13 December 2023

COVID-19 Response Inquiry Panel

Dear Panel Members,

Submission and Evidence to the Commonwealth Government COVID-19 Response Inquiry (the "Inquiry") - Engagement with families by health authorities and management of adverse event reports during COVID-19

I provide this submission and evidence to the Inquiry as a private citizen.

I lost my father during the pandemic on 19 August 2021, most likely as a result of his first AstraZeneca (**AZ**) COVID-19 vaccination approximately three weeks earlier on 26 July 2021.

This submission addresses two aspects of the health system's response in relation to my father's death which need to be enhanced in managing future pandemics:

- The policy of hospital COVID-19 blanket bans on visitor attendance that stopped my family being with my father in hospital, with no alternative means being provided to us to speak to him again, and a lack of communication from the hospital to update us on his condition while conscious or as to any final words spoken.
- The publication of a Therapeutic Goods Administration (**TGA**) report denying any link between the AZ vaccine and my father's death notwithstanding his treating doctors considering his death triggered by the vaccine and repeated correspondence on this issue.

These aspects have long term repercussions.

Hospital COVID-19 blanket visitor bans had an ongoing impact on our family, and on other families who also lost family members during the same period. While the passing of a family member is a natural life event, being forced to abandon them in their time of need should not be.

The publication of reports denying any link between the AZ vaccine and my father's death potentially led to a loss, following an adverse event report, of the opportunity to identify a safety concern with a vaccine that could have fatal consequences. This could reduce public faith in adverse reporting systems which is essential to ongoing adherence to vaccine programs in a pandemic event.

Accordingly, I would urge the Inquiry to look into the:

- Imposition of blanket bans during COVID-19 on patients' family members remaining with or being able to visit loved ones.
- Engagement with patients' families when such blanket bans are imposed.
- Management by health authorities of adverse event reports for pandemic related vaccines.

There are lessons on such aspects that must be learned to enhance the management of future pandemics, in line with the stated goal and purpose of the Inquiry.

If these aspects are considered beyond the scope or focus of the inquiry, then there needs to be an inquiry extending to such aspects, which there has not been to date.

Blanket hospital visitation bans and engagement with families of patients during COVID-19

The Inquiry should consider how patients' families were engaged with during COVID-19 and the need for hospitals to do better in communication with families of deceased patients who were prohibited from being with loved ones due to COVID-19 restrictions.

In my family's case, we drove our father to Emergency at [redacted] on the morning of 17 August 2021 but were not allowed to stay with him due to COVID-19 restrictions at the time.

Despite numerous calls to the hospital that day we were not able to speak to any of his treating practitioners to obtain an update as to his condition, until an overnight phone call from an ICU doctor following which he was placed in a coma and onto a ventilator, from which he did not wake.

We were not given the opportunity to speak to my father, and were only allowed to visit him at end of life to turn off his life support machinery.

While family members would normally be able to be with a patient and comfort them during these difficult stages, and be aware and be able to enquire of their condition and treatment, we were deprived of this during COVID-19. Being able to know:

- How he was?
- Was he in pain?
- Was there anything that he was saying?

Being able to see, hear and respond to these things is something that we and other family members in a similar situation have lost and will never be able to get back. This left a hole in the ability of our family, and other families in a comparable situation, to deal with and ultimately seek closure with the passing of a family member.

In relation to the stated role for the Inquiry to consider how evidence informed decisions regarding interventions, while accepting the need for hospitals to manage the risk of spread of COVID-19, it is not clear what evidence supported our attendance in hospital at my father's end of life as being acceptable, however our earlier attendance while he was critically unwell but still conscious was not acceptable.

I had to battle for over a year with the hospital to have someone talk to us about how my father was before he was placed in a coma. While the Director of Medical Services ultimately acknowledged that the hospital had let us down in our requests, this was cold comfort given that by that time, none of his treating health professionals while he was conscious were available to speak to us.

Accordingly, the Inquiry should address:

- Blanket bans on patients' families remaining with, or being able to visit, loved ones (particularly when in a critical condition) until end of life.
- Lack of updates or information on patient status to family members during such bans.
- Hospitals not making available for meetings with family members the treating medical professionals of patients who have passed, to talk to their condition and any final words.

Management of COVID-19 vaccine adverse event reports (involving death)

The Inquiry should consider how the TGA manages serious adverse event reports involving death in respect of COVID vaccines and the express denial of any links between a death and a COVID vaccine (without qualification) despite evidence to the contrary.

As indicated above, my father passed away at [redacted] in [redacted] on 19 August 2021. He had received his first dose of the AZ vaccine approximately three weeks earlier on 26 July 2021 and began feeling unwell approximately one week after receiving the vaccine.

