PREFACE
The draft 8th Edition of the *Australian Immunisation Handbook* was prepared by the Australian Technical Advisory Group on Immunisation of the Commonwealth Department of Health and Ageing.

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1.1 INTRODUCTION

For more than 200 years, since Edward Jenner first demonstrated that vaccination offered protection against smallpox, the use of vaccines has continued to reduce the burden of many bacterial and viral diseases. For example, as a result of successful vaccination programs, deaths from tetanus, diphtheria, *Haemophilus influenzae* type b and measles are now extremely rare in Australia.\(^1\)

Vaccination not only protects individuals, but also others in the community, by increasing the general level of immunity and minimising the spread of infection. It is vital that health-care professionals take every available opportunity to vaccinate children and adults. It is also important that the public be made aware of the proven effectiveness of immunisation to save lives and prevent serious illness.

The purpose of this *Handbook* is to give Australian immunisation providers clear guidance about vaccination practice, as recommended by the National Health and Medical Research Council (NHMRC). In some instances the NHMRC recommendations differ from vaccine product information sheets; these 'conflicts with product information' are detailed in the relevant vaccine chapters. Where there is such a conflict, the NHMRC recommendation should be considered the best practice.

What’s new? - Changes introduced in this edition of the *Handbook*

For those familiar with the 7th edition of this *Handbook*, it is important to note that the 8th edition introduces some new vaccines, changes to the schedules and to recommendations and procedures for administering vaccines, and changes to the presentation of the *Handbook*. Please refer to the relevant chapters.

New vaccines now available in Australia

- Combination vaccines, including DTPa-hepB-IPV, DTPa-IPV, DTPa-IPV-Hib, DTPa-IPV/Hib and DTPa-hepB-IPV-Hib (the latter is for boosters only). Note that additional combination vaccines are likely to become available in Australia in the near future.
- 7-valent pneumococcal conjugate vaccine (7vPCV).
- Meningococcal C conjugate vaccine (MenCCV).
- Adult/adolescent formulation diphtheria-tetanus-acellular pertussis (dTpa) vaccine suitable for boosting adolescents and adults against pertussis.
- A combination hepatitis A/typhoid vaccine.
- An additional varicella vaccine that can be stored at 2\(^\circ\)C to 8\(^\circ\)C or colder for up to 18 months.

Changes to vaccination schedule


The following recommendations have been formally endorsed by the NHMRC since publication of the 7th edition:

- The fifth dose of oral poliomyelitis vaccine (OPV), previously scheduled at 15 to 17 years of age, is no longer recommended (level III-3 evidence).
- A new 2-dose schedule for the hepatitis B vaccine H-B-Vax II (adult formulation) can be used as an alternative to the standard 3-dose schedule for adolescents aged 11 to 15 years of age.
- The 7-valent pneumococcal conjugate vaccine (7vPCV) is recommended for:

  (i) Aboriginal and Torres Strait Islander infants in a 3-dose series at 2, 4 and 6 months of age with a booster dose of the 23-valent pneumococcal polysaccharide vaccine (23vPPV) at 18 to 24 months of age (level IV evidence). Catch-up is recommended for Aboriginal children in central Australia up
to the fifth birthday and for Aboriginal and Torres Strait Islander children elsewhere up to the second birthday.

(ii) All Australian children with underlying predisposing medical conditions at 2, 4 and 6 months of age with a booster dose of 23vPPV at 4 to 5 years of age (level IV evidence). Catch-up vaccination is recommended for these children up to the fifth birthday.

(iii) All non-Indigenous children residing in central Australia at 2, 4 and 6 months of age, but no booster dose is necessary (unless there is a predisposing medical condition) (level II evidence). Catch-up vaccination is recommended for these children up to the second birthday.

(iv) All Australian children as a 3-dose series at 2, 4 and 6 months of age (level II and IV evidence).

- Meningococcal C conjugate vaccine (MenCCV) is recommended as a single dose at 12 months of age (level III-2 evidence).
- The fourth dose of DTPa, which was previously given at 18 months of age, is no longer required (level IV evidence). Instead, the fourth dose of DTPa is now recommended at 4 years of age.
- An adult/adolescent formulation pertussis-containing vaccine (dTpa) is available for boosting adolescents and adults against pertussis. It is recommended as a single dose at 15 to 17 years of age (level II evidence).
- Oral poliomyelitis vaccine (OPV) is replaced by inactivated poliomyelitis vaccine (IPV) combination vaccines for the 3-dose primary series (2, 4 and 6 months of age) and for the booster dose at 4 years of age (level III-3 evidence).
- Varicella-zoster (chickenpox) vaccine is now recommended for all children at 18 months of age (level II evidence), with a catch-up dose for adolescents 10 to 13 years of age without a history of either varicella or varicella vaccination (level II evidence).

Changes in recommendations and procedures

- Having a 'medical condition affecting the brain or spinal cord' is no longer included in the pre-vaccination checklist as a contraindication to pertussis vaccine.
- The 23-valent pneumococcal polysaccharide vaccine (23vPPV) is now recommended for tobacco smokers (level III-2 evidence). Recommendations for booster doses of 23vPPV in adults have been revised.
- MMR is now recommended for adults born during or since 1966 (previously 1970) who do not have evidence of 2 doses of the vaccine in the past.
- An anaphylactic sensitivity to egg is no longer considered as a cause for concern when administering MMR. In this circumstance, MMR can be safely administered in the usual manner, the vaccinee does not need to be referred for vaccination under close medical supervision.
- The recommended interval for avoidance of pregnancy after administration of a rubella-containing vaccine has been shortened from 2 months to 28 days (expert opinion).
- A new 'rapid' schedule for the combined hepatitis A/B vaccine Twinrix (720/20), with 3 doses given on days 0, 7 and 21, and a (fourth) booster dose at 12 months, can be used if rapid protection is required. A 2-dose schedule of the same vaccine at 0 and 6 to 12 months can be used in 1 to 15 year olds provided that prompt protection against hepatitis B is not required.
- The upper age limit for a single dose of varicella-zoster vaccine has been raised from the thirteenth to the fourteenth birthday. People aged 14 years and older require 2 doses with an optimal interval of 2 months between doses.
- Varicella-zoster vaccine may now be given as soon as 3 months after the intramuscular administration of normal human immunoglobulin (not 5 months as previously recommended).
- Guidelines for the use of varicella-zoster immunoglobulin (VZIG) include a revised definition of 'significant exposure' to varicella.
- Some experts, including the WHO, no longer recommend withdrawing the syringe plunger before injecting a vaccine. However it is still acceptable to do so gently if preferred. If a flash of blood appears in the needle hub, the needle should be withdrawn and a new site selected for injection. For intramuscular injections the angle of insertion of the needle (23 gauge, 25 mm in length) should be 60° (revised from 45° to 60°) (expert opinion).
More comprehensive recommendations for timing of vaccination around administration of immunoglobulin are provided.

For preterm babies, recommendations for hepatitis B vaccination have been revised.

In outbreak situations, it is important to contact the local Public Health Unit, as management policies may vary between States and Territories.

Guidelines for the public health management of pertussis have changed.

Changes in the Handbook

- A separate chapter on vaccination for international travel has been added (Part 2.2).
- The chapter previously entitled 'Special risk groups' has been changed to 'Groups with special vaccination requirements' (Part 2.3). It includes recommendations for patients who have special vaccination needs, those who may experience more frequent adverse advents, and those who may have a suboptimal response to vaccination. Recommendations for immunisation of certain occupational groups are also included.
- Injection technique has been further clarified with new photographs demonstrating intramuscular (IM) and subcutaneous (SC) injections.
- The pre-vaccination questionnaire and assessment table have been revised.
- The risk/benefit table on the back cover of the Handbook has been updated.
- Revised catch-up schedules have been provided for all vaccines in the Australian Standard Vaccination Schedule.
- The table on “Common adverse reactions and what to do about them” (inside back cover) has been revised.
- The information on reporting of adverse events following immunisation has been updated to reflect recent changes to the national reporting arrangements.
- The information on the Australian Childhood Immunisation Register has been updated.
- Table 1.10.1: ‘Information on vaccines exposed to different temperatures’ has been revised.
- Levels of evidence for new recommendations have been included in the fully referenced electronic version of the Handbook. The print version of the Handbook will not be fully referenced nor include levels of evidence.

1.2 STANDARD VACCINATION PROCEDURES

The following vaccination procedures are recommended.

1. **Check availability of the protocols, equipment and drugs necessary for the management of anaphylaxis, before each vaccination session.**

2. **Maintain and monitor vaccine refrigerator, and other ‘cold-chain’ components, according to current recommendations, and preferably check prior to each working day.**

3. **Provide, to the person to be vaccinated, or that person’s parent/caregiver, appropriate information about the risks and benefits of vaccination and the risks of vaccine preventable diseases.**

4. **Perform a pre-vaccination assessment to determine the vaccinee’s medical fitness for vaccination. Any concern about the person’s eligibility for vaccination must be discussed with a medical practitioner, paediatrician or public health physician with expertise in vaccination. (See Appendix 1 for phone numbers for State/Territory public health authorities.) If a person’s health status or suitability for vaccination cannot be determined, defer vaccination.**

5. **Following the provision of appropriate information, (see 3. above) and the pre-vaccination assessment (4. above), obtain valid consent from the person to be vaccinated, or from that person’s parent/caregiver. This should be documented.**

6. **Advise the person to be vaccinated, or that person’s parent/caregiver that the vaccinee should remain under observation in a designated place for a minimum of 15 minutes after the vaccination.**

7. **The schedule, dose, route and technique of administration of the vaccines must be in accordance with NHMRC guidelines. Note: each individual dose must be checked to see that the expiry date has not lapsed, and that there is no particulate matter or colour change in the vaccine.**
8. Administer the vaccine(s). Also check the vaccination status of other family members and offer catch-up vaccination where appropriate.

9. Dispose of needles, syringes and vaccine vials in accordance with standard infection control guidelines.

10. Advise the person, or the parent/caregiver of a child who has just been vaccinated, on the management of the common adverse events that may occur following immunisation. It is important that they be given a contact phone number in case a significant adverse event occurs within 24 to 48 hours of the vaccination.

11. Before departure, inform the person or the child’s parent/caregiver, preferably in writing, of the date of the next scheduled vaccination.

12. Document the details of vaccination: (i) on a record to be retained by the person, or the parent/caregiver of the person; (ii) on the relevant clinical record; and (iii) on an ACIR (or equivalent) encounter form, for children under the age of 7 years.

13. Promptly report any significant adverse event following immunisation to the Adverse Drug Reactions Advisory Committee (ADRAC), or in some instances to the relevant State/Territory Health authorities (see Part 1.6, ‘Adverse events following immunisation’ in ‘Reporting AEFI’, page 23).

Storage
Vaccines are biological products that lose their potency if they are not stored and transported correctly. Vaccines should be refrigerated above 2°C and below 8°C. Except for freeze-dried BCG, OPV and the lyophilised MMR vaccine, PRP-T (but no other Hib vaccine), meningococcal polysaccharide and varicella-zoster vaccines, no vaccines must ever be frozen. Diluent must never be frozen. Some vaccines (eg. BCG and freeze-dried or lyophilised MMR) lose potency if exposed to light. Detailed guidelines on correct storage and transport are found in Part 1.10, ‘Transport, storage and handling of vaccines’.

Reconstitution
Storage conditions differ once vaccines have been reconstituted. Freeze-dried vaccines should be reconstituted with the diluent supplied with the vaccine and the reconstituted vaccines should be used within the recommended time period. Reconstituted vaccines should be checked for signs of deterioration, such as a change in colour or clarity. Most reconstituted vaccines deteriorate rapidly at room temperature. A sterile 21-gauge needle should be used for reconstitution and a separate 23 gauge needle, 25 mm in length, should be used for administration of the vaccine in most circumstances.

Drawing up vaccines from ampoules and vials
Changing needles between drawing up vaccine from an ampoule and injection into a recipient is unnecessary. However, needles should be changed after drawing up from a vial. Small air bubbles do not need to be extruded through the clean needle. Draw up the recommended dose from the ampoule or vial even if there is excess vaccine available.

Multi-dose vials should not be used, unless there is no alternative. If a multi-dose vial must be used, a new sterile disposable needle must be used for each draw-up. A needle or syringe that has already been used to inject an individual must never come into contact with the vial because of the risk of cross-contamination.

Skin cleaning
When the skin is visibly clean, there is no evidence that skin antisepsis is necessary. If the skin needs to be cleaned, alcohol and other disinfecting agents must be allowed to dry before injection of vaccine, since they can inactivate live vaccine preparations and increase injection pain.

Route of administration
Almost all vaccines are given by either intramuscular (IM) injection or subcutaneous (SC) injection. Table 1.2.1 below summarises the route of administration for commonly used vaccines in Australia.

