PART 1: VACCINATION PROCEDURES

INTRODUCTION TO *THE AUSTRALIAN IMMUNISATION HANDBOOK*

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. 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 healthcare 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 *The Australian Immunisation Handbook* is to provide clinical guidelines for health professionals on the safest and most effective use of vaccines in their practice. These recommendations are developed by the Australian Technical Advisory Group on Immunisation (ATAGI) and endorsed by the National Health and Medical Research Council (NHMRC).

The *Handbook* provides clinical recommendations based on the best scientific evidence available at the time of publication from published and unpublished literature. Further details regarding the *Handbook* revision procedures are described in Appendix 2. Where specific empiric evidence was unavailable, recommendations were formulated using the best available expert opinion relevant to Australia. The reference lists for all chapters are included in the electronic version of the *Handbook* which is available via the Immunise Australia website (www.immunise.health.gov.au). The electronic version of the *Handbook* has additional information regarding recommendations in the new vaccine chapters, including systematic reviews of the literature.

In some instances, the NHMRC recommendations differ from vaccine product information sheets (PI); these differences are detailed in the relevant vaccine chapters under the heading 'Variations from product information'. Where a variation exists, the NHMRC recommendation should be considered best practice.

The information contained within the *Handbook* was correct at the time of printing. However, the content of the *Handbook* is reviewed regularly. The 9th edition of *The Australian Immunisation Handbook* will remain current unless amended electronically via the Immunise Australia website or until the 10th edition of the *Handbook* is published.

ELECTRONIC UPDATES to the 9th edition of *The Australian Immunisation Handbook* will be available at:

www.immunise.health.gov.au

References

Full reference list available on the electronic *Handbook* or website http://immunise.health.gov.au.

1.1 WHAT'S NEW?

Changes introduced in this edition of the *Handbook*

All chapters have been updated and revised where necessary. The 9th edition introduces new vaccines, changes to the schedules, changes to recommendations and procedures regarding the administration of vaccines, and changes to the presentation of the *Handbook*. Some changes made since the publication of the hard copy of the 8th edition of the *Handbook* in September 2003, and before the 9th edition, were available online on the Immunise Australia website and are not described below.

The term Australian Standard Vaccination Schedule (ASVS) is no longer used in the *Handbook*.

The National Immunisation Program (NIP) is used throughout the *Handbook* and refers to funded vaccines as they appear on the National Immunisation Program (NIP) schedule. The NIP schedule may change over time and is available via the Immunise Australia website (www.immunise.health.gov.au).

New chapters and chapters which no longer appear in the *Handbook*

- Three new chapters have been included in the *Handbook* – 3.7 *Human papillomavirus*, 3.18 *Rotavirus* and 3.26 *Zoster*.
- There are 4 new appendices in the *Handbook*. These are '*Handbook* development' (Appendix 2); a list of vaccines which are registered in Australia but either not currently available or no longer available in Australia (Appendix 3); a list of major components in the vaccines in the National Immunisation Program (Appendix 4); and a table that is a summary of procedures for a vaccination encounter (Appendix 10).
- Two chapters have been deleted: anthrax and plague. For information about anthrax, please go to the Australian Government website www.health.gov.au and use the index option to select the anthrax fact sheet.
- Three chapters previously in the 8th edition, botulism, cytomegalovirus and respiratory syncytial virus, have been incorporated into the immunoglobulin chapter (3.8 *Immunoglobulin preparations*).

Overview of major changes to existing recommendations and procedures

Part 1

- The layout of Part 1 has been altered from previous editions of the *Handbook* into 3 chapters which are described in Chapter 1.2 *An overview of vaccination*. The new layout applies to Chapter 1.3 *Pre-vaccination procedures* (including cold chain, consent, pre-vaccination screening and catch-up); Chapter 1.4

Administration of vaccines (including route, needle size and injection site); and Chapter 1.5 *Post-vaccination procedures* (including adverse events following immunisation, and the recording of vaccinations).

- Advice on preparing an anaphylaxis response kit has been added to pre-vaccination procedures, Chapter 1.3.
- The pre-vaccination screening checklist and assessment table have been revised and recommended steps for screening added to the section, Chapter 1.3.
- The cold chain guidelines have been updated in Chapter 1.3 and the recommendations summarised to reflect and reference the *National Vaccine Storage Guidelines: Strive for 5*.
- The valid consent section has been redrafted and updated.
- The recommended anatomical site for intramuscular (IM) administration of vaccines in infants <12 months of age is the anterolateral thigh.
- The recommended anatomical site for IM administration of vaccines in those ≥12 months of age is the deltoid.
- The ventrogluteal area is included as an alternative anatomical site for the administration of vaccines at any age. This is based on published data. It is important that vaccine providers using this site are trained in the recognition of the relevant anatomical landmarks.
- The recommended needle size and length for IM injection is 23 or 25 gauge, 25 mm in length.
- The recommended angle of insertion of the needle for IM administration of vaccines is 90° to the skin surface.
- Injection techniques have been described in more detail with additional photographs and/or diagrams demonstrating positions and the recommended anatomical sites.
- Catch-up schedules have been updated for vaccines in the National Immunisation Program and practical tools to assist with catch-up added.
- A table of catch-up schedules for individuals aged ≥8 years has been included.
- Information on reporting of adverse events following immunisation has been updated to reflect recent changes to the national reporting arrangements.
- Information on the Australian Childhood Immunisation Register has been updated.
- The table previously in the 8th edition *Handbook* entitled 'Information on vaccines exposed to different temperatures' has been deleted as some of the information is no longer considered valid.
- Management of anaphylaxis with 1:10 000 adrenaline is no longer recommended; use of 1:1000 adrenaline is recommended.

- Tools to photocopy include the pre-vaccination checklist, catch-up work sheet, and Appendix 10 *Summary table – procedures for a vaccination encounter*.

Part 2

- Recommendations for groups with special vaccination requirements (Chapter 2.3) have undergone substantial revision and incorporate new tables and separate sections for pregnant and breastfeeding women and women planning pregnancy, preterm infants, people with impaired immunity, oncology patients and transplant recipients.
- Recommendations for immunisation of certain occupational groups have been expanded (Chapter 2.3).
- A comprehensive table outlining the suggested intervals between receipt of either a blood product or an immunoglobulin-containing product and administration of either measles, mumps, rubella or varicella vaccines is included (Chapter 2.3).

Part 3

Chapters 3.3 Diphtheria and 3.21 Tetanus

- For adults requiring a primary course of dT, dTpa is recommended for the first dose followed by 2 doses of dT (or dTpa *only* if dT is unavailable).

Chapter 3.6 Hepatitis B

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

Chapter 3.8 Immunoglobulin preparations

- Botulism, cytomegalovirus and respiratory syncytial virus are now incorporated into this chapter.

Chapter 3.9 Influenza

- For children aged 6 months to <3 years the dose of influenza vaccine is 0.25 mL.
- It is recommended that all Aboriginal and Torres Strait Islander people aged ≥15 years receive annual influenza vaccination.
- It is recommended that children ≥6 months of age and adults with a chronic neurological condition receive annual influenza vaccination.

Chapters 3.11 Measles, 3.13 Mumps and 3.19 Rubella

- The second dose of MMR vaccine is recommended at 18 months of age, not at 4 years of age.
- The use of MMRV vaccines, when available, is discussed.

Chapter 3.12 Meningococcal disease

- Close household contacts of a case of invasive meningococcal disease should be vaccinated as well as receiving antibiotic prophylaxis.

Chapter 3.14 Pertussis

- For adults requiring a primary course of dT, dTpa is recommended for the first dose followed by 2 doses of dT (or dTpa *only* if dT is unavailable).
- A new table detailing antibiotic prophylaxis for pertussis cases and their contacts has been included.

Chapter 3.15 Pneumococcal disease

- Children ≤9 years of age with specified underlying medical conditions should receive 2 doses of 7-valent pneumococcal conjugate vaccine followed by a dose of 23-valent pneumococcal polysaccharide vaccine.
- Recommendations for revaccination of adults with 23-valent pneumococcal polysaccharide vaccine have been revised and tabulated.

Chapter 3.24 Varicella

- When combination measles, mumps, rubella and varicella vaccine/s (MMRV) become available, it is recommended that varicella vaccination be given at 12 months of age, using MMRV.
- Administration of a second dose of varicella-containing vaccine in children aged <14 years is recommended to minimise the risk of breakthrough disease.

Chapter 3.25 Yellow fever

- Yellow fever vaccine is now recommended for travellers (provided there are no contraindications) going to urban and/or rural areas of endemic countries.

1.2 AN OVERVIEW OF VACCINATION – PREFACE TO CHAPTERS 1.3–1.5

The following sections of Part 1 (Chapters 1.3–1.5) describe chronologically the steps involved around a vaccination encounter, starting with pre-vaccination requirements (Chapter 1.3), then administration of vaccines (Chapter 1.4) and post-vaccination considerations (Chapter 1.5).

Chapter 1.3 describes the steps required in preparing for a vaccination encounter. This includes preparation of an anaphylaxis response kit and effective cold chain management (transport, storage and handling of vaccines) as described in *National Vaccine Storage Guidelines: Strive for 5*. The next section discusses obtaining valid consent and is followed by information on comprehensive pre-vaccination health screening, including a standard screening checklist and summary tables of precautions and contraindications to vaccination. The chapter ends with a section on how to manage catch-up vaccination. The section is divided into two categories; the first for children <8 years of age and the second for people ≥8 years of age.

Chapter 1.4 provides detailed sections on the administration of vaccines. This chapter discusses occupational health and safety issues and the equipment required for vaccination. Techniques for vaccine administration, including the route and site of vaccine administration, positioning, identifying the vaccination site, and methods for administering multiple vaccine injections at the same visit are described in detail.

Chapter 1.5 provides readers with information on post-vaccination care, including immediate after-care and the recognition and management of adverse events following immunisation (AEFI), including anaphylaxis. There are also sections on how to report AEFI, documentation of vaccination, and details about the Australian Childhood Immunisation Register.

A summary of the key points discussed in these chapters is provided in the table in Appendix 10, *Summary table – procedures for a vaccination encounter.* This is suitable for photocopying for training and auditing purposes.

1.3 PRE-VACCINATION PROCEDURES

The following sections discuss steps and procedures that should occur before a vaccination encounter. In addition, Appendix 10, *Summary table – procedures for a vaccination encounter* provides a table summarising the procedures described in this chapter.

1.3.1 Preparing an anaphylaxis response kit

The availability of protocols, equipment and drugs necessary for the management of anaphylaxis should be checked before each vaccination session. An anaphylaxis response kit should be on hand at all times and should contain:

- adrenaline 1:1000 (minimum of 3 ampoules – check expiry dates),
- minimum of three 1 mL syringes and 25 mm length needles (for IM injection),
- cotton wool swabs,
- pen and paper to record time of administration of adrenaline, and
- laminated copy of *Recognition and treatment of anaphylaxis* (back cover of this *Handbook*).

Section 1.5.2 provides details on recognition and treatment of adverse events following immunisation.

1.3.2 Effective cold chain: transport, storage and handling of vaccines[1,2]

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.

All immunisation service providers should be familiar with and adhere to the *National Vaccine Storage Guidelines: Strive for 5*. This publication can be accessed free of charge from http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store

The *National Vaccine Storage Guidelines: Strive for 5* contain specific details on setting up the infrastructure for a vaccination service, and immunisation service providers should refer to this to ensure that satisfactory equipment and procedures are in place before commencing vaccination services. The *Guidelines* also provide instructions on how to best transport vaccines from the main storage facility to outreach or external clinics using a cooler.

With correct temperature monitoring and adherence to the cold chain *Guidelines*, any problems in vaccine storage should be detected early and handled appropriately before compromised vaccine is administered.

Purpose-built vaccine refrigerators (PBVR) are the preferred means of storage for vaccines. Domestic refrigerators are designed and built for food and drink storage, not for the special temperature needs of vaccines.

Cyclic defrost and bar refrigerators are not recommended because they produce wide fluctuations in internal temperatures and regular internal heating.

Bar refrigerators, in particular, should *not* be used because of the risk of freezing, temperature instability and susceptibility to ambient temperatures.

If the only alternative is to use a domestic refrigerator for vaccine storage, modification of the refrigerator is essential to reduce the risk of adverse vaccine storage events. Please refer to the cold chain *Guidelines* for further information.

The following checklist summarises the ongoing activities required by immunisation service providers to ensure optimal storage of vaccines:

(a) Ensure one staff member is designated as administrator of vaccines and vaccine storage; only one staff member should be responsible for refrigerator thermostat controls at any one time.

(b) Name a back-up vaccine administrator, to take responsibility for vaccines in the absence of the primary vaccine administrator.

(c) Ensure your healthcare service has a written Vaccine Management policy and protocol which, as a minimum, should include:

- how and when to monitor and record the minimum and maximum temperatures of the vaccine refrigerator,
- how to check the accuracy of the thermometer and/or the data logger, and how and when to change the thermometer battery,
- how to order and receive vaccines and rotate stock,
- how to store the vaccine, diluents and ice/gel packs correctly in the refrigerator,
- how to maintain the refrigerator including a regimen of regular servicing,
- what steps to take if the refrigerator temperature goes outside +2°C to +8°C, including identification of a cold chain breach, response procedures, documentation, recording and prevention of recurrences,
- how to manage the vaccines during a power failure,
- how to pack a portable cooler properly, including correct conditioning of ice packs/gel packs,
- training required for staff handling vaccines.

