

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. Severe anaphylactic reactions usually have a rapid onset; life-threatening adverse events are most likely to begin within 15 minutes of vaccination.

The most serious immediate AEFI is anaphylaxis. 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.⁶ 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.⁷ 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 promptly⁸ (see '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.⁹

Table 2.3.1: Clinical features that may assist differentiation between a vasovagal episode and anaphylaxis

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

* Modified from The Brighton Collaboration Case Definition Criteria for Anaphylaxis.⁶

† Neurological symptoms are not listed in the Brighton case definition criteria for anaphylaxis;⁶ however, symptoms of anxiety and distress, including feelings of impending doom, are reported in persons experiencing anaphylaxis.^{7,10}

Management of anaphylaxis see 1 page chart

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 (see '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.¹¹
- 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 guideline¹² (available at www.resus.org.au/policy/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.¹³ Administration of adrenaline in the anterolateral thigh is also in accordance with recommendations from various emergency medicine, anaesthetic and immunology professional bodies.⁹

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 2.3.2: Doses of intramuscular 1:1000 (one in one thousand) adrenaline for anaphylaxis^{c*14}

Approximate age and weight	Adrenaline dose
<1 year (approx. 5–10 kg)	0.05–0.1 mL
1–2 years (approx. 10 kg)	0.1 mL
2–3 years (approx. 15 kg)	0.15 mL
4–6 years (approx. 20 kg)	0.2 mL
7–10 years (approx. 30 kg)	0.3 mL
10–12 years (approx. 40 kg)	0.4 mL
>12 years and adult (over 50 kg)	0.5 mL

* Modified from insert published in *Australian Prescriber*¹⁴ (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.

Routine use of paracetamol at the time of, or immediately after, vaccination is not recommended. 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.¹⁵

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.