<table>
<thead>
<tr>
<th>Intramuscular (IM) injection</th>
<th>Subcutaneous (SC) injection</th>
<th>IM or SC injection</th>
<th>Intradermal injection</th>
<th>Oral</th>
</tr>
</thead>
</table>

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Table 1.2.1: Route of administration for vaccines commonly used in Australia
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<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Vaccines</th>
<th>Vaccines</th>
<th>Vaccines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphtheria, tetanus vaccine (dT)</td>
<td>Meningococcal polysaccharide vaccine (4vMenPV)</td>
<td>Influenza vaccine (2)</td>
<td>BCG vaccine (4)</td>
</tr>
<tr>
<td>Diphtheria, tetanus, acellular pertussis vaccine (DTPa)</td>
<td>Inactivated polio vaccine (IPV) (1)</td>
<td>Measles, mumps, rubella vaccine (MMR)</td>
<td>Q fever skin test (4)</td>
</tr>
<tr>
<td>DTa-combination vaccines</td>
<td>Varicella-zoster vaccine (VZV)</td>
<td>Rubella vaccine (R)</td>
<td>Mantoux skin test (4)</td>
</tr>
<tr>
<td>Tetanus toxoid vaccine (TT)</td>
<td>Q fever vaccine</td>
<td>23-valent pneumococcal polysaccharide vaccine (23vPPV)</td>
<td>Oral poliomyelitis vaccine (OPV)</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>Japanese encephalitis vaccine</td>
<td>Rabies vaccine (3)</td>
<td>Oral cholera vaccine</td>
</tr>
<tr>
<td>Hepatitis B combination vaccines</td>
<td>Plague vaccine</td>
<td>Yellow fever vaccine</td>
<td>Oral typhoid vaccine</td>
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<tr>
<td>Haemophilus influenzae type b (Hib) vaccine</td>
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<tr>
<td>7-valent pneumococcal conjugate vaccine (7vPCV)</td>
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<tr>
<td>Meningococcal C conjugate vaccine (MenCCV)</td>
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<td>Hepatitis A vaccine</td>
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<tr>
<td>Hepatitis A combination vaccines</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>IPV-containing combination vaccines</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

*(1) IPV-containing combination vaccines are administered by IM injection; monovalent IPV is administered by SC injection.

*(2) Influenza vaccine may be administered by either IM or SC injection. The IM route is preferred because it causes fewer local reactions.

*(3) The use of intradermal route for rabies vaccination is the practitioner’s own responsibility as the vaccine is not licensed for use via this route in Australia.

*(4) Mantoux, Q fever skin test and BCG vaccine should only be administered by specially trained health-care workers.

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**Standard techniques, including recommended needle sizes, injection site and angle, for injection of vaccines in children and adults**

Always observe standard occupational health and safety guidelines in order to minimise the risk of needle-stick injury. Use a new, sterile, disposable syringe and needle for each injection. Discard disposable needles and syringes in a clearly labelled, puncture-proof, spill-proof container that meets Australian standards in order to prevent needle-stick injury or re-use. Always keep sharps containers out of the reach of children. All persons injecting vaccines should be familiar with NHMRC Infection Control Guidelines.

**Intramuscular (IM) injections (needle length, gauge, angle and technique) for deltoid and anterolateral thigh**

The use of a short needle for IM injection may lead to inadvertent subcutaneous (SC) injection and increase the risk of significant local reactions, particularly with the aluminium-adjuvanted vaccines.

The recommended standard needle size for administering IM vaccines is 23 gauge and 25 mm in length. The exceptions are:

1. Preterm babies (born at less than 37 weeks' gestation) aged 2 months or younger, or very small infants – use a 23 gauge 16 mm or a 25 gauge 16 mm needle;
2. Very obese adults – use a 23 gauge 38 mm needle.

Firstly, bunch up the thigh or deltoid muscle to increase the muscle mass. Then insert a 23 gauge 25 mm needle at a 60° angle to the skin. At this angle, a 25 mm needle can be safely inserted to a depth of between 16 to 23 mm (skin to needle tip depth). Inserting the needle at a 60° angle results in less tissue resistance as the needle penetrates the muscle. Angle the needle towards the knee when injecting into the anterolateral thigh, (see Figure 1.2.1) and towards the shoulder when injecting into the deltoid (see Figure 1.2.2). The 23
gauge needle allows the vaccine to be injected slowly into the muscle rather than being forced under pressure, which may cause more pain and lead to local muscle trauma including bleeding and local reactions (expert opinion).

Some experts, including WHO, no longer recommend withdrawing the syringe plunger before injecting a vaccine. However it is still acceptable to do so gently if preferred. If a flash of blood appears in the needle hub, the needle should be withdrawn and a new site selected for injection.2,3

Figure 1.2.1: An intramuscular injection into the thigh of an infant using 23 gauge 25 mm needle, inserted at a 60° angle

Figure 1.2.2 An intramuscular injection into the deltoid muscle of a child using 23 gauge 25 mm needle, inserted at a 60° angle

Subcutaneous (SC) and intradermal injections
The standard needle for administering vaccines by SC injection is a 25 gauge needle 16 mm in length. SC injections are usually administered at a 45° angle to the skin (see Figure 1.2.3 below). For very small babies under 2 months of age or preterm infants, a 27 gauge needle 12 mm in length is recommended for SC injections.

There are no data to demonstrate any difference in technique between administration of a SC injection and a deep SC injection. Figure 1.2.3 shows the recommended technique for any SC injection.

Figure 1.2.3: A subcutaneous injection into the deltoid area of the upper arm (using a 25 gauge, 16 mm needle, inserted at a 45° angle
For intradermal injection of BCG vaccine, a 26 to 27 gauge 10 mm needle is recommended. Note that intradermal injection technique requires special training.

**Recommended sites for administering vaccines in children and adults**

- The vastus lateralis muscle in the anterolateral thigh is preferred for IM injection in infants and children under 12 months (see Figure 1.2.5).
- The deltoid muscle is the preferred site for IM injections in children 12 months of age and older and adults.
- SC injections should be administered in the area over the deltoid muscle or over the anterolateral thigh.
- In adults, vaccine injections should not be given in the buttocks because of the possibility of a sub-optimal response. However, IM immunoglobulin can be administered into the upper outer aspect of the buttock.

**Positioning of the child for injection, and location of injection sites for vaccination**

It is important that infants and children do not move during the injection. However, excessive restraint can increase their fear and result in increased muscle tension.

Make sure that the parent/caregiver feels comfortable about holding the infant for injections. Some will prefer not to be involved at all, and others do not even want to be present. These wishes must be respected. If the parent/caregiver is helping to secure the infant, ensure that they understand what is expected of them and what will take place.

**The anterolateral thigh – positioning of infants and location of injection site for IM injections**

The 23 gauge 25 mm length needle should be inserted a finger-width proximal to the junction of the upper and middle thirds of the lateral aspect of the thigh at its bulkiest part. The needle should pierce the skin at an angle of 60°, pointing towards the knee. This ensures that vaccines will be injected into the junction of the upper and middle thirds of the vastus lateralis muscle (see Figures 1.2.1 and 1.2.4).

The infant can be held in the ‘cuddle’ or semi-recumbent position on the lap of the parent or caregiver. It is essential to undo the baby’s napkin when locating the anatomical landmarks of the injection site, otherwise the vaccine may be given too low in the thigh. Alternatively, the infant can be positioned by being placed on his/her back on a table or bed. The forearm is placed across the infant’s pelvis and the thigh is secured between the vaccinator’s thumb and fingers. This position minimises delay between injections and may make the injection process easier.

**Figure 1.2.4: Diagram of the muscles of the thigh showing recommended injection site**
The deltoid – positioning and location of injection site for IM injections
The most convenient way to position a child for a deltoid injection is for the child to sit sideways on the lap of the parent/caregiver. The arm to be injected is held close to the infant’s body while the other arm is tucked behind the back of the parent/caregiver.

It is essential to expose the arm completely from shoulder to elbow when locating the deltoid site. Insufficient retraction of a shirtsleeve may expose only the inferior portion of the deltoid area. The best site is the middle of the muscle, which is halfway between the shoulder tip (acromion) and the muscle insertion at the middle of the humerus (deltoid tuberosity). The 23 gauge 25 mm long needle should be introduced at a 60° angle pointing towards the shoulder (see Figure 1.2.2). If the lower part of the deltoid area is injected, there is a risk of radial nerve injury as the nerve winds forward and emerges from the triceps.

Administration of two or more vaccines on the same day for children and adults
All the scheduled vaccines can be given at the same time on the same day (eg. at 2 months of age) as indicated in the Australian Standard Vaccination Schedule (ASVS). Where possible they should be given in different limbs and always administered using separate syringes and needles. The NHMRC recommend that in those cases where 3 or more injections are required on the ASVS, they should be given at the one visit without unnecessary delay.

The ASVS and catch-up vaccination often require more than 2 vaccines to be given at the same visit. For example, Hib (PRP-OMP)-hep B, MMR, meningococcal C conjugate vaccine and varicella-zoster vaccines may be required at the same visit to a child who has missed the 12 and 18 month scheduled vaccines.
Inactivated and live vaccines may be given on the same day, or at any interval before or after each other. If live virus vaccines (such as MMR and varicella-zoster vaccine) are not given simultaneously, they must be separated by at least 4 weeks. The exception is MMR and OPV, which may be given any time before or after each other. For information on the minimum intervals between live virus vaccines, and between either whole blood or immunoglobulins and live virus vaccines, refer to Table 1.4.2.

Administering multiple injections at the same visit for children under 12 months of age:
When 3 injectable vaccines are to be given at the same visit, 2 injections can be administered in the same anterolateral thigh but the injection sites should be separated by at least 25 mm (2.5 cm), so that local reactions will not overlap (see Figure 1.2.6). The third injection (preferably using the vaccine that may cause slightly more swelling or redness than others, such as 7vPCV) should be administered in the opposite thigh (Figure 1.2.6). The location of each injection should be recorded so that the vaccine associated with a local reaction can be differentiated.

Administering multiple injections at the same visit for children 12 months of age and older
When 3 injectable vaccines are to be given at the same visit for a child aged 12 months and over, it is recommended that both deltoid muscles be used (a single injection into each muscle). The site of the third injection should be determined as follows:
- In children over 18 months of age, there may be sufficient muscle mass to deliver 2 intramuscular injections into one deltoid, spaced by 25 mm (2.5 cm), with a third into the other deltoid. This will ordinarily be the case in older children and adults and will require the judgement of the provider.
- If, in the opinion of the provider, there is insufficient muscle mass for this technique, then one injection should be given into each deltoid, and an anterolateral thigh used for the third injection. If using the thigh, the vaccine least likely to cause swelling and redness should be selected for this site and the vaccine should be injected slowly so as to reduce the risk of local reactions and pain.

Methods for alleviating discomfort and pain associated with vaccination
Comfort measures and distraction techniques (e.g. playing music or encouraging the child to pretend to blow away the pain) may help children cope with the discomfort associated with vaccination. Administering sweet-tasting fluid orally immediately before injection can result in a calming or analgesic effect among certain infants.2

Practices which are not recommended
- Varying from the recommended route and site of injection may result in inadequate protection9 and may increase the risk of an adverse event following immunisation.
- Administering smaller volumes than those recommended, for example ‘split’ or half-doses, may result in inadequate protection. ‘Test’ doses have the same likelihood of triggering major adverse events in susceptible individuals as do full doses, and therefore must not be given. An exception to this is the use of a test dose in the presence of equivocal Q fever pre-vaccination screening results (see Part 3.20, ‘Q fever’).
Any vaccination using less than the standard dose should not be counted as a valid vaccination, and the person should be recalled and vaccinated, following the recommended procedures, as soon as possible.

Larger than recommended doses can also be hazardous and may lead to significant adverse events following immunisation.

Mixing vaccines with other vaccines, drugs or chemicals is not recommended unless specifically registered for use in this manner.

Different vaccines given to a person on the same day should be injected at different sites (in different limbs where possible) using different syringes and needles.

Administering vaccines to an age group for which the vaccine is not registered may increase the risk of an adverse event. The exceptions are those vaccines where a conflict with product information statement indicates otherwise.

1.3 CONSENT

Before vaccination the individual to be vaccinated, or the parent/caregiver, should be given adequate information to make an informed decision. Extra information should be available if parents or the vaccinees request it.

The immunisation provider should allow time for a discussion with the individual to ensure that the issue of risk has been addressed. As with any medical intervention, the provider should make a note in the clinical records that such a discussion has taken place prior to the person giving consent. A stamp or sticker, signed by the provider, is acceptable.