(d) Storage of all vaccines:

- Maintain refrigerator temperature between +2°C to +8°C, check and record the current plus minimum/maximum temperatures at least daily or immediately before vaccines are used.

- Twice-daily temperature checks will give a better indication of any problems in the refrigerator's function and temperature fluctuations over the course of the day.
- Keep the door closed as much as possible.
- Ensure one person is responsible for adjusting refrigerator controls and that all staff are appropriately trained to ensure continuous monitoring.
- Establish and document protocols for response to cold chain breaches.
- A vaccine storage self-audit should be undertaken by the clinic/practice at least every 12 months.
- Most vaccines must be protected from freezing. Diluents must also be protected from freezing, as freezing could cause tiny cracks within the wall of the diluent container. Protect all vaccines from UV and fluorescent light.
- If vaccines have been exposed to temperatures below +2°C or above +8°C, follow the practice protocol for response to a breach of the cold chain. Isolate vaccines and contact the State/Territory health authority for advice on the National Immunisation Program vaccines and the manufacturer/supplier for privately purchased vaccines. Recommendations for the discarding of vaccines may differ between health authorities and manufacturers. Do *not* discard any vaccines until you discuss the necessary actions.
- Perform monthly vaccine stocktake, ensure vaccines with the shortest expiry date are stored at the front of the refrigerator, record and dispose of vaccines that have passed the 'expiry date'.
- Order appropriate levels of stock to ensure the refrigerator is not overcrowded and that sufficient doses of vaccine are available until the arrival of the next order. Monthly usage from previous years can assist with more accurate ordering.
- Ensure all reception staff are familiar with and adhere strictly to the practice vaccine delivery protocols, including timely unpacking of vaccines.
- Ensure people purchasing vaccines from a pharmacy understand the need to handle/transport the vaccines correctly.
- Minimum/maximum thermometers and/or loggers should be checked for accuracy (calibrated) annually. Refer to manufacturer for assistance. Change the battery in digital minimum/maximum thermometers every 12 months.
- Ensure the refrigerator is placed out of direct sunlight and the manufacturer's instructions for air circulation around the back and sides are followed.
- Ensure the refrigerator is in a secure area accessible to staff only.

- Ensure the power source is marked clearly in a way to prevent the refrigerator from being accidentally unplugged or turned off.
- During a power failure, monitor the temperature of your refrigerator. If vaccines are at risk, use alternative storage arrangements with appropriate monitoring.

(e) Using a purpose-built vaccine refrigerator (PBVR):

- PBVRs maintain a stable, uniform and controlled cabinet temperature unaffected by ambient air temperature, and have a defrost cycle that allows defrosting without rises in cabinet temperature.
- PBVRs have a standard alarm and safety feature alert and good temperature recovery.
- Ensure that the PBVR does not constantly display minimum/maximum and ambient temperatures. Separate minimum/maximum temperatures must be used to monitor the refrigerator. There are some PBVRs that require a daily data-logger download to view temperature data.
- PBVRs should alarm if temperatures outside +2°C to +8°C are reached.
- Some PBVRs have a back-plate that may vary in temperature during the defrost cycle. Ensure vaccines are kept 4 cm from the back-plate. Check with PBVR manufacturer to ensure that vaccines can be stored in the bottom of the refrigerator.
- In the event of a power failure, PBVRs with glass doors will lose their cool temperature quickly. Ensure the protocol for responding to power failures is up-to-date and that staff are aware of the procedures.
- Do not overstock or crowd the vaccines by overfilling the shelves. Allow space between stock for air circulation.
- If very small amounts of vaccine are stored in a PBVR it is necessary to add thermal mass (such as bottles of water) to the vacant space to ensure even temperature is maintained throughout the refrigerator.
- If a chart recorder is used, the chart recorder paper must be changed every 7 days and stored in a safe place for auditing purposes.

(f) Using a domestic refrigerator:

- Fill the lower drawers and the door with plastic bottles/containers filled with water.
- Get to know the temperatures throughout the refrigerator by monitoring and recording to identify any 'cold spots'.
- Store the vaccines in an enclosed plastic container, in their original packaging, and label the containers clearly.
- Vaccines must never be stored in the door of the refrigerator.

- Ensure each domestic refrigerator has a Celsius digital minimum/maximum thermometer, with the thermometer probe placed inside vaccine packaging, inside and near the back of an enclosed plastic container. A temperature recording chart is also required.

Cold chain breaches

Do *not* use vaccines exposed to temperatures below +2°C or above +8°C without obtaining further advice. Do *not* discard these vaccines. Isolate vaccines and contact the State/Territory health authorities for advice on the National Immunisation Program vaccines and the manufacturer/supplier for privately purchased vaccines. **Recommendations for the discarding of vaccines may differ between health authorities and manufacturers.** *Do not discard* any vaccines until you discuss the necessary actions.

1.3.3 Valid consent

Valid consent can be defined as the voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to the individual.[3-7]

For consent to be legally valid, the following elements must be present:[8]

- It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of being vaccinated.
- It must be given voluntarily.
- It can only be given after the relevant vaccine(s) and their potential risks and benefits have been explained to the individual.
- The individual must have sufficient opportunity to seek further details or explanations about the vaccine(s) and/or their administration.

Consent should be obtained before each vaccination, once it has been established that there are no medical conditions that contraindicate vaccination.

Consent on behalf of a child or adolescent

In general, a parent or legal guardian of a child has the authority to consent to vaccination of a child.[3,7] A child in this context is defined as being under the age of 18 years in all States and Territories except New South Wales, where the age is 14 years, and in South Australia and the Northern Territory, where the age is 16 years.

If they are of sufficient age and maturity to understand the proposed procedure and the risks and benefits associated with same, children at younger ages may be able to provide consent for procedures such as vaccination. Please refer to your own State or Territory immunisation service provider guidelines for more information.

Should a child or adolescent refuse vaccinations for which a parent/guardian has given consent, the child's wishes should be respected and the parent/guardian informed.[3]

Consent on behalf of people with impaired decision-making ability

A responsible adult family member, preferably with authority to make medical decisions, may give consent for vaccination of an adult with a significant disability. For example, this may occur for influenza vaccination of an elderly person with dementia.

Resources to help communicate the risks and benefits of vaccines

Plain language should be used in communicating information about vaccines and their use to an individual. The individual must be allowed to ask for further information and have time to make a decision about whether to consent or not.[9,10]

It is preferable that printed information is available to supplement any verbal explanations.[11] The summary table *Comparison of the effects of diseases and the side effects of vaccines* inside the front cover of this *Handbook* provides some basic information necessary to communicate the risks and benefits of vaccination. The table can be photocopied and used freely as required.

More detailed information concerning vaccines and their use is available from the following sources:

- www.immunise.health.gov.au
  The Immunise Australia website includes 'Common questions and answers (fact sheets)', 'Understanding childhood immunisation' and links to State and Territory Health Department websites. Several of these sites offer multilingual fact sheets.
- www.ncirs.usyd.edu.au
  The National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases website includes fact sheets related to specific vaccines, vaccine-preventable diseases and vaccine safety.

See also Appendix 5, *Commonly asked questions about vaccination*.

Evidence of consent

General practice or public immunisation clinics

Consent may be given either in writing or verbally, according to the protocols of the health facility, but it must meet the criteria for valid consent. Evidence of verbal consent should be documented in the clinical records. If a standard procedure is routinely followed in a practice or clinic, then a stamp, a sticker or a provider's signature indicating that the routine procedure has been followed, may be used. For paperless medical records, a typed record of verbal consent may be made in the patient's file, or a copy of written consent scanned into the file.

Consent is often given and recorded at the first vaccination visit. Explicit verbal consent is required before subsequent vaccinations even when written consent has been given at previous vaccination encounters.

School-based vaccination programs

Consent is often given for the entire vaccination program and is valid for the number of doses to be given during a school-based vaccination program.

In school-based (and other large-scale) vaccination programs, the parent or guardian usually does not attend with the child on the day the vaccination is given, and written consent from the parent or guardian is desirable in these circumstances. However, if further clarification is required, verbal consent may be sought by telephone from the parent or guardian by the immunisation service provider. This should be clearly documented on the child's consent form. Older adolescents may be able to provide their own consent for vaccinations.[12] However, the vaccination program may vary between jurisdictions. Please refer to your own State or Territory immunisation service provider guidelines for more information.

1.3.4 Pre-vaccination screening

Immunisation service providers should perform a pre-vaccination health screen of all recipients to determine:

- if there are any contraindications or precautions to the vaccines that are to be administered, and
- whether alternative or additional vaccines should be considered.

For some individuals, alterations to the routinely recommended vaccines may be necessary to either eliminate or minimise the risk of adverse events, to optimise an individual's immune response, or to enhance the protection of a household contact against vaccine-preventable diseases.

Such changes to the recommended vaccines may require discussion with an immunisation expert such as the local immunisation coordinator or a medical practitioner with expertise in vaccination.

Steps for pre-vaccination screening

A comprehensive pre-vaccination health screening is necessary to assess a person's medical fitness for vaccination and to determine whether a different vaccine schedule may be recommended. Follow these steps to complete the screening process:

1. Provide the person to be vaccinated or the parent/carer with the *Pre-vaccination screening checklist* (Table 1.3.1). NB. Some of the questions in this checklist are deliberately non-specific so as to elicit as much important information as possible.
    - The pre-vaccination screening checklist may be photocopied and handed to the parent/carer or person to be vaccinated just before vaccination.
    - It may also be photocopied and displayed in the clinic/surgery for easy reference for the immunisation service provider.
2. When any of the conditions or circumstances are identified by using the pre-vaccination screening checklist, refer then to Table 1.3.2 which lists the specific issues pertaining to these conditions or circumstances and provides the appropriate action with a rationale.
3. Where necessary, further expert advice should be sought from a medical practitioner with expertise in vaccination, the immunisation section within your State or Territory health authority, or your local Public Health Unit (see Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control*).
4. No one should be denied the benefits of vaccination by withholding vaccines for inappropriate reasons (see Table 1.3.4 *False contraindications to vaccination*).

Table 1.3.1: Pre-vaccination screening checklist

Pre-vaccination screening checklist

This checklist helps your doctor/nurse decide about vaccinating you or your child. Please tell your doctor/nurse if the person about to be vaccinated:

- ☐ is unwell today
- ☐ 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)
- ☐ has had a severe reaction following any vaccine
- ☐ has *any* severe allergies (to anything)
- ☐ has had any vaccine in the past month
- ☐ has had an injection of immunoglobulin, or received any blood products or a whole blood transfusion within the past year
- ☐ is pregnant
- ☐ has a past history of Guillain-Barré syndrome
- ☐ was a preterm infant
- ☐ has a chronic illness
- ☐ has a bleeding disorder

A different vaccine schedule may be recommended if the person to be vaccinated:

- ☐ identifies as an Aboriginal or Torres Strait Islander
- ☐ does not have a functioning spleen
- ☐ is planning a pregnancy or anticipating parenthood
- ☐ is a parent, grandparent or carer of a newborn
- ☐ lives with someone who has a disease which lowers immunity (eg. leukaemia, cancer, HIV/AIDS), or lives with someone who is having treatment which lowers immunity (eg. oral steroid medicines such as cortisone and prednisone, radiotherapy, chemotherapy)

Note: Please ask your doctor/nurse questions about this information or any other matter relating to vaccination before the vaccines are given.

Before any vaccination takes place, the immunisation service 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 do not have a record, ask your immunisation service provider to give you one. Bring this record with you every time you or your child visit for vaccination. Make sure your doctor/nurse records all vaccinations on it. Your child may need this record to enter childcare, preschool or school.

Conditions or circumstances identified using the pre-vaccination screening checklist

The recommended responses for immunisation service providers to any conditions or circumstances identified by the pre-screening checklist is summarised in Table 1.3.2. NB. Only vaccines recommended on the National Immunisation Program schedule are included in Table 1.3.2. For information on other vaccines, refer to the relevant chapter within this *Handbook* (Part 3) or to vaccine product information. For reference, Table 1.3.3 provides a classification of live attenuated vaccines.

Table 1.3.2: Responses to relevant conditions or circumstances identified by the pre-vaccination screening checklist

Condition or circumstance	Action	Rationale[13-15]
Unwell today: • Acute febrile illness (current T ≥38.5°C). • Acute systemic illness.	Defer all vaccines until afebrile. NB. Children with minor illnesses (without acute systemic symptoms/signs) should be vaccinated.	To avoid an adverse event in an already unwell child, or to avoid attributing symptoms to vaccination.
Has a disease which lowers immunity or receiving treatment which lowers immunity. See Section 2.3.3, *Vaccination of individuals with impaired immunity due to disease or treatment*.	Seek expert advice before vaccination (see Appendix 1). NB. People living with someone with lowered immunity should be vaccinated, including with live viral vaccines.	The safety and effectiveness of the vaccine may be suboptimal in people with impaired immunity.
Anaphylaxis following a previous dose of the relevant vaccine.	Do not vaccinate. See also 'Contraindications to vaccination' below.	Anaphylaxis to a previous dose of vaccine is a contraindication to receiving the vaccine.
A severe (anaphylactic) allergy to a vaccine component. Refer to Appendix 4 for vaccine component checklist.	Do not vaccinate (seek specialist advice as per Appendix 1). See also 'Contraindications to vaccination' below.	Anaphylaxis to a vaccine component is a contraindication to receiving the vaccine.
Received live parenteral vaccine or BCG vaccine in past 4 weeks.	Delay live vaccines by 4 weeks.	The immune response to a live viral vaccine may interfere with the response to a second live viral vaccine if given within 4 weeks of the first.

