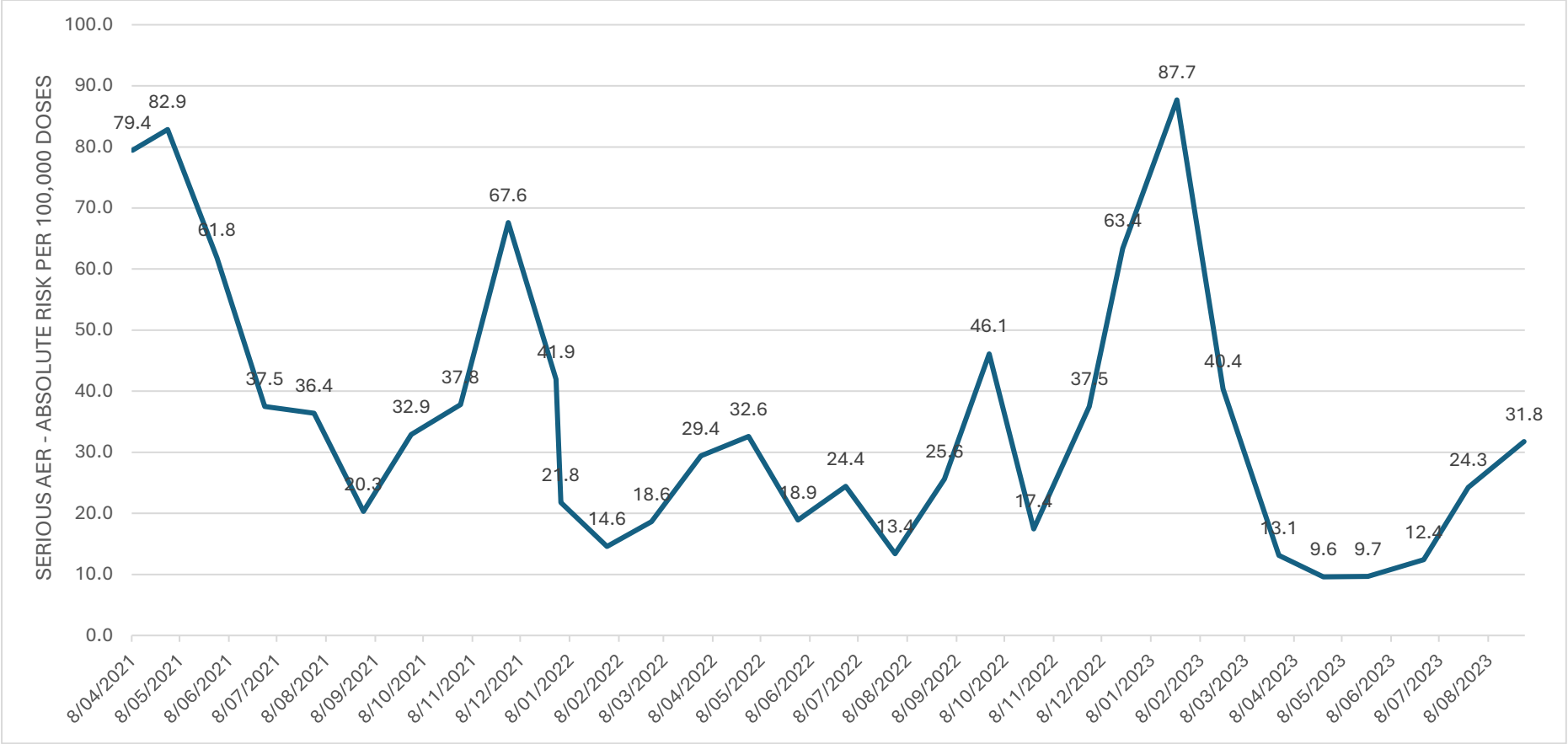

FIGURE 25: Absolute risk (per 100,000) of an adverse event report being made to TGA DAEN between 1 January 1971 to 31 March 2023 where covid-19 vaccines were listed as suspected medicines and cases were classified as suspected serious by the reporter. Doses - vaccine rollout updates for dates *9/04/2021, 1/05/2021, 1/06/2021, 1/07/2021, 1/08/2021, 1/09/2021, 1/10/2021, 1/11/2021, 1/12/2021, 31/12/2021, 2/01/2022, 1/02/2022, 1/03/2022, 1/04/2022, 1/05/2022, 1/06/2022, 1/07/2022, 1/08/2022, 1/09/2022, 29/09/2022, 27/10/2022, 1/12/2022, 22/12/2023, 25/01/2023, 23/02/2023, 31/03/2023, 28/04/2023, 26/05/2023, 29/06/2023, 27/07/2023, 1/09/2023 (https://www.health.gov.au/resources/collections/covid-19-vaccination-rollout-update)*

Common Adverse Events.

The TGA often argue 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 fail to draw attention to is the uniquely high report of chest pain and dyspnoea among 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 (Tables 19 and 20).

As of 31 March 2023, it was noted that "chest pain" had been reported in association with covid-19 vaccines for 15,331 adverse event reports. This represents about 70% of all adverse event reports that report this symptom (Table 19).

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 11,671 (45.2%) of all reports of this adverse event ever submitted to the DAEN (Table 19).

Headache, fatigue, pyrexia, and myalgia associated with Covid-19 vaccines also represented between 43.6% and 72.27% 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.

TABLE 19: Comparison of the report of general MedDRA adverse event reaction terms among adverse event reports submitted to TGA DAEN from 1 January 1971 to 31 March 2023 where influenza vaccines, covid-19 vaccines and non-covid medicines were listed as suspected medicine compared to all medicines.

MedDRA reaction term	All Medicines	Covid-19 Vaccines		Influenza Vaccines		Other Vaccines	
	No. of cases	No. of cases	*(% All)*	No. of cases	*(% All)*	No. of cases	*(% All)*
Chest pain	22,016	15,331	*(69.6)*	221	*(1.0)*	496	*(2.3)*
Dyspnoea	25,849	11,671	*(45.2)*	602	*(2.3)*	1,294	*(5.0)*
Palpitations	10,894	6,843	*(62.8)*	143	*(1.3)*	292	*(2.7)*
Headache	51,421	33,092	*(64.4)*	1,887	*(3.7)*	4,842	*(9.4)*
Fatigue	26,242	16,022	*(61.1)*	814	*(3.1)*	1,953	*(7.4)*
Pyrexia	41,646	18,150	*(43.6)*	4,241	*(10.2)*	13,376	*(32.1)*
Myalgia	28,500	20,585	*(72.2)*	1,075	*(3.8)*	2,175	*(7.6)*

Cases = Reports of adverse events. Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 30 April 2024.

TABLE 20: Comparison of the report of general MedDRA adverse event reaction terms among adverse event reports with an outcome of death submitted to TGA DAEN from 1 January 1971 to 31 March 2023 where influenza vaccines, covid-19 vaccines and non-covid medicines were listed as suspected medicine compared to all medicines.

MedDRA reaction term	All Medicines	Covid-19 Vaccines		Influenza Vaccines		Other Vaccines	
	No. of Cases - Death	No. of Cases - Death	*(% All)*	No. of Cases - Death	*(% All)*	No. of Cases - Death	*(% All)*
Chest pain	152	48	*(31.6)*	4	*(2.6)*	4	*(2.6)*
Dyspnoea	401	87	*(21.7)*	2	*(0.5)*	3	*(0.7)*
Palpitations	13	4	*(30.8)*	1	*(7.7)*	1	*(7.7)*
Headache	121	45	*(37.2)*	0	*(0.0)*	3	*(2.5)*
Fatigue	171	32	*(18.7)*	2	*(1.2)*	3	*(1.8)*
Pyrexia	259	38	*(14.7)*	5	*(1.9)*	20	*(7.7)*
Myalgia	49	14	*(28.6)*	2	*(0.0)*	2	*(0.0)*

Cases = Reports of adverse events. Source: Therapeutic Goods Administration Database of Adverse Event Notification (https://daen.tga.gov.au/medicines-search/) extracted 30 April 2024.

