

IMPORTANCE OF COVID-19 VACCINATION & DEVELOPMENT OF BETTER SYSTEMS FOR MANAGEMENT OF UNCOMMON SUBSEQUENT ADVERSE EVENTS

The aim of this position statement is to

- reinforce the importance of COVID-19 vaccination, and of remaining up to date in line with the ATAGI recommended vaccination schedule, and of supporting global vaccine equity
- remind that part of ensuring the integrity of and confidence in the vaccination programme is the surveillance and management of uncommon adverse incidents following vaccination that may, or may not be related to vaccines
- encourage further development of guidelines and resources for Australian medical practitioners on the appropriate recognition and management of Adverse Events Following Immunisation (AEFIs) to complement TGA reporting
- encourage further development of a framework to support medical practitioner's recognition, assessment and development of protocols to manage rare serious acute and chronic adverse reactions following COVID-19 vaccination
- encourage the reporting of adverse events that follow, but may not be related to vaccination to the Therapeutic Goods Association (TGA).

Disclaimer

This position statement has been written with the best available evidence and was last updated on 7 July 2022. OzSAGE expert members collaborate to develop position statements (PS) on a variety of scientific matters in the public interest. OzSAGE provides position statements in good faith for general information. No individual or other entity may place reliance on this general position statement, which does not take into account personal or local circumstances. OzSAGE accepts no liability in publishing information position statements or for outcomes associated with the implementation of the general advice contained herein. OzSAGE strongly recommends continuous quality assurance activities and ongoing adaptation to the circumstances.

FUNDAMENTAL BENEFIT AND CRUCIAL IMPORTANCE OF VACCINATION

COVID-19 disease has serious acute and chronic consequences for many individuals. It is estimated that 20.7 million lives have been lost due to COVID-19 infection globally, all potentially preventable [i]. Vaccines significantly reduce hospitalisation, morbidity and mortality. The global rollout of COVID-19 vaccines has been and will remain a crucial

element in controlling the pandemic, along with the **vaccines plus strategy** ([LINK TO VACCINES PLUS POSITION STATEMENT](#))

DESCRIPTION OF AEFI, INCIDENCE and DEFICIENCIES in REPORTING SYSTEMS

As new variants emerge the effectiveness of current vaccines is expected to wane. Widespread vaccination can reasonably be expected to reduce the emergence of new variants. As of 26 June 2022, an estimated 12.1-billion doses of COVID-19 vaccines have been administered worldwide. This has provided adverse event data on vaccines with high confidence, especially from communities that have advanced vaccine adverse events monitoring systems such as the USA, EU and UK.

Adverse events following immunisation (AEFI) or vaccination may or may not be caused by the vaccine. There is a formal process for assessing adverse events that follow vaccination to determine if vaccination is likely to be causal or coincidental.

It is important to note that when a vaccine is administered to the whole population, there may appear to be a relationship with some adverse events, which are not in fact causally related.

COVID-19 vaccination is the largest adult vaccination program ever to have been undertaken, and General Practitioners do not have an easy referral path nor resources to manage AEFI. As we move into our 4th year of the pandemic it is clear such clinics and pathways should be available.

This will become more important going forward as more vaccines and doses are required for newer COVID-19 strains because a very small proportion of the population may experience an AEFI.

As with any intervention, decisions on vaccination must be made on the basis of a contemporary risk-benefit assessment. This decision-making process is a reality for clinicians, often in primary care, especially when dealing with people who have had one or two vaccine doses and had a serious adverse event, such as myocarditis. A decision on

timing or actually having a further dose needs a risk-benefit assessment.

Whilst most states have specialised paediatric clinics for assessing vaccine adverse events, the relevant infrastructure is not yet widely available to adults.

It is essential that sufficient adult vaccine reaction clinics be developed with adult medicine physicians subspecialised in immunology and vaccinology to provide the expertise needed to monitor and review AEFI in the adult population receiving vaccines.

The Therapeutic Goods Administration (TGA) issues weekly reports on AEFI [ii] accessible at <https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-23-06-2022>.

There is a wide spectrum of AEFI clinical symptoms and syndromes observed and reported by clinicians – some are anecdotal events with or without official causality ratings that are temporally related or reported in the literature. These events may include allergy and anaphylaxis, cardiovascular, neurological, rheumatological, haematological and autoimmune adverse effects. AEFI may be difficult to recognise in older people, where they may present as non-specific geriatric syndromes [iii].