Condition or circumstance	Action	Rationale[13-15]
Has had any blood product in the past 7 months, or has had IM or IV immunoglobulin in the past 11 months. Refer to Table 2.3.5 *Recommended intervals between either immunoglobulins or blood products and MMR, MMRV or varicella vaccination*.	Make a return appointment for this vaccination, and send a reminder later if necessary.	Antibodies within these products may interfere with the immune response to these vaccines.
Is pregnant. Refer to Table 2.3.1 *Vaccinations in pregnancy*.	Live vaccines* should be deferred until after delivery. Conception should be deferred until at least 28 days after administration of live viral vaccines. Inactivated vaccines are generally not contraindicated in pregnancy.	There is insufficient evidence to ensure the safety of administering live vaccines during pregnancy or within 28 days before conception. NB. Influenza vaccine is recommended for pregnant women. Vaccination of household contacts of pregnant women should be completed according to the NIP schedule.
History of Guillain-Barré syndrome (GBS). See Chapter 3.9, *Influenza*.	Risks and benefits of influenza vaccine should be weighed against the potential risk of GBS recurrence (seek specialist advice as per Appendix 1).	People with a history of GBS may be at risk of recurrence of the condition following influenza vaccine.
Was born preterm. See Section 2.3.2, *Vaccination of women planning pregnancy, pregnant or breastfeeding women, and preterm infants*.	Preterm infants born at <28 weeks' gestation or <1500 g birth weight require an extra dose of PRP-OMP Hib vaccine at 6 months of age. Preterm infants born at <28 weeks' gestation and/or with chronic lung disease require extra pneumococcal vaccinations. Preterm infants born at <32 weeks' gestation or <2000 g birth weight may require an extra dose of hepatitis B vaccine.	Preterm infants may be at increased risk of vaccine-preventable diseases (eg. invasive pneumococcal disease (IPD)), and may not mount an optimal immune response to certain vaccines (eg. hepatitis B, PRP-OMP).

Condition or circumstance	Action	Rationale[13-15]
Has a severe or chronic illness. See Chapter 2.3, *Groups with special vaccination requirements*.	These people should receive pneumococcal vaccine and annual influenza vaccination. If there is significantly impaired immunity, they should not receive live vaccines, but inactivated vaccines should be considered (seek expert advice).	People with a severe or chronic illness may be at increased risk of vaccine-preventable diseases (eg. IPD) but may not mount an optimal immune response to certain vaccines.
Has a bleeding disorder. See Section 2.3.6, *Vaccination of patients with bleeding disorders*.	The subcutaneous route could be considered as an alternative to the intramuscular route (seek specialist advice as per Appendix 1).	Intramuscular injection may lead to haematomas in patients with disorders of haemostasis.
Identifies as an Aboriginal or Torres Strait Islander. See Chapter 2.1, *Vaccination for Aboriginal and Torres Strait Islander people*.	See the National Immunisation Program Indigenous schedules.	Some groups of Indigenous people are at increased risk of some of the vaccine-preventable diseases.
Does not have a functioning spleen. See Section 2.3.3, Subsection 2.3.3.5, *Individuals with functional or anatomical asplenia*.	Check vaccination status for pneumococcal, meningococcal and Hib vaccinations.	Individuals with an absent or dysfunctional spleen are at an increased risk of severe bacterial infections, most notably IPD.
Is planning a pregnancy or anticipating parenthood.	Ensure prospective parents have been offered vaccines recommended for their age-group including 2nd dose of MMR if born after 1966, and dTpa† (unless they have had a previous dose of dTpa).	Vaccinating before pregnancy may prevent maternal illness which could affect the infant, and may confer passive immunity to the newborn. NB. Advise women not to become pregnant within 28 days of receiving live viral vaccines.
Is a parent, grandparent or carer of a newborn.	Ensure parents, grandparents and carers of a newborn have been offered all vaccines recommended for their age-group including dTpa (unless they have had a previous dose of dTpa).	People in close contact are the most likely sources of vaccine-preventable diseases, in particular pertussis, in the newborn.

Condition or circumstance	Action	Rationale[13-15]
Lives with someone who has impaired immunity.	Ensure all vaccines (in particular MMR, varicella and influenza vaccines) recommended for their age-group have been offered to household members of people with impaired immunity.	Household members are the most likely sources of vaccine-preventable diseases among people with impaired immunity (who often are unable to be vaccinated, especially with live viral vaccines).

* Live attenuated vaccines are classified in Table 1.3.3 below.

† See Chapter 3.3, *Diphtheria*, Chapter 3.14, *Pertussis* or Chapter 3.21, *Tetanus* for further information.

Table 1.3.3: Live attenuated parenteral and oral vaccines

Live attenuated parenteral vaccines		Live attenuated oral vaccines	
Viral	**Bacterial**	**Viral**	**Bacterial**
MMR	BCG	Oral rotavirus vaccine	Oral typhoid vaccine
MMRV			
Varicella vaccine (VV)			
Monovalent rubella vaccine			
Yellow fever			

Contraindications to vaccination

There are only 2 absolute contraindications applicable to *all* vaccines:

(i) anaphylaxis following a previous dose of the relevant vaccine, and

(ii) anaphylaxis following any component of the relevant vaccine.

There are 2 further contraindications applicable to live (both parenteral and oral) vaccines:

(iii) Live vaccines should not be administered to individuals with impaired immunity, regardless of whether the impairment is caused by disease or treatment. The exception is that, with specialist advice, MMR can be administered to HIV-infected individuals in whom impaired immunity is mild. (See Section 2.3.3, *Vaccination of individuals with impaired immunity due to disease or treatment*, and individual vaccine chapters.)

(iv) In general, live vaccines should not be administered during pregnancy, and women should be advised not to become pregnant within 4 weeks of receiving a live vaccine (see Table 2.3.1 *Vaccinations in pregnancy*).

False contraindications to vaccination

Conditions listed in Table 1.3.4 below are not contraindications to vaccination. People with these conditions should be vaccinated with all recommended vaccines.

Table 1.3.4: False contraindications to vaccination

The following conditions are not contraindications to any of the vaccines in the National Immunisation Program schedule:
• mild illness without fever (T <38.5°C),
• family history of any adverse events following immunisation,
• past history of convulsions,
• treatment with antibiotics,
• treatment with locally acting (inhaled or low-dose topical) steroids,
• replacement corticosteroids,
• asthma, eczema, atopy, hay fever or 'snuffles',
• previous pertussis-like illness, measles, rubella, mumps or meningococcal disease,
• prematurity (vaccination should not be postponed),
• history of neonatal jaundice,
• low weight in an otherwise healthy child,
• any neurological conditions including cerebral palsy and Down syndrome,
• contact with an infectious disease,
• child's mother is pregnant,
• child to be vaccinated is being breastfed,
• woman to be vaccinated is breastfeeding,
• recent or imminent surgery,
• poorly documented vaccination history.

1.3.5 Catch-up

Every opportunity should be taken to review an individual's vaccination history and, based on documentation, administer the appropriate vaccine(s). If the individual has not received vaccines scheduled in the National Immunisation Program appropriate for his/her age, plan and document a catch-up schedule and discuss this with the individual. The assessment of vaccination status should be based on the schedule for the State/Territory in which the individual is residing.

The objective of catch-up vaccination is to complete a course of vaccination and provide optimal protection as quickly as possible. The information and tables below will assist in planning a catch-up schedule. If the immunisation service provider is still uncertain about how to plan the catch-up schedule, expert advice should be sought (see Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control*).

An on-line 'catch-up calculator' is available at www.health.sa.gov.au/immunisationcalculator

This calculator is regularly updated for all catch-up scenarios relevant to the NIP. For non-NIP vaccines or complicated catch-up scenarios, expert advice should be sought (see Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control*).

To calculate a catch-up schedule, the on-line calculator requires the child's date of birth, State of residence, past vaccination history and Indigenous status. The calculator can be used for children ≤7 years of age (the age up to which vaccinations will be recorded on the ACIR) and can calculate catch-up schedules for children from all States and Territories. For recently arrived immigrants, the World Health Organization web site www.who.int/countries/en lists an immunisation schedule (where provided by that particular country) and may supplement information regarding which vaccines a child/adult may have received (see also Section 2.3.9, *Vaccination of immigrants to Australia*).

Alternatively, the instructions and guidelines below will assist in the manual calculation of a catch-up schedule.

Determining a vaccination history

Individuals with incomplete vaccination records

The most important requirement for assessment of vaccination status is to have written documentation of vaccination. The approach of providers to the problem of inadequate records should be based on the age of the individual, whether previous vaccines have been given in Australia or overseas, and the vaccines being considered for catch-up.

Vaccines given from 1 January 1996

The Australian Childhood Immunisation Register (ACIR) commenced on 1 January 1996 and all vaccinations given to children since then should be available from the ACIR. If the parent states that vaccines not recorded on the ACIR have been given, every effort should be made to contact the relevant immunisation service provider. If confirmation from the nominated provider or the ACIR cannot be obtained, and no written records are available, the vaccines should be considered as not received, and the child should be offered a catch-up course of vaccination appropriate for age (see Section 1.3.5). Parents can obtain an ACIR Immunisation History Statement from Medicare (see Section 1.5.4).

Older children and adolescents <18 years of age

No vaccination information is recorded on the ACIR after a child turns 7 years of age, but any information already held is retained. The information will relate only to vaccines received between birth and the 7th birthday. The ACIR Enquiry Line can be contacted on 1800 653 809 and any record held for an individual who

is ≥7 years of age can be made available to an immunisation service provider or parent/carer.

In older children and adolescents, alternative sources of documentation (such as personal health records) will be needed, but are less likely to be available with increasing age. Individuals who do not have personal vaccination records may seek evidence of past vaccination from their parents, their past and present healthcare providers or immunisation service providers, including Local Government immunisation service providers. Those born after 1990 may have some vaccinations recorded on the ACIR (see Section 1.5.4).

For most vaccines, there are no adverse events associated with additional doses in immune individuals. In the case of diphtheria and tetanus vaccines, additional doses may occasionally be associated with an increase in local adverse events in immune individuals (see Chapter 3.3, *Diphtheria*, Chapter 3.14, *Pertussis* or Chapter 3.21, *Tetanus*). However, the benefits of protection against pertussis are likely to outweigh the risk of an adverse reaction.

Adults (≥18 years of age)

In adults, written documentation of previous vaccination history may not be available. It is important, however, to seek information of any previous doses of diphtheria and tetanus vaccines, and of pneumococcal polysaccharide vaccination in the previous 5 years, as increased local reactions may occasionally occur in immune individuals (see Chapter 3.3, *Diphtheria*, Chapter 3.15, *Pneumococcal disease* or Chapter 3.21, *Tetanus*). Additional doses of MMR, varicella, IPV or hepatitis B vaccine are rarely associated with significant adverse events in adults.

Guidelines for planning catch-up vaccination

There are a number of tables in this section which are designed to help plan a catch-up schedule if not using the on-line calculator.

- Figure 1.3.1 is a worksheet for calculating and recording which vaccines are required, the number of doses outstanding and the timing of these doses.
- Table 1.3.5 can be used to assess the number of doses a child would have received if they were on schedule. Check under the current age of the child to see how many doses they should have already received and use that number of doses as the starting point for calculating a catch-up schedule. For example, a child who is 18 months old now should have received 3 doses of DTPa, 3 doses of IPV etc.
- Table 1.3.6 lists the minimum interval between doses.
- Tables 1.3.8–1.3.11 are for calculating catch-up for Hib and pneumococcal vaccination.

If documentation cannot be produced, assume that the vaccine has not been given previously, unless contact can be made with the immunisation service provider.

- Vaccine doses should not be administered at less than the recommended minimum interval[16] (see Table 1.3.6).
- In exceptional circumstances, where early vaccination is required, Table 1.3.7 indicates the minimum age that the first dose of a vaccine may be given.
- Doses administered earlier than the minimum interval should not be considered as valid doses and should be repeated as appropriate using Table 1.3.5.
- When commencing the catch-up schedule, the standard scheduled 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 1 dose of (any) Hib vaccine is required.
- As a child gets older, the recommended number of vaccine doses may change (or even be omitted from the schedule), as the child becomes less vulnerable to specific diseases.
- For incomplete or overdue vaccinations, build on the previous documented doses.

Never start the schedule again, regardless of the interval since the last dose.

- If more than 1 vaccine is overdue, 1 dose of each due or overdue vaccine should be given now. Further required doses should be scheduled after the appropriate minimum interval (see Table 1.3.6).
- A catch-up schedule may require multiple vaccinations at a visit. Give all the due vaccines at the *same* visit – do not defer. See Section 1.4.9 for procedures for administering multiple injections at the same visit.
- The standard intervals and ages recommended in the NIP schedule should be used once the child or adult is up-to-date with the schedule.
- Some individuals will require further doses of antigens that are available only in combination vaccines. In general, the use of the combination vaccine(s) is acceptable, even if this means the number of doses of another antigen administered exceeds the required number.
- If different Hib vaccines are inadvertently used in the primary series, then 3 doses (of any Hib vaccine) are required at 2, 4 and 6 months of age, with a booster at 12 months of age (see Chapter 3.4, *Haemophilus influenzae type b*).

