



Issue date
23 May 2023

Distributed to:

Chief Executives
Directors of Clinical Governance
Directors, Public Health Units

Action required by:

Chief Executives
Directors of Clinical Governance

We recommend you also inform:

- Directors
- Emergency Departments
 - Intensive Care Units
 - Haematology
 - General Medicine
 - Immunology
 - Neurology
 - Dermatology
 - Cardiology
 - Respiratory

Expert Reference Group

Content reviewed by:
Health Protection Branch NSW MoH

Clinical Excellence Commission

Tel: 02 9269 5500
Email:
Internet Website:
<https://www.health.nsw.gov.au/sabs/Pages/default.aspx>
Intranet Website:
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date
May 2024

Updated: Reporting Adverse Events Following Immunisation

How is this Safety Notice different from SN005/21?

The contact information and links to the relevant resources have been updated.

Situation

Adverse Events Following Immunisation (AEFIs) are notifiable conditions in NSW. NSW Health reports AEFIs to the Therapeutic Goods Administration (TGA). Clinicians should notify Serious AEFIs to their Public Health Unit.

Background

Serious AEFIs are uncommon, however vigilance in reporting unusual or serious conditions assists in the detection of rare safety signals. NSW Health is aware of cases where serious AEFIs occurred, but clinicians closely involved in care did not report promptly.

Assessment

Minor post immunisation reactions are extremely common and include low-grade fever, resolving injection site pain and self-limiting myalgia/ lethargy. Serious adverse events include anaphylaxis, onset of new neurological symptoms, or any other clinically significant, worsening, or serious illness that develops **within six weeks** of vaccination.

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

Clinical Recommendations

Specialist Immunisation Advice

If specialist advice is needed, contact the National Centre for Immunisation Research and Surveillance (NCIRS) NSW Immunisation Specialist Service (NSWISS) ✉ Email: SCHN-NSWISS@health.nsw.gov.au

For urgent after-hours clinical support, contact Immunisation specialist via The Children's Hospital at Westmead switchboard on ☎ 02 9845 0000.

Reporting

Is the event serious?

- Yes
 - This is a **notifiable condition**
 - Contact your local Public Health Unit on **1300 066 055** as soon as practicable
- No
 - These reactions do not need to be reported to your local Public Health Unit
 - These AEFIs can be reported directly to the [TGA](#)



Required actions for the Local Health Districts/Networks

1. Distribute this Safety Information to all relevant clinicians and clinical departments.
2. Include this Safety Information in relevant handovers and safety huddles.
3. Ensure clinicians are aware of their responsibilities to report serious AEFIs to their local Public Health Unit (and hence to the TGA).
4. Report any incidents associated with these medicines into [ims+](#) and [TGA](#).
5. Remind clinicians to remain alert to possible AEFIs, particularly within 6 weeks of vaccination.