Fact Sheet

Vaccine reaction reporting for health professionals: Adverse event following immunisation

Vaccines, like any medication or natural therapy, can have side effects. An adverse event following immunisation (AEFI) refers to any untoward medical occurrence that follows immunisation. It does not necessarily have a causal relationship with the vaccine (Australian Immunisation Handbook).

Most reactions, such as low-grade fever and pain at the injection site, are mild and are usually short lasting, and do not require special treatment.

Who needs to report adverse reactions?

Notifiable adverse event following immunisation is now a notifiable condition in South Australia. Notifiable AEFI is defined as an AEFI that is a not a very common or common AEFI.

Prior to April 2021, the SA Health Communicable Disease Control Branch (CDCB) collected data on AEFI from immunisation providers and the general public on a voluntary basis. In April 2021, AEFI became a notifiable condition in South Australia on a temporary basis by notice in the South Australian Government Gazette. In October 2021, notifiable AEFI became a notifiable condition on an ongoing basis after it was added to the list of notifiable conditions in the South Australian Public Health (Notifiable and Controlled Notifiable Conditions) Regulations 2012.

The following groups are now required to notify AEFI:

- medical practitioners
- pathology services
- registered nurses, midwives and pharmacists who are authorised to vaccinate independently as per the Vaccine Administration Code.

Health practitioners will be exempt from notifying an AEFI if they know or reasonably believe that the notification has already been made by another health practitioner who is required to notify.

The general public will still be able to report AEFI to SA Health on a voluntary basis (a report by the general public does not remove the requirement for a health practitioner to also notify).

What types of adverse reactions require notification?

All AEFI need to be notified except for very common or common adverse events.

A notifiable AEFI which occurs after receiving any vaccine requires notification.

For further detail on what is considered a very common or common adverse event refer to the Australian Immunisation Handbook (the Handbook) or Australian Technical Advisory Group on Immunisation (ATAGI) clinical advice. The Handbook has information on adverse events in a number of sections including the “adverse events” section in each vaccine preventable disease chapter and in a table entitled “Common side effects following immunisation for vaccines used in the National Immunisation Program schedule”. ATAGI clinical advice is particularly relevant for adverse events following COVID-19 vaccines as the Handbook currently does not contain information on COVID-19 vaccines.

Why report an adverse event following immunisation?

Reporting an AEFI is an essential part of ensuring ongoing vaccine safety monitoring. Being able to identify and respond quickly to any issues relating to vaccine safety is an essential part of maintaining public trust and confidence.

The South Australian Vaccine Safety Surveillance (SAVSS) is a passive surveillance system designed for timely detection of signals suggestive of an increase in AEFI associated with a particular vaccine. Reporting suspected AEFI to SAVSS enhances SA Health's ability to provide advice and make recommendations about the safety of vaccines

SAVSS enables the safe monitoring of immunisation programs in South Australia.

How to report an adverse event following immunisation to SA Health

The preferred method to submit a report to SA Health is by completing the online Vaccine Reaction Report Form using the South Australian Vaccine Safety Surveillance System (SAVSS).

On completion of the online report form, a lodgement number will be issued. If you have provided an email address, the option to receive confirmation including your lodgement number by email is available. There is also an option to print a copy of your report.

If you are **unable to complete** an online report, you can phone 1300 232 272 during business hours.

All notifiable AEFIs must be reported to SA Health however, in addition, health care providers may choose to also report these AEFI directly to the Therapeutic Goods Administration (TGA). AEFI reports received by SA Health are deidentified and sent to the TGA which means if an AEFI has been reported to SA Health then there is no requirement to also report this to the TGA.

What happens next?

Each report received by SA Health is assessed and triaged according to urgency. A specialist team provides appropriate advice and follow up for individuals who have experienced an AEFI.

Unexpected or unusual reactions in children may be referred to the Specialist Immunisation Service (SIS).

Adults identified as at risk of AEFI or those who experience AEFIs in the context of a COVID-19 vaccine may be referred to the South Australia COVID-19 Specialist Immunisation Clinic (SACSIC).

SA Health submits all reports to the Therapeutic Goods Administration (TGA). These reports contribute to national vaccine safety surveillance.

Are vaccines tested for safety?

Yes. Before a vaccine can be used in Australia it must be licensed by the TGA. The TGA extensively assess each vaccine for safety and effectiveness, with assessment based on scientific evidence. This testing is required by law and is usually undertaken over many years during the vaccine's development. The TGA continues to monitor the safety of vaccines once they are registered.

Further information

For information on adverse event following immunisation visit www.sahealth.sa.gov.au/immunisationprovider or contact the CDCB Immunisation Section on 1300 232 272 during business hours.

For more information

Communicable Disease Control Branch
Telephone: 1300 232 272
www.sahealth.sa.gov.au/immunisationprovider

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