Proportional Reporting Ratios, PRRs

Analysis of the adverse events for safety signals include: 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 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 21. A summary of the PRR values presented across the nine DPAR dates, overall and separately, are summarised in Table 22.

TABLE 21: 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 22: 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 22). When duplicates adverse event terms here removed, 848 unique adverse events remained.

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 TGAs methods, results and interpretation can again not be independently verified, or the veracity of their statements tested.

Overview of Data Reported for the AusVaxSafety Program.

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).

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.

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 AusVaxSafety Summary 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 23 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 26. 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 that the AusVaxSafety data is only the day 3 data must also be considered.

TABLE 23: 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

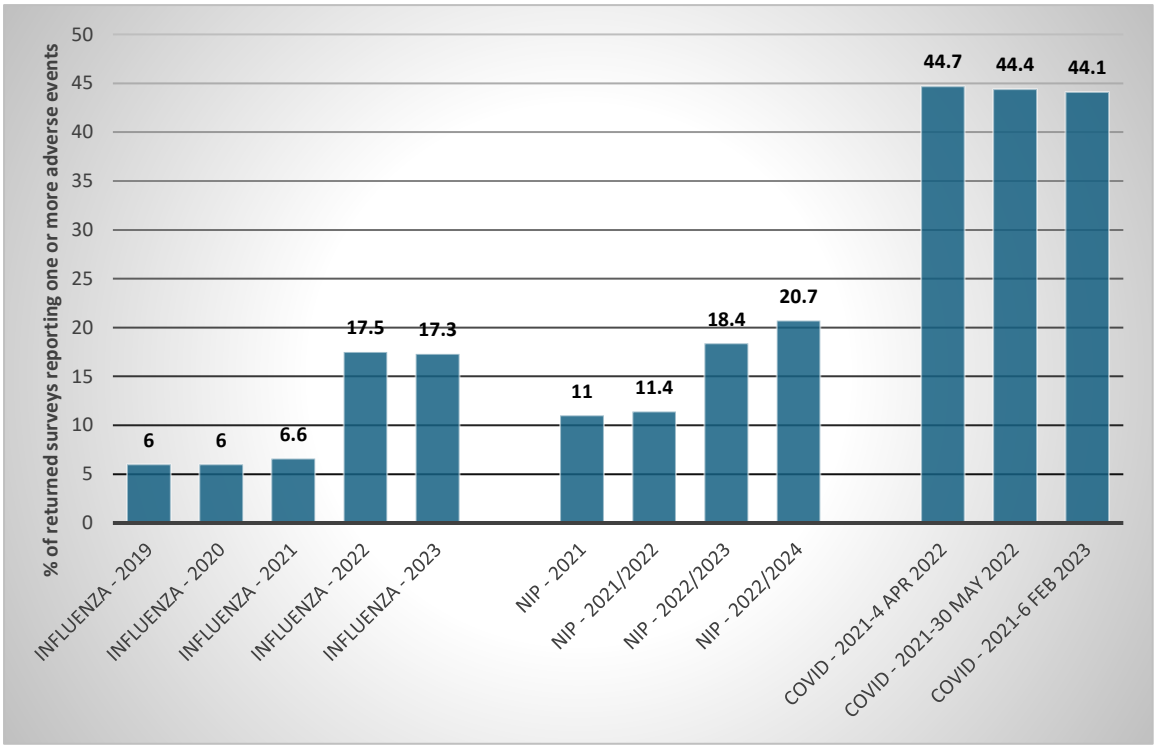

FIGURE 26: Summary of the percentage of surveys returned reporting one or more adverse events on day 3 following vaccination with covid-19, influenza, and the national immunisation program (NIP) vaccines.

Table 24 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 25 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 24: 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 25: 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 in 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, in 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).

Summary
There is general agreement that excess deaths have occurred during the pandemic. What is still a matter of debate are the details regarding the number of excess deaths, the temporal profile of excess deaths, and the factors that may be contributing to excess deaths.

In the current report, 5 methods of calculating excess deaths were reviewed. The estimated number of excess deaths for the period from January 2021 to December 2023 varied from approximately 30,000 to 60,000, with three models suggesting that the figure may be more accurately estimated to be approximately 40,000.

Consideration of factors that may be contributing to excess deaths primarily focus Covid-19 infection with estimates suggesting that Covid-19 infection may account for one third to a half of the excess deaths. However, this assumes that Covid-19 diagnoses are accurate and while it can be argued that limitations to Covid-19 diagnosis may result in under-reporting of Covid-19 deaths, it can also be argued that they may overstate the potential contribution of Covid-19 to excess deaths.

The potential role of Covid-19 vaccine injuries to excess deaths were reviewed through an evaluation of adverse event reports submitted to the Therapeutic Goods Administration Database of Adverse Event Notification and the AusVaxSafety Program. Unprecedented numbers and rates of adverse event reports, including over one thousand deaths, have been associated with Covid-19 vaccines. A broad range of adverse events was noted that included adverse event terms from all MedDRA System Organ Classes, and over 400 adverse events not previously reported over the 52-year history of the DAEN. PRR values also indicated disproportional reporting rates of specific adverse events. The data collectively indicated safety signals that could be contributing to ill health and excess death in the population.

Further evaluation of the potential misclassification of Covid-19 infections and the short-medium- and long-terms impacts of covid-19 vaccines on disease and death is also warranted.

Chapter 7

Details of the Undisclosed Vaccinated Deaths from the Pfizer COVID-19 Vaccine Trial at the Point of Approval

by Dr Jeyanthi Kunadhasan

I am an anaesthetist and peri-operative physician in Victoria, as well as the current Treasurer of the Australian Medical Professionals Society.

Additionally, I am also a member of the DailyClout Pfizer and Moderna research volunteers. We have investigated the data from Pfizer trial C4591001 that formed the basis of the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) of 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 , as well as Professor Anthony Lawler of the Therapeutic Goods Administration, highlighting **undisclosed vaccinated subjects deaths from trial C4591001**. Because Pfizer did not disclose all vaccinated deaths during the trial to the FDA, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) had incomplete data when it met on December 10th, 2020. The December 10th VRBPAC meeting resulted in the recommendation of EUA for Pfizer's COVID-19 vaccine after the members' examination of the C4591001 trial results.

The January 2021 Provisional Approval for the Pfizer COVID-19 vaccine in Australia soon followed. I will briefly highlight some important efficacy and safety analysis from this trial.

It is important to note, at the point of the Pfizer COVID-19 vaccine approval in late 2020/early 2021, there was a gross misrepresentation in the trial data presented to the public. At the point of the U.S. EUA data cut-off date of November 14th, 2020, Pfizer and the FDA publicly reported six deaths. — four deaths in the placebo arm compared to two in the vaccinated arm. In fact, eleven deaths had occurred in the trial prior to November 14th, 2020, with six deaths in the vaccinated arm compared to the five deaths in the placebo arm. Though not statistically significant because of the small numbers involved, it would have been harder to persuade the public to take a drug where more people died in the supposedly lifesaving treatment arm. This incorrect data presentation resulted from delayed recording of subjects' deaths. Pertinent to this inquiry, very few of the patients who died in this clinical trial had autopsies done. None of the autopsy results have been publicly available thus far.

Brief Efficacy Analysis of the Primary Endpoint of the Trial.

Whilst Phase 2/3 of trial C44591001 involved 44,060 subjects, the 95% efficacy claim of Pfizer's COVID-19 vaccine was based on the results of just 170 patients, also known as the evaluable efficacy population.

