COVID-19 vaccine: Enhanced surveillance and adverse event reporting guidelines

Last updated 24 May 2021

AEFI reporting flow chart updated to reflect latest ATAGI advice

Purpose of this guidance

- To describe the adverse event monitoring and surveillance plan for COVID-19 vaccines in NSW 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 a guide for reporting pathways, particularly for serious or unexpected AEFIs.

Summary of reporting requirements and pathways for adverse events identified following COVID-19 vaccination

- Clinical advice is available to support management of serious events
- These are new vaccines and any serious event that does not have an obvious clinical aetiology and results in serious illness, disability, hospital admission or death **must** be reported

Reporting of adverse events following COVID-19 vaccine

Is the event serious?

A serious adverse event following immunisation is an event that:

- results in death
- is life threatening
- requires hospitalisation
- results in persistent or significant disability or incapacity
- is an unexpected reaction for that vaccine[1]

NO

NON-SERIOUS Adverse Event Following Immunisation

This does not need to be reported to your local Public Health Unit

This includes common, expected temporary reactions[1], such as:

- Low grade fever
- Injection site reaction not requiring additional interventions
- Myalgia/lethargy resolving in 24-48 hours

These AEFIs can be reported directly to the TGA at https://aems.tga.gov.au/

YES

SERIOUS Adverse Event Following Immunisation

This is a notifiable condition.

Contact your local Public Health Unit on 1300 066 055

A serious adverse event includes:

- Possible or probable Thrombosis with Thrombocytopenia Syndrome (see THANZ and/or ACEM guidance)
- Anaphylaxis
- New onset neurological symptoms
- Any other clinically significant, worsening or serious illness that develops within six weeks after COVID-19 vaccination.

Specialist immunisation advice

If specialist advice is needed, for example in relation to management of the second dose, contact the National Centre for Immunisation Research and Surveillance (NCIRS) NSW Immunisation Specialist Serv (NSWISS)

Phone: 1800 679 477 (Mon-Fri 9am-5pm) **OR**

Email: SCHN-NSWISS@health.nsw.gov.au

For urgent after-hours clinical support, contact NSWISS via The Children's Hospital at Westmead switchboard on 02 9845 0000 (ask for Immunisation Specialist Service).

[1]Common, expected reactions for COVID-19 vaccines are described in the **product information**

COMIRNATY (BNT162b2 [mRNA]) COVID-19 VACCINE (Pfizer) Product Information

COVID-19 Vaccine AstraZeneca (ChAdOx1-S) Product Information

Also see AusVaxSafety COVID-19 vaccine data for reports received by routine active surveillance

Significant (rare) syndromes reported to date internationally include

- disorders of clotting and haemostasis
- anaphylaxis
- Bell's palsy
- Persistent lymphadenopathy
- Other new onset neurological disorders

Note: Many conditions can arise during normal life, whether or not a vaccine is administered. It remains important to report any new or unexpected events so that safety can be appropriately monitored.

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) 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.

An adverse event 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.

An AEFI is a notifiable condition under the NSW Public Health Act (2010). All uncommon, unexpected or serious AEFI or any event considered by the clinician to be significant following immunisation must be notified by medical practitioners or other health professionals to the local Public Health Unit (PHU) on 1300 066 055 or by email to MOH-covidaefi@health.nsw.gov.au or by using the National Adverse Events Following Immunisation (AEFI) reporting form, or for emergency departments, the NSW Heath AEFI case notification form. Routine notifications can be made during business hours. If using a mobile to notify by phone, the number will prompt the reporter to key in the patient's postcode of residence and connect to the local PHU. For urgent advice after hours, see clinical and immunisation expert support.

An AEFI is considered serious if it:

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

Any medical event that requires intervention to prevent one of the outcomes above may also be considered serious. Examples of serious adverse events following COVID-19 vaccination that should be immediately reported can be found at Table 1.

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.

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

Non-serious adverse events (frequency reported within 7 days following each dose in phase II/III trial)

Adverse reactions	Frequency Dose 1 (16-55y)	Frequency Dose 2 (16-55y)	Frequency Dose 1 (>55y)	Frequency Dose 2 (>55y)	Notification required
Injection site pain	83.1%	77.8%	71.1%	66.1%	No Does 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

Adverse reactions	Frequency	Notification required
Severe persistent lymphadenopathy or injection site pruritis lasting longer than one week, pain not at the injection site (excluding headache or muscle/joint pain)	Uncommon (≥1/1,000 to <1/100))	Yes Requires mandatory notification. • These and any other rare, unusual or unexpected events leading to hospitalisation, disability or death must be reported urgently
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: https://www.health.nsw.gov.au/Infectious/covid-19/Documents/api-pfizer-comirnaty-20210125.pdf.

