



# Safety Information 005/21

## Reporting Adverse Events Following Immunisation

**23 May 2021**

- Distributed to:**
- Chief Executives
  - Directors of Clinical Governance
  - Directors of Public Health

- We recommend you also inform:**
- Directors of:
- Emergency Departments
  - Intensive Care Units
  - Haematology
  - General Medicine
  - Surgery
  - Immunology
  - Neurology
  - Dermatology
  - Burns Units
  - Cardiology
  - Respiratory
  - Pharmacy

- Expert Reference Group**
- Content reviewed by:
- NSW Public Health Response Branch

**Clinical Excellence Commission**

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Internet Website:  
<http://health.nsw.gov.au/sabs>

Intranet Website:  
<http://internal.health.nsw.gov.au/quality/sabs>

**Review date**  
 21 June 2021

### Reporting adverse events following immunisation (AEFI)

Serious adverse events following immunisation are **notifiable conditions** in NSW. Your local Public Health Unit should be **notified on 1300 066 055**

Serious adverse events following immunisation include any illness that:

- results in death
- is life threatening
- requires hospitalisation
- results in persistent or significant disability or incapacity
- is an unexpected reaction for that vaccine.<sup>1</sup>

**Any** serious adverse event following **any** immunisation is notifiable. NSW Health provides these reports to the TGA.

### Assessment of possible Thrombosis with Thrombocytopenia Syndrome after COVID-19 immunisation

Clinicians should keep up to date with guidance regarding appropriate testing and management of people presenting with thromboembolic events (including deep venous thrombosis) in the 30 days following administration of COVID-19 Vaccine Astra Zeneca. Description of this syndrome now includes a spectrum of illness.

Information regarding investigation and management is available from the [Thrombosis and Haemostasis Society of Australia and New Zealand](#) and from the [Australasian College of Emergency Medicine](#)

Any possible or probable cases must be notified to your local Public Health Unit.

### Reporting and investigating anaphylaxis after COVID-19 immunisation

Serious adverse events have been identified following immunisation against COVID-19. These include anaphylaxis following administration of Pfizer COMINARTY<sup>®</sup> vaccine and COVID-19 Vaccine Astra Zeneca.

Guidelines for the management and reporting of anaphylaxis are available on the NSW Health website, including recommended [investigations](#) to assist in evaluation as to whether further doses of COVID-19 vaccine can be given.

### Reporting other serious conditions

Other serious conditions reported rarely following immunisation include new neurological conditions (eg Guillain Barre Syndrome, Bell's Palsy); new occurrence of rare conditions (eg Capillary Leak Syndrome) and myocarditis/pericarditis.

At this time there is no causal link for many of these conditions, however vigilance in reporting unusual or serious conditions assists in the detection of rare safety signals.

### Suggested actions required by Local Health Districts/Networks

1. Ensure clinicians are aware of their responsibilities to report serious Adverse Events Following Immunisation (AEFI) to their local public health unit.
2. Remind clinicians to remain alert to possible Adverse Events Following Immunisation, particularly within 6 weeks of COVID-19 vaccination
3. Encourage clinicians to refer to the AEFI reporting flow chart on page 2.

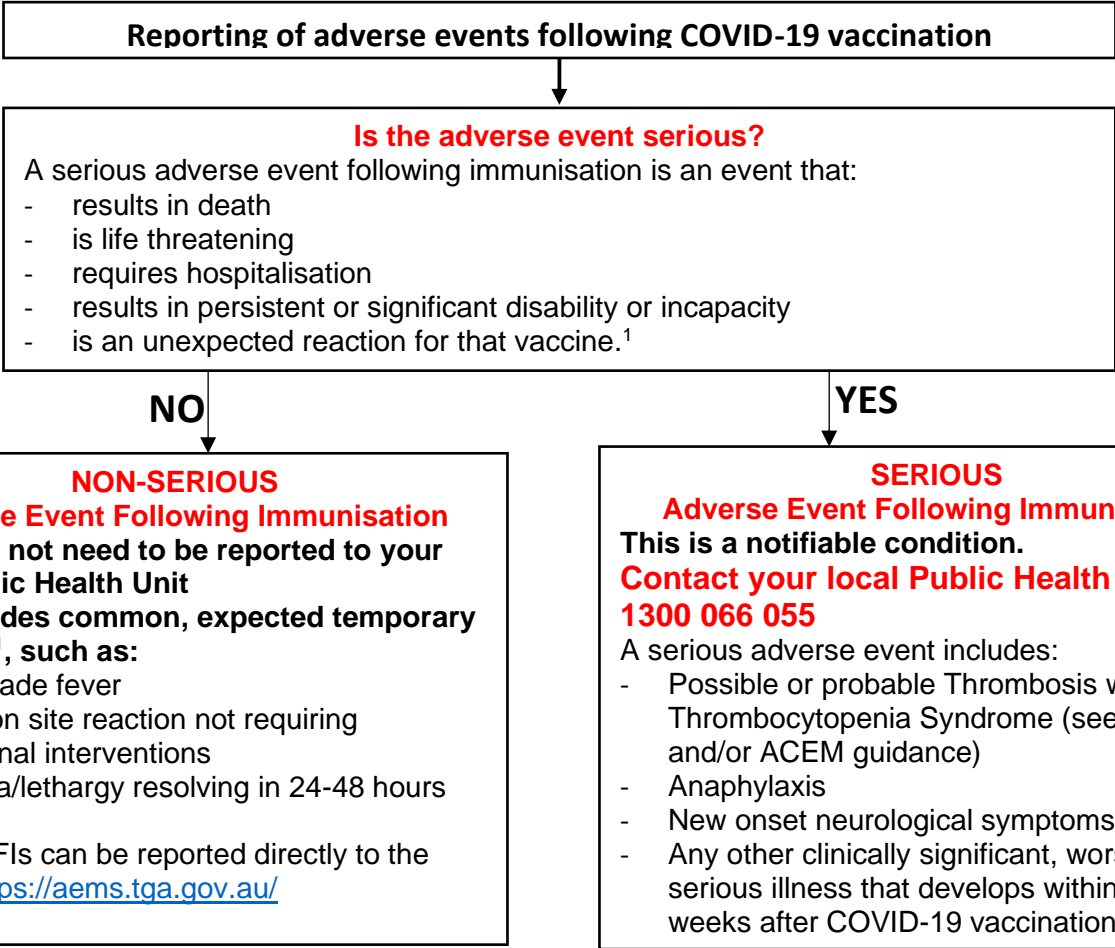


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## Reporting Adverse Events Following Immunisation

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### Reporting Flow chart



### Contraindications and precautions to immunisation with COVID-19 vaccines

It is important that patients are provided with the latest advice regarding recommendations on which vaccine is recommended. Latest information for clinicians is available at <https://www.health.nsw.gov.au/Infectious/covid-19/vaccine/Pages/clinicians.aspx>. This advice changes regularly as additional information around vaccine safety becomes available.

### Specialist immunisation advice

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

☎ Phone: 1800 679 477 (Mon-Fri 9am-5pm) **OR**  
 ✉ Email: [SCHN-NSWISS@health.nsw.gov.au](mailto: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

<sup>1</sup>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](#)