His cause of death was identified as multi-organ failure secondary to [redacted]. [redacted] is a very rare and potentially fatal hyper-immune response clinically resembling sepsis.

Following feedback received from his treating doctors in ICU and a lack of a credible alternative trigger for my father's [redacted], on 3 October 2021 I lodged an adverse event report to the TGA in relation to my father's case. The adverse event report also attached an article published in the BMJ (formerly the British Medical Journal) in July 2021 which linked [redacted] to the AZ vaccine in 3 cases.

Apart from an automated pro-forma response from the TGA following lodgement, I did not receive any follow up from the TGA.

My report made clear the reason for my request was not to discourage AZ vaccine use but rather, given [redacted]'s often fatal consequences, so that any potential connection between the AZ vaccine and [redacted] in my father's case was not lost, and if such connection existed, building awareness of this potential side effect and its early recognition, to prevent irreversible organ damage or death.

On 6 October 2021, I was contacted by the NSW Ministry of Health – Adverse Events Following Immunisation Team (**AEFI**), noting my referral to the TGA and indicating they had also notified my father's case to the TGA following a referral from the haematology team at [redacted].

On 25 February 2022, I received a phone call from a doctor in the haematology team at [redacted] advising that they believed my father's [redacted] was triggered by the AZ vaccine and requesting my consent (which I provided) to the publication of a case report on my father's [redacted] as part of a case series looking at autoimmune and haematological disorders linked to the AZ vaccine.

On 21 May 2022, I received a copy of a proposed final draft of the case series from the haematology team at [redacted], with the first case report in the case series referring to my father. In the case series the authors believed my father's [redacted] "to be triggered by the [AZ] vaccine due to a temporal correlation and a lack of other clear precipitants". I am not aware as to whether the case series was published.

In late 2022, I became aware of a COVID-19 Weekly Safety Report published by the TGA on 17 February 2022 which indicated in relation to four adverse event reports (including for my father) it had investigated that:

- The current evidence does not indicate that the vaccine caused [redacted].
- No causal link could be established between the AZ vaccine and [redacted].

On 18 December 2022, I emailed the TGA and requested it advise whether they spoke to my father's treating doctors at [redacted] (relevantly his haematologists) as part of its investigations and if so, how can the TGA reconcile its conclusions with those of the haematology team at [redacted] who treated the patient and believed his [redacted] was triggered by the vaccine.

On 22 December 2022, I received an email reply from the TGA which sought to clarify how the TGA investigates reports of adverse events following the use of vaccine and advising that, in my father's case, the TGA had shared my adverse event report with NSW Health who subsequently provided them with further information on my father's adverse event. The reply however repeated the stance that the evidence did not suggest a link to the vaccination (either at an individual or population level), while indicating that the TGA had still recorded my father's report as "causality possible" and continues to monitor rates of [redacted] reporting both within Australia and overseas.

I subsequently emailed the TGA on 6 January 2023 and 27 January 2023 to:

- Flag my struggle to reconcile the conclusion of the TGA in its February 2022 report and its recent email that the evidence did not suggest a link between my father's [redacted] and his AZ vaccination, with the conclusions of his treating haematologists that his [redacted] was triggered by the vaccine due to a temporal correlation and a lack of other clear precipitants.
- Indicate my concern that the statement in the TGA's report that "*current evidence does not indicate that the vaccine caused these events*" gives the wrong impression and is misleading.
- Urge the TGA to reconsider its assessment and published statements lest an opportunity to identify a safety concern (having fatal consequences) is lost which would adversely affect the public's faith in the function of adverse event reports, the lodgement of which is crucial to the identification of emerging safety concerns with a vaccine or medication.

Responses to my emails received from the TGA on 16 January 2023 and 3 February 2023 doubled down on its earlier response.

As highlighted in the March 2023 article in The Australian available here, we are not the only ones that have had similar struggles with health bureaucracies on such an issue.

Accordingly, the Inquiry should address:

- The lack of follow up by the TGA with persons making serious adverse event reports (particularly where involving death).
- No causal link findings by the TGA between vaccination and [redacted] despite findings by treating medical practitioners that vaccination triggered the adverse event (particularly where causing death).
- Statements made by the TGA in their publications (without qualification) which may give the wrong impression and mislead patients as to whether a link existed in any prior cases between vaccination and an adverse event, and lead to the loss of an opportunity to identify a safety concern (particularly one having potentially fatal consequences).

Please let me know if you have any questions or you would like to talk through the issues raised above. I have also prepared a detailed timeline addressing each of the above aspects which can assist such further engagement.

Yours sincerely

[redacted]