Adverse events

Reporting AEFI

Surveillance for adverse events following immunisation is an integral part of a national vaccination program. Through surveillance, it is hoped to detect changes in the rates of known adverse events and any adverse events that either were previously undocumented or result from incorrect vaccine delivery.

Any serious or unexpected adverse event occurring following immunisation should be reported. Providers should use clinical judgement and common sense in deciding which adverse events to report, and parents/caregivers should be encouraged to notify the immunisation provider of AEFI.

Any of the adverse events listed in Appendix 5, 'Definitions of adverse events following immunisation' should be reported. No time limit has been set to report AEFI. Notification of an adverse event does not necessarily imply a causal association with vaccination, as some events may occur coincidentally following vaccination.

Immunisation providers are also advised to report any adverse events of concern that do not fit into any of the categories listed in Appendix 5. They should be reported as 'other reactions' with a full description of the adverse event. This will enable new and unexpected AEFI to be identified.

How should AEFI be reported?

The Adverse Drug Reactions Advisory Committee (ADRAC) receives reports of unexpected and serious adverse events for all medicines, including vaccines. Any person (medical or non-medical) can report an AEFI to ADRAC by telephoning or filling in a blue form. ADRAC's reply paid blue form has been modified and should be used for notifying AEFI in Victoria and Tasmania. Additional blue forms are available from:
The Secretary
Adverse Drug Reactions Advisory Committee
PO Box 100
Woden ACT 2606
Telephone: 02 6232 8386
or on-line at www.health.gov.au/tga/adr/bluecard.pdf

ADRAC will forward copies of individual reports of AEFI with vaccines on the Australian Standard Vaccination Schedule to those States/Territories that have follow-up surveillance. In addition, reports from ADRAC and State/Territory Health Departments are aggregated and published in Communicable Diseases Intelligence.

Table 1: Contact details for notification of adverse events following immunisation

State/Territory	Report adverse events to:	Telephone numbers
* NSW	NSW Public Health Units	Look under 'Health' in the White Pages
* WA	State Health Department	08 9321 1312
* QLD	Queensland Health	07 3234 1500
* NT	NT Dept Health & Community Services	08 8922 8044
* SA	Department of Human Services In SA, parents can also report adverse events by calling	08 8226 7177 1-300-364-100 (24 hours)
* ACT	Territory Health Department	02 6205 2300
* VIC	ADRAC	Use blue form
* TAS	ADRAC	Use blue form

Definitions

Notify any events that the reporter considers serious and may be related to the vaccine or vaccines.

- Abscess
- Acute flaccid paralysis
- Allergic reaction (generalised)
- Anaphylaxis
- Arthralgia
- Arthritis
- Brachial neuritis
- Death
- Disseminated BCG
- Encephalopathy
- Encephalitis
- Extensive limb swelling
- Fever
- Guillain-Barré Syndrome (GBS)
- Hypotonic–hyporesponsive episode (shock, collapse)
- Local reaction (severe)
- Lymphadenitis (includes suppurative lymphadenitis)
- Meningitis
- Nodule
- Orchitis
- Osteitis
- Osteomyelitis
- Parotitis
- Rash
- Screaming (persistent)
- Seizure
- Sepsis
- Subacute sclerosing panencephalitis
- Thrombocytopenia
- Toxic-shock syndrome
- Vaccine-associated paralytic poliomyelitis
- Other severe or unusual events