2.3 POST-VACCINATION

2.3.1 Immediate after-care

Immediately after vaccine administration:

- dispose of clinical waste, including sharps and vaccine vials, at the point of use (refer to state/territory health authorities for management guidelines for the safe disposal of clinical waste or refer to the National Health and Medical Research Council’s Australian guidelines for the prevention and control of infection in healthcare)¹
- cover the injection site quickly with a dry cotton ball and tape as needed
- gently apply pressure for 1 or 2 minutes – do not rub the site as this will encourage the vaccine to leak back up the needle track, which can cause pain and may lead to local irritation
- to distract the vaccinated person and reduce distress, immediately change the position of the child/person after completing the vaccination, for example, ask the parent/carer to put the infant over his/her shoulder and move around with the infant²
- remove the cotton wool after a few minutes and leave the injection site exposed to the air
- record the relevant details of the vaccines given (refer to 2.3.3 Documentation of vaccination).

The vaccinated person and/or parent/carer should be advised to remain in the vicinity for a minimum of 15 minutes after the vaccination. The area should be close enough to the immunisation service provider so that the vaccinated person can be observed and medical treatment provided rapidly if needed.

Prophylactic administration of paracetamol at the time of, or immediately after, vaccination to reduce the risk of fever is not routinely recommended, with the exception of children <2 years of age receiving meningococcal B vaccine (refer to 4.10 Meningococcal disease). Paracetamol may be recommended as required for fever or pain occurring following immunisation (refer to ‘Common adverse events following immunisation and their management’ below).

Before departure, inform the vaccinated person or parent/carer, preferably in writing, of any expected adverse events following immunisation, and of the date of the next scheduled vaccination(s).

Take the opportunity to check the vaccination status of other family members (as appropriate) and discuss any catch-up vaccination requirements and options available (this can also be done earlier in the visit).

2.3.2 Adverse events following immunisation

What are adverse events following immunisation?

An adverse event following immunisation (AEFI) is any untoward medical occurrence that follows immunisation and does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.³ Such an event may be caused by the vaccine(s) or may occur by chance (i.e. it would have occurred regardless of vaccination). Most vaccine adverse events are minor, such as low-grade fever, and pain or redness at the injection site; these should be anticipated.⁴ The frequency of adverse events has been classified by regulatory agencies, and is often reported in clinical trials as follows: very common (>10% of persons vaccinated), common (1–10%), uncommon (0.1–<1%), rare (0.01%–<0.1%) and very rare (<0.01%).⁵ Detailed information on types of expected common and rare adverse events is provided below.

An important factor in reducing the likelihood of an adverse event occurring is to screen each person to be vaccinated (using the pre-vaccination screening checklists in Tables 2.1.1 and 2.1.2) to ensure that the person does not have a condition that either increases the risk of an AEFI or is a contraindication to vaccination. Immunisation service providers should also check the relevant chapters of this Handbook, including the variations from product information, and any other relevant sources, such as state/territory guidelines. The use of correct injection procedures is also important (refer to 2.2 Administration of vaccines).

Expected common AEFI are described in the table Comparison of the effects of diseases and the side effects of NIP vaccines inside the back cover of this Handbook. Detailed information on the adverse events that are known to occur after vaccination is contained in the ‘Adverse events’ section of each disease-specific chapter in Part 4. Persons to be vaccinated and/or their parents/carers should be given advice (preferably written) as part of the consent procedure on what common or expected adverse events are likely and what they should do about them. The table inside the front cover of this Handbook, Side effects following immunisation for vaccines used in the National Immunisation Program (NIP) schedule, can be used for this purpose.

Parents/patients should be encouraged to contact their healthcare provider if they are concerned about an adverse event occurring after vaccination, particularly if it is an unexpected, uncommon and/or serious adverse suspected reaction to vaccination. Healthcare providers and parents/carers are encouraged to report any untoward medical occurrence that follows immunisation, particularly events that are serious and/or unexpected, and/or relate to a new vaccine or condition of interest. For more detailed information on reporting AEFI, refer to ‘Reporting adverse events following immunisation’ below and Table 2.3.3 Contact information for notification of adverse events following immunisation. In
addition to reporting AEFI, immunisation providers should provide the patient/parents with information and a plan of management regarding the adverse event experienced, including the implications for subsequent vaccination. This is discussed more in the next three sections on management of immediate, common and rare adverse events, and also in 3.3.1 **Vaccination of persons who have had an adverse event following immunisation.**

**Management of an immediate adverse event following immunisation**

The vaccinated person should remain under observation for a short interval to ensure that they do not experience an immediate adverse event. It is recommended that vaccinated persons remain in the vicinity of the place of vaccination for at least 15 minutes. Driving or operating machinery should not occur in this immediate post-vaccination period.

The most serious immediate AEFI is anaphylaxis. Severe anaphylactic reactions usually have a rapid onset; life-threatening adverse events are most likely to begin within 15 minutes of vaccination. However, in adults and older children, the most common immediate adverse event is a vasovagal episode (fainting), either immediately or soon after vaccination. Because fainting after vaccination can lead to serious consequences, anyone who complains of giddiness or light-headedness before or after vaccination should be advised to lie down until free of symptoms.

