6th April 2024

To the Committee Secretary, Senate Standing Committees on Community Affairs

Re: Inquiry into Excess Mortality

My thanks to the Committee for the invitation to provide a submission to this important Inquiry.

According to the terms of reference, my submission will *'address the factors contributing to excess mortality in 2021, 2022 and 2023'* and will present evidence for the mechanisms supporting the Covid 19 vaccines as a likely key contributing factor. My submission will make recommendations on how to address this preventable driver of excess mortality.

I specifically submit to the Committee that excess deaths are likely to be in large part related to adverse events from the Covid 19 vaccines, including the phenomena of Vaccine Associated Enhanced Disease (VAED).

Vaccine Associate Enhanced Disease

"A syndrome of "disease enhancement" has been reported in the past for a few viral vaccines where those immunized suffered increased severity or death when they later encountered the virus or were found to have an increased frequency of infection. Animal models allowed scientists to determine the underlying mechanism for the former in the case of Respiratory syncytial virus (RSV) vaccine and have been utilized to design and screen new RSV vaccine candidates. Because some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models, this is a particular concern for SARS-CoV-2 vaccines. To address this challenge, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration (BC) Safety Platform for Emergency vACcines (SPEAC) convened a scientific working meeting on March 12 and 13, 2020 of experts in the field of vaccine immunology and coronaviruses to consider what vaccine designs could reduce safety concerns and how animal models and immunological assessments in early clinical trials can help to assess the risk." Emphasis added. Consensus summary report for this CEPI/CE March 2020 meeting is attached as Appendix A and further detail can be found at https://brightoncollaboration.us/brighton-collaboration-cepi-covid-19-web-conference/

The Brighton Collaboration VAED working group was formed in March 2020 and included members with expertise in basic science, virology, animal models, immunology, vaccinology, vaccine safety, clinical care, clinical research, public health, regulatory science and ethics. This working group of experts developed the Brighton Collaboration Case Definition of the term "Vaccine Associated Enhanced Disease", which was published in January 2021 in the journal Vaccine following *"exhaustive review of the literature and expert consultations"* as well as "*peer review by the Brighton Collaboration Network and by selected Expert Reviewer prior to submission".* The Case Definition and Guidelines are attached as Appendix B.

My review of the ABS Provisional Mortality Statistics on excess mortality, as well as the publications authored by the Actuaries Covid 19 Excess Mortality Working Group; has led me to form the opinion that VAED and other potential mechanisms for Covid 19 vaccine related mortality have not been adequately examined and the Brighton Collaboration expert Guideline has not been followed.

I will summarise several of the important points found in the expert case definition for VAED, with commentary of my opinions for the consideration of the committee.

"All cases of vaccine failure should be investigated for VAED. Vaccine failure is defined as the occurrence of the specific vaccine-preventable disease in a person who is appropriately and fully

vaccinated, taking into consideration the incubation period and the normal delay for the protection to be acquired as a result of immunization"

The Covid 19 Vaccination program in Australia could perhaps be best characterised as one of 'vaccine failure' whereby the overwhelming majority of the population contracted Covid 19, sometimes multiple times, despite being vaccinated. According to the Brighton Collaboration guideline, public officials ought to have carefully investigated all cases of vaccine failure, instead of reassuring the public that breakthrough infections were common and an expected phenomena in a highly vaccinated population.

The Case Definition for VAED:

1. **Is an illness that occurs in persons who receive a vaccine and who are subsequently infected with the pathogen that the vaccine is meant to protect against.**
2. VAED may present as severe disease or modified/unusual clinical manifestations of a known disease presentation. The illness presumably is more severe or has characteristics that distinguish it from illness that might occur in unvaccinated individuals.
3. VAED may involve one or multiple organ systems.
4. VAED may also present as an increased incidence of disease in vaccinees compared with controls or known background rates.