'Valid' consent is consent obtained after either the person to be vaccinated or that person's parent/caregiver is able to make an informed decision based on the risks and benefits of vaccination. The table on the back cover of this book is a summary of the effects of some vaccine-preventable diseases so that they can be compared with the events following the administration of vaccines that are used to protect against these diseases. Valid consent should be obtained before each vaccination, after it has been established that there are no medical conditions that contraindicate vaccination. It is preferable that printed information is available to supplement any verbal explanations. Translated material or interpreter services should be available for use by people from non-English speaking backgrounds.

In large-scale vaccination programs, such as those carried out at schools, the consent requirements are different from those that apply to the vaccination of individuals in general practice or at public immunisation clinics. In large-scale school programs, the parent/caregiver might not attend with the child on the day the vaccination is given. Vaccination in these circumstances should therefore proceed only after written consent from the parent or guardian has been obtained. In circumstances where the parent or guardian is in attendance, explicit verbal consent is required for vaccination, even when written consent has been given for previous vaccinations.

If a child is old enough to adequately understand the benefits and risks of the proposed vaccination, yet refuses the vaccination in spite of such understanding his/her wish should be respected. Laws on consent for treatment for children under the legal age may differ for each State/Territory.

1.4 PRE-VACCINATION CHECKLIST

The pre-vaccination checklist that follows (Table 1.4.1) can be photocopied and given to parents or the person to be vaccinated, just prior to vaccination. The pre-vaccination checklist can also be photocopied and displayed in the clinic for easy reference to help the immunisation provider assess a person's suitability for vaccination.
Table 1.4.1: Pre-vaccination checklist for a person to be vaccinated or that person's parent/caregiver

<table>
<thead>
<tr>
<th>The following information is needed to assess whether a person/child can be vaccinated, and which vaccines they may require. Please tell the immunisation provider if any of the following apply:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The person to be vaccinated:</td>
</tr>
<tr>
<td>▪ is unwell today;</td>
</tr>
<tr>
<td>▪ has a disease which lowers immunity (eg. leukaemia, cancer, HIV/AIDS) or is having treatment which lowers immunity (eg. oral steroid medicines such as cortisone and prednisone, radiotherapy, chemotherapy);</td>
</tr>
<tr>
<td>▪ lives with someone who has a disease which lowers immunity, or lives with someone who is having treatment which lowers immunity;</td>
</tr>
<tr>
<td>▪ has had a severe reaction following any vaccine;</td>
</tr>
<tr>
<td>▪ has any severe allergies (to anything);</td>
</tr>
<tr>
<td>▪ has had a live vaccine within the last month (this includes measles-mumps-rubella vaccine, oral poliomyelitis vaccine, varicella (chickenpox) vaccine, yellow fever vaccine);</td>
</tr>
<tr>
<td>▪ has had an injection of immunoglobulin, or a whole blood transfusion within the last 3 months;</td>
</tr>
<tr>
<td>▪ is pregnant;</td>
</tr>
<tr>
<td>▪ is living with someone who is not vaccinated;</td>
</tr>
<tr>
<td>▪ identifies as an Aboriginal or Torres Strait Islander person.</td>
</tr>
</tbody>
</table>

Note: If you have any questions about this information or any other matter relating to vaccination, please ask the immunisation provider before the vaccine is given.

Before any vaccination takes place, the immunisation provider will ask you:
| Did you understand the information provided to you about immunisation? |
| Do you need more information to decide whether to proceed? |
| Did you bring your/your child’s vaccination record card with you? |

It is important for you to receive a personal record of your or your child’s injections. If you don’t have a record card, ask your immunisation provider to give you one. Bring this record with you every time you bring your child for his/her injections. Make sure your immunisation provider records all vaccinations on it. Your child may need this card to enter day-care, kindergarten or school.
Table 1.4.2: Pre-vaccination assessment of conditions that may preclude vaccination

Immunisation providers can use this chart as a quick guide to assess the patient before vaccination. Please refer to the appropriate section about the specific vaccines within the Handbook for more detailed information.

**NB. Only vaccines recommended on the Australian Standard Vaccination Schedule are included. For information on other specific vaccines (such as those used for travel), please refer to relevant vaccine chapters.**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Defer vaccine until condition resolved (or discuss with the appropriate health professional)</th>
<th>Seek further advice (a)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute febrile illness (current T ≥38.5°C)</td>
<td>All vaccines</td>
<td>NA</td>
</tr>
<tr>
<td>Diarrhoea and vomiting</td>
<td>OPV</td>
<td>MMR, R, VZV, OPV</td>
</tr>
<tr>
<td>Immunosuppressive illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Allergies to vaccine components (b)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin</td>
<td>NA</td>
<td>IPV (IPOL), DTPa-IPV-Hib (Pediacl)</td>
</tr>
<tr>
<td>Neomycin</td>
<td>NA</td>
<td>OPV, IPV (IPOL), MMR, Influenza (Fluvax, Vaxigrip, Fluvinir, Fluad), VZV, DTPa-IPV (Infanrix IPV, Quadracel), DTPa-hepB-IPV (Infanrix Penta), DTPa-IPV-Hib (Pediacl), DTPa-IPV/Hib (Poliocel), DTPa-hepB-IPV-Hib (Infanrix Hexa)</td>
</tr>
<tr>
<td>Polymyxin</td>
<td>NA</td>
<td>IPV (IPOL), Influenza (Fluviren, Fluvac), DTPa-IPV (Infanrix IPV, Quadracel), DTPa-hepB-IPV (Infanrix Penta), DTPa-IPV-Hib (Pediacl), DTPa-IPV/Hib (Poliacel), DTPa-hepB-IPV-Hib (Infanrix Hexa)</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>NA</td>
<td>Influenza (Fluvax, Fluarc)</td>
</tr>
<tr>
<td>Yeast protein</td>
<td>NA</td>
<td>All monovalent and combination hepatitis B vaccines</td>
</tr>
<tr>
<td>Egg protein</td>
<td>NA</td>
<td>All influenza vaccines</td>
</tr>
<tr>
<td>Gelatin</td>
<td>NA</td>
<td>MMR (M-M R II only), R, VZV (Varivax Refrigerated only)</td>
</tr>
<tr>
<td>Thiomersal</td>
<td>NA</td>
<td>Hepatitis B (Engerix B only); Influenza (Fluvax, Infuvac, Fluad), dT (ADT), CDI</td>
</tr>
<tr>
<td>Phenoxyethanol</td>
<td>NA</td>
<td>DTPa (Tripecel, Infanrix); DTPa-hepB (Infanrix HepB), DTPa-IPV (Infanrix IPV, Quadracel), DTPa-hepB-IPV (Infanrix Penta), DTPa-IPV-Hib (Pediacl), DTPa-IPV/Hib (Poliacel), DTPa-hepB-IPV-Hib (Infanrix Hexa), dTpa (Boostrix), 23vPPV (Pneumovax)</td>
</tr>
<tr>
<td><strong>Drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td>MMR, R, VZV, OPV</td>
<td>NA</td>
</tr>
<tr>
<td>Live virus vaccine (other than OPV) in last 4 weeks</td>
<td>MMR, R</td>
<td>NA</td>
</tr>
<tr>
<td>Whole blood transfusion in last 3 months</td>
<td>MMR, R, VZV</td>
<td>NA</td>
</tr>
<tr>
<td>IM immunoglobulin in last 3 months</td>
<td>MMR, R, VZV</td>
<td>NA</td>
</tr>
<tr>
<td>IV immunoglobulin in last 9 months</td>
<td>MMR, R, VZV</td>
<td>NA</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Previous severe local and/or systemic adverse event | NA | All vaccines
---|---|---
Pregnancy | MMR, R, VZV, OPV | NA

Note:
(a) Seek further advice from a medical practitioner, paediatrician or public health physician with expertise in vaccination; contact the immunisation section within your State or Territory Health authority or your local Public Health Unit.
(b) Omit only if a patient has an anaphylactic sensitivity to a vaccine component.

Abbreviations
- DTpa diptheria-tetanus-acellular pertussis vaccine
- hepB hepatitis B vaccine
- Hib *Haemophilus influenzae* type b vaccine
- IM intramuscular
- IPV inactivated poliomyelitis vaccine
- IV intravenous
- 7vPCV 7-valent pneumococcal conjugate vaccine
- 23vPPV 23-valent pneumococcal polysaccharide vaccine
- MMR measles-mumps-rubella vaccine
- OPV oral poliomyelitis vaccine
- R rubella vaccine (monovalent)
- VZV varicella-zoster vaccine
- NA not applicable

1.5 RECORDING OF VACCINATION

A permanent vaccination record should be established for each vaccinee and newborn infant, and kept by that person or the child's parent/caregiver. Immunisation providers should record all relevant vaccination information on this record. The parent/caregiver should be urged to present the record every time the child is seen by a health professional.

The following items should be recorded in the vaccinee's Personal Health Record:
- the vaccinee's full name and date of birth
- the details of the vaccine given, including the dose, brand name, batch number and route and site of administration;
- the name of the person providing the vaccination;
- the date of vaccination;
- the date the next vaccination is due.

Document the above information, as well as the fact that valid consent was given, in the clinical notes.

The Australian Childhood Immunisation Register (ACIR)

The Australian Childhood Immunisation Register (ACIR) is a national database for recording details of vaccinations given to children under the age of 7 years who live in Australia. It is administered by the Health Insurance Commission (HIC) under the legislative mandate of the Commonwealth *Health Insurance Act 1973* Part IVA. Section 46B of the *Health Insurance Act* specifies how the ACIR is to be kept. Section 46E sets out the provisions for giving both de-identified and identified information to recognised immunisation providers and other specified agencies.

Children enrolled in Medicare are automatically included on the ACIR. Children not enrolled in Medicare will also be included when an immunisation provider sends details of a vaccination to the ACIR.

The ACIR provides an important means of accountability and evaluation of the childhood immunisation program. It is the primary means of determining immunisation coverage at national, State/Territory and local levels. It also provides a central immunisation history for each child that is accessible to any immunisation provider wishing to assess immunisation status. Since 1998, data held on the ACIR have been used to determine a family’s entitlement to Commonwealth payments of the Child Care Benefit and the Maternity
Immunisation Allowance. It is, therefore, important that vaccination data are submitted to the ACIR promptly.

**Reporting to the ACIR**

Immunisation providers should send details of all vaccinations given to children under the age of 7 years to the ACIR. Vaccination details may be submitted by sending data electronically via Electronic Data Interchange (EDI) or the Internet, or using a paper form. Immunisation providers in Queensland and the Northern Territory currently sending data to the ACIR via their State/Territory Health Department should continue to do so. Immunisation providers in all other States/Territories can send data directly to the ACIR.

A child’s immunisation record can also be updated with vaccination details, where the vaccination was performed by another immunisation provider, by completing and sending an Immunisation History form to the HIC.

For further information about the ACIR and reporting vaccination information, see ‘The ACIR Internet Site’ below. In addition, assistance on any reporting issues can be obtained from the ACIR Information Line, free call 1800 653 809.

**Child History Statement**

Child History Statements, containing details of all vaccines administered to the child and recorded on the ACIR, are automatically generated 2 weeks before a child turns 12 months, 2 and 5 years of age. They are also automatically generated on a State/Territory change of address, on request by the parent or legal guardian, and on completion of the childhood vaccination schedule.

**Recording details of a deceased child**

The ACIR should be notified of a deceased child to prevent a Child History Statement being sent to bereaved parents. Advice of a child’s death can be provided by calling 1800 653 809 (free call), or by sending details on practice stationery. Details should include name, address, date of birth, Medicare number and date of death.

**Ascertaining individual vaccination status**

Parents can telephone the ACIR on 1800 653 809 (free call) for information about their child’s immunisation status, regardless of where the child’s vaccination was given in Australia. The information will be mailed to the address most recently recorded on the ACIR for that child.

Immunisation providers can also request a child’s vaccination status. They will need the parent’s consent to obtain this information.

**Immunisation coverage and other reports**

ACIR reports assess progress towards national targets, and help to identify areas with low vaccination levels and assist in planning vaccination programs.

Practices that are registered for the General Practice Immunisation Incentive (GPII) program can receive quarterly reports on vaccination coverage for children within that practice. Other reports, including those that identify a child’s immunisations and due and overdue details, are available via the secure area of the ACIR Internet site to approved service providers.

**The ACIR Internet Site**

The ACIR Internet site has two main parts, a general information area and a secure area. The Internet address for the ACIR is: www.hic.gov.au. Any person with Internet access may view the ACIR site for general vaccination information and reports.