**Anaphylaxis and vasovagal episodes**

Anaphylaxis following routine vaccination is very rare, but can be fatal. All immunisation service providers must be able to recognise all the symptoms and signs of anaphylaxis and distinguish between anaphylaxis, convulsions and fainting. The features listed in Table 2.3.1 may be useful in differentiating between fainting (vasovagal episode) and anaphylaxis.

Anaphylaxis is a severe adverse event of rapid onset, characterised by sudden respiratory compromise and/or circulatory collapse. Early signs include involvement of the skin (e.g. generalised erythema, urticaria and/or angioedema) and/or gastrointestinal tract (e.g. diarrhoea, vomiting). In severe cases, there is circulatory collapse with alteration in the level of consciousness, hypotension and weak or absent pulses, and/or marked respiratory compromise from upper airway oedema or bronchospasm.

Fainting (vasovagal episode) is relatively common after vaccination of adults and adolescents, but infants and children rarely faint. Sudden loss of consciousness in young children should be presumed to be anaphylaxis, particularly if a strong central pulse is absent. A strong central pulse (e.g. carotid) persists during a faint or convulsion.

If a diagnosis of anaphylaxis is suspected, treatment, including administration of adrenaline, should be instituted promptly (refer to ‘Management of anaphylaxis’ below). Under-treatment of anaphylaxis is more harmful, and potentially life-threatening, than over-treatment of a mild or moderate allergic reaction.
### Table 2.3.1: Clinical features that may assist differentiation between a vasovagal episode and anaphylaxis

<table>
<thead>
<tr>
<th></th>
<th>Vasovagal episode</th>
<th>Anaphylaxis*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Onset</strong></td>
<td>Immediate, usually within minutes of, or during, vaccine administration</td>
<td>Usually within 15 minutes, but can occur within hours, of vaccine administration</td>
</tr>
<tr>
<td><strong>Symptoms/Signs</strong></td>
<td><strong>Respiratory</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal respiration; may be shallow, but not laboured</td>
<td>Cough, wheeze, hoarseness, stridor, or signs of respiratory distress (e.g. tachypnoea, cyanosis, rib recession)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Upper airway swelling (lip, tongue, throat, uvula or larynx)</td>
</tr>
<tr>
<td></td>
<td><strong>Cardiovascular</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bradycardia, weak/absent peripheral pulse, strong carotid pulse</td>
<td>Tachycardia, weak/absent carotid pulse</td>
</tr>
<tr>
<td></td>
<td>Hypotension – usually transient and corrects in supine position</td>
<td>Hypotension – sustained and no improvement without specific treatment (Note: in infants and young children, limpness and pallor are signs of hypotension)</td>
</tr>
<tr>
<td></td>
<td>Loss of consciousness – improves once supine or in head-down position</td>
<td>Loss of consciousness – no improvement once supine or in head-down position</td>
</tr>
<tr>
<td></td>
<td><strong>Skin</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Generalised pallor, cool, clammy skin</td>
<td>Pruritus (skin itchiness), generalised skin erythema (redness), urticaria (wells) or angioedema (localised or general swelling of the deeper layers of the skin or subcutaneous tissues)</td>
</tr>
<tr>
<td></td>
<td><strong>Gastrointestinal</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Nausea/vomiting</td>
<td>Abdominal cramps, diarrhoea, nausea and/or vomiting</td>
</tr>
<tr>
<td></td>
<td><strong>Neurological†</strong></td>
<td>Sense of severe anxiety and distress</td>
</tr>
</tbody>
</table>

* Modified from The Brighton Collaboration Case Definition Criteria for Anaphylaxis.⁶
† Neurological symptoms are not listed in the Brighton case definition criteria for anaphylaxis; however, symptoms of anxiety and distress, including feelings of impending doom, are reported in persons experiencing anaphylaxis.⁷

### Management of anaphylaxis

Rapid IM administration of adrenaline is the cornerstone of treatment of anaphylaxis. Adrenaline is life saving and must be used promptly.⁸

Anaphylaxis occurs without warning, usually within 15 minutes of giving a vaccine. A protocol for the management of anaphylaxis, adrenaline and 1 mL syringes must always be immediately at hand whenever vaccines are given.

- If the patient is unconscious, lie him/her on the left side and position to keep the airway clear.
- If the patient is conscious, lie him/her supine in ‘head-down and feet-up’ position (unless this results in breathing difficulties).
- If there are any respiratory and/or cardiovascular symptoms or signs of anaphylaxis, give adrenaline by IM injection into the anterolateral thigh (refer to ‘Use of adrenaline’ below for dosage). Adrenaline is not required for generalised non-anaphylactic reactions (such as skin rash or angioedema). If in doubt, IM adrenaline should be given. No serious or permanent harm is likely to occur from mistakenly administering adrenaline to an individual who is not experiencing anaphylaxis.¹⁰
- Call for assistance. Never leave the patient alone.
- If oxygen is available, administer by facemask at a high flow rate.
- If there is no improvement in the patient’s condition within 5 minutes, repeat doses of adrenaline every 5 minutes until improvement occurs.
- Check breathing; if absent, commence basic life support or appropriate cardiopulmonary resuscitation (CPR), as per the Australian Resuscitation Council guideline ¹¹ (available at www.resus.org.au/guidelines).
- In all cases, transfer the person to hospital for further observation and treatment.
- Complete full documentation of the event, including the time and dose(s) of adrenaline given.
Antihistamines and/or hydrocortisone are not recommended for the emergency management of anaphylaxis.

