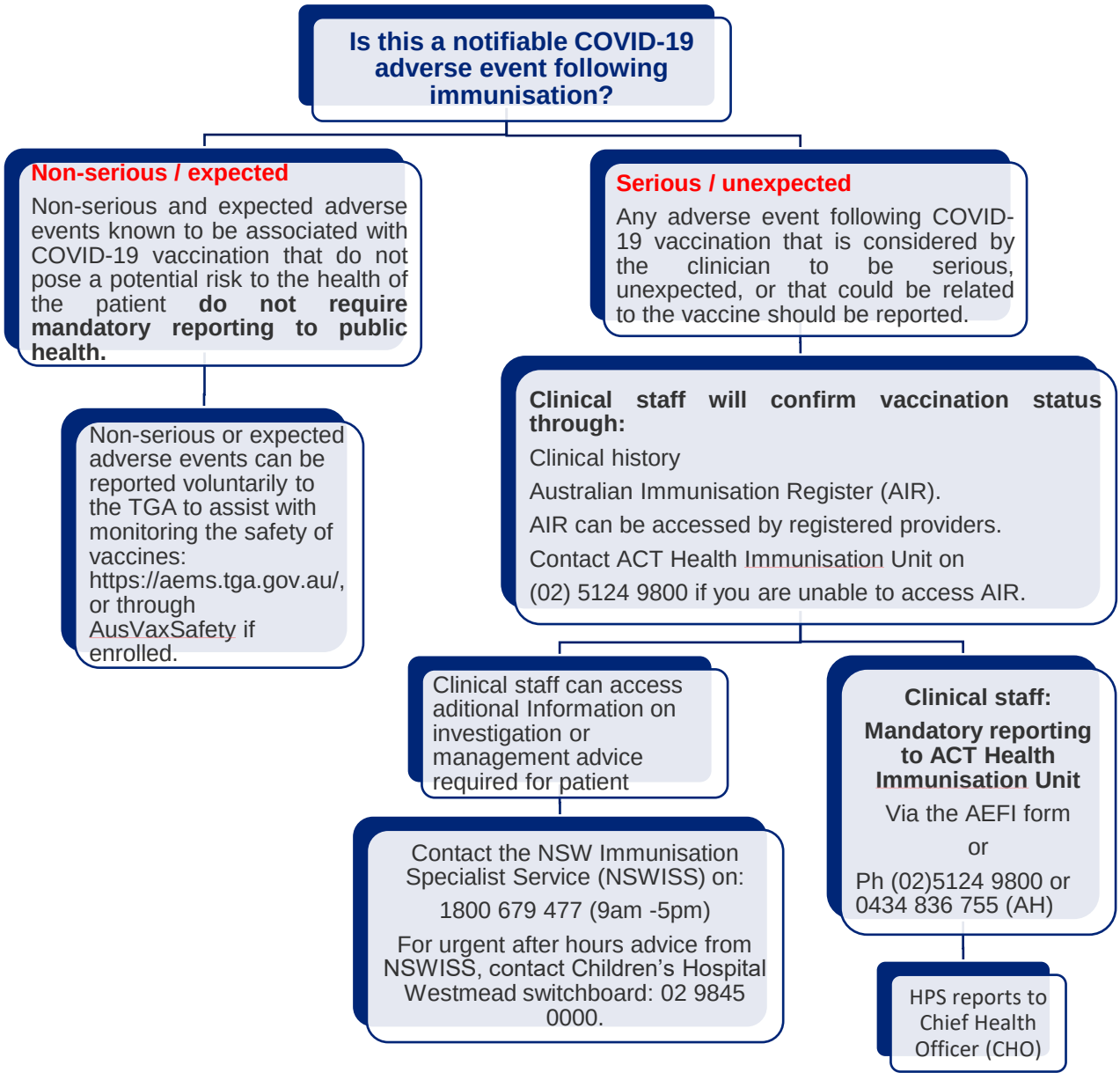
COVID-19 vaccine enhanced surveillance and adverse event following immunisation (AEFI) reporting for healthcare professionals

Purpose of this guidance

- To describe the adverse event monitoring and surveillance plan for COVID-19 vaccines in ACT and how this links to the national plan
- To provide pathways for clinical support if an adverse event following immunisation (AEFI) is suspected
- To provide guidance for the response to a serious, unexpected or rare AEFI



Vaccine safety and monitoring

Regulation by the Therapeutic Goods Administration (TGA)

The TGA is responsible for assessing COVID-19 vaccines before they are used in Australia. For information on this process, you can visit the TGA website: https://www.tga.gov.au/covid-19-vaccine-approval-process

The TGA is also responsible for regulating and monitoring the use of COVID-19 vaccines in Australia. Monitoring involves detecting and responding to any emerging safety concerns related to COVID-19 vaccines, particularly any adverse events following immunisation (AEFI), which includes adverse events of special interest (AESI) (see appendix) where there is a temporal association with vaccination (usually within around six weeks).