NB. Routine rotavirus vaccine 'catch-up' of older children is *not* recommended. Infants should commence the course of rotavirus vaccination within the recommended age limits for the first dose. It is also necessary to ensure that doses are not given beyond the upper age limits for the final dose of the vaccine course (see Chapter 3.18, *Rotavirus*).

Interruption to a vaccination

- If the process of administration of a vaccine given parenterally (IM or SC) is interrupted (eg. by syringe-needle disconnection) the whole dose should be repeated as soon as practicable.
- If an infant regurgitates or vomits part of a dose of oral rotavirus vaccine, it is not necessary to repeat the dose. Therefore, the regurgitated (and incomplete volume) dose is still considered as the valid dose (see Chapter 3.18, *Rotavirus*).

Determining a catch-up schedule for children <8 years of age

A catch-up schedule for a child <8 years of age should be planned by taking into account the guidelines above and using Table 1.3.5. The Catch-up Worksheet (Figure 1.3.1) provides a method of recording these steps. All catch-up vaccines administered to children aged <7 years should be reported as soon as is practicable to the ACIR.

Using the Catch-up Worksheet

1. Record the child's details including date of birth and current age in the top left corner of the worksheet.
2. For each vaccine, determine how many doses have been received and the date that the last dose was given. Record this on the worksheet.
3. Refer to Table 1.3.5 to check how many doses of each vaccine are required for the child's current age. Enter this number in the appropriate column of the worksheet.
4. Assess other factors that may affect the type or number of vaccines required, including:
   - anaphylaxis to any vaccine or one of its components (that vaccine is contraindicated),
   - impaired immunity due to disease or treatment (see Chapter 2.3, *Groups with special vaccination requirements*),
   - identifying as an Aboriginal or Torres Strait Islander (see Chapter 2.1, *Vaccination for Aboriginal and Torres Strait Islander people*),
   - children with an underlying medical risk condition which predisposes them to invasive pneumococcal disease (see Chapter 3.15, *Pneumococcal disease*),
   - a reliable history of previous varicella infection (varicella vaccine not required), and
   - babies born at <32 weeks' gestation (see Hib vaccine and hepatitis B vaccine catch-up below).

   Record any relevant factor in the 'comments' column beside the relevant vaccine.

5. If any variations to the schedule are necessary due to recorded factors (eg. a child with impaired immunity may require different vaccines), adjust the 'number of doses required' accordingly.
6. For each vaccine, compare the 'last dose given' with the number required for the child's current age.
7. If the child has already received the number of doses required, the relevant 'dose number due now' and 'further doses' cells should be crossed through.
8. If the number of the 'last dose given' is less than the number required, a dose of the relevant vaccine should be administered now, and recorded in the 'dose number due now' cell. If this dose still does not complete the required doses, enter the further dose numbers in the 'further doses' cell.
9. Refer to Table 1.3.6 to determine the recommended minimum intervals required between doses and record in the relevant 'further doses' cells.
10. Convert this information into a list of proposed appointment dates, detailing vaccines and dose number needed at each visit on the Catch-up Worksheet.
11. Record this catch-up schedule in your provider records and provide a copy to the parent/carer.

Figure 1.3.1: Catch-up Worksheet for children <8 years of age

CATCH-UP WORKSHEET					
Name: **DOB:** **Age:**	**Last dose given** *Dose number and date*	**Number of doses required at current age***	**Dose number due now**	**Further doses** *Interval or date*	**Comments**
DTPa					
Poliomyelitis (IPV)					
Hepatitis A					
Hepatitis B					
Hib					
7vPCV & 23vPPV					
MenCCV					
MMR					
Rotavirus					DO NOT give after upper age limits for each dose. See Table 3.18.1.
Varicella					
CATCH-UP APPOINTMENTS					
Date	**Vaccines & Dose number**	**Interval to next dose**			**Comments**

* See step 5 'Using the Catch-up Worksheet' above.

Table 1.3.5: Number of vaccine doses that should have been administered by the current age of the child (table to be used in conjunction with Catch-up Worksheet)

VACCINE	CURRENT AGE						
	0–<2mo	2–<4mo	4–<6mo	6–<12mo	12–18mo	>18mo–<4yr	4yr–<8yr
DTPa*		1	2	3	3	3	4
Poliomyelitis (IPV)		1	2	3	3	3	4†
Hepatitis A‡					1‡	2‡	2‡
Hepatitis B	birth dose given§	2	3	4	4	4	4
	birth dose not given	1	2	3^	3	3	3
Hib	Complex – see Table 1.3.8 for Hib vaccine catch-up						
7vPCV & 23vPPV	Complex – see Tables 1.3.9, 1.3.10 and 1.3.11 for pneumococcal vaccine catch-up						
MenCCV					1	1	1
MMR					1	2	2
Rotavirus#	There are specific age limits as per Chapter 3.18, *Rotavirus*, Table 3.18.1.			**NO CATCH-UP**			
Varicella						1	1

* Some children may have received 4 doses of DTP by 18 months of age, especially if moved from overseas. These children will require a 5th dose of DTPa at 4 years of age.

† If the 3rd dose of IPV is given after 4 years of age, a 4th dose is not required. However, if using a combination vaccine it is acceptable to receive a 4th dose.

‡ Indigenous children resident in NT, QLD, SA and WA only. Dependent on jurisdiction, the 1st dose is given at 12–18 months of age followed by the 2nd dose 6 months later at 18–24 months of age. Consult relevant State/Territory authorities for advice regarding catch-up in children older than 2 years of age.

§ Birth dose should be given within 7 days of birth. Although a birth dose of hepatitis B vaccine is recommended for all infants, a catch-up dose is not necessary if it was not given. Even if the birth dose was given, a further 3 doses of hepatitis B vaccine are required.

^ Some States/Territories schedule a 3rd dose (or the 4th dose) of hepatitis B vaccine at 6 months of age rather than 12 months.

There is *no catch-up* for rotavirus vaccine (see Chapter 3.18, *Rotavirus*).

Table 1.3.6: Minimum dose intervals for NIP vaccines for children <8 years of age (table to be used in conjunction with Catch-up Worksheet)

Vaccine		Minimum interval between dose 1 & 2	Minimum interval between dose 2 & 3	Minimum interval between dose 3 & 4
DTPa*		4 weeks	4 weeks	6 months
Poliomyelitis (IPV)		4 weeks	4 weeks	4 weeks†
Hepatitis A (Indigenous children in NT, QLD, SA & WA only)		6 months		
Hepatitis B				
If first dose given at birth or at ≤7 days after birth‡		4 weeks	8 weeks	8 weeks
If first dose is not given at birth or at >7 days after birth§		4 weeks	8 weeks	
Hib (PRP-OMP)		See Table 1.3.8 Hib vaccine catch-up		
Hib (PRP-T)				
Pneumococcal (7vPCV)		See Tables 1.3.9, 1.3.10, 1.3.11 Pneumococcal vaccine catch-up		
MenCCV^				
MMR#		4 weeks		
Rotavirus**	Rotarix	4 weeks		
	RotaTeq	4 weeks	4 weeks	
Varicella		4 weeks		

* If DTPa is only available in combination with other antigens (eg. DTPa-IPV, DTPa-hepB-IPV-Hib or DTPa-HepB-IPV), these formulations can be used where necessary for primary course or catch-up doses in children <8 years of age.

† If the 3rd dose of IPV is given after 4 years of age, a 4th dose is not required. However, if using a combination vaccine, it is acceptable to receive a 4th dose.

‡ If dose given at birth or within 7 days of birth (considered dose 1 for this table), then 3 subsequent doses should be given.

§ If dose 1 is not given at birth or within 7 days of birth, then it should be given at 2 months of age, followed by a further 2 doses.

^ The schedule is a single dose given at 12 months of age. Alternative schedules are available for children <12 months of age (see Chapter 3.12, *Meningococcal disease*).

MMR vaccine may be given from 9 months of age if in contact with case, but dose *must* be repeated at 12 months of age.

** Consult Chapter 3.18, *Rotavirus*, Table 3.18.1 for upper age limits for administration of rotavirus vaccines. Catch-up is *not* recommended.

Table 1.3.7: Minimum age for the first dose of vaccine in exceptional circumstances*

Vaccine	Minimum age for first dose in exceptional circumstances	Minimum age accepted as valid by ACIR
DTPa	6 weeks	6 weeks
Poliomyelitis (IPV)	6 weeks	6 weeks
Hepatitis A (Indigenous children in NT, QLD, SA & WA only)	12 months	12 months
Hepatitis B	6 weeks	6 weeks
Hib (PRP-OMP)	6 weeks	6 weeks
Hib (PRP-T)	6 weeks	6 weeks
MenCCV	6 weeks†	12 months
MMR	9 months‡	11 months
Pneumococcal (7vPCV)	6 weeks	6 weeks
Rotavirus	6 weeks	not stated
Varicella	9 months§ (Varilrix) 12 months^ (Varivax)	not stated

* Exceptional circumstances may include infants/children being vaccinated before overseas travel, or opportunistic vaccination following early attendance to a provider. These ages may differ from routinely recommended ages of administration under the NIP.

† If 2 doses of MenCCV are given before 12 months of age, then a booster dose should be given at 12 months of age (see Chapter 3.12, *Meningococcal disease*).

‡ MMR vaccine may be given from 9 months of age if in contact with case, but dose *must* be repeated at 12 months of age.

§ If a child receives varicella vaccine at <12 months of age, a further dose should be given at 18 months of age.

^ Receipt of at least 1 dose of varicella vaccine is recommended from 12 months of age.

Catch-up guidelines for individual vaccines

- **DTPa**

Monovalent pertussis vaccine is not available in Australia. If a child has received previous doses of DT and requires pertussis catch-up, then DTPa or DTPa-combination vaccines can be used provided that no more than 6 doses of diphtheria and tetanus toxoids are given before the 8th birthday.

NB. If no birth dose of hepatitis B vaccine was given, and a DTPa-hepatitis B-containing combination vaccine is used, there should be a *minimum interval* of 8 weeks between doses 2 and 3.

- **Hepatitis B vaccine**

If the infant received the birth dose of hepatitis B vaccine, catch-up doses can be given 4–8 weeks apart.

If the infant did not receive the birth dose, a catch-up of this dose is not necessary. In this circumstance, hepatitis B vaccination should commence at 2 months of age. There should be a *minimum interval* of 8 weeks between doses 2 and 3.

In preterm babies under 32 weeks' gestation at birth or <2000 g birth weight, it is recommended to give hepatitis B vaccine at 0, 2, 4 and 6 months of age, and either:

(a) measure anti-HBs at 7 months of age and give a booster at 12 months of age if antibody titre is <10 mIU/mL, or

(b) give a booster at 12 months of age without measuring the antibody titre.

(See also Section 2.3.2, *Vaccination of women planning pregnancy, pregnant or breastfeeding women, and preterm infants* and Chapter 3.6, *Hepatitis B*).

- **Hib vaccine**

The recommended number of doses and recommended intervals of Hib vaccines vary with the vaccine type and with the age of the child (see Table 1.3.8). PRP-OMP is the Hib formulation contained in Liquid PedvaxHIB and COMVAX. PRP-T is the Hib formulation contained in Hiberix and Infanrix hexa.

Where possible, the same brand of Hib vaccine should be used for all doses. If different Hib vaccines are used in the primary series, then 3 doses (of any Hib vaccine) are required at 2, 4 and 6 months of age, with a booster at 12 months of age. Only 1 dose (of any Hib vaccine) is required after 15 months of age.

When PRP-OMP is used in an extremely preterm baby (<28 weeks' gestation or <1500 g birth weight), an additional dose should be given at 6 months of age, ie. doses should be given at 2, 4, 6 and 12 months of age (see Section 2.3.2, *Vaccination of women planning pregnancy, pregnant or breastfeeding women, and preterm infants*).

- **MMR vaccine**

If no previous documented doses have been given, catch-up for MMR consists of 2 doses given at least 4 weeks apart.

- **MenCCV**

MenCCV is recommended on the NIP for children at 12 months of age. If no dose was received at ≥12 months of age or if all doses have been received at <12 months of age, a single dose of any meningococcal conjugate vaccine is recommended (see Chapter 3.12, *Meningococcal disease*).

- **7vPCV**

The number of doses and recommended intervals of 7vPCV for catch-up vary with the age of the child, health and Indigenous status of the child, as well as the State/Territory of residence (see Tables 1.3.9, 1.3.10 and 1.3.11 below).

Low-risk children (including all Indigenous children) aged ≥2 years of age do *not* require catch-up.

If <2 years of age at presentation, use Table 1.3.9 for low-risk children (including Indigenous children living in the Australian Capital Territory, New South Wales, Victoria and Tasmania) and Table 1.3.10 for Indigenous children residing in the Northern Territory, Queensland, South Australia and Western Australia. Table 1.3.11 provides catch-up details for children aged ≤5 years with an underlying medical condition. Please also refer to Chapter 3.15, *Pneumococcal disease* for further details.

- **Poliomyelitis vaccine**

If no previous documented doses of poliomyelitis vaccine have been given, give 3 doses of IPV or IPV-containing vaccines at least 4 weeks apart. (Previous doses of OPV are interchangeable with IPV.)

If the third dose of IPV is administered before 4 years of age, give the fourth (booster) dose at either the 4th birthday or 4 weeks after the third dose, whichever is later. If the third dose is given after the 4th birthday, a fourth dose is not required. However, if the use of combination vaccines is necessary, a further IPV-containing dose may be given.