**Use of adrenaline**

The use of 1:1000 adrenaline is recommended because it is universally available. Adrenaline 1:1000 (one in one thousand) contains 1 mg of adrenaline per mL of solution in a 1 mL glass vial. Adrenaline 1 in 10 000 is no longer recommended for the treatment of anaphylaxis. A 1 mL syringe should be used to improve the accuracy of measurement when drawing up small doses of adrenaline.

The recommended dose of 1:1000 adrenaline is 0.01 mL/kg body weight (equivalent to 0.01 mg/kg or 10 µg/kg) up to a maximum of 0.5 mL, given by deep IM injection *preferably in the anterolateral (upper outer) thigh*. The anterolateral thigh is the preferred site because there is a more predictable dispersal of adrenaline from this site. Administration of adrenaline in the anterolateral thigh is also in accordance with recommendations from various emergency medicine, anaesthetic and immunology professional bodies.

Adrenaline 1:1000 must not be administered intravenously.

Table 2.3.2 lists the dose of 1:1000 adrenaline to be used if the exact weight of the person is not known.

The dose of 1:1000 (one in one thousand) adrenaline may be repeated every 5 minutes, as necessary, until there is clinical improvement.

<table>
<thead>
<tr>
<th>Approximate age and weight</th>
<th>Adrenaline dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 year (approx. 5–10 kg)</td>
<td>0.05–0.1 mL</td>
</tr>
<tr>
<td>1–2 years (approx. 10 kg)</td>
<td>0.1 mL</td>
</tr>
<tr>
<td>2–3 years (approx. 15 kg)</td>
<td>0.15 mL</td>
</tr>
<tr>
<td>4–6 years (approx. 20 kg)</td>
<td>0.2 mL</td>
</tr>
<tr>
<td>7–10 years (approx. 30 kg)</td>
<td>0.3 mL</td>
</tr>
<tr>
<td>10–12 years (approx. 40 kg)</td>
<td>0.4 mL</td>
</tr>
<tr>
<td>&gt;12 years and adult (over 50 kg)</td>
<td>0.5 mL</td>
</tr>
</tbody>
</table>

*Modified from insert published in *Australian Prescriber* (available at www.australianprescriber.com/magazine/34/4/article/1210.pdf). Endorsed by the Australasian Society of Clinical Immunology and Allergy, the Royal Australasian College of Physicians, the Royal Australian College of General Practitioners, the Australasian College for Emergency Medicine, the Royal Australian and New Zealand College of Radiologists, the Internal Medicine Society of Australia and New Zealand, and the Australian Dental Association.

**Use of adrenaline autoinjectors for anaphylaxis treatment**

Adrenaline autoinjectors, EpiPen or Anapen, are devices that administer a single, pre-measured dose of adrenaline. They are designed for use by any person, whether medically trained or not. Clear instructions on correct use are provided on the barrel and in the packaging of these devices. They are designed to be administered in the mid-outer thigh.

Autoinjectors are usually recommended or prescribed for an individual who is at risk of anaphylaxis due to an existing allergy or where skin testing indicates a high risk of an allergic reaction on exposure to an allergen. If a patient who carries an autoinjector device develops anaphylaxis post vaccination, it is appropriate to use their autoinjector to administer adrenaline.

Autoinjectors are generally not appropriate for inclusion in first aid kits for general use, due to several limitations:

- they are single-use only
- they are dose-specific
  - EpiPen Jr or Anapen Jr containing 150 µg of adrenaline are recommended for children weighing between 10 kg and 20 kg
  - EpiPen or Anapen containing 300 µg of adrenaline are recommended for children and adults weighing over 20 kg
- multiple pens would be required to allow for repeat dosing and varying ages/weights of patients, and shelf-life is limited to 1 to 2 years maximum.

Autoinjectors are not recommended for use in children weighing less than 10 kg.

**Common adverse events following immunisation and their management**

Commonly occurring AEFI are described in the table *Comparison of the effects of diseases and the side effects of NIP vaccines* inside the back cover of this *Handbook* and in the disease-specific chapters in Part 4.
The most commonly encountered adverse events are local reactions related to vaccine injection(s), such as pain, redness, itching, swelling or burning at the injection site. These are to be expected, are generally mild and usually last for 1 to 2 days. Injection site nodules are also relatively common. They are fibrous remnants of the body’s interaction with the vaccine components (usually an adjuvant) in the muscle. They may remain for many weeks after vaccination and do not require any specific treatment.

Low-grade fever and tiredness (malaise), lasting a few days, are also common after many vaccines. These responses are usually mild and self-limiting, and generally do not require specific treatment.