The TGA works closely with state and territory health departments and expert bodies such as the National Centre for Immunisation Research and Surveillance (NCIRS) and AusVaxSafety to monitor and respond to safety concerns.

Adverse events following immunisation (AEFI) is a notifiable condition

An adverse event following immunisation (AEFI) is any untoward medical event that occurs after a vaccination has been given which may be related to the vaccine itself or to its handling or administration. A conclusion regarding a causal relationship with the vaccine is not necessary to suspect or report an AEFI.

Common reactions, such as low-grade fever or pain at the injection site, do not need to be reported unless they are worsening or there are specific concerns. Check the vaccine product information for a full list of common reactions.

AEFI are a **notifiable condition** under the *ACT Public Health Act (1997)*. **All uncommon, unexpected or serious AEFI or any event considered to be significant following immunisation must be notified** by medical practitioners or other health professionals to the **ACT Health Immunisation Unit on (02) 5124 9800** (Monday-Friday 8.30am-4.30pm) or by email to immunisation@act.gov.au using the **COVID-19 AEFI reporting form.** Routine notifications can be made during business hours. **For urgent advice after hours advice contact the Immunisation Unit on 0434 836 755.**

An AEFI is considered serious if it:

- is an unexpected reaction for that vaccine (for common reactions consult the product information sheet)
- requires hospitalisation
- is life threatening
- results in persistent or significant disability or incapacity
- results in a congenital anomaly/birth defect
- results in death

Any medical event that requires intervention to prevent one of the outcomes above may also be considered serious. A list of specific serious AEFIs of interest for COVID-19 vaccines that should be immediately reported can be found at *Table 1* on the following page.

A temporally associated death is defined as occurring within 6 weeks of vaccination where it is plausible that vaccination contributed to, or caused, the conditions resulting in death. This timeframe is a guide only, and if a death occurs outside this timeframe and meets criteria for a serious AEFI it should still be reported.

Table 1: Frequency of selected adverse events following BNT162b2 (Pfizer-BioNTech) (30µg/dose) immunisation

Adverse reactions	Frequency				Notification required
Non-serious adverse events (frequency reported within 7 days following each dose in phase II/III trial)					
	Dose 1 (16-55y)	**Dose 2** (16-55y)	**Dose 1** (>55y)	**Dose 2** (>55y)	
Injection site pain	83.1%	77.8%	71.1%	66.1%	NO **Do NOT require mandatory notification unless concerned, more serious, persistent or not resolving.**
Fever	3.7%	15.8%	1.4%	10.9%	
Fatigue	47.4%	59.4%	22.6%	50.5%	
Headache	41.9%	51.7%	25.2%	39%	
Chills	14%	35.1%	6.3%	22.7%	
Muscle pain	21.3%	37.3%	13.9%	28.7%	
Joint pain	11%	21.9%	8.6%	18.9%	
Required paracetamol	27.8%	45%	19.9%	37.7%	
Serious adverse events					
Severe persistent lymphadenopathy or injection site pruritis lasting longer than one week, pain not at the injection site	Uncommon (≥1/1,000 to <1/100))				YES **REQUIRES mandatory notification.**
Acute peripheral facial paralysis (Bell's palsy)	Rare (≥1/10,000 to <1/1,000))				
Anaphylaxis or other hypersensitivity	Rare (around 1/200,000)				

Source: [Clinical guidance on use of COVID-19 vaccine in Australia in 2021. (health.gov.au)]

Non-serious adverse events

Non-serious adverse events known to be associated with COVID-19 vaccination (see table 1) that do not pose a potential risk to the health of the patient, do not need to be reported by immunisation providers. Any event that is considered by the immunisation provider to be significant, of concern, or affect confidence in future immunisations and may not fit in with the criteria for a serious AEFI can be reported.

Advice for healthcare professionals with patients wishing to report a non-serious adverse event

If a patient would like to report a non-serious adverse event (Table 1), healthcare professionals can provide the following guidance:

- Participate in the AusVaxSafety surveillance system through the text message received post vaccination, if enrolled at the time of vaccination
- Report their concern to the Therapeutic Goods Administration

Reporting support for vulnerable people

Clinicians providing care to vulnerable people, including those living in Residential Aged Care Facilities, are encouraged to report on behalf of those who may be unable to report for themselves.

Vaccine safety surveillance in the ACT

AEFI are monitored through a combination of passive and active surveillance systems.

Passive vaccine safety surveillance is the reporting of AEFIs by individuals, including the patient, GP, specialist doctor, immunisation provider or the vaccine manufacturing company. In the ACT, all serious or unexpected AEFIs must be reported to **ACT Health Immunisation Unit on (02) 5124 9800**, or by email to immunisation@act.gov.au using the **COVID-19 AEFI reporting form**, because they are a **notifiable condition**.

