Submission to Commonwealth Government Covid-19 Response Inquiry

I am a research scientist (PhD) with over 25 years of experience working in Life Sciences, Medicine and Public Health. I have been concerned about the accuracy of data being presented by various levels of Government, Government Authorities and Public Health officials regarding case numbers, hospitalizations and deaths associated with SARS-CoV-2 infection, and the safety of the Covid-19 vaccines.

I have spent three years conducting independent research and have generated a substantial number of analyses that do not support the broad and generally unsubstantiated claims made by the Governments, Government Authorities and Public Health Officials to support the COVID-19 response.

The following document lists several items that I propose for inclusion within the framework of the Commonwealth Government Covid-19 Response Inquiry. I believe the requested investigations are vital given the central role of the information in informing the COVID-19 response. I request that the findings of the investigations are made available in sufficient detail for peer-review of all methods and interpretations.

Review of methodology for testing and classifying case numbers, hospitalizations and deaths associated with infection with SARS-CoV-2 infection.

A core component of evaluating the COVID-19 response is examining the impact COVID-19 infection has had on the health of the Australian population. Key to this is the accurate and reliable identification of health outcomes resulting from Sars-CoV-2 infection including infection rates, hospitalisations, admissions to Intensive Care Units (ICU), and deaths. The latter is, in turn, dependent on the availability of reliable and valid criteria for classifying COVID-19 cases.

It is recommended that the Covid-19 Response Inquiry include a full review of the available data regarding the suitability, validity and accuracy of the principal methodology used in the detection of COVID-19 infection, the polymerase chain reaction (PCR) test for COVID-19, a test touted as the gold standard for use in identifying COVID-19 cases, hospitalisations, and deaths.

This includes: a full review of research that properly establishes (1) the range of false positive and false negative rates for COVID-19 PCR tests conducted on asymptomatic and symptomatic individuals; (2) a review of whether these rates are acceptable for a "gold standard" diagnostic tool; (3) how methodological factors such as sample storage, processing, transport, temperatures and the number of amplification cycles used in the analyses of samples can impact the false positive and false negative rates, and (4) a clear determination of any cross-reactivity that the COVID-19 PCR test may have with other microbes or compounds.

It is also recommended that the enquiry review each testing site to examine (1) the specific methodological characteristics of each site (regarding all items listen in item 3 of the above paragraph) and (2) the adequacy of training of laboratory staff conducting the PCR tests or otherwise managing samples and/or results. These investigations are essential to an assessment of the accuracy and validity of the results from each testing site, and therefore to the accuracy and validity of the broader case counts etc.

It is recommended that the enquiry also include a review of the quality and validity of COVID-19 case and death classifications using the WHO recommended ICD code of U07.1 and U07.2. This includes a review of the false positive and false negative rates that results from the application of these codes, and other issues potentially affecting the accuracy, validity and clinical relevance of classifications of COVID-19 cases using these ICD codes.

Evaluation of the definitions of these two code definitions illustrates how their application may impact, and potentially inflate case numbers and the numbers of hospitalisations, ICU admissions and deaths.

Definition of U07.1 - individuals with 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, hospitalisation and/or COVID death, based on a positive test result alone. In the absence of symptoms, and a relevant estimate of the false positive rates of the PCR and other test used to identify COVID-19 cases, it is uncertain whether a case defined this way is valid and has any clinical significance at all. The application of this classification code may have inflated case counts substantially and engenders the hospitalization, ICU and death data potentially misleading and uninterpretable. This issue is exacerbated in NSW where the classification of cases, hospitalisations and

deaths has included back-capturing positive COVID-19 test results from 14 to 28 days prior to presentation at hospital, regardless of whether covid symptoms were present or whether an individual is currently registering as positive to the disease.

Definition of U07.2 = an individual who is suspected of having COVID-19 but laboratory testing for COVID-19 is inconclusive or unavailable and a clinical determination of COVID-19 has 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 viral pneumonia, and a myriad of vaccine injuries such as multi-inflammatory disease, myocarditis, TSSI, also has the potential to inflate case counts and health outcomes and engender a misinterpretation of data.

Review of Any Changes to Testing for Non-COVID-19 Infections with Similar Symptomatology
There has been claims that medical professionals were instructed not to test for influenza infection at certain periods during 2021 and 2022, regardless of symptom presentation, and to only test for COVID-19 infection. Such a directive may inflate the false categorisation of individuals as COVID-19 infections under ICD code U07.2 through restricting the ability to identify alternative diagnoses with over-lapping clinical presentation and may explain a drop in influenza cases and non-COVID-19 respiratory infections reported in 2021.

Review of the storage/management of genetic information generated via the conduct of PCR tests
Also recommended is a full review of the fate of genetic profiles generated during the conduct of each individual PCR test. Was all genetic information generated during the conduct of tests (except for the test's outcome) destroyed following the test? If not, why not, and what are the details of the information's storage and use following the test. Is there any evidence that the genetic information generated by these tests has been provided to anyone for uses other than for the determination of COVID-19 status?

Review of any payments paid to pharmacies, health professionals, and specialist doctors regarding the identification and management of covid 19 patients.
This includes a comprehensive review of (1) any payments paid to pharmacies, health professionals, and specialist doctors who were administering the vaccines and (2) any payments made to COVID-19 testing laboratories, medical and allied health professionals, clinics, hospitals, coroners, or any other person involved in the categorization of individuals as having COVID-19 infection.

Review of classification of vaccination status in public health and media reports comparing cases, hospitalisations, ICU admissions and death
Recommendation to review how SARS-CoV-2 cases were classified in public health reports involving COVID-19 vaccination status. A review of reports where vaccinated individuals (individuals who have had a COVID-19 vaccine at any time) were included in the unvaccinated or no-effective dose group, and how this categorisation impacted interpretations, is required.