Prophylactic administration of paracetamol at the time of, or immediately after, vaccination to reduce the risk of fever is not recommended, with the exception of specific recommendations for prophylactic administration of paracetamol with meningococcal B vaccine in infants <2 years of age (refer to 4.10 Meningococcal disease). However, if an infant, child or adult has a fever of >38.5°C following vaccination or has pain at the injection site, paracetamol can be given. The dose of paracetamol for an infant or child up to 12 years of age is 15 mg/kg/dose, up to a maximum dose of 60 mg/kg per day in four divided doses. Adults and children aged ≥12 years can receive 500 to 1000 mg every 4 to 6 hours; dosage must not exceed 4 g in 24 hours. Paracetamol should not be given for more than 48 hours without seeking medical advice.14

If patients exhibit unexpected, serious or prolonged adverse symptoms or signs following immunisation, medical advice should be sought. The symptoms and signs from medical illness unrelated to vaccination can sometimes be attributed to a recent immunisation and should be investigated and managed accordingly.

### Uncommon/rare adverse events following immunisation

Some vaccines have been shown to cause uncommon or rare serious adverse events, although the rate of vaccine adverse events is usually hundreds to thousands times less frequent than the disease complications. Information on the benefits compared with risks of immunisation is always taken into account when making recommendations for vaccine use. It is important to provide persons to be vaccinated or their parent/carer with advice regarding known, but rare, adverse events following immunisation, and to place the advice in the context of the benefits of vaccination (refer to 3.3.1 Vaccination of persons who have had an adverse event following immunisation).

If a patient has experienced a serious or uncommon/rare AEFI, it is important that they or their immunisation service provider seek advice from a specialist immunisation clinic or contact state/territory health authorities for more information regarding the need for further investigation and management (refer to Appendix 1 Contact details for Australian, state and territory government health authorities and communicable disease control). This will enable an assessment to determine the relationship to vaccination, consideration of the benefits and risks of further vaccination, and planning for receiving additional doses of that or other vaccines, as appropriate. Persons who have had a serious adverse event following immunisation (other than a contraindication, such as the confirmed identity of the vaccine component that triggered anaphylaxis) can usually subsequently be vaccinated under close medical supervision. For more detailed information refer to 3.3.1 Vaccination of persons who have had an adverse event following immunisation.

Examples of uncommon and rare adverse events are given below. It is important to remember that, although these events are uncommon or rare, they are still not necessarily causally related to vaccination, even if they occur following vaccination.

- **Febrile convulsions** are a relatively common response to fever of any cause in young children, particularly in those aged <3 years, with a peak incidence at 14–18 months of age. Overall, by the age of 5 years, approximately 3% of all children will have experienced a febrile convulsion, irrespective of vaccination. Febrile convulsions are rare following immunisation. They do, however, occur more commonly, but still at a low rate, after some vaccines. For example, MMR and MMRV vaccines are associated with an increased risk of febrile convulsions approximately 7 to 12 days after the 1st vaccine dose (refer to 4.9 Measles for more information). Co-administration of trivalent influenza vaccine and 13-valent pneumococcal conjugate vaccine may also be associated with an increased risk of febrile convulsions (refer to 4.7 Influenza and 4.13 Pneumococcal disease). In 2010, there was an increased incidence of high fevers and febrile convulsions (estimated at 4.4 per 1000 doses in Western Australia) following administration of one brand of seasonal influenza vaccine (bioCSL Fluvax and Fluvax Junior) in children aged <5 years in Australia.15 This vaccine is no longer registered for use in this age group. An excess risk of fever and febrile convulsions was not observed with the other influenza vaccines given to children.15,16

- **Brachial neuritis** (inflammation of a nerve in the arm, causing weakness or numbness) has been described following the administration of tetanus toxoid-containing vaccines, with an estimated excess risk of approximately 0.5–1 in 100 000 doses in adults.5,17 Case reports of brachial neuritis following administration of other vaccines, including HPV vaccines,18 are rare and a causal relationship has not been established.19

- **Oral rotavirus vaccines** are associated with a small increased risk of intussusception (IS), a rare form of bowel blockage caused by telescoping of the intestine into itself. This risk appears to be particularly in the 7 days following the 1st vaccine dose; however, a smaller increased risk in the week following the 2nd dose has also been reported.20–22 It is not currently clear whether there is an overall increase in the risk of IS above that which would be expected in the 1st year of infancy without vaccine use. The increased risk represents approximately 6 additional cases of intussusception among every 100 000 infants vaccinated, or 14 additional cases per year in Australia.22 Children who have had IS are recommended not to receive rotavirus vaccine (refer to 4.17 Rotavirus).
• Anaphylaxis following receipt of vaccines has been reported, but generally occurs very rarely. For example, the estimated incidence rate of anaphylaxis following 4vHPV vaccine in Australia as at June 2010 was 2.6 anaphylaxis episodes per million doses of vaccine distributed. This is within the same rate range as for other vaccines given to children and adolescents in international studies, such as hepatitis B vaccine, which is associated with anaphylaxis in approximately 1 in 1.1 million doses distributed. (For more information on the management of immediate AEFI/anaphylaxis, refer above.)

• Hypotonic-hyporesponsive episode (HHE) is the sudden onset of pallor or cyanosis, limpness (muscle hypotonia), and reduced responsiveness or unresponsiveness occurring after vaccination, where no other cause is evident such as a vasovagal episode or anaphylaxis. The episode usually occurs 1 to 48 hours after vaccination and resolves spontaneously. There are no known long-term side effects from HHE. In Australia during 2009, 3.2 cases of HHE were reported per 100,000 doses of DTPa-containing vaccine given to children <1 year of age.