- **Rotavirus vaccine**

Infants should commence the course of rotavirus vaccination within the recommended age limits for the first dose, that is by either 12 or 14 weeks of age depending on the vaccine to be used. It is recommended that vaccine doses are not given beyond the upper age limits specified in Table 3.18.1, Chapter 3.18, *Rotavirus*.

- **Varicella vaccine**

If a child receives varicella vaccine at <12 months of age, a further dose should be given at 18 months of age.

Table 1.3.8: Recommendations for Hib catch-up vaccination for children <5 years of age when doses have been delayed or missed

Previous vaccination history	Age at presentation	Type of Hib vaccine to be used	1st dose	2nd dose	3rd dose	Booster dose
0 doses	**3–6 months**	PRP-OMP	Give now	1 month later	Not needed	12 months of age
		PRP-T	Give now	1 month later	1–2 months later	12 months of age
	7–11 months	PRP-OMP	Give now	2 months later	Not needed	12 months of age or 2 months after 2nd dose (whichever is later)
		PRP-T	Give now	2 months later	Not needed	12 months of age or 2 months after 2nd dose (whichever is later)
	12–14 months	PRP-OMP	Give now	Not needed	Not needed	2 months later
		PRP-T	Give now	Not needed	Not needed	18 months of age
	15–59 months	PRP-OMP or PRP-T	Give now	Not needed	Not needed	Not needed
1 previous dose (given at least 4 weeks previously)	**3–6 months**	PRP-OMP	PRP-OMP previously given	Give now	Not needed	12 months of age
		PRP-T	Either PRP-OMP or PRP-T previously given	Give now	1–2 months later	12 months of age
	7–14 months	PRP-OMP or PRP-T	Previously given	Give now	Not needed	12 months of age or 2 months after 2nd dose (whichever is later)
	15–59 months	PRP-OMP or PRP-T	Previously given	Not needed	Not needed	Give now*
2 previous doses of PRP-OMP	**12–59 months**	PRP-OMP or PRP-T	Previously given	Previously given	Not needed	At least 2 months after last dose*
2 previous doses of PRP-T (or 1 of each of PRP-OMP and PRP-T)	**7–14 months**	PRP-OMP or PRP-T	Previously given	Previously given	At least 1 month after last dose	12–18 months of age, at least 2 months after last dose
	15–59 months	PRP-OMP or PRP-T	Previously given	Previously given	Not needed	At least 2 months after last dose*

*A booster dose is not needed if the last previous dose was given at >15 months of age.

Table 1.3.9: Recommendations for pneumococcal catch-up vaccination for low-risk children (including Indigenous children living in ACT, NSW, VIC and TAS) <2 years of age, when doses have been delayed or missed

CATEGORY	Previous doses of 7vPCV	Age at presentation	1st dose 7vPCV	2nd dose 7vPCV	3rd dose 7vPCV
All non-Indigenous children **and** Indigenous children living in ACT, NSW, VIC and TAS	None	3–6 months	Give now	1 month later	1–2 months later*
		7–17 months	Give now	1–2 months later*	Not needed
		18–23 months	Give now	Not needed	Not needed
	1 previous dose (given at least 4 weeks previously)	5–11 months	Previously given	Give now	1–2 months later*
		12–23 months	Previously given	Give now	Not needed
	2 doses	7–11 months	Previously given	Previously given	Give now
		12–23 months	Previously given	Previously given	Not needed

* Catch-up doses of 7vPCV can be given a minimum of 1 month apart to infants aged <12 months. For children aged ≥12 months, there should be a 2 month interval between doses of 7vPCV.

Table 1.3.10: Recommendations for pneumococcal catch-up vaccination for Indigenous children <2 years of age in NT, QLD, SA and WA, when doses have been delayed or missed

CATEGORY	Previous doses of 7vPCV	Age at presentation	1st dose 7vPCV	2nd dose 7vPCV	3rd dose 7vPCV	23vPPV*
Indigenous children living in NT, QLD, SA and WA	None	3–6 months	Give now	1 month later	1–2 months later†	18–24 months of age
		7–17 months	Give now	1–2 months later†	Not needed	18–24 months of age or 2 months after 2nd dose of 7vPCV (whichever is later)
		18–23 months	Give now	Not needed	Not needed	18–24 months of age or 2 months after 1st dose of 7vPCV (whichever is later)
	1 dose (given at least 4 weeks previously)	5–11 months	Previously given	Give now	1–2 months later†	18–24 months of age
		12–23 months	Previously given	Give now	Not needed	18–24 months of age or 2 months after 2nd dose of 7vPCV (whichever is later)
	2 doses	7–11 months	Previously given	Previously given	Give now	18–24 months of age
		12–23 months	Previously given	Previously given	Not needed	18–24 months of age or 2 months after 2nd dose of 7vPCV (whichever is later)

* The timing of 23vPPV varies between States and Territories. Contact your State or Territory health authority for the appropriate timing.

† Catch-up doses of 7vPCV can be given a minimum of 1 month apart to infants aged <12 months. For children aged ≥12 months, there should be a 2 month interval between doses of 7vPCV.

Table 1.3.11: Recommendations for pneumococcal catch-up vaccination for children ≤5 years of age* with underlying medical conditions

CATEGORY	Previous doses of 7vPCV	Age at presentation	1st dose 7vPCV	2nd dose 7vPCV	3rd dose 7vPCV	Booster dose 7vPCV	23vPPV
Children ≤5 years of age with underlying medical conditions	None	3–6 months	Give now	1 month later	1–2 months later†	12 months of age	4–5 years of age
		7–11 months	Give now	1–2 months later†	Not needed	12 months of age or 2 months after 2nd dose of 7vPCV (whichever is later)	4–5 years of age
		12–59 months	Give now	2 months later	Not needed	Not needed	4–5 years of age or 2 months after 2nd dose of 7vPCV (whichever is later)
	1 dose	5–6 months	Previously given	Give now	1 month later	12 months of age	4–5 years of age
		7–11 months	Previously given	Give now	Not needed	12 months of age or 2 months after 2nd dose of 7vPCV (whichever is later)	4–5 years of age
		12–59 months	Previously given	Give now	Not needed	Not needed	4–5 years of age or 2 months after 2nd dose of 7vPCV (whichever is later)
	2 doses	7–11 months	Previously given	Previously given	Give now	12 months of age or 2 months after 3rd dose of 7vPCV (whichever is later)	4–5 years of age
		12–59 months	Previously given	Previously given	Give now	Not needed	4–5 years of age or 2 months after 3rd dose of 7vPCV (whichever is later)
	3 doses	12–59 months	Previously given	Previously given	Previously given	Give now	4–5 years of age or 2 months after booster dose of 7vPCV (whichever is later)

*** Children up to the age of 10 years who, after the 6th birthday, develop asplenia, HIV infection, or a haematological malignancy, or who receive a transplant, should receive 2 doses of 7vPCV 2 months apart, and a dose of 23vPPV 2 months later. If these children need catch-up doses of 7vPCV, the recommendations are the same as for the 12–59 month age-group in Table 1.3.11, with a dose of 23vPPV 2 months after the last dose of 7vPCV. See Chapter 3.15, *Pneumococcal disease* recommendations and Table 3.15.1**

† Catch-up doses of 7vPCV can be given a minimum of 1 month apart to infants aged <12 months. For children aged ≥12 months, there should be a 2 month interval between doses of 7vPCV.

Catch-up schedules for children ≥8 years of age, adolescents and adults

Catch-up is much less commonly required for these age groups than for young children. Nevertheless, issues surrounding booster doses or revaccinations are common, particularly in adults. People who escaped natural infection as children and were not vaccinated remain at unnecessary risk of vaccine-preventable diseases.

If a vaccine course is incomplete, never start the course again, regardless of the interval since the last dose.

Recommendations on vaccination for adults at occupational risk or in a special risk group can be found in Chapter 2.3, *Groups with special vaccination requirements*.

Use Table 1.3.12 to determine:

- how many doses of a particular vaccine a person should have received to be considered completely vaccinated (column 2: Doses required),
- deduct any previous doses of the vaccine from that number, and
- go to the appropriate minimum interval column.

For example, a 32-year-old woman who has received only 1 dose of hepatitis B vaccine, 4 doses of the oral poliomyelitis vaccine, 1 dose of MMR vaccine and 2 doses of DTPw as a child, would require:

- 2 adult doses of hepatitis B, 1 dose given now and a further dose in 8 weeks,
- 1 dose of dT (preferably given as dTpa),
- no further doses of poliomyelitis vaccine (is fully vaccinated against poliomyelitis),
- varicella vaccine if non-immune,
- 1 dose of MMR vaccine.

Where several vaccines are required, eg. dTpa, hepatitis B and poliomyelitis vaccines, *never* use the available childhood combination vaccines as the antigen content differs and may result in a severe adverse event. The childhood combination vaccines are not registered for use in children aged ≥8 years, adolescents or adults.

Table 1.3.12: Catch-up schedules for individuals ≥8 years of age

Vaccine		Doses required	Minimum interval between Dose 1 & 2	Minimum interval between Dose 2 & 3
dT (dTpa*)		3 doses	4 weeks	4 weeks
Hepatitis B	Aged 8–19 years	3 paediatric doses	4 weeks	8 weeks
Hepatitis B	Aged 11–15 years only	2 adult doses	4–6 months	Not required
Hepatitis B	Aged ≥20 years	3 adult doses	4 weeks	8 weeks
IPV		3 doses	4 weeks	4 weeks
Human papillomavirus (females aged 10–26 years only)		3 doses	4 weeks	3 months
MMR		2 doses	4 weeks	Not required
Varicella vaccine†		At least 1 dose if aged <14 years	If 2nd dose given, a 4 week interval is required	Not required
		2 doses if aged ≥14 years	4 weeks	Not required

* One of the doses should be given as dTpa (or dTpa-IPV if poliomyelitis vaccination is also needed) and complete the course with dT. In the unlikely event that dT is *not* available, dTpa or dTpa-IPV may be used for all 3 primary doses *but this is not routinely recommended as there are no data on the safety, immunogenicity or efficacy of dTpa for primary vaccination* (see also Chapter 3.14, *Pertussis*).

† Varicella vaccine should be given to either non-immune people or people with no history of previous varicella infection. At least 1 dose should be given to those aged <14 years, and all must receive 2 doses if aged ≥14 years.

References

Full reference list available on the electronic *Handbook* or website http://immunise.health.gov.au.

1.4 ADMINISTRATION OF VACCINES

1.4.1 Occupational health and safety issues

Standard occupational health and safety guidelines should always be followed during a vaccination encounter to minimise the risk of needle-stick injury.[1]

Gloves are not routinely recommended for immunisation service providers. Work practices should include the use of standard precautions to minimise exposure to blood and body fluids. If exposure does occur, guidelines for post-exposure prophylaxis should be followed (refer to Chapters 23 and 24 of the Australian Government Department of Health and Ageing *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*).[1]

A new, sterile, disposable syringe and needle must be used for each injection. Disposable needles and syringes must be discarded into a clearly labelled, puncture-proof, spill-proof container that meets Australian standards in order to prevent needle-stick injury or re-use.[1] Always keep sharps containers out of the reach of children. All immunisation service providers should be familiar with the handling and disposal of sharps according to the Australian Government Department of Health and Ageing *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*, Chapters 14 and 23.[1]

1.4.2 Equipment for vaccination

Preparing for vaccination

- Depending on the vaccine(s) that are to be administered, and the age and size of the person to be vaccinated, decide on the appropriate injection site and route, and the injection equipment required (ie. syringe size, needle length and gauge).
- The equipment chosen will vary depending on whether the vaccine is a reconstituted vaccine, a vaccine from an ampoule or vial, or a vaccine in a pre-filled syringe.

Equipment may include:

- medical waste (sharps) container,
- vaccine, plus diluent if reconstitution is required,
- 2 or 3 mL syringe (unless vaccine is in pre-filled syringe),
- appropriate drawing-up needle (19 or 21 gauge needle if required, to draw up through rubber bung and for reconstitution of vaccine),
- appropriate injecting needle (see Table 1.4.2 *Recommended needle size, length and angle for administering vaccines*),
- clean cotton wool and hypoallergenic tape to apply to injection site after vaccination, and
- a rattle or noisy toy for distraction after the injection.

Preparing the vaccine

- Wash hands carefully and prepare the appropriate injection equipment for the vaccine to be administered.
- Ensure that the minimum/maximum thermometer displays temperatures within the +2°C to +8°C range before removing vaccine from the refrigerator.
- Ensure that the correct vaccine is taken from the refrigerator and that it is within the expiry date.
- Check that there is no particulate matter or colour change in the vaccine.
- Ensure that the diluent container is not damaged and potentially contaminated.

PRECAUTIONS:

If a pre-filled syringe is provided, check carefully whether reconstitution with vaccine (provided in a separate vial) is required.

The diluent of one brand of oral rotavirus vaccine (Rotarix) is provided in a syringe-like oral plunger. Do not administer this vaccine by injection (parenteral) after reconstitution.

Both rotavirus vaccines are administered orally.