The evaluable efficacy population was the primary endpoint of Pfizer's trial and the basis for the FDA's EUA. 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 two-dose vaccination regimen at this point of the trial as randomized within the predefined window. (In the trial protocol, the dosing interval between dose 1 and Dose 2 was 21 days with an allowed variance of 19 to 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 would have 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 these events should have disqualified the patients from being part of the evaluable efficacy population, yet they were not disqualified. Two other patients had been withdrawn from the trial prior to issuance of the EUA. These disqualified patients would have brought the final number of cases to fewer than the 164-target patient threshold set by Pfizer, 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 of 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 1,410 patients whose results would have normally been discontinued, or excluded, from an efficacy analysis 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 than 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/

Safety Analysis

Below are the summary points from the first peer-reviewed paper, which I co-authored, looking into the original trial data of study C4591001:

1. The C4591001 placebo-controlled, randomized clinical trial of 22,030 vaccinated and 22,030 placebo subjects was the world's only opportunity for an unbiased evaluation of the Pfizer/BioNTech BNT162b2 vaccine.
2. Unblinding of placebo subjects starting in Week 20 effectively terminated the placebo-controlled clinical trial, thereby ending all unbiased evaluation of possible adverse event signals and drug safety.
3. The modified mRNA-LNP platform is novel, not previously Phase 2/3 tested in humans; and the Spike protein toxicity was unknown. Taken together, a 20-week, 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.

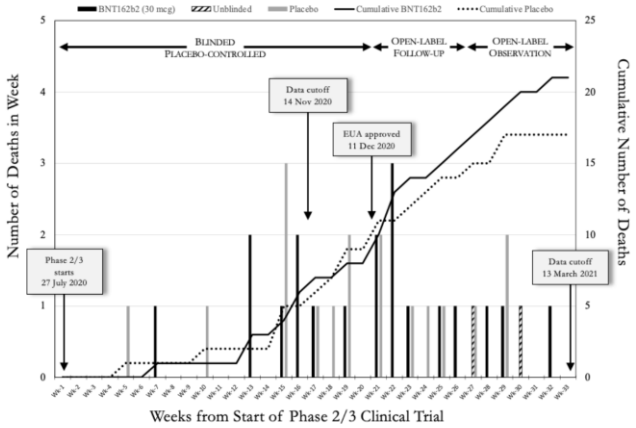

Figure 1: Weekly subject deaths during the initial 33 weeks of Pfizer/BioNTech Clinical Trial C4591001. The 38 subjects who died are accounted for in the order of their date of death during the 33 weeks starting Monday, July 27, 2020, and ending Saturday, March 13, 2021. Each bar between the horizontal lines on the graph represents a single death (no more than 3 ever occurred on the same day). Solid black bars represent BNT162b2 vaccinated subjects who died; solid grey bars represent placebo subjects; hatched bars are unblinded placebo subjects who accepted a BNT162b2 injection after December 11, 2020. The cumulative number of deaths for BNT162b2 recipients is shown in the solid line rising from left to right whereas the dotted line shows cumulative deaths of the placebo only recipients. The placebo recipients who opted to accept a BNT162b2 injection and died are counted as BNT162b2 recipients. The three trial periods from left to right are: Blinded placebo-controlled period, July 27 – December 10, 2020; Open-label Follow-up period, December 11, 2020 – January 24, 2021; Open-label Observation period, January 25 – March 13, 2021.

https://ijvtpr.com/index.php/IJVTPR/article/view/86 p. 980

6. Delayed reporting of BNT162b2 group subject deaths into their Case Report Forms (CRFs), which was in violation of the trial protocol, allowed exclusion of the deaths from the EUA data, as well as permitted 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 who were "Lost to Follow-up."
8. In the trial, 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, nine of whom were BNT162b2 vaccinated.
10. The cardiac adverse event signal was obscured by delays in reporting the accurate dates of subject deaths that were known to Pfizer/BioNTech through the subjects' Narrative Reports.

To further elucidate on point 10, the delayed reporting of deaths, uncovered in the forensic analysis, was in contravention of legal and ethical obligations of the clinical trial sponsor.

This is clearly explained in my letters to Attorney General Ken Paxton and Professor Anthony Lawler. The correspondence between myself and Professor Lawler is attached at the end of this document.

How did we get to a situation where we are unable to accurately track the people who died in this trial? 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). Such shoddy tracking of deaths in a trial, especially for a novel drug, is unacceptable.

By painstakingly going through all the documentation available for each of the 38 dead subjects in this trial, my co-authors and I identified first the six patients whose deaths were

publicly disclosed. This allowed us to look even more deeply into those who died before the November 14, 2020, data cut-off date but whose deaths were not disclosed as part of the EUA dataset.

In a death notification, the onus falls to the loved ones and emergency contacts to inform the trial site of the death. Once informed of the death, as per the trial protocol, the information was to be entered into the Pfizer Safety Vaccine SAE (serious adverse event) form within 24 hours, and under no circumstances to exceed 24 hours. 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 five remaining patients (four vaccinated and one placebo), we found evidence that loved ones had in fact called the clinical site for two of the patients on the day they died.

Subject 11141050, from Kansas, from the vaccinated arm of the trial, was a 63-year-old, overweight, and depressed woman who was found dead on October 19, 2020 (forty-one days after receiving dose 2). 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 November 14th and should have been disclosed in the data submitted to the FDA. 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 December 9, 2020, (the day before the VRBPAC meeting to consider recommendation of EUA), leading one to a conclusion that this undisclosed death from the vaccinated arm possibly had an autopsy result available the day prior to that 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 (October 19, 2020), this was entered into the patient's notes 37 days later on November 25, 2020. Was this a way to circumvent publicly disclosing this death in the EUA dataset? November 25th was still before the VRBPAC meeting of December 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-old female subject from the vaccinated arm of the trial died in her sleep on November 7, 2020 (seventy-two days after receiving dose 2). Her husband called the clinical site on November 7th informing them of her death. On the patient's CRF, it is explicitly stated that the notification of the death happened on November 7th, 2020. This patient was not one of the six deaths publicly disclosed as part of the EUA dataset. It is troubling, considering that the death notification 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 concluded 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 four deaths that occurred in this trial in the vaccinated arm were in those aged 56 to 64 who died from a cardiac event, who were found dead. An autopsy was performed on only one of these four patients. A similar level of documentation is not available for the remaining three undisclosed deaths at the time of the EUA approval.

In my correspondence with Professor Lawler, he assured me that none of the deaths in the trial have been attributed to the vaccine. I am perplexed as to how this conclusion can be reached as only seven of the 38 deaths in the 6-month report had autopsy reports. None of the autopsy reports are available for independent scrutiny.

In the vaccinated arm, there were 21 deaths, and only three of them (subjects 11141050, 11271112 and 11351033) had autopsies done. One had a diagnosis of sudden cardiac death (subject 11141050); the other two reports are still not available. How can one dispositively conclude something based on an unavailable report? I can understand autopsies not being done for certain patients who had a period of illness prior to dying. However, 10 out of 21 of the deaths in the vaccinated subjects occurred in those who were found dead or suffered sudden adult death. Of these 10, only two (subjects 11141050 and 11271112) had reported autopsies done, with only one result (subject 11141050, sudden cardiac death) made available.

There were 17 deaths in the placebo group, and only four (subjects 11521085, 11561124, 11681083, 12314987) had autopsies. Of these, two (subjects 11561124 and 11681083) had a cause of death. The other two results are still not available.

The committee should seek answers from the TGA regarding how it arrived at the conclusion that none of the deaths in the clinical trial were attributed to the vaccine.

Finally, the committee should also probe what role Australia's TGA played in the data cover-up by Pfizer, especially if the TGA themselves had found the undisclosed deaths at the point of the EUA approval. If they did not know about these hidden deaths, had due diligence been followed when scrutinizing trial data? What went wrong to lead the TGA to approve and continue to approve a drug where more subjects died in the supposedly lifesaving intervention arm of its clinical trial compared to the placebo arm?