• Guillain-Barré syndrome (GBS) is a rare autoimmune condition with acute onset of a rapidly progressive, ascending, symmetrical flaccid paralysis, with or without sensory loss. Diagnosis of GBS is complex and must be made by a physician. A small increased risk of GBS was associated historically with one influenza vaccine in the United States in 1976, but since then close surveillance has shown that GBS has occurred at a very low rate of up to 1 in 1 million doses of influenza vaccine, if at all.

• Complex regional pain syndrome (CRPS) is an uncommon and poorly understood condition characterised by chronic pain in one or more of the extremities, along with autonomic dysfunction in the affected limb(s), that occurs in response to trauma such as injury, stroke and/or medical procedures. Rare cases of CRPS following vaccination have been reported. However, this has been postulated to be a non-specific reaction to the minor trauma of the injection and not specific to the vaccine(s) used.

Events where evidence demonstrates no causal link with immunisation

Since vaccines are mainly given to healthy people, a range of conditions that occur after a vaccine dose may be attributed to vaccination. This is particularly so for illnesses that are complex and have an unknown or unclear cause. As many of these illnesses are rare and/or manifest months to years after vaccination, they are difficult to study in randomised controlled clinical trials, which are typically conducted before vaccines are registered for use. However, there is strong epidemiological evidence, usually derived from multiple well-conducted post-marketing studies, that indicates there is no causal association between immunisation and many diseases/conditions in which vaccines were suggested to have been involved.

Examples of events unrelated to vaccination include:

• sudden infant death syndrome (SIDS) and any vaccine
• autism and MMR vaccine
• multiple sclerosis and hepatitis B vaccine
• inflammatory bowel disease and MMR vaccine
• diabetes and Hib vaccine
• asthma and any vaccine.

Despite this evidence, patients/parents seeking further advice should discuss this with their immunisation provider or could be referred to a specialist immunisation clinic for further reassurance (refer to Appendix 1 Contact details for Australian, state and territory government health authorities and communicable disease control).

Reporting adverse events following immunisation

Surveillance for adverse events following immunisation is an integral part of the Australian National Immunisation Program, and underpins the safe use of all vaccines in Australia. Surveillance of AEFI aims to detect changes in the rates of known adverse events, any unrecognised or unexpected adverse events, or adverse events that result from program errors, such as incorrect vaccine schedule, delivery or storage. It is very important that all immunisation service providers report AEFI, particularly if serious or unexpected, as this will enable vaccine safety issues to be identified and managed appropriately as soon as possible. For example, reporting of AEFI by immunisation service providers in Australia in 2010 resulted in the detection of an unexpectedly high rate of fever and febrile convulsions in young children, associated with the use of one brand of seasonal influenza vaccine. All reported AEFI are included in the Adverse Drug Reactions System (ADRS) database of the Therapeutic Goods Administration (TGA). For details on how to report AEFI, refer to the next section below.

Any serious or unexpected adverse event following immunisation should be promptly reported. Providers should use clinical judgment in deciding which adverse events to report and parents/carers should be encouraged to notify the immunisation service provider or health authorities of any untoward medical occurrence that follows immunisation.
No time limit has been set to report AEFI; however, timely notification of adverse events, particularly rapid reporting of serious events, is important to identify any potential concerns. Notification does not necessarily imply a causal association with vaccination, as some events may occur coincidentally following vaccination. Any event that is suspected of being related to vaccination can be reported. All identifying information relating to the reporter and patient is kept strictly confidential. Any person, medical or non-medical, including providers who did not give the vaccine(s), can report an AEFI; however, it is very important that as much detail as possible is provided on all reports.

In addition to reporting of AEFI, immunisation service providers may need to provide additional clinical management and advice regarding future vaccination(s) for their patient and may require expert advice. Information about specialist immunisation clinics, or the contact details for paediatricians or medical specialists with experience in management of patients with AEFI, are usually available from state and territory health authorities (refer to Appendix 1 Contact details for Australian, state and territory government health authorities and communicable disease control) and from the Immunise Australia website (www.immunise.health.gov.au). For more information on managing common and rare AEFI, refer above and also to 3.3.1 Vaccination of persons who have had an adverse event following immunisation.

How to report adverse events following immunisation

AEFI are notifiable via different routes; immunisation service providers should be aware of the method of reporting for their location. In most jurisdictions (the Australian Capital Territory, New South Wales, the Northern Territory, Queensland, South Australia, Victoria and Western Australia), AEFI should be reported directly to the relevant state/territory health authority (refer to Table 2.3.3). AEFI notified to these state and territory health departments are then forwarded to the TGA, who manage the ADRS database, which includes all adverse reaction reports related to drugs and vaccines. Reporting can also be done directly to the TGA as described below.