Recommendation to re-evaluate differences in rates of infection, hospitalisation, ICU admission and death between unvaccinated (no dose) and vaccinated individuals using standardised methodology to identify cases (i.e. a current diagnosis of COVID-19 infection, excluding individuals previously classified as cases based on historical, unstandardised back-capturing of positive test results for periods of between 14 and 28 days) and following strict adherence to standardised classification criteria that do not include vaccinated individuals (who have received a covid-19 vaccine at any time), or people of unknown vaccination status, in the unvaccinated group/no dose group, and where the percentages of the comparative groups who become infected with COVID-19, or are hospitalised, admitted to ICU, or die "from/or with" COVID-19 are calculated based only on the individuals of known vaccination status.

Review of post-marketing pharmacovigilance by Therapeutic Goods Administration (TGA)
Request a review and report of the processes undertaken by the TGA to monitor the safety of the COVID-19 vaccines which were initially released on provisional approval and listed on the Black Triangle Scheme. The provision of detailed information around the TGAs processes, their findings, and ultimately their interpretations and decisions relating to the safety and full registration of the vaccines is essential to allow peer-review of their methodology and evaluations, and to ensure that people and not product is protected. The TGA is heavily sponsored by pharmaceutical companies (`95%) and was previously suggested to lack independence and to display processes that may be interpreted as protecting product over people

(https://www.health.wa.gov.au/Reports-and-publications/Ministerial-Review-Public-Health-Response-into-the-Adverse-Events-to-the-Seasonal-Influenza-Vaccine). The latter is particularly important in the framework of mandating provisional medications that are so classified for the very fact that the TGA has acknowledged that safety has not been fully established.

It is also indicated by the sheer number of Adverse Event Reports that list the Covid-19 vaccines as the suspected medicine that have been added to the Database of Adverse Event Notification (DAEN) since the release of the COVID-19 vaccines https://daen.tga.gov.au/medicines-search/. As of 15 December 2023, the TGA DAEN has a total of 612,167 adverse event reports (AERs) that have been listed in association with 10,164 medical terms across 52 years from 1 Jan 1971 to 1 Dec 2023. 44,050 of these AERs listed a cardiac disorder and 14,630 were associated with an outcome of death. AERs where Covid-19 vaccines are listed as the suspected medicine relate to only 11 of the 10,164 terms (0.1%) over a period from 1 Dec 2020 until 1 Dec 2023 but have contributed 139,606 of the AERs (22.8%) and 16,618 of the AERs including cardiac disorders (37.7%). For 1006 of the AERs listing COVID-19 vaccines as the suspected medicine, death was reported as an outcome. This is 6.9% of all deaths ever listed on the DAEN.

The review of AERs where COVID-19 vaccines is listed as a suspected medicine should include the following: (1) a summary and evaluation of the number of adverse events reported to the TGA; (2) a review of the total number of AERs listed in the internal Adverse Event Management System (AEMS) database including specification of the number with death as an outcome; (3) detail regarding the process of review of the AERs listed in the AEMS including the inclusion/exclusion criteria applied when determining which AERs will be submitted to the DAEN, how many AERs were excluded from the DAEN under each of exclusion criteria, where duplicates are indicated, the DAEN case number of the duplicate, and an outline of the demographics and adverse event terms associated with the AERs excluded from the DAEN; (4) an outline of data audit processes; (5) an outline of management of incomplete data (missing age, gender and/or adverse event data); (6) how deaths are reviewed and, to date, how many can be ruled out as being the result of the COVID-19 vaccination (7) a review of the protocols undertaken to evaluate the number and types of adverse events reported against the background of AER typically reported with the purpose of identifying safety signals; (8) the provision of detail regarding the tolerance limits and stopping criteria related to the assessment of safety signals, what has TGA done to date to assess safety signals, what they have observed and on what basis were safety signals, if found, ignored; and (8) what are the details of the product testing procedures, including tolerance limits and rejection criteria, and what was found in regards to quality.

Review of post-marketing pharmacovigilance by the National Centre for Immunisation Research and Surveillance (NCIRS)

AusVaxSafety is an active post-marketing pharmacovigilance program that collects data through a survey sent via text to individuals who receive vaccines at participating centres/clinics. Surveys are sent 3, 8 and 42 days after vaccination. The surveys collect information about: (1) whether one or more adverse events were experienced following vaccination; (2) whether the adverse event(s) resulted in the person seeking medical help and, what type of help was sort (phone advice, GP, visit to hospital emergency); (3) whether vaccination impacted routine activities, and (4) whether a number of specific, more generalised adverse events were experienced. Participants were also provided a free text box to provide further information. In addition to these general surveys, AusVaxSafety is working with the TGA and other government departments to conduct an Adverse Events of Special Interest (AESI) long-term follow up program that specifically tracks AESI such as anaphylaxis, myocarditis, and Thrombosis with Thrombocytopenia Syndrome (TTS).

Despite all the data being collected by AusVaxSafety and others, only a summary of the findings for the Day 3 survey has been provided on the AusVaxSafety website for the public for review. The Day 8 and Day 42 data have not been provided. Neither has any data relating to the free text response given with any of the three surveys, or any of the results of the AESI long-term follow up program, been provided by the NCIRS. The AusVaxSafety surveys have been being conducted since 2021 and the failure to provide access to the study findings is unacceptable.

Request a review of data collection processes and an outline of all findings to date for the day 3, 8, and 42 surveys and the AESI programs, as a matter of urgency. This should include a detailed provision of methodology, and access to adverse event data provided in the free text responses.