Preparing vaccine provided in a pre-filled syringe, ampoule or liquid vial

- If the vaccine is in a vial, remove the cap carefully to maintain sterility of the rubber bung. Do not wipe the rubber bung. Use a 19 or 21 gauge needle to draw up the recommended dose through the bung.
- If the vaccine is in an ampoule, use a 23 gauge, 25 mm needle to draw up the recommended dose.
- Needles should be changed after drawing up from a vial with a rubber bung, but it is not necessary to change needles between drawing up a vaccine from an ampoule and giving the injection.
- Small air bubbles do not need to be extruded through the needle.
- 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.

Preparing vaccines requiring reconstitution

- Reconstitute the vaccine as needed immediately before administration.
- Never mix other vaccines together in the one syringe (unless that is the manufacturer's registered recommendation, eg. Infanrix hexa).
- Never mix a local anaesthetic with a vaccine.
- A sterile 21 gauge needle should be used for reconstitution and a separate 23 or 25 gauge needle, 25 mm in length, should be used for administration of the vaccine in most circumstances.
- Use only the diluent supplied with the vaccine; do not use sterile water for injection instead of a supplied diluent. Ensure that the diluent and vaccine are completely mixed.
- Reconstituted vaccines should be checked for signs of deterioration, such as a change in colour or clarity.
- Reconstituted vaccines may deteriorate rapidly and, in general, should be administered as soon as practicable after they have been reconstituted.
- Never freeze a vaccine after it has been reconstituted.

1.4.3 Route of administration

Almost all vaccines are given by either IM or SC injection, and a few vaccines are given orally. Rotavirus vaccines are *only* available for oral administration and must *never* be injected. Special training is required for intradermal administration, which is important for several vaccines (see Chapter 3.17, *Q fever* and Chapter 3.22, *Tuberculosis*). Table 1.4.1 below summarises the route of administration for vaccines commonly used in Australia.

Table 1.4.1: Route of administration for vaccines commonly used in Australia

Intramuscular (IM) injection	Subcutaneous (SC) injection	IM or SC injection	Oral
Diphtheria, tetanus vaccine (dT)	Inactivated polio vaccine (IPV)*	Influenza vaccine†	Rotavirus vaccine
Diphtheria, tetanus, acellular pertussis vaccine (DTPa and dTpa)	Meningcoccal polysaccharide vaccine (4vMenPV)	Measles, mumps, rubella vaccine (MMR)	Cholera vaccine
DTPa- and dTpa-combination vaccines	Varicella vaccine (VV)	Rubella vaccine	Typhoid vaccine
Hepatitis A vaccine	Q fever vaccine‡	23-valent pneumococcal polysaccharide vaccine (23vPPV)	
Hepatitis B vaccine	Japanese encephalitis vaccine	Rabies vaccine (HDCV)	
Hepatitis B combination vaccines	Measles, mumps, rubella, varicella vaccine (MMRV) (when available)	Yellow fever vaccine	
Haemophilus influenzae type b (Hib) vaccine			
Human papillomavirus vaccine (HPV)			
IPV-containing combination vaccines*			
7-valent pneumococcal conjugate vaccine (7vPCV)			
Typhoid Vi polysaccharide vaccine			
Meningococcal C conjugate vaccine (MenCCV)			
Rabies vaccine (PCECV)			

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

† The IM route is preferred because it causes fewer local adverse events.[2]

‡ Q fever vaccine should be administered only by specially trained immunisation service providers.

1.4.4 Preparation for vaccine administration

Skin cleaning

Provided the skin is visibly clean, there is no need to wipe it with an antiseptic (eg. alcohol wipe).[3,4] If the immunisation service provider decides to clean the skin, or if the skin is visibly not clean, alcohol and other disinfecting agents *must* be allowed to dry before vaccine injection (otherwise there may be some increased injection pain).

Distraction techniques

The routine use of distraction, relaxation and other measures have been shown to reduce distress and pain following vaccination in young children.[5-8] Reducing infant distress may enhance parents' timely attendance for subsequent vaccinations.

Distraction measures that may decrease discomfort following vaccination in young children include:[5-8]

- swaddling and holding the infant securely (but not excessively),
- shaking a noisy toy (for infants and very young children),
- playing music,
- encouraging an older child to pretend to blow away the pain using a windmill toy or bubbles, or
- administering sweet-tasting fluid orally immediately before the injection (with parental consent). In infants, 15–20% sucrose drops have been used.

Topical anaesthetic agents, including vapocoolant sprays, are available but to be effective must be applied at the correct time before vaccine administration. Topical anaesthetics, such as EMLA, are not recommended for routine use, but could be considered in a child with excessive fear or dislike of needles, and require application 30 to 60 minutes before an injection.[9] Vapocoolant sprays are applied 15 seconds before vaccination. Topical lignocaine/prilocaine is not recommended for children younger than 6 months due to the risk of methaemoglobinaemia.[5]

1.4.5 Vaccine injection techniques

IM injection technique[10,11]

- For IM injection, a 25 mm needle should be used in most cases (see Table 1.4.2 below).
- Depending on the injection site, the limb should be positioned so as to relax the muscle into which the vaccine is to be injected.
- The 25 mm needle should pierce the skin at an angle of 90° to the skin, and can be safely inserted to the hub.[12] Provided an injection angle of >70° is used, the needle should reach the muscle layer.[13]
- Studies have demonstrated that, for most vaccines, local adverse events are minimised and immunogenicity enhanced by ensuring vaccine is deposited into the muscle and not into the subcutaneous layer.[5,14-17] However, some vaccines, eg. inactivated poliomyelitis, varicella and meningococcal polysaccharide vaccines, are only licensed for SC administration.
- A recent clinical trial demonstrated that long (25 mm) needles (with the skin stretched flat and the needle inserted at 90°) for infant vaccination were associated with significantly fewer local adverse events while achieving comparable immunogenicity. Little difference was found between needles the same length but with different gauges in local adverse events or immune response.[12]
- If using a 25 gauge needle for an IM vaccination, ensure the vaccine is injected slowly over a count of 5 seconds to avoid injection pain and muscle trauma.
- It is not considered necessary to draw back on the syringe plunger before injecting a vaccine.[5] However, if this is done, and a flash of blood appears in the needle hub, the needle should be withdrawn and a new site selected for injection.[18]
- After completing the injection, perform post-vaccination care (see Chapter 1.5, *Post-vaccination procedures*).

SC injection technique

- SC injections are usually administered at a 45° angle to the skin.
- The standard needle for administering vaccines by SC injection is a 25 or 26 gauge needle, 16 mm in length.

Intradermal injection technique

For intradermal injection of BCG vaccine or Q fever skin test vaccine, a 26 or 27 gauge, 10 mm needle is recommended. The intradermal injection technique requires special training, and should be performed only by a trained provider (see Chapter 3.22, *Tuberculosis* and Chapter 3.17, *Q fever*).

Table 1.4.2: Recommended needle size, length and angle for administering vaccines[5,10,12,14,19]

Age or size of child/adult	Needle type	Angle of needle insertion
Infant, child or adult for IM vaccines	23 or 25 gauge,* 25 mm in length†	90° to skin plane
Preterm babies (<37 weeks' gestation) up to age 2 months; very small infants	23 or 25 gauge,* 16 mm in length	90° to skin plane
Very large or obese patient	23 gauge, 38 mm in length	90° to skin plane
Subcutaneous injection in all individuals	25 or 26 gauge, 16 mm in length	45° to skin plane

* If using a narrow 25 gauge needle for an IM vaccination, ensure vaccine is injected slowly over a count of 5 seconds to avoid injection pain and muscle trauma.

† The use of short needles for administering IM vaccines may lead to inadvertent subcutaneous (SC) injection and increase the risk of significant local adverse events, particularly with aluminium-adjuvanted vaccines (eg. hepatitis B vaccine, DTPa, DTPa-combinations or tetanus vaccine).

1.4.6 Recommended injection sites

The choice of injection sites depends primarily upon the age of the individual being vaccinated. The 2 anatomical sites recommended as routine injection sites are the anterolateral thigh (Figure 1.4.6) and the deltoid muscle (Figure 1.4.9). All practitioners should ensure that they are familiar with the landmarks used to identify any anatomical sites used for vaccination. Photographs and diagrams are provided in this section but are not a substitute for training. Further detail on identifying the recommended injection sites is provided in Section 1.4.8.

Infants <12 months of age

The vastus lateralis muscle in the anterolateral thigh is the recommended site for IM vaccination in infants <12 months of age (see Figures 1.4.5 and 1.4.6, Section 1.4.8).

The ventrogluteal area (see Figures 1.4.7 and 1.4.8, Section 1.4.8) is an alternative site for IM vaccination of infants. It is important that vaccine providers who choose to use this site are familiar with the landmarks used to identify it. The reactogenicity and immunogenicity of vaccines given in this site are comparable to those of vaccines given in the anterolateral thigh.[20-22]

The deltoid muscle is not recommended for IM vaccination of infants <12 months of age.

Children ≥12 months of age

The deltoid muscle is the recommended site for IM vaccination in children ≥12 months of age (see Figure 1.4.9, Section 1.4.8).

The ventrogluteal area is an alternative site for IM vaccination of children ≥12 months of age. However, vaccine providers should be familiar with the landmarks used to identify this site.

The vastus lateralis in the anterolateral thigh may also be used in children ≥12 months of age, but if this site is used, the less locally reactogenic vaccines, eg. MMR, should be given in the thigh.

Adolescents and adults

The deltoid muscle is the recommended site for IM vaccination in adolescents and adults (see Figure 1.4.9, Section 1.4.8).

The anterolateral thigh can also be used in older children and adults.

The ventrogluteal area is an alternative injection site. However, vaccine providers should be familiar with the landmarks used to identify this site.

PRECAUTION:

Vaccine injections should not be given in the dorsogluteal site or upper outer quadrant of the buttock because of the possibility of a suboptimal immune response.[23,24] Immunoglobulin can be administered intramuscularly into the upper outer quadrant of the buttock, but care must be taken to ensure that the other quadrants are not used.

1.4.7 Positioning for vaccination

It is important that infants and children do not move during injection of vaccines. However, excessive restraint can increase their fear and result in increased muscle tension. The following section describes a variety of positions which may be used for vaccinating different age groups.

Positioning of infants <12 months of age

- **Cuddle position for infants**

Position the infant in a semi-recumbent cuddle position on the lap of the parent/carer. The infant's arm adjacent to the parent/carer should be restrained underneath the parent/carer's arm or against the parent/ carer's chest. The knee should be flexed to encourage relaxation of the vastus lateralis for IM vaccinations. The infant's other arm must also be held securely (see Figure 1.4.1). This position can also be used for young children.

Figure 1.4.1: The cuddle position for vaccination of a child <12 months of age

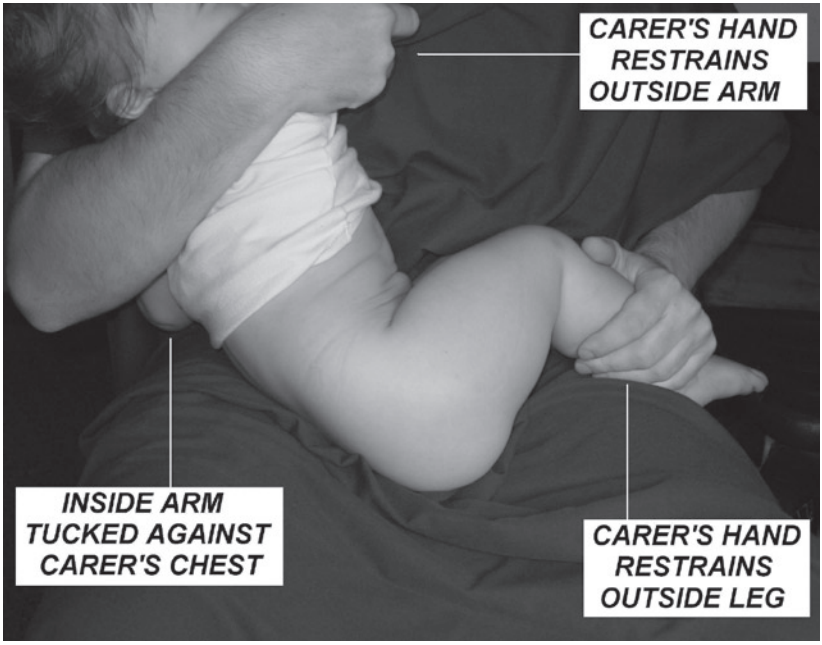


Photo courtesy Dr Joanne Molloy, VIC

- **Positioning infant on an examination table**

An alternative is to lay infants on their backs on an examination table, with the infant's feet towards the immunisation service provider, and the parent/carer beside the provider to immobilise and distract the baby (see Figure 1.4.2).

Keep the infant's hip and knee flexed by cupping the patella in the non-injecting hand.

The thumb and index finger of the non-injecting hand may be used to stabilise the hub of the needle once the needle has been inserted.

Figure 1.4.2: Positioning an infant on an examination table for vaccination

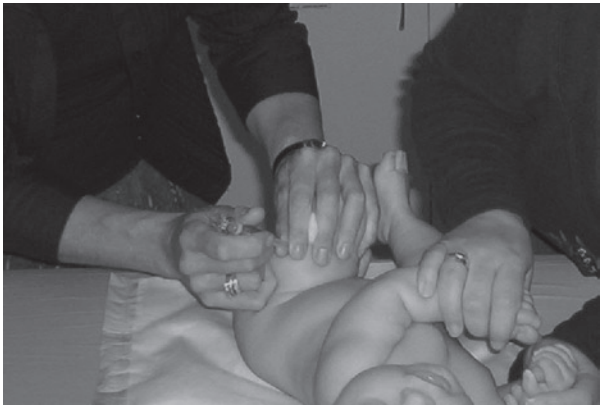


Photo courtesy Dr Joanne Molloy, VIC

- **Prone position across the lap for ventrogluteal vaccination**

For ventrogluteal injection, position the child face-down across the parent/carer's lap. This allows the hips to be flexed and provides access to the ventrogluteal area (see Figure 1.4.8).