Table 2.3.3: Contact information for notification of adverse events following immunisation

<table>
<thead>
<tr>
<th>State/Territory</th>
<th>Report adverse events to</th>
<th>Contact information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australian Capital Territory</td>
<td>ACT Health Department</td>
<td>02 6205 2300</td>
</tr>
<tr>
<td>New South Wales</td>
<td>NSW Public Health Units</td>
<td>1300 066 055 (for connection to Public Health Unit)</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>NT Department of Health</td>
<td>08 8922 8044</td>
</tr>
<tr>
<td>Queensland</td>
<td>Queensland Health</td>
<td>Complete an AEFI initial report form, available at:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fax the completed form to the number provided on the form.</td>
</tr>
<tr>
<td>South Australia</td>
<td>SA Health</td>
<td>1300 232 272</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="http://www.sahealth.sa.gov.au">www.sahealth.sa.gov.au</a></td>
</tr>
<tr>
<td>Tasmania</td>
<td>Direct to the TGA</td>
<td>1800 044 114</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or complete the ‘Blue card’ reporting form (refer below)</td>
</tr>
<tr>
<td>Victoria</td>
<td>SAEFVIC</td>
<td>03 9345 4143</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or online at <a href="http://www.saefvic.org.au">www.saefvic.org.au</a></td>
</tr>
<tr>
<td>Western Australia</td>
<td>State Health Department, WAVSS</td>
<td>08 9321 1312</td>
</tr>
<tr>
<td></td>
<td></td>
<td>or online at wavss.health.wa.gov.au</td>
</tr>
</tbody>
</table>

Alternatively, reporting directly to the TGA can be done by any person in any jurisdiction. Reports are submitted using the ‘Blue card’ adverse reaction reporting form. Paper copies of the ‘Blue card’ are available from:

Office of Product Review
Therapeutic Goods Administration
Reply Paid 100
Woden ACT 2606
Telephone: 1800 044 114


Alternatively, the adverse reaction reporting form can be completed and submitted online via the TGA website at www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase.
Consumers and immunisation service providers can also report AEFI (and adverse drug reactions) via the national Adverse Medicines Events telephone reporting line on 1300 134 237. This service is operated by the National Prescribing Service (NPS) (www.nps.org.au) and funded by the Australian Government through the Department of Health.

The TGA, in turn, forwards copies of individual reports of AEFI from vaccines on the NIP schedule back to state/territory health departments for their information.

Information on vaccine AEFI reports to the TGA from all sources are aggregated, and detailed information on AEFI reporting rates and trends in AEFI are published in the journal Communicable Diseases Intelligence (www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-cdiintro.htm).33,51

The TGA also transfers reports of adverse events to all medicines, including vaccines, to a publicly accessible search facility, the Database of Adverse Event Notifications (www.tga.gov.au/database-adverse-event-notifications-danen).

### 2.3.3 Documentation of vaccination

It is essential that immunisation service providers ensure there is appropriate documentation of all vaccinations given to persons of any age. There are a number of ways in which this should be done.

All vaccines administered to children should be documented in the child’s clinical file and the individual child health record that is established for all newborn infants. This record should be kept by the parent/carer and presented every time the child is seen by a health professional.

Vaccines administered to adolescents and adults should be recorded in both the vaccinated person’s clinical file and the personal health record, or individual record, of vaccination. The following details should be recorded:

- the person’s full name and date of birth
- the details of the vaccine given, including the brand name, batch number and dose number
- the date and time of vaccination
- the site of administration
- the name of the person providing the vaccination
- the date the next vaccination is due.

Some state/territory health departments also have specific requirements for documentation of vaccines administered to healthcare workers/healthcare students undertaking work or clinical placement within state/territory health facilities. Refer to the relevant state/territory health department for further details (refer to Appendix 1).

Immunisation service providers should also report vaccination details to the appropriate immunisation register(s) – discussed in detail below.

### 2.3.4 Immunisation registers

In 2016, expansion of Australia’s immunisation registers began with the aim of improving data capture and vaccine coverage rates across the entire Australian community. Historically, there have been two national immunisation registers in place in Australia: the Australian Childhood Immunisation Register (ACIR) and the National Human Papillomavirus Vaccination Program Register (the HPV Register). The ACIR, administered by the Australian Government Department of Human Services, commenced on 1 January 1996 and recorded details of vaccinations given to children <7 years of age who live in Australia. The HPV Register, currently operated by the Victorian Cytology Service on behalf of the Australian Government Department of Health, was established in 2007 to record information about HPV vaccine doses administered in Australia, supporting the implementation and monitoring of the National HPV Vaccination Program funded by the Australian Government the same year.

The Australian Immunisation Register Act 2015 came into effect on 1 January 2016 and provides the legal authority for the expansion and ongoing administration and keeping of the registers. From 1 January 2016, the ACIR began accepting vaccination information from all children, adolescents and young adults ≥20 years of age (expanded from <7 years of age). From September 2016, the ACIR will further expand to become the Australian Immunisation Register (AIR), capturing vaccinations given throughout a person’s life through general practice and community clinics (refer to ‘Australian Childhood Immunisation Register and Australian Immunisation Register’ below).

From the 2017 school year, the HPV Register will become the Australian School Vaccination Register (ASVR) which will capture certain adolescent vaccinations which are given through school programs (refer to ‘School vaccination program registers’ below).

**Australian Childhood Immunisation Register and Australian Immunisation Register**

Children, adolescents and young adults <20 years of age who are enrolled in Medicare are automatically included on the ACIR. Adults ≥20 years of age enrolled in Medicare will automatically be included on the register once the register is expanded from September 2016. Individuals not enrolled in Medicare will be included when an immunisation service
provider sends details of a vaccination to the register. Immunisation providers other than general practitioners need to register with the ACIR before they can send data to the register.