The following outcomes would be concerning for VAED or VAERD in a person with confirmed infection:

a. Death. This would be particularly concerning if death occurs in person without other risk factors for mortality (note phase I-II trials with selected healthy population) or if it occurs at higher rates than expected.
b. Hospitalization, including hospitalization above expected rates.
c. Worsening or clinical deterioration over time, particularly, although not exclusively, if differing from the anticipated natural course of the disease.
d. Prolonged clinical course compared to natural disease.
e. Complications of acute disease, new morbidities or new diagnoses subsequent to natural infection post-vaccination (for example higher rate of MIS-C or MIS-A)

Examination of excess deaths by vaccination status and timing is therefore and according to this expert Guideline, absolutely imperative for the committee to review as part of this Inquiry.

The Guideline further states that:

"*Recognizing VAED in an individual patient is particularly challenging. VAED might be identified first as a vaccine failure. The clinical presentation may be variable within a spectrum of disease that ranges from mild to severe, life threatening, with or without long term sequelae, to fatal.*"

Although the overall case fatality rate for Covid 19 remained low and well under 0.5% throughout the pandemic, it was noteworthy that most states did not publicly release data on ICU admissions and deaths by vaccination status, and the Federal Government did not publish this important data https://www.aap.com.au/factcheck/truth-a-casualty-in-australian-covid-vaccination-deaths-claim/ NSW published this data only until June 2022. For several months this data demonstrated that a majority of Covid 19 related ICU admissions and deaths were in the vaccinated population, eg https://www.health.nsw.gov.au/Infectious/covid-19/Documents/weekly-covid-overview-20220611.pdf

Instead of carefully evaluating each of these Covid 19 cases, ICU admissions and Covid related deaths in vaccinated individuals for VAED; public health officials stated - *"Cases that are fully vaccinated represent vaccine breakthrough events. Breakthrough infections are expected among people who are fully vaccinated. A breakthrough infection is when someone tests positive for COVID after being fully vaccinated, regardless of symptoms. It is expected that the level of 'breakthrough infections' among those vaccinated will rise as vaccination coverage increases, but this does not mean the vaccines are not working."* https://www.health.gov.au/sites/default/files/documents/2022/05/foi-3597-release-documents-covid-19-related-deaths.pdf

Disregard of the expert Guideline with respect to monitoring for outcomes by vaccination status is highly alarming and it is incumbent upon this Committee to examine excess mortality by vaccination status in these circumstances.

In addition to VAED, other adverse events following vaccination and resulting in death ought to be examined by the Committee.

To date more than 1000 deaths have been reported to the TGA where in the opinion of the reporters (in the majority of reports a medical professional or State Health Department) Covid 19 vaccination was the suspected likely cause for the death. Passive reporting systems such as the DAEN are acknowledged to represent underreported figures for adverse events, and this is supported by a comparison of AusVax Safety active data with the DAEN case reports for the Covid 19 vaccines, which suggests a 200-fold underreporting rate of suspected adverse events; see FASOC document attached to this submission as Appendix 3.

According to the TGA the majority of these deaths occurred within 6 weeks or less from vaccination and 28% within one week of vaccination https://www.tga.gov.au/sites/default/files/2023-05/foi-4205-01.pdf which is highly suggestive of likely causality based on the temporal relationship.

The TGA has 'linked' only 14 of those more than 1000 reported deaths to the Covid 19 vaccines. The TGA does not provide to the public the details of their process for 'linking' deaths after vaccination to the vaccine. I attempted to obtain this information, for example the TGA causality assessment reports, through the Freedom of Information process and experienced an unexpectedly arduous process to obtain these reports.

My first request was for the causality assessments for each of the 900 or so deaths at the time. I had numerous circular discussions with the TGA FOI team until ultimately, I negotiated for the release of a selection of just 10 reports, having been required to gradually reduce this number throughout the consultation process.

The information on these reports is listed below. Only the first case, 729139, has been accepted to be causally linked to the vaccines by the TGA.