Adverse reactions to vaccines in Australia are reported through a range of mechanisms and coordinated by the TGA which provides a crucial role in collating the adverse reactions and providing data on their website. If medical practitioners are not reporting all suspected AEFI, then it is more difficult to identify when there is a significant cause for concern for safety of a vaccine. TGA has regular meetings with counterparts in the WHO, US, UK and other countries, and keeps abreast of much larger datasets on vaccine safety than could ever be generated in Australia. Defining cases of specific AEFI is an emerging and complex area that needs international harmonisation, with useful resources collated through groups like the Brighton Collaboration.

AusVax Safety and the National Centre for Immunisation Research and Surveillance are monitoring and assessing reported adverse events following COVID vaccinations and overall, demonstrating that most reactions are mild and self-limiting [iv] [v].

Rarely, AEFI are serious and prolonged.

Australia is a member of the World Health Organisation Program for International Drug monitoring and pharmacovigilance research to collect sufficient information about the efficacy and adverse drug reactions of treatments used against COVID-19. Therefore, it is crucial that all adverse events are recorded and reported as quickly as possible. Optimising safety surveillance for COVID-19 vaccines is essential to ensure public confidence in vaccination programs [vi-viii].

As with other AEFI reporting from vaccines and therapeutics generally, reporting of AEFIs is voluntary in Australia and unfortunately the rate of reporting is likely to be very low [ix]. Unlike adverse drug events, AEFIs are notifiable conditions under the public health acts in most states and must be notified on diagnosis to the public health unit. The Australian Government does provide a no-fault compensation scheme for injuries resulting from a restricted range of adverse reactions following COVID vaccine [x].

BARRIERS TO REPORTING

Barriers likely contributing to under-reporting are many and include:

- The time it takes for GPs and medical specialists to register with their state reporting site first [takes about 5 minutes] and then to fill out all the fields to submit the report for a patient (minimum 10-15 minutes)– if a field is left out, the report does not proceed and can take longer.
- Reports not being made unless the reaction is considered “severe” or the patient is hospitalised.
- If the patient is hospitalised due the adverse reaction prior to seeing a GP this is left to hospital staff to report. This is highly dependent on staffing levels and currently they are in crisis. Hospital staff are not trained in reporting severe adverse reactions, which results in further delays.
- Medical practitioners sometimes dismiss symptoms, and by not validating patient concerns about potential reactions, leave patients feeling frustrated and perplexed.

- Difficulty assessing AEFI in patients who are managed as outpatients or via telehealth
- When patients become aware how to report their adverse reaction, they are happy to do so but significant parameters that a medical practitioner is more likely to provide may be omitted, for example a diagnosis, symptoms, and signs.

RECOMMENDATIONS FOR IMPROVEMENTS

- **CLINICIAN RECOGNITION AND REPORTING OF AEFI**
 - Continue to raise awareness of the importance of and how to report AEFI with COVID-19 vaccines
 - Collaborate with TGA and specialist colleges and societies to develop resources and education for medical professionals on recognition and reporting of AEFIs
 - Emphasise the importance of accurate reporting of AEFI reactions, including suspected possible unusual reactions
 - Identify barriers to reporting of adverse reactions and ensure that reporting processes are streamlined
 - Ensure medical and allied health professions codify adverse vaccine reactions using MedDRA terms
- **ASSESSMENT AND MANAGEMENT**
 - Develop harmonised state-wide protocols for recognising and treating serious or prolonged adverse vaccine reactions and specialist vaccine AEFI referral services in all jurisdictions. The Victorian and NSW adult referral services for AEFI to COVID-19 vaccines are potential models. In NSW, treating clinicians, relevant medical specialists and public health physicians work together to gather information to assess and advise on management of serious AEFI.
 - Government funding for establishment and operation of AEFI clinics for adults and children, with the greatest capacity required for adult clinics, as adults are 80% of the population.

- Protocols for 2nd or 3rd or subsequent vaccine doses when there has been a recognised adverse event following vaccination.
- Set up a national hotline for people who are unable to obtain support or help from local resources.
- Consumer Medicines Information resources about COVID19 AEFI information for patients



- CAPACITY BUILDING

- Encourage and fund research into future preventative interventions including alternate vaccines where spike-protein based vaccines are contraindicated or alternate formulations e.g. nasal or oral vaccine, if appropriate.
- Ensure medical curricula are up to date with emerging trends and practice requirements.
- Ensure funding for easily accessible resources and clinical pathways.

OZSAGE