National immunisation registers provide an important means of accountability and evaluation of Australia’s funded National Immunisation Program and are the primary means of determining vaccination coverage at national, state/territory and local levels. They provide a central record of the vaccination history of each Australian, which is accessible by Australian immunisation service providers wishing to assess a patient’s vaccination history to assist in planning vaccination needs.

Since 1998, data held on the ACIR have been used to determine a family’s entitlement to government family assistance payments including the Child Care Benefit and Child Care Rebate and, from July 2012, the Family Tax Benefit Part A supplement. From January 2016, immunisation requirements for eligibility for these payments were expanded to include children, adolescents and young adults up to 20 years of age. It is, therefore, important that immunisation service providers submit vaccination data to the ACIR promptly. More information on immunisation requirements for family assistance payments can be found on the Australian Government Department of Human Services website (www.humanservices.gov.au/customer/subjects/immunising-your-children).

Reporting to the Australian Childhood Immunisation Register

Immunisation service providers should send to the ACIR details of all NIP and private vaccinations given to all children, adolescents and young adults <20 years of age. Vaccination details can be submitted by sending data electronically via Medicare Online or the ACIR secure Internet site (refer to ‘Resources on the Australian Childhood Immunisation Register website’ below), or by using a paper form (either an Immunisation Encounter form or an Immunisation History form). An individual’s vaccination record can also be updated with vaccination details where there is documentation that the vaccination was performed by another immunisation service provider (including vaccines given while the child, adolescent or young adult was overseas) by completing and sending an Immunisation History form. Immunisation service providers in Queensland and the Northern Territory who currently send data to the ACIR via their state/territory health department should continue to do so.

When required, exemptions to immunisation due to medical contraindications or natural immunity to certain diseases (refer to 2.1.5 Catch-up, ‘Use of laboratory testing to guide catch-up vaccination’) can be submitted to the ACIR via the approved ACIR Immunisation Medical Exemption form. This form can only be completed by general practitioners. The form includes guidance for general practitioners on what is, and is not, considered a valid reason for a medical exemption. As of January 2016, vaccine objection on non-medical grounds is not accepted as a valid exemption from immunisation requirements. The medical exemption form for general practitioners to complete is available on the Australian Government Department of Human Services website (www.humanservices.gov.au/health-professionals/forms/im011).

For further information about the ACIR and reporting vaccination information, refer to ‘Resources on the Australian Childhood Immunisation Register website’ below.

Resources on the Australian Childhood Immunisation Register website

The Australian Government Department of Human Services website (www.humanservices.gov.au) houses ACIR information and resources. The website has a general information area for individuals and families, a general information area for health professionals and a secure area for immunisation service providers only. Immunisation-related forms, such as the Immunisation History form and the Immunisation Medical Exemption form, can be found in the health professionals area of the website.

The ACIR secure site, which is within Health Professionals Online Services (HPOS) (www.humanservices.gov.au/hpos), allows immunisation service providers to obtain a range of statistical and identified reports. Depending on the access level granted to the provider, these reports enable approved providers to view a child, adolescent or young adult’s vaccination details, record vaccination information and access a range of other reports. All general practitioners with access to HPOS can access the ACIR secure site through this platform. Other immunisation service providers can register for access to the ACIR secure site by completing the online request form, available from the Department of Human Services website.

Further information or assistance on any reporting issues can be obtained by calling the ACIR Internet Helpline on 1300 650 039.

Immunisation History Statement

Immunisation History Statements contain details of all vaccines administered to a child, adolescent or young adult <20 years of age that are recorded on the ACIR and list the vaccines that are next due. These statements are automatically generated on completion of the childhood vaccination schedule (usually around 4 years of age). These statements will be mailed to the address most recently recorded by Medicare for that individual.

Parents/carers of children <14 years of age, and adolescents and young adults ≥14 years of age, can get a copy of their immunisation history at any time:

- via their Medicare online account through myGov
through the Express Plus Medicare mobile app

by calling 1800 653 809 (free call).

Immunisation History Statements can be used to assist in recalling vaccination history when required. For example:

- for school enrolment
- to determine eligibility for the Child Care Benefit, the Child Care Rebate and the Family Tax Benefit Part A supplement – this requires that children are assessed as fully immunised.

Recording details of a deceased child

The ACIR receives notification of the death of a child or young individual <20 years of age via Medicare. This information no longer needs to be provided to the ACIR by an immunisation service provider.

Children who have moved to live overseas

If a child, adolescent or young adult <20 years of age has moved overseas, their immunisation service provider can inform the ACIR by phone or secure site email. This prevents their name continuing to appear on ACIR reports of overdue individuals.

Children born overseas who have moved to live in Australia permanently

A child, adolescent or young adult <20 years of age born overseas who has moved permanently to Australia will be automatically added to the ACIR upon enrolment with Medicare. Individuals residing temporarily in Australia are not included on the ACIR until an immunisation service provider notifies the register of a vaccination administered to that individual.