Correspondence of Dr Jeyanthi Kunadhasan with the Department of Health and Aged Care follows:

1. Letter from AMPS to Professor Tony Lawler, copied to: Professor Paul Kelly, Mr Blair Comley, Professor Paul Kelly, Professor Nigel Crawford and Minister Mark Butler.
2. Response from Professor Anthony Lawler.
3. Response to Professor Lawler, with further concerns regarding the hidden deaths, and containing two more questions.
4. After no reply, a further letter to Professor Lawler.

21 March, 2024

Dr Tony Lawler, head of the TGA
Anthony.lawler@health.gov.au

Copied to:
Professor Paul Kelly
Paul.kelly@health.gov.au
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Blair.Comley@health.gov.au
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RE: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Dear Dr Tony Lawler

You will find at the end of this paper three specific questions which are being directed to you. This letter comes to you not only on my own behalf, but on behalf of The Australian Medical Professionals Society. Please treat it as being on the record.

I am Dr. Jeyanthi Kunadhasan, an anaesthetist and perioperative physician. I investigated the data, released on the Public Health and Medical Professionals for Transparency website,[1] which formed the basis of the Food and Drug Administration's emergency use authorization (EUA) of Pfizer-BioNTech's BNT162b2 mRNA COVID vaccine. Additionally, I serve as Treasurer of the Australian Medical Professionals Society.[2]

I co-authored Pfizer reports 42[3] and 76[4], available on dailyclout.io. Additionally, I contributed as a coauthor of "Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial."[5] This analysis of the Pfizer's COVID vaccine represents the inaugural examination of the original trial data by a group unaffiliated with clinical trial sponsorship.

I wish to highlight two undisclosed deaths of American trial participants in the BNT162b2-vaccinated arm of Pfizer's clinical trial. Pfizer's nondisclosure of these deaths occurred before Pfizer's data cut-off date for its EUA submission to the FDA (Michels et al., 2023).

The clinical trial data reportedly supporting the safety and efficacy of the BNT162b2 mRNA vaccine have been published twice. Polack et al. released their findings, 'Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine,' [6] on December 10, 2020, one day before the FDA issued Pfizer's EUA. Subsequently, on September 15, 2021, Stephen J. Thomas, MD, et al. published, 'Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months.'[7] The Polack publication in the *New England Journal of Medicine* stated, 'All the trial data were available to all the authors, who vouch for its accuracy and completeness and for adherence of the trial to the protocol,

which is available with the full text of this article at NEJM.org. An independent data and safety monitoring board reviewed efficacy and unblinded safety data' (Polack et al., 2020).

The Polack paper disclosed six deaths — two in the BNT162b2 arm and four in the placebo arm. Both the journal article and the EUA approval documentation[8] showed the six deaths during the period of July 27, 2020, till November 14, 2020. This letter will demonstrate that Pfizer-BioNTech had records showing eight deaths, four in the BNT162b2 arm and four in the placebo arm, that Pfizer should have disclosed to the FDA. Additionally, the two undisclosed deaths indicated a cardiac event signal in the clinical trial's BNT162b2 recipients (Michels et al., 2023).

Pfizer's clinical trial protocol required prompt reporting – immediately upon awareness and, under no circumstances, to exceed 24 hours – of serious adverse events (SAE), via the Vaccine SAE Reporting Form, to Pfizer Safety.[9] Investigators were responsible for documenting all directly observed and spontaneously reported adverse events, including serious adverse events reported by participants, into the patient's Case Report Form (CRF). In the unfortunate event of a death, the next of kin or emergency contact had the responsibility to promptly inform the clinical trial site, distinguishing it from the self-reporting process for other adverse events. The clinical trial site's swift notification about an SAE to the trial sponsor, BioNTech in this instance, played a crucial role in meeting legal obligations and ethical responsibilities concerning participant safety and the study intervention under clinical investigation. BioNTech, as the sponsor, bore the legal duty to quickly notify both the local regulatory authority and other regulatory agencies about the safety of the study intervention under clinical investigation. Compliance with country-specific regulatory requirements for safety reporting to the regulatory authority, Independent Review Boards (IRBs)/Ethics Committees (ECs), and investigators was also obligatory.

Examining the table below, which is adapted from the 'Forensic Analysis of the 38 Subject deaths in the 6-Month Interim Report of the Pfizer-BioNTech BNT162b2 mRNA Vaccine Clinical Trial' (Michels et al., 2023), reveals that as of the data cut-off date of November 14, 2020, a total of 11 deaths (six deaths in the vaccinated arm of the study and five in the placebo arm) were recorded. This stands in contrast to the six deaths publicly disclosed at the VRBPAC meeting and in the Polack article. 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).

Days of delay in recording subject deaths

BNT162b2 arm

Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
*P-C	11621327	13Sept2020	24Sept2020	11
P-C	11141050	19Oct2020	25Nov2020	37
*P-C	10071101	21Oct2020	5Nov2020	15
P-C	11201050	07Nov2020	3Dec2020	26
P-C	11521497	11Nov2020	18Nov2020	7
P-C	10891073	12Nov2020	4Dec2020	22

Placebo arm

Period	Subject ID	Date of Death	Officially Recorded Date (from Case Report Form)	Delay Recording Death (Days)
#P-C	11521085	26Aug2020	27Aug2020	1
#P-C	12313972	28Sept2020	1Oct2020	3
P-C	11561124	02Nov2020	19Nov2020	17
#P-C	10661350	03Nov2020	10Nov2020	7
#P-C	10811194	04Nov2020	11Nov2020	7

SHADING — undisclosed at the Dec 10th VRPBAC meeting

To unravel the discrepancies in reported deaths, my co-authors and I initiated our investigation with the assumption that, as of November 14, 2020, Pfizer-BioNTech had no knowledge of any deaths during the trial. The only way to convincingly disprove this was to demonstrate, through publicly available records, that Pfizer-BioNTech had knowledge of the deaths. By examination of these records, we were able to show Pfizer-BioNTech indeed did possess knowledge of them. Scrutinizing each patient's notes accessible on the Public Health and Medical Professionals for Transparency (PHMPT) website, we identified the six deceased subjects, whose deaths were reported in the initial Polack publication and at the VRBPAC meeting on December 10, 2020. These subjects include

vaccinated patients 11621327 and 10071101 along with the unvaccinated subjects 11521085, 12313972, 10661350, and 10811194. Their deaths occurred prior to November 14, 2020, and the documentation of their deaths was available in their respective Case Report Forms (CRFs) prior to November 14, 2020.

Below are two BNT162b2 subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer's Knowledge of the Death
11621327	13-SEP-20	24-SEP-20	YES	Subject's Case Report File, 10/15/2020, page 123, 10/2/2020 07:36:13 page 122 notes that death was listed in Safety DB but missing in the CRF. Notification of death noted as 9/24/2020 on page 122.[10]
10071101	21-OCT-20	5-NOV-20	YES	Subject's Case Report File, 11/5/2020 16:40:57 page 188, Nov-05-2020 16:39:49 page 196 of the CRF.[11]

Below are the four placebo subjects whose deaths were included in the EUA submission:

Subject ID	Actual Date of Death	Date Pfizer Had Knowledge of the Death	Did Pfizer Have Knowledge of the Death Prior to the 11/14/20 EUA Data Cut-Off?	Source for Pfizer's Knowledge of the Death
11521085	26-Aug-20	27-Aug-20	YES	Subject's Case Report File, Page 118 Aug-27-2020 09:33:16.[12]
12313972	28-Sep-20	01-Oct-20	YES	Subject's Case Report File, Oct-01-2020 16:07:36 page 149-150, Oct-01-2020 16:08:33 page 156.[13]
10661350	3-Nov-20	10-Nov-20	YES	Subject's Case Report File, Nov-10-2020 13:41:45 page 121, Nov-10-2020 13:41:02 page 122.[14]
10811194	4-Nov-20	11-Nov-20	YES	Subject's Case Report File, Nov-11-2020 15:19:14 page 343, Nov-12-2020 07:51:29 mentions 11Nov202 as the date of notification of death.[15]

The examination of the CRFs for the remaining 32 deaths did not reveal any additional notifications of death prior to the November 14, 2020, data cut-off date. (Reference Appendix A.) Our investigation confirmed that Pfizer-BioNTech relied on the data entry of the death notification in the CRF as perhaps the sole determinant used to include a death as reportable. However, our investigation of publicly available records at that time could not elucidate why the other deaths were not reported.

