COVID-19 vaccine: Enhanced surveillance and response to a temporally associated death following vaccination

Last updated on 22 February 2021 with:

- advice on which AEFI form to use

**Purpose of this guidance**

- To provide pathways to expert clinical support if a death reported to the Coroner is temporally associated with COVID-19 vaccination
- To provide guidance and criteria for referral of deaths to the Coroner under the conditions of the Coroners Act 2009 (NSW) where there is a temporal relationship with COVID-19 vaccination

**Vaccine safety and monitoring**

**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.

AEFIs are notifiable under the Public Health Act 2010 (NSW). **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 local Public Health Unit on 1300 066 055 or by email to MOH-covidaefi@health.nsw.gov.au using the National Adverse Events Following Immunisation (AEFI) reporting form, or for emergency departments, the NSW Health AEFI case notification form.

An AEFI is considered serious when 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. AEFIs may include temporally associated serious adverse events of special interest (AESI) for COVID-19 vaccine. A list of potential AESIs following COVID-19 vaccination can be found at Appendix 1.

**Forensic medicine and deaths reportable to the Coroner**

The Coroners Act 2009 (NSW) specifies deaths reportable to the Coroner.

Deaths occurring in temporal relationship to COVID-19 vaccination may be reportable to the State Coroner under certain circumstances. Clinicians should use the Coronial Checklist to determine whether such a death is reportable to the Coroner ([https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/IB2010_058.pdf](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/IB2010_058.pdf)).
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.

**AEFI/AESIs relevant to COVID-19 vaccine**

A death reportable to the Coroner, such as a sudden death without a known cause or a death that is not the reasonably expected outcome of a health-related procedure, will consider whether there was a temporal association with COVID-19 vaccination. If a temporal relationship exists, the forensic pathologist will conduct relevant investigations to assist in the assessment of potential AEFI or other causes as contributing factors, with support from the NSW Health vaccine safety expert panel.

**Clinical and immunisation expert support**

**Australian Immunisation Register (AIR)**

All COVID-19 vaccines will be registered to the AIR including the vaccine type and date of administration. This information should be routinely gathered at the triage assessment for any death notified to the Coroner.

**Clinical guidance**

If COVID-19 vaccination is found to have been administered proximate to the time of death and the condition leading to death is plausibly linked to vaccination, clinical support and advice should be sought 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 (Monday-Friday 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 NCIRS through The Children’s Hospital at Westmead switchboard on 02 9845 0000 for urgent after hours clinical support.

Depending on the discussion with the NSWISS clinician, further investigations may be recommended.

**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* following COVID-19 vaccination to provide guidance on and interpretation of investigations. In the case of a temporally associated death, the expert panel may recommend further investigation to the forensic pathologist, such as those investigations used to rule out other potential causes of death.

These investigations will be provided by the expert panel to the National Vaccine Safety Investigation Group (VSIG), to assist in causality assessment, if required. The expert panel will also provide a report of findings to support the Coroner in their determination of the cause of death, where this is unclear.

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.

*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 causing 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.
Contacts

NSW Forensic Medicine
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.

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

Afterhours support NSWISS
*urgent advice on the investigation or clinical management of serious AEFI
Through the Children’s Hospital Westmead switchboard: 02 9845 0000.
Appendix 1: Potential specific AESIs (provisional list following COVID-19 vaccination)

Except where indicated, these are not recognised adverse events for COVID-19 vaccination but will be monitored as a component of the broader vaccine safety surveillance strategy.

**AESI relevant to vaccination in general**
- Generalised convulsion (including seizures, convulsions, fits)
- Guillain-Barre syndrome (GBS)
- Anaphylaxis
- Vasculitides
- Encephalitis/encephalomyelitis (including acute disseminated encephalomyelitis (ADEM))
- Peripheral facial nerve palsy
- Thrombocytopenia
- Enhanced disease following immunisation (including worsening or relapse of pre-existing condition)

**AESI relevant to specific vaccine platforms for potential COVID-19 vaccines**
- Aseptic meningitis (live viral vaccines)
- Arthritis (Recombinant Vesicular Stomatitis Virus (r-VSV) platform)
- 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**
- Multisystem inflammatory syndrome
- Acute cardiac injury including microangiopathy, heart failure and cardiogenic shock, stress cardiomyopathy, coronary artery disease, arrhythmia, myocarditis, pericarditis
- Coagulation disorder including deep vein thrombosis, pulmonary embolus, cerebrovascular stroke, limb ischaemia, haemorrhagic disease
- Acute kidney injury
- Acute liver injury
- Anosmia, ageusia
- Chilblain-like lesions
- Erythema multiforme
- Subacute thyroiditis
- Pancreatitis
- Rhabdomyolysis

Therapeutic Goods Administration (TGA) provisional AESI list. As new information emerges, this list will be updated.