School vaccination program registers

Since its introduction in 2007, the HPV Register has played an essential role in monitoring and evaluating the HPV Vaccination Program by recording information about HPV vaccine doses administered in Australia. From the 2017 school year, vaccinations given through school programs, including HPV and varicella vaccines and the diphtheria-tetanus-pertussis booster, will be captured in the Australian School Vaccination Register (ASVR), replacing the HPV Register. Until this date, the HPV Register will continue to record information about HPV vaccine doses administered in Australia (refer to ‘National Human Papillomavirus Vaccination Program Register’ below).

Some states and territories also maintain records of vaccinations delivered through school-based programs. Information on how to obtain such records can be obtained from state and territory government health departments (refer to Appendix 1 Contact details for Australian, state and territory government health authorities and communicable disease control).

National Human Papillomavirus Vaccination Program Register (the HPV Register)

Reporting to the HPV Register

Details on HPV vaccinations given in the community are provided to the HPV Register by the immunisation service provider who administers the vaccine. Vaccination details may be submitted electronically, via data uploads or direct entry using the secure website, or in hard copy, using one of the approved notification forms. Immunisation service providers in Queensland and the Northern Territory report data to the HPV Register via their state/territory health authority. Immunisation service providers wishing to submit vaccination data electronically need to be approved and registered with the HPV Register in order to notify administered doses. General practitioners are required to register with the HPV Register in order to notify administered doses. Further information about registration and notification procedures is available from the HPV Register website (www.hpvregister.org.au) or by phoning 1800 478 734 (1800 HPV REG).

HPV vaccination coverage and other reports

For immunisation service providers, the HPV Register has developed overdue HPV vaccine dose reports for their patients, which are available online via the secure website. De-identified HPV vaccination coverage data and other reports have also been developed to inform policy making, and support program delivery and approved research. National coverage data are made publicly available via the Immunise Australia website (www.immunise.health.gov.au).

HPV Register statements

The HPV Register sends Completion Statements and History/Reminder Statements. Immunisation History Statements, containing details of the vaccinations recorded on the HPV Register, are sent to persons who are overdue for HPV vaccination within the school-based program. Completion Statements are sent to persons who have completed the 3-dose HPV vaccination course. Vaccinated persons and parents/guardians can request a statement at any time by phoning 1800 478 734 (1800 HPV REG). In the event that booster doses are required in future, all eligible persons will be notified by the HPV Register.
HPV vaccination status

Vaccinated persons and parents/guardians can phone the HPV Register on 1800 478 734 (1800 HPV REG) to obtain their or their child’s HPV vaccination status. Immunisation service providers can also request a person’s vaccination status by phone or can view these online if they are registered with the HPV Register. The HPV Register initially only recorded vaccinations for females, but since 2013 also records vaccinations given to males.

HPV Register secure website

The HPV Register secure website allows registered and approved immunisation service providers to view a patient’s vaccination history as well as to access overdue dose reports. Further information on how to request access to the HPV Register secure website can be found on the health professionals page of the HPV Register website (www.hpregister.org.au) or by phoning 1800 478 734 (1800 HPV REG).

Other immunisation registers

The Australian Q Fever Register (www.qfever.org), established by Meat and Livestock Australia (MLA), has records of receipt of Q fever vaccination for some individuals, which can be accessed by registered users (refer also to 4.15 Q fever). Some state/territory governments operate a jurisdictional immunisation register, though the scope of these varies.

Queensland

The Vaccine Information and Vaccine Administration System (VIVAS) is a database of vaccination events for all children up to 10 years of age, adolescents and (some) adults in Queensland who are vaccinated with nationally- or state-funded vaccines.

Immunisation service providers in Queensland are encouraged to report all vaccinations, either directly to VIVAS via the Queensland Health Vaccination Record form or using practice software to electronically transfer data (via the ACIR) to Queensland Health. Vaccination Record forms can be posted reply paid to VIVAS or faxed directly. Providers reporting to VIVAS should do so at least once a week to ensure the supply of data is not delayed and is available for the purposes of calculating parental and provider incentive payments using ACIR data.

Immunisation service providers enrolled on VIVAS have access to a range of services, such as reminder notices for overdue or unimmunised patients, individual vaccination records via local public health units, and Queensland’s centralised Vaccine Distribution System (www.health.qld.gov.au/clinical-practice/guidelines-procedures/diseases-infection/immunisation/service-providers/records/default.asp).

The Northern Territory

The NT Immunisation Register records details of all vaccines administered to anyone in the Northern Territory (NT). Immunisation service providers in the NT are encouraged to report all administered vaccines to the NT Immunisation Register. This can be done by direct electronic transfer from some services or via printed lists from clinical software programs and/or by completing the NT childhood or adult vaccination recording form (www.health.nt.gov.au/Centre_for_Disease CONTROL/Immunisation/Recording_and_Reporting_Forms/index.aspx).

The NT Immunisation Register routinely provides relevant data on vaccination encounters to the ACIR and the HPV Register.

The NT Immunisation Register provides a number of services, such as recall lists for childhood immunisations in remote areas, individual vaccination records, and web-based access for NT immunisation service providers for immunisation histories for children <15 years of age (www.health.nt.gov.au/Centre_for_Disease_CONTROL/Immunisation/NT_Immunisation_Register/index.aspx).

References

A full reference list is available on the electronic Handbook or website www.immunise.health.gov.au.


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