Approved immunisation providers are able to access the secure area of the ACIR Internet site and obtain a range of statistical and identified reports. These reports are available, depending on the access level granted to the provider, and enable approved providers to view a child’s vaccination details, record vaccination information and access a range of other reports. To register to access the secure area of the ACIR Internet site, providers should complete the online request form at www.hic.gov.au. Further information or assistance may be obtained by calling the ACIR Internet inquiry number on 1300 650 039 (local call).
1.6 ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

What are AEFI?
An adverse event is an unwanted or unexpected event following immunisation. Such an event may be caused by the vaccine or may occur by chance after immunisation (i.e., it would have occurred regardless of vaccination). Most vaccines cause frequent minor adverse events (see Table ‘Comparison of effects of vaccines and diseases’ at the back of the book). Mild events, such as fever, pain or redness at the site of injection, commonly follow immunisation with some vaccines and should be anticipated. Any vaccine may cause an adverse event. Adverse events following immunisation fall into 3 categories that are not mutually exclusive: local, systemic or allergic.

Local reactions are usually the least severe and most common. Systemic reactions (e.g., fever) occur less commonly than local reactions. Serious allergic reactions (such as anaphylaxis) are the least common but the most severe adverse events. The frequency of adverse events can be classified as follows: very common (>10%), common (1–10%), uncommon (0.1–1%), rare (0.01-0.1%) and very rare (<0.01%).

Common AEFI
Although not serious the following adverse events are common, or even very common, and should be anticipated. They can be distressing for parents, but they do not contraindicate further vaccination. In general, unless they are significant, common AEFI do not usually need to be reported.

Parents should be given advice on what to do about common minor adverse events following immunisation with the vaccines on the ASVS (see Table inside back cover, ‘Common adverse events following immunisation and what to do about them’). Parents of children being vaccinated and other vaccinees should be informed of the risk of these events as part of the consent.

- DTPa vaccine may cause mild to moderate local and systemic effects, such as local swelling and redness, fever, crying and irritability.
- There is an increased risk of more extensive local reactions after the fourth dose of DTPa. A local reaction that involves extensive limb swelling should be reported. For definition of extensive limb swelling, see Appendix 5, ‘Definitions of adverse events following immunisation’. Hib vaccine causes transient swelling and redness at the injection site in about 5% of infants.
- MMR vaccine may be followed about 7 to 10 days later by a fever lasting 2 or 3 days, malaise and/or rash. This is not infectious.
- Hepatitis B vaccine may cause transient, minor adverse events including soreness at the injection site and low-grade fever.
- Influenza vaccine may cause soreness at the vaccination site. Fever, malaise, and myalgia occur less often.
- The 7-valent pneumococcal conjugate vaccine (7vPCV) causes low-grade fever and/or mild pain at the site of injection in about 10% of infant recipients. The 23-valent pneumococcal polysaccharide vaccine (23vPPV) causes mild local reactions in up to half the adult recipients. A booster dose of 23vPPV is associated with moderately severe local reactions in about 10% of recipients.
- Meningococcal C conjugate vaccines (MenCCV) are generally well tolerated. Very common (>10%) adverse events are pain, redness and swelling at the injection site, fever, irritability, anorexia and headache.
- Varicella-zoster vaccine may cause mild local soreness and swelling. A mild maculopapular or papulovesicular rash occurs in up to 5% of vaccinated children (see also Part 3.27, ‘Varicella-zoster’).
- Injection site nodules are uncommon. They are fibrous remnants of the body’s interaction with the vaccine components (usually an adjuvant) in the muscle, and they may remain for many weeks after the immunisation. Injection site nodules do not require any specific treatment.

Managing common side effects
(i) Advice to parents on common side effects
Many vaccine injections may result in soreness, redness, itching, swelling or burning at the injection site for 1 to 2 days. Paracetamol might be required to ease the discomfort.
See inside back cover for the parent advice sheet: ‘Common adverse events following immunisation and what to do about them’. This can be photocopied and given to parents as post-vaccination advice.

(ii) Managing fever after immunisation
Although the routine use of paracetamol at the time of vaccination is no longer necessary, it may be required if, for example, an infant or child has a high fever following vaccination. The dose of paracetamol is 15 mg/kg of paracetamol liquid, up to a maximum daily dose of 90 mg/kg/day.

(iii) Preventing AEFI
The key to preventing many serious adverse events is to screen each person to be vaccinated using the pre-vaccination checklists (Tables 1.4.1 and 1.4.2) to ensure that the person does not have a condition which either increases the risk of an adverse event or is a contraindication to vaccination. The use of correct injection technique is also important. Immunisation providers should also check the relevant chapters of this Handbook for more details on precautions and contraindications for each vaccine they are to administer.

Late AEFI
Late events that follow immunisation may or may not be causally related to the vaccine(s). There are a number of conditions which have been suggested at different times might be associated with immunisations, but substantial evidence indicates that the association is due to chance, and that the vaccine does not cause the condition.

On the other hand, some vaccines have been shown to cause serious late events, although the rate is always hundreds to thousands times less frequent than the disease complications. Examples are given below.

(i) Rare, late events shown to be causally related to some vaccines
One in one million doses of MMR vaccine causes acute encephalitis occurring 8 to 9 days after vaccination. In comparison, between one in 1000 and one in 5000 cases of wild-type measles result in severe acute encephalitis with a 10% mortality and considerable morbidity.

Oral poliomyelitis vaccine (OPV) can rarely cause vaccine-associated paralytic poliomyelitis (VAPP). The incidence is one in 2.4 million doses of OPV, which means that Australia would expect one case of VAPP every 3 years, although the reported incidence is one case every 8 to 9 years.

Vaccines containing diphtheria and tetanus have been described as causing brachial neuritis, with an incidence of approximately one in 100 000 (adults).

(ii) Late events where evidence demonstrates no causal link with immunisation
For the following situations, late events have been reported following immunisation, but there is strong epidemiological evidence that there is no causal association between:
- 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

Immediate AEFI
Observation after vaccination
Recipients of vaccines should remain under observation for a short interval to ensure that they do not experience an immediate adverse event. It is recommended that recipients remain in the vicinity of the place of vaccination for at least 15 minutes. In general, the more severe the reaction, the more rapid the onset. Most life-threatening adverse events begin within 10 minutes of vaccination.

The most serious immediate reaction to vaccination 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 immunisation should be advised to lie down until
free of symptoms. Most faints following immunisation occur within 5 minutes, and 98% occur within 30 minutes. Adults should therefore be warned of the risk of driving or operating machinery for at least 30 minutes after vaccination. 21

Children who have had a serious adverse event (other than a contraindication, such as anaphylaxis) to a previous vaccine may subsequently be vaccinated under close medical supervision. Check with State/Territory health authorities for more information.

**Anaphylaxis and vasovagal episodes**

Anaphylaxis following routine vaccination is very rare, but can be fatal. All immunisation providers must be able to distinguish between anaphylaxis, convulsions and fainting.

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 an anaphylactic reaction, particularly if a strong central pulse is absent. A strong central pulse (eg. carotid) persists during a faint or convulsion.

The features listed in Table 1.6.1 may be useful in differentiating these two conditions. If the diagnosis is unclear and anaphylaxis is considered, management for this should be instituted with the prompt administration of adrenaline.

### Table 1.6.1: Clinical features which may assist differentiation between a vasovagal episode and anaphylaxis

<table>
<thead>
<tr>
<th>Onset</th>
<th>Vasovagal episode</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptoms/ signs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>Immediate – usually within minutes of or during vaccine administration.</td>
<td>Skin itchiness, generalised skin erythema (redness), urticaria (wheals) or angio-oedema (localised oedema of the deeper layers of the skin or subcutaneous tissues).</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Normal respiration; may be shallow, but not laboured.</td>
<td>Cough, wheeze, stridor, or signs of respiratory distress (tachypnoea, cyanosis, rib recession).</td>
</tr>
<tr>
<td>Neurological</td>
<td>Sense of light-headedness. Loss of consciousness – improves once supine or head down position.</td>
<td>Sense of severe anxiety and distress. Loss of consciousness – no improvement once supine or head down position.</td>
</tr>
</tbody>
</table>

**Signs of anaphylaxis**

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

Immunisation providers should be able to recognise all the following symptoms and signs of anaphylaxis:

- cutaneous, such as the rapid development of widespread urticarial lesions (circumscribed, intensely itchy wheals with erythematous raised edges and pale, blanched centres) or erythema;
- upper airway obstruction, such as hoarseness and stridor, resulting from angioedema of the hypopharynx, epiglottis and larynx;
lower airway obstruction, such as subjective feelings of retrosternal tightness, and dyspnoea with audible expiratory wheeze from bronchospasm;
- limpness and pallor, which are signs of severe anaphylaxis in children;
- profound hypotension in association with tachycardia, and/or other signs of cardiovascular disturbance, such as sinus tachycardia or severe bradycardia;
- abdominal cramps, diarrhoea and/or vomiting.

Management of anaphylaxis

Rapid administration of adrenaline is the cornerstone of treatment of anaphylaxis. (It is also the cornerstone of treatment of an anaphylactoid reaction, regardless of the certainty of the diagnosis.)

Anaphylaxis occurs without warning, usually within 5 minutes of giving the vaccine. Both a protocol for the management of anaphylaxis and adrenaline 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.
- Give adrenaline by intramuscular injection (see below for dosage) for any signs of anaphylaxis, except for erythema (flushing) or itching alone, which are observed for progression.
- If there is no improvement in the patient’s condition by 5 minutes, repeat doses of adrenaline every 5 minutes until improvement occurs.
- If oxygen is available, administer by facemask at a high flow rate.
- Send for professional assistance. Never leave the patient alone.
- Begin expired air resuscitation for apnoea, check for a central pulse. If central pulse not palpable, commence external cardiac massage (ECM).
- All cases should be admitted to hospital for further observation and treatment.

Experienced practitioners may choose to use an oral airway if the appropriate size is available, but its use is not routinely recommended unless the patient is unconscious.

Antihistamines and/or hydrocortisone are not recommended for the emergency management of anaphylaxis.

Adrenaline dose

Adrenaline 1:1000 (one in one thousand)
Adrenaline 1:1000 contains 1 mg of adrenaline per mL of solution in a 1 mL glass vial.

The recommended dose of 1:1000 adrenaline is 0.01 mL/kg body weight (equivalent to 0.01 mg/kg) up to a maximum of 0.5 mL or 0.5 mg given by deep intramuscular injection. The following table lists the doses of 1:1000 adrenaline to be used if the exact weight of the individual is not known.

Please Note: “NHMRC recommends 1:10 000 adrenaline be administered by IM injection, in conflict with the product information, which states the route of administration to be SC injection.”
Table 1.6.2: Doses of 1:1000 (one in one thousand) adrenaline for infants and children

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</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>11-12 years (approx. 40 kg)</td>
<td>0.4 mL</td>
</tr>
<tr>
<td>13 years and over</td>
<td>0.4–0.5 mL</td>
</tr>
</tbody>
</table>

The use of 1:1000 adrenaline is recommended because it is universally available. Use a 1 mL syringe to improve the accuracy of measurement when drawing up small doses.

The dose of 1:1000 (one in one thousand) adrenaline for adults is 0.5 mL (0.5 mg). Repeat every 5 minutes as necessary until there is clinical improvement.

Adrenaline 1:10 000 (one in ten thousand)

Adrenaline 1:10 000 contains 1 mg of adrenaline per 10 mL solution.

An alternative approach to dealing with the problem of measurement of small volumes of adrenaline in children up to 10 years of age is to use 1:10 000 adrenaline.

Table 1.6.3: Doses of 1:10 000 (one in ten thousand) adrenaline for infants and children up to 30 kg

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</td>
<td>0.5–1 mL</td>
</tr>
<tr>
<td>1–2 years (approx. 10 kg)</td>
<td>1 mL</td>
</tr>
<tr>
<td>2–3 years (approx. 15 kg)</td>
<td>1.5 mL</td>
</tr>
<tr>
<td>4–6 years (approx. 20 kg)</td>
<td>2 mL</td>
</tr>
<tr>
<td>7–10 years (approx. 30 kg)</td>
<td>3 mL</td>
</tr>
</tbody>
</table>

If 1:10 000 adrenaline is not available, a 1 mL ampoule of 1:1000 adrenaline may be diluted with 9 mL water for injection or normal saline to give 10 mL of 1:10 000 solution. The dose of 1:10 000 adrenaline is 0.1 mL per kg (maximum 3 mL). If the weight of the child is in doubt, this can be roughly calculated on the basis of 0.5 mL per year of age (maximum 3 mL equivalent to 0.3 mL of 1:1000 adrenaline).