Positioning of children ≥12 months of age

- **Cuddle position for older child**

Sit the child sideways on the lap of the parent/carer, with the arm to be injected held close to the child's body while the other arm is tucked under the armpit and behind the back of the parent/carer.

The child's exposed arm should be secured at the elbow by the parent/carer, and the child's legs also secured by the parent/carer (see Figure 1.4.3).

Figure 1.4.3: Positioning an older child in the cuddle position

Photo courtesy Ann Kempe, MCRI, VIC

- **Straddle position**

An older child may be positioned facing the parent/carer with the legs straddled over the parent/carer's lap. The child's arms should be folded in front, with the parent/carer hugging the child's body to the parent/carer's chest. Alternatively, the child may be positioned to 'hug' the parent with the parent's arms holding the child's arms in a reciprocal hug (see Figure 1.4.4). This position allows access to both deltoids and both anterolateral thighs.

Figure 1.4.4: Positioning a child in the straddle position

Photo courtesy Dr Joanne Molloy, VIC

- **Prone position across the lap for ventrogluteal vaccination**

For ventrogluteal injection, position the child face-down across the parent/carer's lap (see Figure 1.4.8).

Positioning of older children, adolescents and adults

- **Solo sitting position for deltoid injections**

Most vaccines can be administered into the deltoid area. Adults should sit in a straight-backed chair, feet resting flat on the floor with forearms and hands in a relaxed position on the upper thighs. Keep the arms flexed at the elbow to encourage the deltoid muscle to relax.

Encourage shoulders to drop by asking the person to raise the shoulders up while taking a deep breath in and to drop them while breathing out fairly forcefully. Use distraction to keep muscles relaxed during the procedure, eg. have an interesting poster or similar for the person to concentrate on during the procedure and ask him/her to give you a detailed description of what can be seen.

The ventrogluteal and vastus lateralis are alternative sites if needed (see above, and below).

1.4.8 Identifying the injection site

The choice of injection site depends upon the age of the person, and is discussed in Section 1.4.6.

The anterolateral thigh (vastus lateralis)

- The infant's nappy must be undone to ensure the injection site is completely exposed and the anatomical markers easily identified.
- Position the leg so that the hip and knee are flexed and the vastus lateralis is relaxed (see Figure 1.4.6).
- The upper anatomical marker is the midpoint between the anterior superior iliac spine and the pubic tubercle, and the lower marker is the upper part of the patella.
- Draw an imaginary line between the 2 markers down the front of the thigh. The correct site for IM vaccination is lateral to the midpoint of this line, in the outer (anterolateral) aspect (see Figures 1.4.5 and 1.4.6).
- Do not inject into the anterior aspect of the thigh where neurovascular structures can be damaged.

Figure 1.4.5: Diagram of the muscles of the thigh showing the anatomical markers to identify the recommended (vastus lateralis) injection site (X)

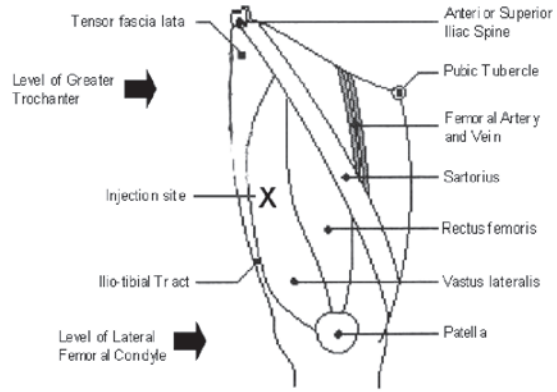


Figure 1.4.6: Photograph of the thigh showing the recommended (vastus lateralis) injection site (X)

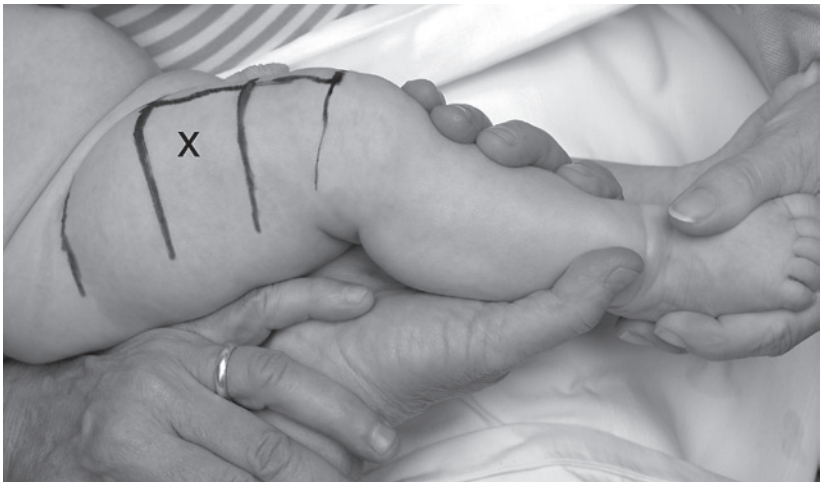


Photo courtesy Lloyd Ellis, RCH, VIC

The ventrogluteal area

NB. This area should not be confused with the dorsogluteal area (buttock).

The ventrogluteal site provides an alternative site for administering vaccines to a child of any age, especially when multiple injections at the same visit are required. The ventrogluteal area is relatively free of major nerves and blood vessels, and the area provides the greatest thickness of gluteal muscle.[25,26] There is a relatively consistent thinness of subcutaneous tissue over the injection site.[26,27]

- The child's nappy must be undone to ensure the injection site is completely exposed and the anatomical markers easily identified by sight and palpation. Anatomical markers are the anterior superior iliac spine (ASIS), the greater trochanter of the femur and the iliac crest (see Figure 1.4.7).
- Place the child in a prone position (face-down) on parent/carer's lap or on the clinic table/bed with arms tucked against the child's chest. Allow the child's legs to dangle towards the floor (see Figure 1.4.8).
- The knee and hip should be turned inwards to encourage muscle relaxation at the injection site.
- The injection site should be that which is closest to the immunisation service provider.
- Place the palm over the greater trochanter (the uppermost bony prominence of the thigh bone) with the thumb pointing towards the umbilicus. The index finger points to the anterior superior iliac spine, and the middle finger is spread so that it aims at the iliac crest, thus creating a 'V' outlining the ventrogluteal triangular area. The injection site is at the centre of this area (see Figures 1.4.7 and 1.4.8).

Figure 1.4.7: Diagram showing the anatomical markers to identify the ventrogluteal injection site (X) (ASIS = anterior superior iliac spine)

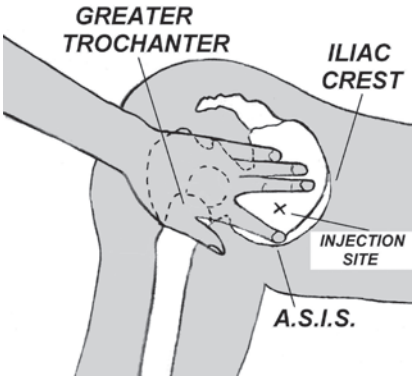


Figure 1.4.8: Photograph with infant prone across carer's lap, showing markers to identify the ventrogluteal injection site (X)

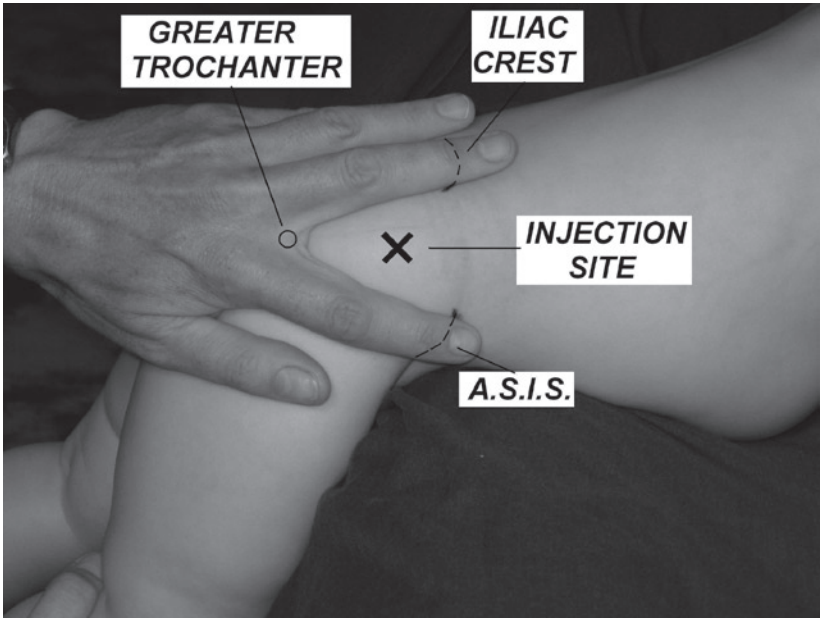


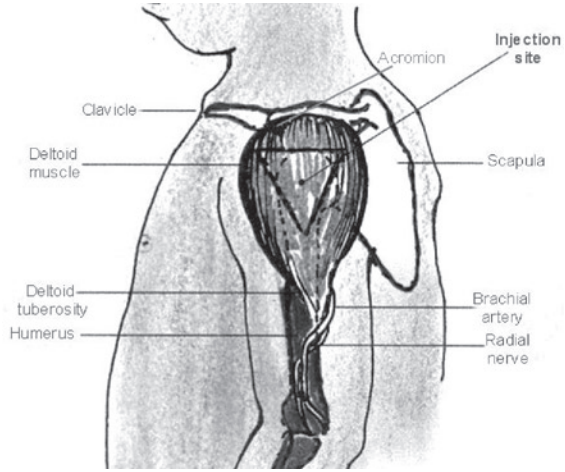
Photo courtesy Dr Joanne Molloy, VIC

The deltoid area

It is essential to expose the arm completely from the top of the shoulder to the elbow when locating the deltoid site (see Figure 1.4.9). Roll up the sleeve or remove the shirt if needed.

- The injection site is halfway between the shoulder tip (acromion) and the muscle insertion at the middle of the humerus (deltoid tuberosity).
- Draw an imaginary, inverted triangle below the shoulder tip, using the identified anatomical markers.
- The deltoid site for injection is the middle of the muscle (triangle) (see Figure 1.4.9).

Figure 1.4.9: Diagram showing the anatomical markers to identify the deltoid injection site



Subcutaneous injection sites

Subcutaneous injections should be administered either over the deltoid muscle or over the anterolateral thigh. There are no data to demonstrate any difference in technique between administration of a SC injection and a deep SC injection. Figure 1.4.10 demonstrates the recommended technique for *any* SC injection.

Figure 1.4.10: A subcutaneous injection into the deltoid area of the upper arm using a 25 gauge, 16 mm needle, inserted at a 45° angle

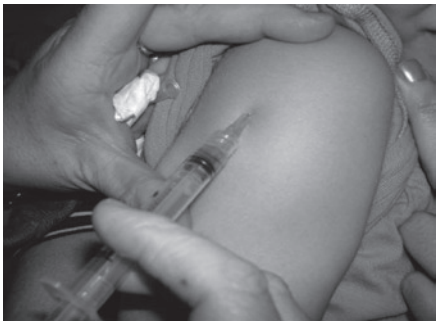


Photo courtesy Ann Kempe, MCRI, VIC

1.4.9 Administering multiple vaccine injections at the same visit

The location of each separate injection given should be recorded, so that if a local adverse event occurs, the implicated vaccine(s) can be identified.

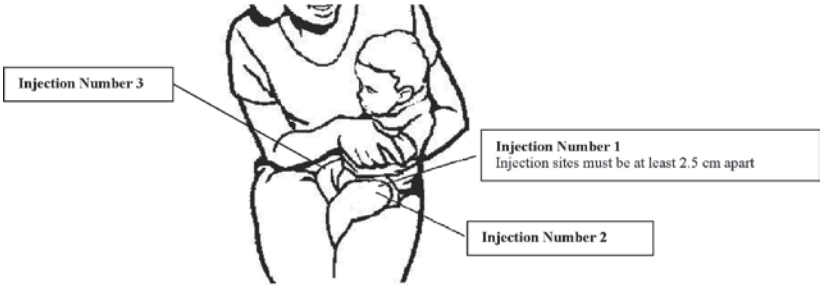
Infants <12 months of age

The suitable sites for this age group are the anterolateral thighs and the ventrogluteal areas. Two vaccines can be given into the same anterolateral thigh, separated by at least 2.5 cm. However, only 1 vaccine should be given into each ventrogluteal area.

When 3 or 4 IM vaccines are to be given at the same visit, the options are:

- 2 injections can be administered in the same anterolateral thigh, separated by at least 2.5 cm (see Figure 1.4.11); further IM vaccines can be given in this way in the other thigh, or
- 1 injection can be given into each anterolateral thigh and 1 injection can be administered into each ventrogluteal area.

Figure 1.4.11: Recommended technique for giving multiple vaccine injections to an infant <12 months of age into the anterolateral thigh



Children ≥12 months of age, adolescents and adults

A single injection can be given into each deltoid muscle.