Nonetheless, the September 2023 Pfizer-BioNTech data released by the FDA introduced a document named '125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf,'[16] which included information revealing that Pfizer-BioNTech was, in fact, informed of two additional deaths in the

BNT162b2 arm of the trial well before the EUA data cut-off date, and that Pfizer-BioNTech did not disclose those deaths to the FDA. If the deaths had been disclosed in the EUA submission, they would have shown that the BNT162b2 mRNA COVID vaccine intervention did not reduce deaths.

Subject 11141050[17] from Alliance for Multispecialty Research LLC , Newton, Kansas[18], in the vaccinated arm of the study, died on October 19, 2020. Contrary to Pfizer-BioNTech's clinical trial protocol, neither Polack et al., nor the EUA submission documentation, nor the VRBPAC meeting on December 10, 2020[19], disclosed this patient's death.

The death occurred well before the data cut-off date of November 14, 2020. The public lacks access to any of the original clinical trial records, specifically Pfizer Safety's Vaccine SAE Reporting Form for subjects. However, from the patient narratives (Pfizer, 2023, p. 71), it is evident that the emergency contact confirmed on the day of death (October 19, 2020) that the subject had died. The narrative documents further state that the subject had an autopsy, determining the cause of death to be 'sudden cardiac death.'

Upon reviewing this subject's Case Report Form (CRF), I found the specific diagnosis 'sudden cardiac death' was mentioned on December 9, 2020.[20] On page 71 of this subject's CRF, the date of death notification was November 25, 2020. Since the clinical site had been informed by the emergency contact on the day the patient died, we know there was a 37-day delay in recording this death in the CRF, violating Pfizer's trial protocol. As this death occurred well before the data cut-off date of November 14, 2020, and was known to Pfizer on November 25, 2020, there was ample opportunity to disclose this subject's death, and possibly the autopsy results, at the December 10, 2020, VRBPAC meeting.

Compound: PF-07302048; Protocol: C4591001 **Page 71 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

I also want to highlight another undisclosed death of a vaccinated subject. Subject 11201050, from Meridian Clinical Research LLC, Savannah, Georgia, died on November 7, 2020. The patient narratives explicitly state that the clinical site received notification of the subject's death on November 7, 2020, from her husband (Pfizer 2023, p. 75). This information is further supported by documentation found in that patient's CRF clearly stating that the death notification occurred on November 7, 2020.[21]

Given these established facts, it is puzzling that the death of this subject was not included with the other data to the FDA when seeking EUA. Moreover, it was not disclosed by the clinical trial investigators to the regulators during the December 10, 2020, VRBPAC meeting (Vaccines and Related Biological Products Advisory Committee, 2020). This is particularly perplexing as the death occurred and was acknowledged as known before the November 14, 2020, data cut-off date.

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1120	**Site Name:** (1120) Meridian Clinical Research
Subject No: 11201050	**Subject Initials:** ---
Generated By: (b) (4)	**Generated Time (GMT):** 29-Mar-2021 11:09

eCRF Audit Trail History

Death Details		
1.	Date of Collection / Notification of Death:	Nov/7/2020
Cause of Death		
2.a	Cause of Death Status:	PRIMARY CAUSE OF DEATH
	Cause of Death:	[cardiac arrest]

We have documentation in the publicly available Pfizer clinical trial documents that confirms the patients' loved ones promptly communicated the subjects' deaths to the clinical trial sites. However, in violation of legal requirements, the regulatory authorities were apparently not informed of these deaths within the specified time frame. The critical time period under scrutiny is the issuance of the EUA on December 11, 2020, which relied upon the clinical trial data collected through November 14, 2020. Beyond the ethical issues raised, which I have highlighted, there are legal obligations to promptly report deaths to local regulatory authorities, a practice essential for ensuring trial subjects' safety.

The public does not have access to records that would demonstrate the actual notifications of death for the other undisclosed deaths that occurred before November 14, 2020 — specifically, two BNT162b2-vaccinated subjects (11521497 and 10891073) and placebo subject 11561124. It is currently not possible to determine whether there were any additional errors in reporting during this period. Compelling Pfizer-BioNTech and the clinical trial sites to provide all available information is essential to establish the facts and a correct timeline.

During the December 10, 2020, VRBPAC meeting, one reason cited for vaccine approval was 'the known and potential benefits of the vaccine outweigh the known and potential risks of the vaccine when used for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older' (Vaccines and Related Biological Products Advisory Committee, 2020).

Patients who volunteered for the clinical trial likely did so, at least in part, in service of humanity. The failure to disclose the patients' deaths, despite timely notification by loved ones, constitutes a betrayal of their altruism and trust and deserves further investigation. Further, and even more notably, the omission of the two deaths from the vaccinated arm of the study at this critical juncture of EUA issuance raises substantial concerns about the overall safety reporting of Pfizer's clinical trial.

Accordingly, we ask:

1. Did the TGA know about the hidden deaths in the vaccinated arm of the trial that were not declared prior to the issuing of the EUA?
2. If the TGA did not know about these hidden deaths, had due diligence been followed by direct scrutiny of the trial data?
3. Alternatively, did the TGA instead choose to rely on the FDA, which in turn had relied on Pfizer?

In closing, we wish to make it perfectly clear: this letter, as you have seen, is copied to a number of others, but considering your responsibility in checking the evidence of efficacy is valid, these questions are specifically for you. We would appreciate an answer within fourteen days.

Sincerely,

Dr Jeyanthi Kunadhasan

MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)

Appendix A

1. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf
2. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf
3. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1152-11521497.pdf
4. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1089-10891073.pdf
5. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1039-10391010.pdf
6. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1127-11271112.pdf
7. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1021-10211127.pdf
8. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1136-11361102.pdf
9. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1097-10971023.pdf
10. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1156-11561160.pdf
11. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1252-12521010.pdf
12. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1140-11401117.pdf
13. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1084-10841266.pdf

14. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201266.pdf
15. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1129-11291166.pdf
16. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1036-10361140.pdf
17. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881139.pdf
18. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1156-11561124.pdf
19. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1168-11681083.pdf
20. https://phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1128-11281009-reissue.pdf
21. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1088-10881126.pdf
22. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1231-12314987.pdf
23. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1019-10191146.pdf
24. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1094-10941112.pdf
25. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1084-10841470.pdf
26. https://phmpt.org/wp-content/uploads/2023/08/125742_S1_M5_CRF_c4591001-1089-10891088.pdf
27. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1229-12291083.pdf
28. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1135-11351033.pdf
29. https://phmpt.org/wp-content/uploads/2023/06/125742_S1_M5_CRF_c4591001-1231-12315324.pdf
30. https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1207-12071055.pdf
31. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1027-10271191.pdf
32. https://phmpt.org/wp-content/uploads/2023/07/125742_S1_M5_CRF_c4591001-1131-11311204.pdf

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Footnotes

[1] ‘Pfizer 16+ Documents.’ *Public Health and Medical Professionals for Transparency*, Food and Drug Administration, 17 Feb. 2021, phmpt.org/pfizer-16-plus-documents/.

[2] ‘Australian Medical Professionals’ Society: A Society for Australian Medical Professionals.’ amps.redunion.com.au/. Accessed 31 Dec. 2023.