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 online 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 1.6.4: Contact details for notification of adverse events following immunisation

<table>
<thead>
<tr>
<th>State/Territory</th>
<th>Report adverse events to:</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td>*NSW</td>
<td>NSW Public Health Units</td>
<td>Look under ‘Health’ in the White Pages</td>
</tr>
<tr>
<td>*WA</td>
<td>State Health Department</td>
<td>08 9321 1312</td>
</tr>
<tr>
<td>*QLD</td>
<td>Queensland Health</td>
<td>07 3234 1500</td>
</tr>
<tr>
<td>*NT</td>
<td>NT Dept Health &amp; Community Services</td>
<td>08 8922 8044</td>
</tr>
<tr>
<td>SA</td>
<td>Department of Human Services</td>
<td>08 8226 7177</td>
</tr>
<tr>
<td></td>
<td>In SA, parents can also report adverse events by calling</td>
<td>1-300-364-100 (24 hours)</td>
</tr>
<tr>
<td>ACT</td>
<td>Territory Health Department</td>
<td>02 6205 2300</td>
</tr>
<tr>
<td>Victoria</td>
<td>ADRAC</td>
<td>Use blue form</td>
</tr>
<tr>
<td>Tasmania</td>
<td>ADRAC</td>
<td>Use blue form</td>
</tr>
</tbody>
</table>

*AEFI are notifiable in these States/Territories and health professionals should report directly to their respective Health Department as listed above, which will in turn notify ADRAC.

1.7 THE AUSTRALIAN STANDARD VACCINATION SCHEDULE

The Australian Standard Vaccination Schedule (ASVS) shown below is recommended by the NHMRC. Over recent years a considerable variety of vaccines, which combine together various antigens, have become available in Australia. The ASVS is therefore now based on antigens rather than on specific vaccines.

The new immunisation schedule (Table 1.7.1) incorporates all vaccines recommended as 'best practice'. Immunisation providers are responsible for advising patients and parents/caregivers of available vaccine choices at the time of consultation, including those provided free under the National Immunisation Program. Information about the National Immunisation Program can be obtained from your State or Territory health authority.
### Table 1.7.1: Australian Standard Vaccination Schedule

<table>
<thead>
<tr>
<th>AGE</th>
<th>VACCINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth</td>
<td>Monovalent hepatitis B vaccine.</td>
</tr>
<tr>
<td>2 months</td>
<td>Hepatitis B&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>4 months</td>
<td>Hepatitis B&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>6 months</td>
<td>Hepatitis B&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>12 months</td>
<td>Hepatitis B&lt;sup&gt;3&lt;/sup&gt;</td>
</tr>
<tr>
<td>18 months</td>
<td></td>
</tr>
<tr>
<td>2 years</td>
<td></td>
</tr>
<tr>
<td>4 years</td>
<td></td>
</tr>
<tr>
<td>10 – 13 years</td>
<td>Hepatitis B&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>15 – 17 years</td>
<td></td>
</tr>
<tr>
<td>50 years</td>
<td>dT</td>
</tr>
<tr>
<td>and over</td>
<td></td>
</tr>
<tr>
<td>65 years</td>
<td></td>
</tr>
<tr>
<td>and over</td>
<td></td>
</tr>
</tbody>
</table>

**Schedule key**

- **Hepatitis B<sup>1</sup>** Monovalent hepatitis B vaccine.
- **Hepatitis B<sup>2</sup>** Hepatitis B vaccine given as either monovalent vaccine or in combination with DTP<sub>a</sub>, 3 doses at 2, 4 and 6 months, in addition to the birth dose for a total of 4 doses.
- **Hepatitis B<sup>3</sup>** Hepatitis B vaccine in combination with Hib (PRP-OMP), 3 doses at 2, 4 and 12 months, in addition to the birth dose for a total of 4 doses.
- **Hepatitis B<sup>4</sup>** Hepatitis B vaccine for 10 to 13 year olds who have not received a primary course.
- **Hib<sup>1</sup>** PRP-T, HbOC (non-Indigenous children).
- **Hib<sup>2</sup>** PRP-OMP (all children).
- **23vPPV<sup>1</sup>** Pneumococcal polysaccharide vaccine (Aboriginal and Torres Strait Islander children only); this dose can be given between 18 months and 2 years of age (refer to State/Territory Public Health Units for recommended age for administration).
- **23vPPV<sup>2</sup>** National Indigenous Pneumococcal and Influenza Immunisation Program.
- **VZV<sup>1</sup>** Vaccination only for children with a negative history of varicella disease or vaccination.

**Notes:**

Aboriginal and Torres Strait Islander children receive 3 doses of PRP-OMP Hib vaccine.

Non-Indigenous children can receive 3 doses of PRP-OMP Hib vaccine or 4 doses of either PRP-T or HbOC Hib vaccine. (Mixing Hib schedules is not recommended. Infants starting with PRP-OMP should continue with PRP-OMP.)

Adolescent hepatitis B and VZV are not required if a primary vaccination course has been given in early childhood.

Access to free pneumococcal conjugate vaccine is provided to the following groups; all Aboriginal and Torres Strait Islander children aged up to 2 years, Aboriginal children in central Australia aged up to 5 years, non-Indigenous children in central Australia aged up to 2 years, and all children under 5 years with medical risk factors that predispose them to high rates or high severity of pneumococcal infection.

---

"IPV is preferred to OPV, subject to the availability of IPV or IPV-combination vaccines, but both IPV and OPV are acceptable for use in the ASVS."
### Vaccine Key

- **Hepatitis B**  
  Hepatitis B vaccine
- **DTPa**  
  Diphtheria-tetanus-acellular pertussis infant/child formulation
- **dTpa**  
  Adult/adolescent formulation diphtheria-tetanus-acellular pertussis vaccine
- **Hib**  
  *Haemophilus influenzae* type b (Hib) vaccine PRP-OMP, PRP-T, HbOC (as monovalent or in combination)
- **IPV**  
  Inactivated poliomyelitis vaccine (in combination)
- **MMR**  
  Measles-mumps-rubella vaccine
- **VZV**  
  Varicella-zoster vaccine
- **7vPCV**  
  7-valent pneumococcal conjugate vaccine
- **23vPPV**  
  23-valent pneumococcal polysaccharide vaccine
- **MenCCV**  
  Meningococcal C conjugate vaccine
- **Inf luenza**  
  Influenza vaccine
- **dT**  
  Adult diphtheria-tetanus vaccine.

### Table: 1.7.2: List of currently registered vaccines for the Australian Standard Vaccination Schedule

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccine</th>
<th>Available products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>hepB</td>
<td>Engerix B; H-B-Vax II</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis</td>
<td>DTPa</td>
<td>Infanrix; Tripacel</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis</td>
<td>dTpa (adult)</td>
<td>Boostrix</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-hepatitis B</td>
<td>DTPa-hepB</td>
<td>Infanrix HepB</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-hepatitis B-poliomyelitis</td>
<td>DTPa-hepB-IPV</td>
<td>Infanrix Penta</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-poliomyelitis</td>
<td>DTPa-IPV</td>
<td>Infanrix-IPV; Quadracel</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-poliomyelitis-<em>Haemophilus influenzae</em> type b</td>
<td>DTPa-IPV-Hib</td>
<td>Pedicacel</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-Haemophilus influenzae type b</td>
<td>DTPa-hepB-IPV-Hib</td>
<td>Infanrix Hexa</td>
</tr>
<tr>
<td>Diphtheria-tetanus-pertussis-<em>Haemophilus influenzae</em> type b</td>
<td>DTPa-Hib</td>
<td>Infanrix-Hib</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> type b</td>
<td>Hib (PRP-OMP)</td>
<td>PedvaxHIB</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> type b</td>
<td>Hib (PRP-T)</td>
<td>ActHIB; Hiberix</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> type b</td>
<td>Hib (HbOC)</td>
<td>HibTITER</td>
</tr>
<tr>
<td><em>Haemophilus influenzae</em> type b, hepatitis B</td>
<td>Hib (PRP-OMP)-hepB</td>
<td>Comvax</td>
</tr>
<tr>
<td>Poliomyelitis</td>
<td>OPV</td>
<td>Polio Sabin</td>
</tr>
<tr>
<td></td>
<td>IPV</td>
<td>IPOL</td>
</tr>
<tr>
<td></td>
<td>IPV in combination with DTPa, Hep B and Hib various, see above</td>
<td></td>
</tr>
<tr>
<td>Pneumococcal disease</td>
<td>7vPCV</td>
<td>Prevenar</td>
</tr>
<tr>
<td></td>
<td>23vPPV</td>
<td>Pneumovax23</td>
</tr>
<tr>
<td>Measles-mumps-rubella</td>
<td>MMR</td>
<td>M-M-R II; Priorix</td>
</tr>
</tbody>
</table>
Meningococcal C disease                               MenCCV                            Meningitec; NeisVac-C; Menjugate
Diphtheria-tetanus                                  dT                                  ADT Vaccine
Influenza                                            Influenza                          Fluarix; Fluvax; Fluad; Fluvirin; Influvac; Vaxigrip
Varicella                                            VZV                                  Varilrix; Varivax Refrigerated

1.8 GUIDELINES FOR ADMINISTERING SCHEDULE VACCINES

General contraindications to vaccination
There are only two contraindications applicable to all vaccines:
(i) a known anaphylactic sensitivity to any component of the relevant vaccine
(ii) anaphylaxis following a previous dose of the relevant vaccine

There are 2 further contraindications applicable to (both parenteral and oral) live vaccines:
(i) live vaccines should not be administered to immunosuppressed individuals, regardless of whether the suppression is caused by disease or treatment (the exception is MMR, which should be administered to HIV-infected individuals provided that the immunosuppression is not severe (see Part 2.3, ‘Groups with special vaccination requirements’).
(ii) in general, live vaccines should not be administered during pregnancy.

Precautions to vaccination
Children with minor illness (without an acute systemic illness and with a current temperature below 38.5°C) may be vaccinated safely. Major illness or high fever may be confused with vaccine side effects and increase discomfort to the child. Therefore vaccination should be postponed for 2 to 3 days until the child is well. A return appointment for vaccination should be made at the time of deferral.

Live parenteral vaccines, if not administered simultaneously, should be given at least 4 weeks apart. Live parenteral vaccines should not be given within 3 months of receipt of either normal human immunoglobulin (NHIG) or a whole blood transfusion.

There are other precautions applicable to individual vaccines: see relevant chapters for details.

False contraindications to vaccination
The following conditions are NOT contraindications to any of the vaccines in the ASVS:
- family history of any adverse events following immunisation;
- family history of convulsions;
- previous pertussis-like illness, measles, rubella, mumps or meningococcal infection;
- prematurity (vaccination should not be postponed);
- neurological conditions including cerebral palsy and Down’s syndrome;
- contact with an infectious disease;
- asthma, eczema, atopy, hay fever or ‘snuffles’;
- treatment with antibiotics;
- treatment with locally acting (inhaled or low-dose topical) steroids;
- child’s mother is pregnant;
- child to be vaccinated is being breastfed;
- woman to be vaccinated is breastfeeding;
- history of neonatal jaundice;
- low weight in an otherwise healthy child;
- recent or imminent surgery;
- replacement corticosteroids.

Interchangeability of vaccines
In general, vaccines from different manufacturers that protect against the same disease (e.g., hepatitis B, MMR) may be administered interchangeably for an individual patient. However, until data supporting interchangeability of acellular pertussis-containing vaccines are available, vaccines from the same manufacturer should be used, whenever feasible, for the first 3 doses. If the previous acellular pertussis vaccine type is unknown or not available, vaccination should proceed with any registered product. If a combination of different Hib vaccines is inadvertently used in the primary series, then 3 doses at 2, 4 and 6 months of age are required, with a booster at 12 months of age.

**Disposal of clinical waste after vaccination**

Clinical waste, including sharps and live vaccine vials and used OPV spoons, must be disposed of immediately following administration of vaccine and at its point of use. Refer to your State/Territory for management guidelines for the safe disposal of clinical waste or refer to the NHMRC Infection Control Guidelines.

1.9 CATCH-UP VACCINATION

**Introduction**

Not infrequently, children who present for immunisation have missed out on previously scheduled vaccines. To ensure that these 'overdue' children can be protected as quickly as possible, 'catch-up' vaccination schedules, based on the ASVS, are available.

Every opportunity should be taken to check vaccination status and to provide missing doses. When infants and children have missed scheduled vaccine doses, a catch-up schedule should be commenced. The information and tables below are designed to assist in planning a catch-up program based on the ARVS.

If the vaccine provider is uncertain about how to plan the catch-up schedule, contact either a public health professional or a paediatrician with vaccination expertise.


**Vaccination with incomplete vaccination records**

The most important requirement for assessment of vaccination status is to have written documentation of vaccination. In children 7 years of age and under, vaccination status should be available from the Australian Childhood Immunisation Register (ACIR), unless the course of vaccines was commenced overseas. In persons over this age, the approach of providers to the problem of inadequate records should be based on the age of the individual, whether the vaccines in question have been given in Australia or overseas and the vaccines being considered for catch-up.

(i) Children 8 years of age or less

In this age group, the primary reference point should be the ACIR. If the parent states that vaccines not recorded on the ACIR have been given, every effort should be made to contact the provider. If confirmation from the nominated provider or the ACIR cannot be obtained, unless other convincing evidence of vaccination such as written records is available, children should be offered a catch-up course of vaccination appropriate for age.