AusVaxSafety is the national active vaccine surveillance system led by the National Centre for Immunisation Research and Surveillance (NCIRS). AusVaxSafety monitors adverse events following immunisation and facilitates early detection of potential vaccine safety issues. The program uses Vaxtracker or SmartVax to send automated SMS or email at specific time points to some patients following vaccination to collect information on adverse events following immunisation.

Clinical and immunisation expert support

Clinical guidance and specialist immunisation clinics

All COVID-19 vaccinations will be recorded in the Australian Immunisation Registration (AIR) including vaccine type, date of immunisation and dose number. A patient's vaccination history can be accessed by authorised vaccination providers through AIR, the patient's My Health Record or myGov account.

Clinicians can access advice regarding investigation and management of suspected AEFIs from the **NSW Immunisation Specialist Service (NSWISS)**, supported by the National Centre for Immunisation Research and Surveillance (NCIRS). They can be reached on **1800 670 477** (Mon-Fri 9am-5pm) or email: SCHN-NSWISS@health.nsw.gov.au. **After hours** support should be reserved for advice on the immediate investigation and management of serious AEFI. Clinicians may **contact NSWISS** through The Children's Hospital at Westmead switchboard on **02 9845 0000** for urgent after-hours clinical support.

Should further immunisation specialist consultation or assessment be required, individuals can be referred to appropriate services in consultation with the NSWISS.

To make a mandatory notification, or to seek advice on whether an event is notifiable, contact **ACT Health Immunisation Unit on (02) 5124 9800** or by email to immunisation@act.gov.au using the **AEFI reporting form.**

NSW Health COVID-19 vaccine safety expert panel

An expert panel of adult and paediatric medical subspecialists will review adverse events of special interest, serious AEFI and temporally associated deaths with COVID-19 vaccination to provide guidance on and interpretation of investigations. The expert panel will also assist in the conduct of any causality assessment by the National Vaccine Safety Investigation Group (VSIG). In the case that a causality assessment is required, the expert panel will provide their assessment findings to the VSIG.

When required for cases from the ACT, the panel will include representatives from ACT health, immunisation specialist/s from the NSWISS and invited medical experts in fields relevant to the AEFI notified.

Contacts for clinicians	
Immunisation Unit, Health Protection Service, Public Health, Protection and Regulation, ACT Health	(02) 5124 9800 (Monday- Friday 8.30am-4.49pm) or 0434 836 755 After hours. Email: Immunisation@act.gov.au
NSW Immunisation Specialist Service (NSWISS) Advice on the investigation or clinical management of a serious AEFI or AESI	**1800 679 477** Operating hours: Monday to Friday 9:00am – 5pm Email: SCHN-NSWISS@health.nsw.gov.au
After hours support NSWISS *Urgent advice on the clinical management of serious AEFI or AESI	Through the Children's Hospital Westmead switchboard: **02 9845 0000.**
Contacts for members of the public wishing to report a non-serious adverse event	
Participate in the AusVaxSafety surveillance system through the text message received post vaccination Text messages inviting participation in a brief survey are sent to some individuals following immunisation if enrolled at the time of vaccination	
Therapeutic Goods Administration Adverse event reporting form: **https://aems.tga.gov.au/**	

Appendix

Potential specific AESI (provisional list)

All AESIs temporally associated with vaccination (generally within around six weeks) require mandatory notification to ACT Health Immunisation Unit on (02)5124 9800. Except where indicated, these are not recognised adverse events for COVID vaccination but are monitored as a component of the broader vaccine safety surveillance strategy.

AESI relevant to vaccination in general	a. Generalised convulsion (including seizures, convulsions, fits) b. Guillain-Barre syndrome (GBS) c. Anaphylaxis d. Vasculitides e. Encephalitis/encephalomyelitis (including acute disseminated encephalomyelitis (ADEM)) f. Peripheral facial nerve palsy g. Thrombocytopaenia h. Enhanced disease following immunisation (including worsening or relapse of pre-existing condition)
AESI relevant to specific vaccine platforms for potential COVID-19 vaccines	a. Aseptic meningitis (live viral vaccines) b. Arthritis (Recombinant Vesicular Stomatitis Virus (r-VSV) platform) c. Myocarditis (Modified Vaccinia Ankara (MVA) platform)
AESI related to COVID-19 disease, based on the rationale that they have been observed in association with the disease	a. Multisystem inflammatory syndrome b. Acute cardiac injury including microangiopathy, heart failure and cardiogenic shock, stress cardiomyopathy, coronary artery disease, arrhythmia, myocarditis, pericarditis c. Coagulation disorder including deep vein thrombosis, pulmonary embolus, cerebrovascular stroke, limb ischaemia, haemorrhagic disease d. Acute kidney injury e. Acute liver injury f. Anosmia, ageusia g. Chilblain-like lesions h. Erythema multiforme i. Subacute thyroiditis j. Pancreatitis k. Rhabdomyolysis
Therapeutic Goods Administration (TGA) provisional AESI list. As new information emerges, this list will be updated.	