[3] Kunadhasan, Jeyanthi, et al. ‘Report 42: Pfizer’s EUA Granted Based on Fewer than 0.4% of Clinical Trial Participants. FDA Ignored Disqualifying Protocol Deviations to Grant Eua.’ *DailyClout*, 26 Sept. 2022, 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/.

[4] Kunadhasan, Jeyanthi, and Ed Clark. 'Report 76: Pfizer Had Data to Announce Its COVID-19 Vaccine's Alleged "Efficacy" in October 2020. Why Did Pfizer Delay the Announcement until November 9, 2020, Six Days after the 2020 U.S. Presidential Election?' *DailyClout*, 10 July 2023, dailyclout.io/report-76-pfizer-had-necessary-data-to-announce-its-covid-19-vaccines-alleged-efficacy-in-october-2020-why-did-pfizer-delay/.

[5] Michels, Corinne, et al. 'Forensic Analysis of the 38 Subject Deaths in the 6-Month Interim Report of the Pfizer/Biontech Bnt162b2 Mrna Vaccine Clinical Trial.' *International Journal of Vaccine Theory, Practice, and Research*, 17 Oct. 2023, ijvtpr.com/index.php/IJVTPR/article/view/86.

[6] Polack, Fernando, et al. 'Safety and Efficacy of the BNT162B2 Mrna Covid-19 Vaccine.' *New England Journal of Medicine*, nejm.org, 10 Dec. 2020, www.nejm.org/doi/full/10.1056/NEJMoa2034577.

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[11] Pfizer Site 1007 Cincinnati Children's Hospital Medical Center. '125742_S1_M5_CRF_c4591001-1007-10071101.Pdf.' *Public Health and Medical Professionals for Transparency*, phmpt.org, 1 June 2022, phmpt.org/wp-content/uploads/2022/06/125742_S1_M5_CRF_c4591001-1007-10071101.pdf.

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Australian Government

Department of Health and Aged Care

Deputy Secretary

Dr Jeyanthi Kunadhasan
Treasurer
Australian Medical Professionals' Society
41 Campbell Street
BOWEN HILLS QLD 4006

Dear Dr Kunadhasan

Thank you for your letter, dated 21 March 2024, concerning undisclosed deaths in C4591001 Trial.

First, I would like to clarify that while the Therapeutic Goods Administration (TGA) does work closely with international counterparts, including the US Food and Drug Administration (FDA), the TGA independently reviews data submitted as part of a submission to register a medicine or vaccine, and makes its own decision based on the Australian context. Questions pertaining to the FDA's conduct of its own investigations are best directed to the FDA itself.

Second, the TGA is not aware of any 'hidden deaths'. At the time of provisional approval, the interim report provided to the TGA included 6 deaths. This is articulated on page 29 of the Australian Public Assessment Report (AusPAR) for COMIRNATY (accessible at: www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf). Subsequently, the final report of the trial, with updated figures on safety outcomes including deaths over the 6-month double-blind period and subsequent open-label follow-up, has been provided to the TGA.

Large, multicentre clinical trials in humans present complex logistic challenges and despite preplanned protocols, detailed procedures and strict monitoring, similar errors and protocol deviations are commonly reported in clinical trials. These are not considered a breach of Good Clinical Practice or 'hidden deaths'. The subsequent reports or supplementary addenda capture or correct any missing or incorrectly reported data and if needed revised reports are issued.

Phone: (02) 6289 4200 **Email:** anthony.lawler@health.gov.au
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It is reassuring to note that, in this case, none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid. The accumulating published evidence over time continues to support the significant public health benefit of the safety and efficacy of mRNA vaccines, as well as an overwhelmingly favourable risk/benefit ratio.

I would like to emphasise that the TGA takes the issue of data integrity very seriously. It is not possible to audit all clinical trials routinely, however random or targeted inspections are conducted when appropriate. In addition, information is shared across various regulators where significant issues are suspected. In the case of this clinical trial, there has not been any evidence or suggestion of impropriety that would have required such action or revision of findings.

I thank you for your effort in corresponding and hope to have addressed your concerns.

Yours sincerely

Professor Anthony Lawler
Health Products Regulation Group

27 March 2024

6 April 2024

Professor Anthony Lawler - Deputy Secretary Health Products Regulation, Department of Health and Aged Care
Anthony.lawler@health.gov.au

Copied to:
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Re: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Dear Professor Lawler:

Thank you for your reply dated March 27, 2024.

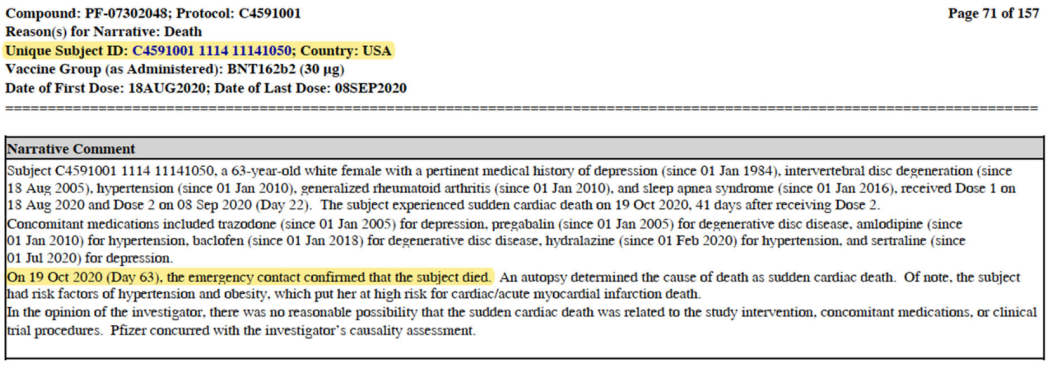
An essential aspect of pharmacovigilance involves continuously reassessing provided data. I wish to once again emphasise the two undisclosed deaths (that is, hidden deaths) at the time of considering Pfizer's COVID-19 vaccine emergency use authorization (EUA) in the United States in December 2020. The data that I highlight concerning timelines and date stamps may not have been available to the TGA at the time of Pfizer's December 2020 COVID vaccine EUA, but would have certainly been accessible from April 2021 onward at the issuance of the six-month safety report.

During its independent review of the data, the TGA team would have encountered the data I am about to discuss. I understand not all clinical trials can be audited extensively. However, because of the immense societal, economic, and psychological implications of the COVID-19 vaccination rollout, where people's livelihoods became dependent upon receiving the COVID-19 vaccine, the onus for ensuring data integrity would have been higher with the C4591001 trial.

At the six-month data review, the TGA team investigating the C4591001 trial data would have discovered a gross misrepresentation in the data presented to the public up to the data cut-off date of November 14th, 2020. Instead of the reported six deaths, with more deaths in the placebo arm (four deaths) compared to the vaccinated arm (two deaths), there were 11 deaths, with six deaths in the vaccinated arm compared to the five in the placebo arm. Though not statistically significant because of the small numbers involved, it would have been difficult to persuade the public to take a drug where more people died in the supposedly lifesaving intervention arm.

Subject 11141050 died on October 19th, 2020, well before the data cut-off date of November 14th, 2020. Documentation shows that the subject's emergency contact notified the clinical site of the death on the date of death, as per protocol requirements. The protocol also required the clinical site to notify Pfizer, via its vaccine SAE form, within 24 hours of receiving a death notification. However, the

clinical staff waited 37 days to enter this patient's death into Pfizer's records. Because of that delay, Pfizer did not submit this death as part of its EUA data, raising questions about the reasons for the delay and potential breaches of Good Clinical Practice.