(ii) Children and adolescents 9 to 17 years

In children over the age of 8 years and adolescents, alternative sources of documentation to the ACIR such as personal health records will be needed, but are less likely to be available with increasing age. The relevant vaccines for catch-up in this age group are hepatitis B, measles, mumps, rubella (MMR), meningococcal C conjugate (MenCCV), varicella-zoster (VZV), inactivated poliomyelitis (IPV), diphtheria, tetanus and pertussis vaccines. For hepatitis B, MenCCV, VZV, IPV and MMR vaccines there are no adverse effects associated with additional doses in immune individuals. In the case of diphtheria and tetanus, additional doses are associated with a significant increase in local and systemic reactions in immune individuals. This means that if catch-up vaccination requiring more than one diphtheria or tetanus containing vaccine is considered because of lack of documentation, particular attention should be paid to the occurrence of local or systemic reactions before proceeding with a second or third catch-up dose.
(iii) Adults (18 years and over)
In adults, written documentation of previous vaccination history may not be available. The main antigens where past history is important because of the potential for adverse reactions in immune individuals are diphtheria and tetanus. Pneumococcal polysaccharide vaccine history in the previous 5 years is also an issue. Additional doses of MMR, VZV, IPV or hepatitis B vaccine are rarely associated with significant adverse reactions in adults. If a tetanus-prone wound is the reason for considering additional tetanus vaccine, NHMRC recommends giving additional tetanus-containing vaccines if there is any uncertainty (see Table 3.25.1).

Interrupted vaccine doses
If the recommended intervals between doses are exceeded, there is no need to recommence the schedule or give additional doses, because the immune response is not impaired by such delay. If the process of administration of vaccine is interrupted (e.g. by syringe-needle disconnection or vomiting of OPV within 10 minutes of administration) the whole dose should be repeated as soon as practicable.

Issues to be considered when planning catch-up vaccination
- Plan the catch-up on the basis of the available, and preferably documented, evidence of previous vaccination.
- Vaccine doses should not be administered at less than the minimal intervals or less than the minimum age (see Table 1.9.1).
- Doses administered earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age-appropriate using the minimum interval table (see Table 1.9.1).
- When commencing the recommended catch-up vaccination schedule the interval between doses may be reduced or extended and the numbers of doses required may reduce with age. For example from 15 months of age, only one dose of (any) Hib vaccine is required.
- As a child gets older the recommended vaccines change or they might need to be omitted from the schedule.
- For incomplete vaccination or overdue vaccinations, build on previous documented doses. Never start the schedule again, regardless of the interval (unless there are no written vaccination records).
- If more than one vaccine is overdue, it will often be appropriate to give all the vaccines at one visit. In such cases, the next visit should be scheduled for a time after the appropriate minimal interval (e.g. normally one to two months between first and second dose, and second and third doses of DTPa-containing vaccines).
- Check rules on interchangeability of vaccines. Some vaccines and vaccine brands are not interchangeable.
- The optimal intervals recommended in the ASVS should be used once the child or adult is back to the recommended vaccine and dose number for their age.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Minimum interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1–2</td>
</tr>
<tr>
<td>DTPa (1)</td>
<td></td>
</tr>
<tr>
<td>DTPa-IPV</td>
<td>1 month</td>
</tr>
<tr>
<td>DTPa-IPV-Hib</td>
<td>1 month</td>
</tr>
<tr>
<td>DTPa-IPV/Hib</td>
<td></td>
</tr>
<tr>
<td>dT (ADT) (4)</td>
<td>1 month</td>
</tr>
<tr>
<td>DT (CDT) (4)</td>
<td>1 month</td>
</tr>
<tr>
<td>PRP-OMP</td>
<td></td>
</tr>
<tr>
<td>Hib (PRP-OMP)-hepB</td>
<td>1 month</td>
</tr>
<tr>
<td>HbOC</td>
<td>1 month</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Vaccine</th>
<th>1 month</th>
<th>1 month</th>
<th>2 months (5)</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRP-T</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td>1 month</td>
<td>1 month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IPV</td>
<td>1 month</td>
<td>1 month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td>1 month</td>
<td>NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTPa-hepB</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTPa-hepB-IPV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DTPa-hepB-IPV-Hib</td>
<td>1 month</td>
<td>2 months (7)</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA= not applicable

1. If possible, the same brand of DTPa-containing vaccine should be used for the first 3 doses. If this is not possible, vaccination should be completed with the available brand. DTPa-IPV vaccines can be interchanged for the fourth (booster) dose. Administer all 4 doses of DTPa at the recommended intervals in children under 8 years of age.

2. The minimum interval between the third and fourth doses is based on the DTPa requirements. Follow the recommendations below (5) for Hib vaccines.

3. All people should be offered a dose of either dT or adult/adolescent formulation DTPa at 50 years of age unless a dose of either has been administered within 10 years.

4. Use DTPa or CDT until the eighth birthday.

5. Booster doses (third dose for PRP-OMP or fourth doses for HbOC or PRP-T) are given no earlier than the first birthday and at least 2 months after a previous dose. If the child is aged 15 months or more, only one dose of any brand of Hib vaccine is required.

6. Preferably administer (fourth) booster dose as DTPa-IPV at 4 years of age if required.

7. A one-month interval between doses 2 and 3 is appropriate, but only if a birth dose of hepatitis B vaccine was given; otherwise the minimum interval between doses 2 and 3 should be 2 months.

### Catch-up using acellular pertussis-containing vaccines and dT for children and adults

Monovalent pertussis vaccine is not available in Australia. Therefore any necessary pertussis catch-up vaccination can only be undertaken with either DTPa or DTPa-containing combination vaccines.

#### Catch-up for DTPa vaccines in children under 8 years of age

If a child has received previous doses of DT, then DTPa or DTPa combinations can be used for catch-up provided that no more than 6 doses of diphtheria and tetanus toxoids are given in total. An excessive number of total doses may increase the risk of severe local reactions.

With the introduction of a 4-dose DTPa schedule on the ASVS:

- children under 8 years of age require 3 doses of DTPa, or DTPa-combination vaccines that do not contain hepatitis B, at a minimum interval of 4 weeks between doses to complete the primary series (see Table 1.9.1).
- if children under 8 years of age are given a DTPa-combination vaccine that contains hepatitis B for catch-up then there should be a minimum interval of 2 months between doses 2 and 3 if no birth dose of hepatitis B vaccine was given (Table 1.9.1).
- a fourth (booster) dose, usually given as DTPa-IPV, should be given at 4 years of age or 6 months after the third dose, whichever is later.

#### Catch-up using dT (ADT) in those 8 years of age and over, and the use of adult/adolescent formulation DTPa vaccine for boosters
Using dT (ADT) vaccine
The minimum age for using dT (ADT) or tetanus toxoid (TT) is 8 years of age. Those aged 8 years and older who do not have a documented history of a primary series (ie at least 3 doses of DTP, DTPa or DTPa-combination vaccine) should be given the missing doses as dT (ADT) with a minimum interval of one month between the doses.

Adults over 17 years of age who have only received 3 doses of DTP or dT-containing vaccines require a further two booster doses at a minimum interval of 10 years.

All people should be offered the routine booster dose of dT (ADT) vaccine at 50 years of age unless a dose has been administered within the previous 10 years. The adult/adolescent formulation dTpa (Boostrix) can be used at 50 years of age instead of ADT, provided that no prior doses of dTpa have been administered (see Part 3.16, ‘Pertussis’).

Using adult/adolescent formulation dTpa vaccine for boosters
The adult/adolescent formulation dTpa (Boostrix) is available for use in Australia in those 8 years of age and older. However, dTpa should not be used for the primary immunisation of adolescents/adults against pertussis, and therefore is not appropriate for catch-up immunisation.

A booster dose of adult/adolescent formulation dTpa on a single occasion is recommended for the following groups. Once a booster dose of dTpa has been given, subsequent booster doses to the same individual should not be administered even if he/she qualifies for another of these groups:
- routine use at 15 to 17 years of age, replacing the dose of ADT at 15 to 19 years of age in the ASVS,
- adults planning a pregnancy, or for both parents as soon as possible after delivery of an infant,
- adults working with young children, in particular health-care and child-care workers,
- adults at 50 years of age, as an alternative to the recommended ADT.

(For further details on these recommendations, and on adult/adolescent formulation dTpa see Part 3.16, ‘Pertussis’). NB: Because data on the duration of immunity to pertussis following adult/adolescent formulation dTpa are limited, no recommendations on further doses of dTpa following an initial booster can be given at this time.

Catch-up for Hib vaccines (for children under 5 years of age)
Hib vaccines should not be administered before 6 weeks of age. Hib vaccines are not necessary after the fifth birthday, except for patients with asplenia. Tables 1.9.2 and 1.9.3 should be read together when determining the correct schedule.

Table 1.9.2: Recommended catch-up schedule when start of Hib vaccination has been delayed

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Trade name</th>
<th>3-6 months</th>
<th>Age now 7-11 months</th>
<th>12-14 months</th>
<th>15-59 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRP-OMP</td>
<td>PedvaxHIB</td>
<td>2 doses, 1-2 months apart, and booster at 12 months</td>
<td>2 doses, 1-2 months apart, and booster at least 2 months later, at 12-15 months</td>
<td>1 dose, and booster at least 2 months after previous dose (4)</td>
<td>Single dose (3) (4)</td>
</tr>
<tr>
<td>Hib (PRP-OMP)</td>
<td>Comvax hepB</td>
<td>2 doses, 1-2 months apart, and booster at 12 months</td>
<td>1 dose, and booster at least 2 months after previous dose (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbOC (3)</td>
<td>HibTITER</td>
<td>3 doses, 2 months apart, and booster at 12 months</td>
<td>2 doses, 2 months apart, and booster at 12 months and at least 2 months after previous dose</td>
<td>1 dose, and booster 18 months</td>
<td>Single dose (3) (4)</td>
</tr>
<tr>
<td>PRP-T (3)</td>
<td>Hiberix ActHIB</td>
<td>3 doses, 2 months apart, and booster at 12 months</td>
<td>2 doses, 2 months apart, and booster at 12 months and at least 2 months after previous dose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(1) Extremely preterm babies (<28 weeks or <1500 grams) who commence catch-up Hib vaccination with PRP-OMP between 3-11 months of age require a 3-dose primary series (not 2 doses). The third dose should be given 1-2 months after the second dose of PRP-OMP. The booster dose should be given at 12 months as usual.

(2) Where possible, use the same brand of Hib vaccine throughout the primary course.

(3) When a booster is given after the age of 15 months, any of the 3 available conjugate Hib vaccines can be used.

(4) Depending on the combination used, further doses of hepatitis B or IPV are required.

**Table 1.9.3: Recommendations for Hib catch-up vaccination when doses have been delayed or missed**

<table>
<thead>
<tr>
<th>Age at presentation (months)</th>
<th>Previous vaccination history</th>
<th>Recommended regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 – 11</td>
<td>1 dose</td>
<td>1 dose of Hib vaccine at 7 to 11 months, and booster at least 2 months later, at 12-15 months (1)</td>
</tr>
<tr>
<td>7 – 11</td>
<td>2 doses of PRP-OMP</td>
<td>Give third dose of PRP-OMP at 12 months and at least 2 months after previous dose</td>
</tr>
<tr>
<td>7– 14</td>
<td>2 doses of HbOC, PRP-T, unknown brand or mixture of vaccine brands</td>
<td>Give third dose 1 or more months after second dose, and fourth dose at 18 months (1)</td>
</tr>
<tr>
<td>12 –14</td>
<td>1 dose before 12 months</td>
<td>2 additional doses of any registered Hib vaccine, separated by 2 months</td>
</tr>
<tr>
<td>15 – 59</td>
<td>Any incomplete schedule</td>
<td>A single dose of any Hib vaccine</td>
</tr>
</tbody>
</table>

(1) Where possible, the same brand of vaccine should be given for all doses.

**Catch-up for hepatitis B vaccines**

The first dose of hepatitis B vaccine can be given as soon as possible after birth (within 24 hours) and should be given within 7 days of birth. The first dose should *not* be counted as a valid dose if given after 7 days and before 8 weeks of age. Following the birth dose, a total of 3 doses is required to achieve optimum protection in infants and young children. Provided that the birth dose was administered at least one month apart. Otherwise, ensure each child has a minimum interval of 4 weeks between the first and second doses, and 2 months between the second and third doses (Table 1.9.1). A catch-up schedule may be completed with hepatitis B containing combination vaccines or monovalent vaccines.

Different brands of hepatitis B vaccine, including the hepatitis B component of multivalent vaccines such as DTPa-hepB and Hib (PRP-OMP)-hepB can be used interchangeably throughout the schedule.