Table 2: Frequency of selected adverse events following COVID-19 AstraZeneca vaccine (ChAdOx1-S)

Non-serious adverse events (generally milder and less frequent in older adults ≥65y)

Adverse reactions	Frequency COVID-19 Vaccine (AstraZeneca)	Frequency Control	Notification required
Injection site tenderness	63.7%	39.5%	No Does NOT require mandatory notification unless concerned, more serious, persistent or not resolving.
Fever	7.9%	1.2%	
Fatigue	53.1%	38.2%	
Malaise	44.2%	20.2%	
Headache	52.6%	39.0%	
Chills	31.9%	8.3%	

Muscle pain	44%	21.6%	
Joint pain	26.4%	12.4%	
Nausea	21.9%	13.1%	

Serious adverse events

Adverse reactions	Frequency	Notification required
Neurological demyelinating events	Very rare	**YES** **REQUIRES mandatory notification.** **These and any other rare, unusual or unexpected events leading to hospitalisation, disability or death must be reported urgently.**
Anaphylaxis or other hypersensitivity	Very rare (around 1/1,000,000)	

- Rare cases of thrombosis have been associated with thrombocytopenia were reported following administration of COVID-19 Vaccine AstraZeneca overseas. The onset of reported cases was between 4 to 20 days after vaccination.
- Providers should be aware of warning signs of a severe condition associated with thrombosis and thrombocytopenia. This has presented as either central venous sinus thrombosis (CVST) or thrombosis in other sites, such as intra-abdominal venous systems. CVST may present as a new onset persistent headache not settling with analgesia, features of raised intracranial pressure (including acute severe headache, vomiting, confusion), focal neurological deficits, and/or seizures.
- If CVST or another severe thrombotic complication with thrombocytopenia is suspected in a patient who has received COVID-19 Vaccine AstraZeneca, refer them to an emergency department for further assessment and haematology consultation. Clinical guidance here: https://www.thanz.org.au/resources/covid-19. Confirmed cases must be reported to the relevant Public Health Unit urgently.

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 (see 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
- Patients can call the National Prescribing Service on 1300 134 237 from anywhere in Australia. It operates Monday–Sunday 8am–8pm AEDT/AEST (including public holidays).
- 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 or disability care facilities, are encouraged to report on behalf of those who may be unable to report for themselves.

Vaccine safety surveillance in NSW

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 NSW, all serious or unexpected AEFIs must be reported to the PHU on 1300 066 055, or by email using the NSW Health AEFI case notification form to MOH-covidaefi@health.nsw.gov.au, as 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.

All COVID-19 vaccines, including those administered to NSW Health staff, will be recorded in NSW specific databases that will feed into AusVaxSafety for AEFI monitoring and will also be recorded in the Australian Immunisation Register (AIR).

The Paediatric Active Enhanced Disease Surveillance (PAEDS) network is a hospital-based active surveillance system monitoring for AEFI, multisystem inflammatory syndrome in children (MIS-C), and vaccine-associated enhanced disease (VAED) at The Children's Hospital Westmead and the Sydney Children's Hospital, Randwick.

The Public Health Rapid, Emergency, Disease and Syndromic Surveillance (PHREDSS) system is a near real-time system that identifies changes in trends of ED presentations of specific AEFI and supports active case finding. Serious and non-serious AEFIs are monitored via PHREDSS to ensure prompt investigation and management, and to detect emerging safety signals. The expected rates of conditions which may be relevant to detecting AEFI trends have been analysed through other sources to support this approach.

International collaboration and benchmarking

NSW Health is working closely with NCIRS to ensure benchmarking and information sharing with international partners such as the Brighton Collaboration and the Safety Coalition for Epidemic Preparedness Innovations (CEPI), specifically the Safety Platform for Emergency Vaccines (SPEAC).

These collaborations ensure safety assessments and pharmacovigilance knowledge are shared rapidly and globally.

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 679 477 (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 the local Public Health Unit on 1300 066 055 during business hours, through the public health officer on-call through the hospital switchboard after hours, or by email using the NSW Health AEFI case notification form to MOH-covidaefi@health.nsw.gov.au.

NSW Health Pathology, Forensic Medicine and deaths reportable to the State Coroner

Deaths occurring in temporal relationship to COVID-19 immunisation may be reportable to the NSW State Coroner under certain circumstances. Clinicians should use the Coronial Checklist to determine whether such a death is reportable to the Coroner. Where any doubt exists as to whether a death should be reported, the Duty Forensic Pathologist or the Forensic Medicine Clinical Nurse Consultant at the relevant Forensic Medicine facility can be contacted:

Business hours (8am – 4:30 pm):

- Sydney (Lidcombe): 02 9563 9000
- Wollongong: 02 4222 5466
- Newcastle: 02 4935 9700

All after hours calls should be directed to the Sydney (Lidcombe) number. The relevant Duty Pathologist will be notified by the Sydney Forensic Medicine staff.

The State Coroner's Court may also be contacted for advice on 02 8584 7777.

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.

The panel will include the local Public Health Unit, immunisation specialist/s from the NSWISS and invited medical experts in fields relevant to the AEFI notified.

Contacts for clinicians

NSW Public Health Unit (PHU)

*Make a mandatory AEFI report, or for advice on whether an event is notifiable.

1300 066 055 – key in the postcode of residence for the relevant public health unit

Operating hours: Monday to Friday 8:30am – 5pm

Email: MOH-covidaefi@health.nsw.gov.au

NSW Immunisation Specialist Service (NSWISS)

Advice on the investigation or clinical management of a serious AEFI

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

Through the Children's Hospital Westmead switchboard: **02 9845 0000**.

Contacts for members of the public wishing to report a non-serious adverse event

AusVaxSafety

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/