" FOI 3727-01. Case 729139. 21 year old female, Myocarditis, cardiac arrest, cardiogenic shock, femoral artery embolism, spinal chord infarction and others. Spikevax.

Decision: Causality assessment outcome: WHO=U Awaiting (redacted)

FOI 3727-02. Case 724023. 9 year old cardiac arrest

Decision: [Causality assessment outcome]

FOI 3727. Case 718277. 24 year old female. Cardiac arrest, Comirnaty

Decisions: Causality

FOI 3727-04. Case 631625. 19 year old female. Cardiac Arrest, Comirnaty.

Decisions: Unlikely causality- Update should any further pathology become available.

FOI 3727-05. Case 719838. 7 year old male, cardiac arrest. Comirnaty.

Decisions: Causality. WHO=U

FOI 3727-06. Case 644148. 21 Year old male. Comirnaty.

Decisions: ? Causality

FOI 3727- 08. Case 644735. 44 year old female, AstraZeneca.

Decisions: Unlikely causality

FOI 3727- 09. Case 647663. 14 year old female, Spikevax

Decisions: Unlikely Causality

FOI 3727- 10. Case 717851. 46 year old male, cardiac arrest. Comirnaty

Decisions: Unlikely Causality"

Another FOI request for the details of a 5-year-old reported to have died from eosinophilic myocarditis contains the following information-

"FOI 4313-01. Case 734187. 5 year old male. Myocarditis, abdominal pain, cardiac arrest. Comirnaty

Decisions: Causality assessment outcome: WHO= U"

It is extremely alarming to note that these causality assessment reports do not appear to have been completed with the detail and rigour required according to the WHO Manual for Causality assessment of an adverse event following immunization. It is also extremely alarming that VSIG (Vaccine Safety Investigation Group) was not convened to provide independent expert input regarding the causality assessment of these reported deaths (with the exception of Case 729139), when this was required for each serious unexpected event according to the VSIG working group instructions. https://www.tga.gov.au/sites/default/files/2023-01/foi-4029-06.PDF

Consequent to my speaking publicly about Covid 19 vaccine safety issues and my involvement in instigating a class action seeking compensation for Covid 19 vaccine injuries and bereavements, I have come to have first-hand knowledge of the circumstances of multiple deceased persons through information provided by their family members who have contacted me. In all cases the family members report these deceased persons being healthy and well prior to vaccination, the loved one dying soon after vaccination, with no other likely cause for their death and that the death was untimely and unexpected.

The family members report that TGA has declined to 'accept' the deaths as causal for a variety of reasons, for example stating that further information is being awaited from the coroner, or that young people die every year and that deaths after vaccination are coincidental with a population wide vaccination campaign.

These deaths that I have knowledge of have occurred in people who were well, with no alternative explanation for their deaths, most within days to weeks after vaccination.

By way of examples- 23 year old [redacted], whose parents [redacted] made their emotional submission to the Long Covid Inquiry, which information is now on the public record. Despite having a well-controlled non palliative chronic medical condition and dying unexpectedly soon after vaccination, [redacted] parents were advised that since her neurological adverse event is not known to be related to the vaccination, that her death is also considered unrelated.

Another is a healthy man in his 50's who developed malignant hypertension soon after vaccination and within weeks died of an intracranial haemorrhage. The medical expert provided the opinion to the coroner that since he did not die of TTS, and TTS being at that time the only accepted cause for death after vaccination, that this man did not die from the vaccine; despite no alternative explanation for his unexpected death.

Another mother whose daughter was found dead at home 3 weeks after her vaccine, after waiting over 12 months for the coroner report was advised a cause of death of sedation due to her long-term medication for anxiety and depression leading to coma and death. Her mother asked the coroner why detail was provided about her appointment with her GP three weeks prior to death where she discussed her anxiety, but there was no mention of the fact that she received her mRNA vaccine at that appointment also. The mother was advised this was due to the coroner deciding the vaccine had nothing to do with her death.