If using two dose schedules (see Table 3.9.1), the minimum interval between doses of H-B-Vax II 10 μg for 11 to 15 year olds is 4 months, but is 6 months for 1 to 15 year olds when using Twinrix (720/20).

**Table 1.9.4: Hepatitis B vaccine catch-up schedule for adolescents aged 11 to 15 years**

<table>
<thead>
<tr>
<th>Hepatitis B vaccine history</th>
<th>Recommended catch-up schedule*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No previous doses</td>
<td>Complete with 2 adult doses of H-B-Vax II, 4 to 6 months apart.</td>
</tr>
<tr>
<td>1 dose of paediatric hepatitis B vaccine (any brand)</td>
<td>Complete with 2 doses of paediatric hepatitis B vaccine (any brand). There should be a minimum interval of one month between the first and second doses, and 2 months between the second and third.</td>
</tr>
<tr>
<td>2 doses of paediatric hepatitis B vaccine (any brand)</td>
<td>Complete with 1 dose of paediatric hepatitis B vaccine (any brand) at least 2 months after the previous dose.</td>
</tr>
<tr>
<td>1 dose of unknown formulation</td>
<td>Complete with 2 doses of paediatric hepatitis B vaccine (any brand). There</td>
</tr>
</tbody>
</table>
(adult or paediatric) should be a minimum interval of one month between the first and second doses and 2 months between the second and third.

1 dose of adult H-B-Vax II Complete with 1 dose of adult H-B-Vax II at 4 to 6 months after previous dose.

2 doses of adult H-B-Vax II BUT with interval of less than 4 months between doses Complete with 1 adult dose of H-B-Vax II but at least 2 months after the previous dose.

Table 1.9.5: Hepatitis B vaccine catch-up schedule for adolescents aged 16 to 19 years*

<table>
<thead>
<tr>
<th>Hepatitis B vaccine history</th>
<th>Recommended catch-up schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>No previous doses</td>
<td>Start a 3-dose hepatitis B vaccine schedule using paediatric formulation (any brand). Administer at intervals of 0, 1 and 2–6 months</td>
</tr>
<tr>
<td>1 dose of paediatric hepatitis B vaccine (any brand)</td>
<td>Complete with 2 doses of paediatric hepatitis B vaccine (any brand). There should be a minimum interval of one month between the first and second doses and 2 months between the second and third doses.</td>
</tr>
<tr>
<td>2 doses of paediatric hepatitis B vaccine (any brand)</td>
<td>Complete with 1 dose of paediatric hepatitis B vaccine (any brand) at least 2 months after the previous dose.</td>
</tr>
<tr>
<td>1 dose of adult formulation of H-B-Vax II given before the sixteenth birthday</td>
<td>Give either 1 dose of adult H-B-Vax II at least 4 months after the previous dose, or two doses of any paediatric hepatitis B vaccine at the recommended minimum intervals.</td>
</tr>
</tbody>
</table>

*Only one monovalent hepatitis B vaccine (H-B-Vax II 10 μg formulation) is approved for use in Australia in a 2-dose schedule and only for adolescents aged 11–15 years. Catch-up for people aged 16–19 years must be administered using a 3-dose paediatric formulation.

**Catch-up for OPV or IPV**

If no previous documented doses of polio vaccine have been given, commence a catch-up program preferably using IPV. Give 3 doses of IPV at least 4 weeks apart. Although IPV and OPV can be used interchangeably, IPV is now the preferred vaccine for all doses for catch-up. If the child is less than 4 years of age, give the fourth booster dose at the fourth birthday preferably as DTPa-IPV and ensure that it is administered at least 4 weeks after the third dose of polio vaccine.

Any unimmunised person at increased risk of the disease (eg. those travelling to a country where wild polio disease is circulating) should be informed that it takes 2 to 3 months before vaccines produce adequate protection against all 3 polioviruses.

**Catch-up for MMR vaccine**

If no previous documented doses have been given, catch-up for MMR consists of 2 doses, at least 4 weeks apart. If a single dose has been given more than a month earlier, give one dose.

**Catch-up for meningococcal C conjugate vaccine**

In infants 2-3 months of age require 3 doses of meningococcal C conjugate vaccine, with a minimum interval of 4 weeks between doses. In infants aged 4–11 months require 2 doses with a minimum interval of 4 weeks between doses. Children aged 12 months and over, adolescents and adults, require a single dose only.

**Catch-up for pneumococcal conjugate vaccine**

See Part 3.18 'Pneumococcal infections'.

**Catch-up for varicella-zoster vaccine**

Children between 12 months and 13 years of age require one dose of varicella-zoster vaccine. Adolescents 14 years and over, and adults require 2 doses of varicella-zoster vaccine, administered one to two months apart.
1.10 TRANSPORT, STORAGE AND HANDLING OF VACCINES

Introduction
The ‘cold-chain’ is the system of transporting and storing vaccines within the temperature range of 2°C to 8°C from the place of manufacture to the point of administration. This temperature range is recommended because outside this range vaccines may (very quickly) lose their potency. Immunisation service providers should maintain their vaccine refrigerators as close as possible to 5°C, as this gives a safety margin of + or – 3°C. Maintenance of the cold-chain system requires that processes are in place to ensure that a potent vaccine reaches recipients.

The World Health Organization’s Expanded Program on Immunization (EPI) has developed detailed guidelines on the maintenance of an effective cold-chain. The guidelines here are based on the EPI recommendations, and on research and experience in Australia.

Purpose-built vaccine refrigerators
Purpose-built vaccine refrigerators are the preferred refrigerators for vaccine storage. It is recommended that if possible purpose-built refrigerators are used by larger vaccination services, including hospitals, pharmacies, larger community health centres and larger general practices. It is also recommended that they be used in remote settings in central and northern Australia.

There are several manufacturers and/or distributors of purpose-built vaccine refrigerators in Australia. Although they are considerably more expensive than domestic refrigerators, they have the advantage of not having to be modified for vaccine storage (see below). Also, they are programmed to maintain an internal temperature between 2°C to 8°C, they automatically defrost, they have an external temperature reading display and a maximum/minimum temperature continuous display, and an alarm for deviations outside the programmed temperature range. Information about these products can be obtained from most medical equipment wholesalers or distributors.

Safe vaccine storage when using a domestic refrigerator
‘Frost-free’ rather than cyclic type domestic refrigerators are recommended for storage of vaccines. Cyclic refrigerators are not recommended because they produce wide fluctuations in the internal temperatures, with regular internal heating. Frost-free refrigerators do not have heating cycles but remain frost-free with low levels of frequent warming temperatures.

Do not use ‘multi-flow’ refrigerators that direct air from the freezer compartment to the main cabinet. These types of refrigerators can easily be recognised by the presence of 2 thermostat controls.

Domestic refrigerators and many industrial refrigerators are designed only for the storage of food and drink and usually have several temperature zones to meet the requirements of different foods. They are not designed for the special temperature needs of vaccines. Domestic refrigerators that have a separate freezer compartment are recommended for vaccine storage.

Safe vaccine storage is possible in most refrigerators if the following procedures or modifications are carried out (see Figure 1.10.1):

- follow storage guidelines;
- store vaccine in a dedicated refrigerator if possible. Do not store food or drink in vaccine refrigerators. It is more difficult to maintain correct vaccine storage temperatures in ‘Bar’ refrigerators;
- store vaccines only on the middle and upper shelves in the refrigerator;
- allow air to circulate within the refrigerator, by not crowding or overfilling the refrigerator with the vaccines. A gap of at least 4 cm from all walls and between large packages of vaccine vials is recommended;
- rotate stock so that shortest date vaccines are used first;
- maintain a space between vaccine packages and the evaporation plate, to prevent the vaccines from freezing through contact with the plate;
- place plastic bottles containing salt water in the lower drawers and the door of the vaccine refrigerator. The salt water bottles help to stabilise the internal temperature quickly and reduce warming after the door is opened. Allow space between the bottles for air circulation. To make the
salt water for the bottles, add enough salt to make the water undrinkable (about 1-2 tablespoons per litre) and label 'Warning salt water. Do not drink'.

- open the door only when necessary and close it as soon as possible;
- check and record temperatures daily;
- give one person responsibility for adjusting the refrigerator control (it is important that other staff are also trained to ensure continuous monitoring);
- prevent ice build up in the freezer of non 'frost-free' refrigerators by defrosting regularly.
- ensure the power source is secured in a way to prevent the refrigerator from being accidentally unplugged or turned off. Tape in power plug and over switch to prevent accidental disconnection.

If a dedicated vaccine fridge is not available, store the vaccines in a (pre-cooled) Styrofoam container with lid closed and place in the middle of the refrigerator. Ensure the vaccines inside the container are monitored and place a label on the outside stating 'Vaccines – keep refrigerated'.

Thermostat overrides have not been recommended due to the lack of published testing data on their performance when fitted to available refrigerator brands available in Australia. The temperature of the vaccine refrigerator must be recorded daily even if a thermostat override has been fitted.

When preparing ice packs or freezer blocks for transport, cool the thawed ice packs on the lower shelf of the refrigerator during the day before placing in the freezer. Place these ice packs in the freezer at the end of the day for freezing overnight and allow a minimum of 2 days for complete freezing before using these ice blocks for transporting vaccines. Do not stack ice packs on top of each other in the freezer but set them on their edge and allow space between them.

**Maintaining and monitoring refrigerator temperatures**

Refrigerators used for vaccines should have a minimum/maximum thermometer placed on a middle shelf and temperatures should be checked and recorded daily. The most effective minimum/maximum thermometer is a digital type with a probe.

If using a digital thermometer with a probe, place the probe directly in contact with a vaccine vial or package. Do not put the probe into fluid. The recommendation of keeping the vaccine storage temperature at between 2°C to 8°C is based on air, not fluid temperatures.

The refrigerator temperature should be read around the same time each day, preferably prior to each working day. One person only should be responsible for adjusting the refrigerator to maintain the temperature in the recommended range of 2°C to 8°C.

Refrigerators used for vaccine storage should have an uninterrupted power supply and door openings should be kept to a minimum.

During a power failure of 4 hours or less, the refrigerator door should be left closed. If the power fails for more than 4 hours, store vaccines in a pre-cooled, insulated container with ice packs to keep them cool (see ‘Transporting vaccines in insulated containers’ for more information).

**Maintenance of the vaccine refrigerator**

Refrigerator breakdowns should be repaired immediately. The door seals should be in good condition so that the door closes securely. Refrigerators that are not ‘frost-free’ should be defrosted regularly to prevent ice build-up. Ice build-up can reduce the efficiency and performance of a refrigerator.

During defrosting or cleaning of the refrigerator, move the vaccines to a second refrigerator. This temporary storage refrigerator must also be monitored to ensure the correct temperature is maintained. Alternatively the vaccines can be stored in a pre-cooled insulated container with ice packs or ice until the normal vaccine refrigerator is ready for use again (see ‘Transporting vaccines in insulated containers’).

**Unpacking vaccines after transport**

Do not remove vaccines from their packaging regardless of their bulkiness. Removal from original packaging exposes vaccines to room temperature and/or lighting. Check cold-chain monitors when the vaccines arrive to ensure they have not been exposed to temperatures above 8°C or below 0°C.
If cold-chain monitors have not been included, check that the ice packs are still partially frozen; if they have completely thawed, the vaccines have not been kept sufficiently cold and may not be effective. **Do not discard any vaccines until you discuss the necessary actions with your State/Territory vaccine distribution centre, vaccine supplier, hospital pharmacy or local public health unit.**

**Figure 1.10.1: Thermal lag modification and storage patterns in a domestic refrigerator**

![Figure 1.10.1: Thermal lag modification and storage patterns in a domestic refrigerator](image)

**Cold-chain monitors**

Cold-chain monitors (CCM) include time-temperature (heat monitors) and freeze monitors. The CCM should accompany all vaccines during any long distance vaccine transport. A minimum/maximum thermometer is an acceptable alternative for monitoring temperature inside cold boxes during transport to outreach settings.

The CCM should not be removed from the (cold box) container until all vaccines have been removed for either use or storage. The index on the time-temperature or freeze monitor (or alternatively, the minimum/maximum thermometer if working in an outreach setting) should be checked when a vaccine is removed from the cold box. Any changes should be recorded. If possible, the CCM that arrived with the vaccines should remain with a portion of the vaccines during storage in the refrigerator until the vaccines have been used or discarded.

Always contact the State/Territory vaccine distribution centre, vaccine supplier, hospital pharmacy or the local public health unit for more information if required. See Appendix 1 for contact details.

CCMs work by showing colour change on an indicator strip when the temperature reaches or exceeds a threshold for a set period of time. The indicator strip should be attached to a card on which instructions for use are printed, in accordance with World Health Organization (WHO) format.