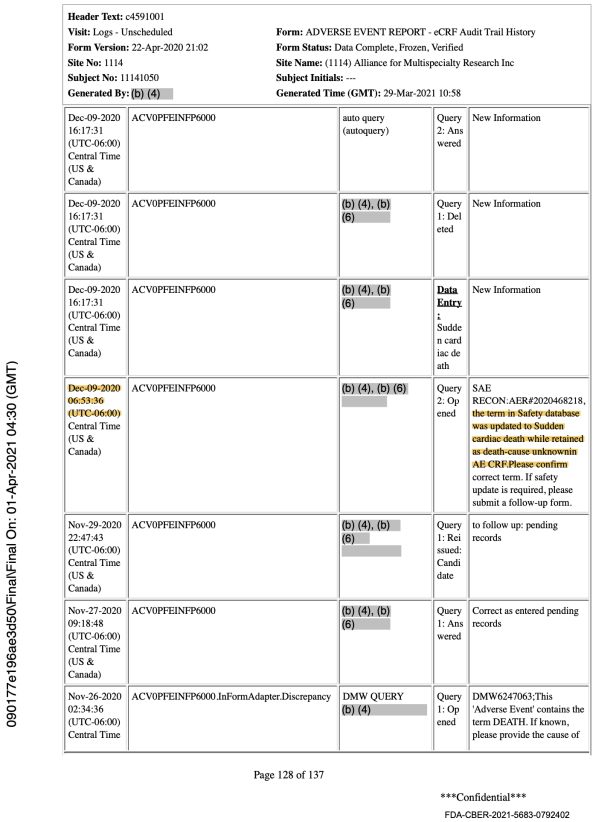


Compound: PF-07302048; Protocol: C4591001 **Page 71 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Further inquiry is needed into the TGA's conclusion that this undisclosed death in the vaccinated arm was not due to the vaccine. On what basis was this determination made? This patient had an autopsy result that is not publicly available. If the TGA has access to this autopsy result, it would be in the public interest for it to be available for independent scrutiny.

Per the autopsy, the patient died from 'sudden cardiac death,' with her known risk factors of hypertension and obesity putting her at high risk of cardiac-acute myocardial infarct. The clinical site staff entered the specific diagnosis of 'sudden cardiac death' into her notes on December 9th, 2020, the day before the Vaccine and Related Biologicals Products Advisory Committee (VRBPAC) meeting on December 10th, 2020, which suggests that this hidden death also had autopsy results available at the critical juncture of consideration of vaccine emergency use authorization.



Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1114 **Site Name:** (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sudden cardiac death	New Information
~~Dec-09-2020 06:53:36 (UTC-06:00)~~ Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020468218, ~~the term in Safety database was updated to Sudden cardiac death while retained as death-cause unknownin AE CRF.Please confirm~~ correct term. If safety update is required, please submit a follow-up form.
Nov-29-2020 22:47:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	to follow up: pending records
Nov-27-2020 09:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered pending records
Nov-26-2020 02:34:36 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6247063;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of

Page 128 of 137

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FDA-CBER-2021-5683-0792402

0901177e196ae3d50\FinalFinal On: 01-Apr-2021 04:30 (GMT)

https://www.phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf, p. 128

To be eligible for inclusion in this clinical trial, participants had to be deemed healthy based on medical history, physical examination (if required), and the clinical judgement of the investigator. The protocol allowed healthy participants with pre-existing stable disease – defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the six weeks before enrolment – to participate in the clinical trial. I cannot find a blood pressure reading in her publicly available case notes. Consequently, I can only assume the patient's high blood pressure, from which she had suffered since January 1st, 2010, was well controlled when she was admitted to the trial.

The patient weighed 74.1kg at a height of 165cm. Hence, her BMI of 27.2 put her in the overweight category, not obese. Without reviewing autopsy results, does the TGA believe that such anthropometric readings put a person at high risk of sudden cardiac death? She died 41 days after Dose 2 of the vaccine. On what basis did the TGA discount this intervention as a cause of death?

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1114
Site Name: (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/18/2020
2.	Weight:	[74.1]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.2]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[37.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf, p. 10

Subject 11201050 died on November 7th, 2020. Her husband reported her death to the clinical site on November 7th, 2020. Seventy-two days after receiving Dose 2 of the vaccine, she died in her sleep. No hospital visit or autopsy occurred. A coroner pronounced her death and listed the cause of death on her death certificate as cardiac arrest.

Compound: PF-07302048; Protocol: C4591001 **Page 75 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1120 11201050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 04AUG2020; Date of Last Dose: 27AUG2020

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

As no autopsy results were available, it remains unclear how the TGA concluded that this death could not be attributed to the vaccine. Would the TGA be similarly incurious for other 58-year-old women suddenly dying in their sleep after signing up for different experimental drug clinical trials? Pfizer documented receiving notification of her death on November 7th, 2020, well before the data cut-off date of November 14th, 2020. The reasons for not disclosing this death from the vaccinated arm at the December 10th, 2020, VRBPAC meeting or in the Polack *New England Journal of Medicine* publication need clarification.

I continue to highlight the hidden deaths in this trial to draw attention to a larger issue that my co-authors and I found in our forensic analysis peer-reviewed paper. Given the large number of clinical trial participants, the 38 deaths reported in the 6-Month Interim Report was surprisingly low (18% of the expected number). Did the TGA come to a similar conclusion in its scrutiny of the data? As of November 14th, 2020, 203 subjects had been lost to follow-up, (a higher number than the primary endpoint population of 170, from which the 95% efficacy claim came).

Additionally, delays in reporting the accurate date of subject deaths, known to Pfizer-BioNTech from the subjects' Narrative Reports, obscured the vaccine's cardiac adverse event signal. Adults aged 56 to 64 accounted for the first four deaths in the vaccinated arm of this trial. I have highlighted two of those patients, subjects 11141050 and 11201050, in this letter. Has the TGA investigated the clinical trial protocol violation of delayed death reporting in these cases?

I trust you agree that substantial safety reporting issues in this trial require further attention. I appreciate your ongoing correspondence and eagerly await your response to these concerns.

Yours sincerely,

Dr. Jeyanthi Kunadhasan
MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)

17 May 2024

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Re: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) Meeting on December 10, 2020.

Dear Professor Lawler:

I have not yet received a reply to my second letter to you dated 6th April 2024. Once again, I would like to draw the TGA's attention to the undisclosed deaths, especially in the vaccinated arm, in the C4591001 trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020. I believe my co-authors and I have identified serious safety issues based on our scrutiny of publicly available clinical trial documentation which formed the basis of the emergency use authorisation (EUA) of the Pfizer-BioNTech's COVID-19 vaccine approval in December 2020 in the United States, and subsequently in Australia.

The delayed reporting of vaccinated deaths in the study led to a misrepresentation of the deaths during the trial. Subsequently, Pfizer submitted incorrect death data to the U.S. Food and Drug Administration (FDA) when seeking EUA. In fact, the data through the cut-off date of 14th November 2020 were a gross misrepresentation of the trial results. Instead of the reported six deaths, with more deaths in the placebo arm (four deaths) compared to the vaccinated arm (two deaths), eleven deaths occurred, with six deaths in the vaccinated arm compared to five deaths in the placebo arm. Pfizer's delayed reporting of deaths also obscured the cardiac adverse event signal that was emerging in the vaccinated arm of the study.

In your 27th March 2024 reply to my first letter, you stated, "*It is reassuring to note that, in this case none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid.*".