Another father who's 17-year-old healthy son died one month after vaccination received the report that the cause of death was 'unascertainable', and despite an enlarged heart and focal myocardial necrosis on autopsy that there was no *definite* evidence of myocarditis; and therefore, the vaccine was not confirmed to be the cause. Again, there was no more likely explanation and no cause of death provided.

The case of 23-year-old [redacted] is a further tragic example. Her mother [redacted] arrived to find her daughter's body on the pavement at her workplace following an unsuccessful resuscitation attempt after she was found deceased in her car at work. [redacted] was diagnosed as dying from asthma, despite the fact that she had not ever had a serious asthma attack and had been diagnosed with only episodic viral induced reactive airways previously. It was also despite the fact that she had her mRNA vaccine just weeks before she died, and had been unwell with allergy symptoms and dyspnoea which started soon after her vaccination. She later presenting to hospital with dyspnoea just days before she died. She had no wheeze on examination according to the hospital records. She did not undergo an ECG or troponin blood test. She was discharged and died suddenly days later. On autopsy focal myocardial necrosis and myocardial inflammatory cell infiltrate on histology was found as well as cardiomegaly on autopsy, and only mild lung hyperinflation as might be anticipated following CPR efforts; which would make a diagnosis of myocarditis, not status asthmaticus, more likely. However, as asthma was provided as the cause of death, Raelene has been assured her daughter's death was not due to the vaccine, as the vaccine 'does not cause asthma'.

I could go on for many more pages regarding horrific stories of the deaths and serious events after vaccination. Spouses and parents needing to perform CPR on their loved one whilst waiting for an ambulance. The incomprehensible grief of finding a teenager dead in their bed. When the TGA and other officials refuse to acknowledge that vaccination is the most likely cause for the death these families are subjected to dismissal and belittling of their concerns. The result of this is that these people now suffer the significant psychological trauma of being treated in this manner and are being denied compensation claims for the Government Covid 19 compensation scheme.

Deaths due the vaccines have been accepted by the TGA for myocarditis, Guillain Barre syndrome, acute disseminating encephalitis, transverse myelitis, central venous thrombosis and thrombosis with thrombocytopenia syndrome.

Based on my professional and clinical knowledge and education, this is conclusive evidence of the TGA's own determination that the vaccines may cause death due severe neurological adverse events, immunologically mediated clotting disorders and cardiovascular system inflammation of a likely autoimmune pathology.

Based on my clinical knowledge it must follow that the vaccines can cause a variety of immunological, autoimmune, neurological and clotting conditions including of a serious nature resulting in death. It is my opinion that the TGA ought to have expanded their efforts to review adverse events of all clotting, autoimmune, neurological and cardiac events including any deaths resulting from such diagnoses, as all these events have a confirmed causal pathological mechanism by the TGA's own evaluation.

A class action on behalf of injured and bereaved persons has been filed in the Federal Court, NSD349/2023, with statement of claim (FASOC) attached to this submission. The statement provides further particulars to the claim that the vaccines may have caused the excess deaths noted in 2021, 2022 and 2023, including as a consequence of myocarditis, increased cancer risk, neurological and vascular events, VAED and many other severe adverse events for which an increased Proportionality Reporting Ratio was found in the passive adverse event monitoring and reports to the DAEN.

I request the Committee carefully consider any submissions by family members who report deaths of their loved ones after vaccination. I request the Committee carefully review any submissions by family members who report deaths after Covid infection in vaccinated individuals. I further request and that a thorough review of the timing and number of vaccine doses in relationship with deaths be undertaken.

I request the Committee recommend an immediate suspension of Covid 19 vaccines and mRNA vaccines until these safety issues including risk of death is examined in further detail in order to address this preventable driver of excess mortality.

Dr Melissa McCann