**Time-temperature monitors (for monitoring exposure to heat over time)**

There is one time-temperature monitor available that has 2 separate temperature thresholds.
The Monitor Mark™ (Model 10N/34AA) manufactured by 3M; with +10°C, irreversible colour change (14 days to full scale colour change at +12°C); plus 34°C, irreversible colour change (3 hours to full scale colour change at 37°C).

If an equivalent monitor to this one recommended by the WHO becomes available in Australia, it should also be considered for use.

An Australian vaccine manufacturer/distributor uses an in-house time-temperature monitor, Bulls Eye™. This is a heat-sensitive monitor and the manufacturer claims that it changes colour from 'satisfactory' to 'unsatisfactory' at 30 hours at 21°C, and 10 days at 12°C. It is more heat sensitive than the Monitor Mark™ and this might mean that, if the monitor activates, vaccines could be discarded even though they are still potent. If the Bulls Eye™ monitors activate, vaccine providers should always seek advice from their State/Territory vaccine distribution centre before vaccines are discarded. There is currently insufficient evidence to assess the manufacturer's claims about this monitor's performance under various temperature conditions.

**Freeze indicators**
Freeze indicators work by a colour spot change at threshold temperatures at or below freezing. There are different models available in Australia made by different manufacturers. Activation is shown by staining of the indicator paper from the solution in the bulb.

- **Freeze Watch™** (freeze) indicator (Berlinger or 3M). There are 2 models available: one is set to activate at 0°C and the other activates at –5°C. The model that activates at 0°C is recommended for use in Australia.
- **ColdMark™** (freeze) indicator (IntroTech™). There are 2 models available: one is set to activate at 0°C and the other activates at –3°C. The model that activates at 0°C is recommended for use in Australia.

**Procedures to be observed when using vaccines**
Vaccines should remain in the refrigerator until they are required and all unused vaccines should be immediately returned to the refrigerator. The expiry date on the vial or container should be checked before use.

BCG vaccine that has been taken in and out of refrigeration during a clinic session should be discarded at the end of the clinic day. Reconstituted BCG is very unstable and should be discarded after one working session of 5 to 6 hours.

OPV can be stored either in the refrigerator at 2°C to 8°C or in a freezer at below –20°C. Frozen OPV will not lose potency if it is quickly thawed and then refrozen. The freeze-thaw cycle can occur until the vial is empty as long as the vaccine is stored in a freezer capable of achieving temperatures below –20°C. Most domestic refrigerators (with freezer compartments) are not capable of achieving this temperature. A minimum/maximum thermometer should be used to check the freezer temperature.

If storing OPV in a refrigerator at 2°C to 8°C, opened multidose vials of OPV can be used in subsequent sessions if the following three conditions are met:
- the expiry date has not passed;
- the cold chain is maintained between 2°C to 8°C;
- the vaccine has not been taken away from the health centre (e.g. outreach immunisation setting).

NB: In contrast to OPV, which can be kept frozen, IPV must not be frozen.

**Transporting vaccines in insulated containers**
Refrigerated transport is the best way to distribute vaccines from the central (usually State/Territory) vaccine centre to the door of the immunisation provider (clinic or surgery). This transport should include appropriate temperature control and monitoring equipment. When this is not feasible, other methods can be used to achieve an effective cold chain.
Containers specifically designed for transporting vaccines should be used if available. If such a container is not available, the following guidelines for packing vaccine for transport in an insulated container should be observed:

- Before packing ice packs with vaccines, remove the ice packs from the freezer at least 30 minutes prior to packing and allow them to ‘sweat’. A ‘sweated’ ice brick is one that has been removed from the freezer for about 30 minutes. This action reduces the risk of freezing vaccines since the ice brick temperature is about –20°C when it is first taken out of the freezer.

- Place vaccines (and time-temperature monitors and freeze monitor as required) in a small Styrofoam container (‘six-pack’ container). Close the lid and secure with tape. Pack the small Styrofoam container inside a larger insulated container (a ‘cooler’ such as the Esky™) and surround it with ice packs. Close and secure the lid of the large container. The vaccines must not be in direct contact with the ice packs because of the risk of freezing.

- If the vaccines are not packed using the above technique, an alternative method is to pack the vaccines inside a pre-cooled cold box (eg. Esky™). Place the ice packs on top of the vaccines, ensuring they are separated from the vaccines by a layer of polystyrene foam, shredded paper or bubble-wrap plastic. Ensure the vaccines, CCM, ice packs and ‘filler’ material are packed to ensure they do not move around during transport. Vaccines must be packed to ensure the ice packs do not come into direct contact with the vaccines or CCM, and the cold air can circulate freely around the vaccines.

- Remove vaccines only as they are required, making sure the lids are replaced on both the small and large containers each time (if this is the method of transport). If the time-temperature monitors and/or freeze indicators (or alternatively, the min/max thermometer in an outreach situation) are used, they should be checked before administering the vaccine. If the time-temperature monitor indicates that vaccine is being subjected to temperatures above 10ºC while being transported, use more freezer blocks to reduce and maintain the internal temperature at the correct level.

**Stability of vaccines at different temperatures**

High temperatures affect all vaccines whereas freezing damages only some vaccines. In Australia, freezing has been shown to be the major cause of vaccine damage in both tropical and temperate areas. If concerned that vaccines may have been exposed to excessively high or low temperatures, contact your State/Territory immunisation coordinator.

**The following vaccines are unstable at room temperature:**
- BCG (Bacille Calmette-Guérin) vaccine
- Measles-mumps-rubella (MMR) vaccine
- Oral poliomyelitis vaccine (OPV)
- Varicella-zoster vaccine
- Yellow fever vaccine
- All reconstituted vaccines

**Do not freeze the following vaccines:**
- Diphtheria-tetanus-pertussis containing vaccines
- *Haemophilus influenzae* type b (the exception being the lyophilised PRP-T vaccines)
- Hepatitis B-containing vaccines
- Hepatitis A-containing vaccines
- Influenza vaccine
- Pneumococcal ( polysaccharide and conjugate ) vaccines
- Meningococcal C conjugate vaccines
- Japanese encephalitis vaccine
- All reconstituted vaccines
- All combinations of these vaccines
- Vaccine diluents

Note: Several other less frequently used vaccines (eg. rabies and typhoid) are also damaged by freezing. If the vaccines listed above have been exposed to temperatures 0ºC and below, do not use.

**The following vaccines must not be exposed to light:**
- BCG (Bacille Calmette-Guérin) vaccine
- Reconstituted measles-mumps-rubella (MMR) vaccine
- Monovalent rubella vaccine
- Oral poliomyelitis vaccine (OPV)
- Varicella-zoster vaccine (VZV)
- Most DTPa-containing vaccines
- Meningooccal C conjugate vaccine
- Yellow fever vaccine.
Table 1.10.1: Information on vaccines exposed to different temperatures

<table>
<thead>
<tr>
<th>Vaccine (3) (4)</th>
<th>Stability at different temperatures (1) (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt; 0°C</td>
</tr>
<tr>
<td><strong>BCG</strong> (freeze-dried or lyophilised vaccine) (3) (4)</td>
<td>Can be stored at up to –20°C. Do not expose to light (ultraviolet and/or fluorescent). Safe storage for 12 months. Do not expose to light (ultraviolet and/or fluorescent). Diluent – do not freeze (5) Store between 2°C and 8°C.</td>
</tr>
<tr>
<td>BCG (Reconstituted with diluent) (3) (4)</td>
<td><strong>DO NOT FREEZE.</strong></td>
</tr>
<tr>
<td><strong>Diphtheria, tetanus and/or acellular pertussis-containing vaccines</strong> Includes DTPa, DTPa-hepB, DTPa-Hib, DTPa-IPV, DTPa-IPV-Hib, DTPa-IPV-Hib, DTPa-hepB-IPV-Hib, dTpa, DT (CDT), DT (ADT).</td>
<td><strong>DO NOT FREEZE.</strong></td>
</tr>
<tr>
<td>Freeze dried (lyophilised) monovalent PRP-T Hib vaccine</td>
<td>Freeze-dried or lyophilised vaccine PRP-T can be frozen. Diluent – do not freeze (5) Store between 2°C and 8°C.</td>
</tr>
<tr>
<td>Reconstituted monovalent PRP-T Hib vaccine</td>
<td>Reconstituted vaccine must NOT be frozen. Store all components of the vaccine between 2°C and 8°C.</td>
</tr>
<tr>
<td>Other Hib-containing vaccines (PRP-OMP, HibOC, Hib (PRP-OMP)-hepB)</td>
<td><strong>DO NOT FREEZE.</strong> The precise freezing point is not established. Manufacturers state freezing temperature of HibOC is −1.0°C. Discard if exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Vaccine Type</td>
<td>Storage Requirements</td>
</tr>
<tr>
<td>------------------------------------</td>
<td>---------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Monovalent hepatitis A vaccine</td>
<td><strong>DO NOT FREEZE.</strong> Discard if vaccine has been exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Monovalent hepatitis B vaccine</td>
<td><strong>DO NOT FREEZE.</strong> Freezing point of hepatitis B vaccine is – 0.5°C and vaccine is destroyed at this temperature. Discard if exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Inactivated polio vaccine</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Influenza vaccine</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Measles-mumps-rubella (MMR)</td>
<td><strong>DO NOT FREEZE.</strong> May be stored in freezer at 0°C or below. Protect from light, which may inactivate virus.</td>
</tr>
<tr>
<td>Reconstituted measles-mumps-rubella (MMR)</td>
<td><strong>DO NOT FREEZE.</strong> Protect from light. Can be stored between 2°C to 8°C. Protect from light, which may inactivate the vaccine virus. Should be used in one vaccination session (8 hours) if kept cool and protected from sunlight. If not, discard after 1 hour.</td>
</tr>
<tr>
<td>Meningococcal C conjugate vaccine (MenCCV) NeisVac-C Meningitec (freeze-dried or lyophilised vaccine)</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperatures of 0°C or below. Store in refrigerator between 2 and 8°C. Shelf life 18 months at this temperature.</td>
</tr>
<tr>
<td>Meningococcal C conjugate vaccine (MenCCV) Menjugate</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperatures of 0°C or below. Store between 2 and 8°C. Shelf life is 24 months at this temperature. Reconstituted vaccine must be used immediately. Diluent – do not freeze (5) Store between 2 to 8°C.</td>
</tr>
<tr>
<td>Oral poliomyelitis vaccine (OPV) opened vials</td>
<td><strong>DO NOT FREEZE.</strong> May be stored for up to 2 years at around –20°C. The freeze-thaw-refreeze cycle can occur until the vial is empty. Can be stored at 2°C to 8°C between use as long as the expiry date has not passed, and the vaccine has not been taken out of the health centre (eg outreach immunisation setting).</td>
</tr>
<tr>
<td>Pneumococcal conjugate vaccine (7vPCV)</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperature of 0°C or below.</td>
</tr>
<tr>
<td>Pneumococcal polysaccharide vaccine, 23-valent (23vPPV)</td>
<td><strong>DO NOT FREEZE.</strong> Discard if exposed to temperature of 0°C or below.</td>
</tr>
</tbody>
</table>

Note: *(3) (4)* indicates availability status. *(5)* indicates diluent storage requirements.
Varicella-zoster vaccine:
Varivax Refrigerated, Varilrix (freeze-dried or lyophilised vaccine) (3) (4)

May be stored in frost-free freezer at an average temperature of –15ºC or colder.
Maintains potency for 24 months (Varilrix) or 18 months (Varivax Refrigerated).
Protect from light.

Prior to reconstitution, varicella-zoster vaccine retains potency when stored between 2ºC to 8ºC for up to 2 years (Varilrix) or 18 months (Varivax Refrigerated).
Diluent – do not freeze (5)
Store between 2ºC and 8ºC.

Not available.
Not available.
Not available.

Reconstituted varicella-zoster vaccine: Varilrix and Varivax Refrigerated (3) (4)

DO NOT FREEZE.
Protect from light.

Administer immediately after reconstitution to minimise loss of potency. Discard if reconstituted vaccine is not used within 90 minutes (Varilrix) or within 30 minutes (Varivax Refrigerated).
Diluent – do not freeze (5)
Store between 2ºC and 8ºC.

Not available.
Not available.
Not available.

(1) For thermostability information on other vaccines not listed in this Table, refer to the specific chapter in this Handbook.
(2) The information in this Table is in many cases not consistent with the Australian product information documents. However, this Table provide guidelines based on the WHO (1998) Thermostability of Vaccines, WHO/ GV.98.07.
(3) The vaccines that are most unstable at room temperature are OPV and reconstituted MMR, varicella-zoster and BCG vaccines.
(4) OPV and reconstituted MMR, varicella-zoster and BCG vaccines must be protected from exposure to light.
(5) DO NOT FREEZE DILUENT AS THIS MAY CAUSE UNDETECTABLE CRACKS IN THE AMPOULE LEADING TO CONTAMINATION.

References