I would like to further explore this statement and try to ascertain the evidentiary basis upon which the TGA reached this conclusion.

i) Subject 11141050, a 63-year-old female subject from the vaccinated arm of the study died unexpectedly 41 days after receiving Dose 2 of BNT162b2. The autopsy result, which was probably available prior to the December 10th VRBPAC meeting, concluded the cause of death was "sudden cardiac death". The trial investigator expressed, "…there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures". The trial investigators noted that the subject had risk factors of hypertension and obesity, which put her "at high risk for cardiovascular/acute myocardial infarction death". As noted in my previous letter, this subject weighed 74 kg (with a BMI of 27 – overweight) and had no blood pressure readings noted in her clinical records. I find it beyond credible that the TGA would accept that someone with these anthropometric readings is at risk of "sudden cardiac death". Her autopsy results are not publicly available. I implore the TGA to make the autopsy results publicly available for independent experts' scrutiny. https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 71.

ii) Subject 11621327, a 60-year-old male subject from the vaccinated arm of the trial, was found dead in his house by the police three days after Dose 1 of BNT162b2. The police went to his house to perform a welfare check and found his body cold with visible lividity. It is unknown whether an autopsy was done. According to the medical examiner, the probable cause of death was "progression of atherosclerotic disease". The trial investigator's opinion was, "…there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures". In the absence of autopsy results, and with a death that happened in such close temporal proximity to receiving the intervention, what was the evidentiary basis that the TGA relied upon to not include BNT162b2 as a possible cause of death? Please note that there was confusion amongst trial investigators indicated in the patient's medical records as to whether atherosclerosis could be a cause of death as the subject did not have any documented history of it. https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 123.

iii) Subject 10071101, a 56-year-old female subject from the vaccinated arm of the study, suffered cardiac arrest 59 days after receiving Dose 2 of BNT162b2. She may have been a resident at a nursing facility and was brought in intubated. She showed signs of anoxic brain injury, and treatment was aimed at improving neurological outcomes. This proved futile, and she died three days later. It is unknown if an autopsy was performed. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, as the death occurred 2 months after receiving Dose 2." What was the evidentiary basis that the TGA relied upon to concur with this statement?

https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 6.

iv) Subject 11201050, a 58-year-old female from the vaccinated arm of the study was found dead in her sleep by her husband 72 days after receiving Dose 2 of BNT162b2. She had no preceding symptoms or illnesses, so the death was unexpected. She was not seen in hospital, and no autopsy was performed. The death certificate listed cardiac arrest as the cause of death. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures." What was the evidentiary basis that the TGA relied upon to concur with that conclusion?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 75.

v) Subject 11401117, a 58-year-old male subject from the vaccinated arm of the study, suffered cardiac arrest 116 days after receiving Dose 2 of BNT162b2. He was obese, weighing 138.7 kg with a BMI of 38. His comorbidities included coronary artery disease, hyperlipidaemia, hyperglycaemia, and hypertension. His was a witnessed cardiac arrest, and he experienced seizure-like activity, collapsed, and received bystander cardiopulmonary resuscitation. Despite resuscitation efforts by the bystander and the emergency department, he died that day. No autopsy was done. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to underlying comorbidities." I am sure you would appreciate that a significant proportion of the Australian population has similar comorbidities. What was the evidentiary basis that the TGA relied upon to dispositively conclude, in the absence of an autopsy, that this sudden death could not be due to the novel experimental medical intervention but, instead, comorbidities alone?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 105.

vi) Subject 11361102, a 76-year-old male subject from the vaccinated arm of the study, died of cardiac arrest 30 days after receiving Dose 2 of BNT162b2. He had collapsed whilst on a walk, received cardiopulmonary resuscitation, and was found to be in ventricular fibrillation by emergency medical services. Resuscitative efforts proved futile, and he died. It is not known if an autopsy was done. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures". What is the evidentiary basis for the TGA to concur with this opinion in the absence of an autopsy?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 101.

vii) Subject 11271112, a 53-year-old male subject from the vaccinated arm of the trial was found sitting, slumped forward and dead by his mother in the laundry 85 days after receiving Dose 2 of BNT162b2. An autopsy was performed, but

results were not available at the time the trial investigator examined his case. His comorbidities included hypoglycaemia, chronic obstructive pulmonary disease, and a myocardial infarction in 2008. The preliminary cause of death was cardiopulmonary arrest. In the opinion of the investigator, "…there was no reasonable possibility that the cardiopulmonary arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather to underlying cardiac disease." With an autopsy result still pending, how could this conclusion be reached? What was the evidentiary basis that the TGA relied upon to concur?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 81.

viii) Subject 10391010, an 84-year-old male subject from the vaccinated arm of the study, had a witnessed loss of consciousness 70 days after Dose 2 of BNT162b2. His family attempted resuscitation but it was unsuccessful, and he died. He was not taken to the hospital or the physician's office. No autopsy was performed. His comorbidities included hypertension, hyperlipidaemia, carotid artery stenosis, and coronary artery disease. He had a right carotid stent placed in 2016. He had regular follow-ups with his primary care physician and had no reported events or complications prior to his death. The trial investigators ascribed cause of death to arteriosclerosis and hypertensive heart disease. In the opinion of the investigator, "…there was no reasonable possibility that the arteriosclerosis and hypertensive heart disease was [sic] related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to cardiovascular disease." What was the evidentiary basis that the TGA relied upon to concur, especially in the absence of an autopsy result?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 26.

ix) Subject 11311204, an 84-year-old male, was initially in the placebo arm of the trial. When the trial was unblinded, he went on to receive BNT162b2. He died of cardiopulmonary arrest 25 days after receiving Dose 1 of BNT162b2. There was documentation of worsening aortic stenosis 10 days prior to his death, and he required hospitalisation. He had an angiogram, and a stent was recommended; but the cardiologist did not feel it was urgently needed. He was discharged home three days prior to his death. However, at home, he took a nap and was found dead by his wife. No autopsy was done. The death certificate stated the cause of death to be cardiopulmonary arrest secondary to a cerebrovascular event. In the opinion of the investigator, "…there was no reasonable possibility that the worsening aortic stenosis and cardiopulmonary arrest were related to BNT162b2, concomitant medications, or clinical trial procedures". This subject had gone through the trial uneventfully in the placebo arm, had a sudden deterioration 15 days after receiving Dose 1 of BNT162b2, and died 25 days after receiving Dose 1 of the vaccine. What was the evidentiary basis that the TGA relied upon to determine that this sudden deterioration and demise could not be due to the studied intervention (BNT162b2), especially in the absence of an autopsy?

https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 93.

x) Subject 11291166, a 78-year-old female from the vaccinated arm of the study, was found dead in her apartment by her neighbours, because of the odour, 128 days after receiving Dose 2 of BNT162b2. Her son, who had been alerted by the neighbours, found a large amount of blood and fluids pooled on the floor around her body. Her skin was mottled, bruised, and rigid. Her actual death date is unknown. No autopsy was performed, with the medical examiner reporting her cause of death as myocardial infarct. Her comorbidities were hypercholesterolaemia, peripheral vascular disease, and hypertension. She had been on a cholesterol-lowering drug since 2017. In the opinion of the investigator, "…there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but related to hyperlipidaemia". Again, in the absence of an autopsy, what was the evidentiary basis for the TGA to accept this conclusion so dispositively?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf page 89

When one looks at the deaths overall in the trial, the vaccinated arm had 21 deaths, and only three of them (subjects 11141050, 11271112, and 11351033) had autopsies done. One autopsy resulted in a diagnosis of sudden cardiac death (subject 11141050), and the other two reports are still not available. I can understand autopsies not being done for certain patients who had a period of illness prior to dying. However, 10 of the 21 deaths in the vaccinated subjects occurred in those who were found dead or suffered sudden adult death, as highlighted above. Of those 10, only two (subjects 11141050 and 11271112) had reported autopsies done, with only one result (subject 11141050 - sudden cardiac death) made available.

There were 17 deaths in the placebo group, and only four (subjects 11521085, 11561124, 11681083, and 12314987) had autopsies. Of these, two (subjects 11561124 and 11681083) listed a cause of death. The other two results are still not available.

Based on the cases I have highlighted, I find it difficult to accept the statement in your letter dated 27th March 2024, "*It is reassuring to note that, in this case/ none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid."* I hope you can appreciate that I am continuing to highlight the substantial efficacy and safety issues in this trial despite reputational, regulatory, financial, and personal risk to myself. I am doing so because I want to continue to uphold my oath and code of conduct.

I hope to receive a reply from you within 14 days.

Sincerely,

Dr Jeyanthi Kunadhasan
MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)