When 3 or 4 IM vaccines are to be given to a child at the same visit, the options will depend on the muscle mass of the child's deltoid.

If the deltoid mass is adequate:

- a further injection can be given into each deltoid muscle (separated by 2.5 cm from the initial vaccine).

If the deltoid muscle mass is small:

- further injections can be given into either the anterolateral thighs (2.5 cm apart if 2 vaccines are given in the same thigh), or
- give 1 injection into each ventrogluteal area.

For younger children, the cuddle or straddle position (Figures 1.4.3 and 1.4.4) are suitable for accessing multiple limbs during the one vaccination encounter.

References

Full reference list available on the electronic *Handbook* or website http://immunise.health.gov.au.

1.5 POST-VACCINATION PROCEDURES

1.5.1 Immediate after-care

- Dispose of clinical waste, including sharps and vaccine vials, immediately after administration of the vaccine and at its point of use. Refer to the State/Territory health authority for management guidelines for the safe disposal of clinical waste or refer to the Australian Government Department of Health and Ageing *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*.[1]
- Cover the site quickly with a dry cotton ball and tape as needed.
- Gently apply pressure for 1 or 2 minutes. Do not rub the site as this will encourage the vaccine to leak back up the needle track, which can cause pain and may lead to local irritation.
- Remove the cotton wool after a few minutes and leave the injection site exposed to the air.
- Paracetamol is not routinely used before or at the time of vaccination, but may be recommended as required for fever or pain.
- To distract the individual and reduce distress, immediately change the position of the child/person after completing the vaccination, eg. ask the parent/carer to put the infant over the shoulder and move around with the infant.[2]
- The vaccinated person and/or parent/carer should be advised to remain in a nearby area for a minimum of 15 minutes after the vaccination. The area should be close enough to the immunisation service provider, so that the individual can be observed and medical treatment rapidly provided if needed.
- Take the opportunity to check the vaccination status of other family members (as appropriate) and provide (or refer) for catch-up vaccination.
- Record the relevant details of the vaccines given in a record to be retained by the person or parent/carer, in the surgery/clinic record and, for children aged <7 years, forward records to the ACIR (see Section 1.5.3, *Documentation of vaccination*).
- Before departure, inform the individual or parent/carer, preferably in writing, of the date of the next scheduled vaccinations.

1.5.2 Adverse events following immunisation

What are AEFI?

An adverse event following immunisation (AEFI) is an unwanted or unexpected event occurring after the administration of vaccine(s). Such an event may be caused by the vaccine(s) or may occur by chance after vaccination (ie. it would have occurred regardless of vaccination). Most vaccines cause minor adverse events such as low-grade fever, pain or redness at the injection site and these

should be anticipated[3] (see the table *Comparison of the effects of diseases and the side effects of vaccines* inside the front cover of this *Handbook*).

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%).[4]

Common adverse events

The following common adverse events should be anticipated following vaccination.[5] They can be distressing for parents/carers, but they do not contraindicate further vaccination. In general, unless these adverse events are significant, they do not need to be reported by immunisation service providers to the Adverse Drug Reactions Advisory Committee (ADRAC) (see Table 1.5.3, *Contact details for notification of AEFI).*

Parents/carers should be given advice (preferably written) as part of the consent procedure on what common adverse events are likely and what they should do about them (the table inside the back cover of this *Handbook*, *Commonly observed adverse events following immunisation with vaccines used in the National Immunisation Program (NIP) schedule and what to do about them*, can be used for this purpose).

- DTPa, dTpa, hepatitis B, Hib, IPV and their various combinations may cause transient minor adverse events including swelling, redness or soreness at the injection site, and low-grade fever, crying and irritability (in infants).
- There is an increased risk of more extensive local adverse events after booster doses of DTPa and DTPa-combination vaccines.[6] A local adverse event that involves extensive limb swelling should be reported. For the definition of extensive limb swelling, see Appendix 6, *Definitions of adverse events following immunisation.*
- MMR vaccine may be followed 5 to 12 days later by a fever lasting 2 or 3 days, malaise and/or rash. This is not infectious. Fever >39.4°C is very common, occurring in 5 to 15% of vaccinees, 5 to 12 days after vaccination.
- Human papillomavirus vaccine may cause mild injection site adverse events (pain, swelling and erythema) and, occasionally, headache, fever and nausea.
- Influenza vaccine may cause soreness at the injection site. Fever, malaise, and myalgia occur less commonly.
- The 7vPCV causes low-grade fever and/or mild pain at the injection site in about 10% of infant recipients. The 23-valent pneumococcal polysaccharide vaccine (23vPPV) causes mild local adverse events in up to half the adult recipients.
- MenCCV is generally well tolerated. Very common (>10%) adverse events are pain, redness and swelling at the injection site, fever, irritability, anorexia and headache.

- Varicella vaccine may cause mild local soreness and swelling. A mild maculopapular or papulovesicular rash occurs in up to 5% of vaccinated children (see also Chapter 3.24, *Varicella*).
- Injection site nodules are not 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 vaccination. Injection site nodules do not require any specific treatment.
- Oral rotavirus vaccine may cause mild fever and/or diarrhoea (see Chapter 3.18, *Rotavirus*).

Managing common adverse events

Advice to parents on common adverse events

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.

Managing fever after vaccination

Routine use of paracetamol at the time of vaccination is no longer recommended. If an infant or child has a fever of >38.5°C following vaccination, paracetamol can be given. The dose of paracetamol is 15 mg/kg/dose of paracetamol liquid, up to a maximum daily dose of 90 mg/kg per day in 4 to 6 divided doses for up to 48 hours.

Preventing AEFI

The key to preventing uncommon or rare adverse events is to screen each person to be vaccinated using pre-vaccination screening (Tables 1.3.1 and 1.3.2) 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 correct injection technique is also important. Immunisation service providers should also check the relevant chapters of this *Handbook* or the product information supplied with the vaccine for more details on precautions and contraindications for each vaccine they are to administer.

Uncommon and rare AEFI

Some vaccines have been shown to cause uncommon or rare adverse events, although the rate is always hundreds to thousands times less frequent than the disease complications. Examples are given below.

Rare, late events shown to be causally related to some vaccines

The use of oral poliomyelitis vaccine (OPV) in Australia was discontinued in 2005. OPV can rarely cause vaccine-associated paralytic poliomyelitis (VAPP). The incidence is 1 in 2.4 million doses of OPV, which means that Australia would have expected 1 case of VAPP every 3 years when OPV was in use. However,

the reported incidence of VAPP was only 1 case every 8 to 9 years in Australia.[7] VAPP does not occur from vaccination with IPV or IPV-containing vaccines.

Vaccines containing diphtheria and tetanus have been described as causing brachial neuritis, with an incidence of approximately 1 in 100 000 (adults).

Events where evidence demonstrates no causal link with immunisation

There is epidemiological evidence which indicates that there is no causal association between immunisation and the following events:

- sudden infant death syndrome (SIDS) and any vaccine,[8-10]
- autism and MMR vaccine,[11-14]
- multiple sclerosis and hepatitis B vaccine,[15-18]
- inflammatory bowel disease and MMR vaccine,[19]
- diabetes and Hib vaccine,[20-22]
- asthma and any vaccine.[23]

Management of an 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. Severe anaphylactic reactions usually have a rapid onset; most life-threatening adverse events begin within 10 minutes of vaccination.

The most serious immediate AEFI is anaphylaxis. However, in adults and older children, the most common immediate adverse event is a vasovagal episode (fainting), either immediately or soon after vaccination. Because fainting after vaccination can lead to serious consequences, anyone who complains of giddiness or light-headedness before or after vaccination should be advised to lie down until free of symptoms. Most faints following vaccination 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.[24]

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 (see Section 2.3.1, *Vaccination of children who have had a serious adverse event following immunisation* and Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control*).

Anaphylaxis and vasovagal episodes

Anaphylaxis following routine vaccination is very rare, but can be fatal. All immunisation service 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 1.5.1 may be useful in differentiating these 2 conditions. If the diagnosis is unclear and anaphylaxis is considered, management for this should be instituted with the prompt administration of adrenaline.

Table 1.5.1: Clinical features which may assist differentiation between a vasovagal episode and anaphylaxis

		Vasovagal episode	Anaphylaxis
ONSET		Immediate, usually within minutes of or during vaccine administration.	Usually within 15 minutes, but can occur within hours, of vaccine administration.
Symptoms/ Signs	Skin	Generalised pallor, cool, clammy skin.	Skin itchiness, generalised skin erythema (redness), urticaria (weals) or angioedema (localised oedema of the deeper layers of the skin or subcutaneous tissues).
	Respiratory	Normal respiration; may be shallow, but not laboured.	Cough, wheeze, stridor, or signs of respiratory distress (tachypnoea, cyanosis, rib recession).
	Cardiovascular	Bradycardia, weak/ absent peripheral pulse, strong carotid pulse. Hypotension – usually transient and corrects in supine position.	Tachycardia, weak/absent peripheral and carotid pulse. Hypotension – sustained and no improvement without specific treatment.
	Neurological	Feels faint, light-headed. Loss of consciousness – improves once supine or head down position.	Sense of severe anxiety and distress. Loss of consciousness – no improvement once supine or head down position.

Signs of anaphylaxis

Anaphylaxis is a severe adverse event of rapid onset, characterised by sudden respiratory compromise and/or circulatory collapse. Early signs include involvement of the skin, eg. generalised erythema, urticaria and/or angioedema (swelling), and/or gastrointestinal tract, eg. diarrhoea, vomiting. In severe cases, there is circulatory collapse with alteration in the level of consciousness,

hypotension and weak or absent pulses, and/or marked respiratory compromise from upper airway oedema or bronchospasm.

Immunisation service 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 weals with erythematous, raised edges and pale, blanched centres) and/or erythema and/or angioedema (soft tissue swelling usually affecting the face and/or limbs),
- 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 hypotension in infants and young children,
- profound hypotension in association with other signs of cardiovascular disturbance, such as sinus tachycardia or severe bradycardia, absent central pulses and reduced peripheral circulation, and/or
- abdominal cramps, diarrhoea and/or vomiting.

Management of anaphylaxis

Rapid IM administration of adrenaline is the cornerstone of treatment of anaphylaxis.

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

- If the patient is unconscious, lie him/her on the left side and position to keep the airway clear. If the patient is conscious, lie supine in 'head down and feet up' position (unless this results in breathing difficulties).
- Give adrenaline by IM injection (see below for dosage) for any signs of anaphylaxis with respiratory and/or cardiovascular symptoms or signs. Adrenaline is not required for generalised non-anaphylactic reactions (such as skin rash or angioedema). If in doubt, IM adrenaline *should* be given.
- 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.
- Call for assistance. Never leave the patient alone.
- Begin expired air resuscitation for apnoea, check for a central pulse. If pulse is not palpable, commence external cardiac massage (ECM).
- All cases should be admitted to hospital for further observation and treatment.

- Document the time and dose of adrenaline given.

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. Adrenaline 1 in 10 000 is no longer recommended for the treatment of anaphylaxis. 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 recommended dose of 1:1000 adrenaline is 0.01 mL/kg body weight (equivalent to 0.01 mg/kg or 10 µg/kg) up to a maximum of 0.5 mL, given by deep IM injection (*not the deltoid*). Adrenaline 1:1000 *must not* be administered intravenously. Table 1.5.2 lists the dose of 1:1000 adrenaline to be used if the exact weight of the individual is not known.

Table 1.5.2: Doses of intramuscular 1:1000 (one in one thousand) adrenaline for anaphylaxis

Less than 1 year	0.05–0.1 mL
1–2 years (approx. 10 kg)	0.1 mL
2–3 years (approx. 15 kg)	0.15 mL
4–6 years (approx. 20 kg)	0.2 mL
7–10 years (approx. 30 kg)	0.3 mL
11–12 years (approx. 40 kg)	0.4 mL
13 years and over (over 40 kg)	0.5 mL

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

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 program errors, such as incorrect vaccine schedule, delivery or storage.

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

Any of the adverse events listed in Appendix 6, *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 service providers are also advised to report any adverse events of concern that do not fit into any of the categories listed in Appendix 6. 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?

AEFI are notifiable directly to the relevant health authority in Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Victoria and Western Australia. In Tasmania, AEFI should be reported using the Adverse Drug Reactions Advisory Committee (ADRAC) blue card.

AEFI are notifiable conditions in Australian Capital Territory, New South Wales, Northern Territory, Queensland, South Australia, Victoria and Western Australia and must be reported directly to the relevant health authority (see Table 1.5.3 below). These State and Territory health authorities then forward AEFI notifications to ADRAC.

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 the numbers listed in Table 1.5.3 below, or by filling in a blue card or completing a web-based report (https://www.tgasime.health.gov.au/SIME/ADRS/ADRSLodg.nsf/wNotification?OpenForm).

Additional blue cards are available from:

The Secretary
Adverse Drug Reactions Advisory Committee
PO Box 100
Woden ACT 2606
Telephone: 1800 044 114 or on-line at www.tga.gov.au/adr/bluecard.htm

ADRAC will forward copies of individual reports of AEFI with vaccines on the National Immunisation Program 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*.[25]

Table 1.5.3: Contact details for notification of AEFI

State/Territory	Report adverse events directly to:	Telephone number
*Australian Capital Territory	ACT Health Department	02 6205 2300
*New South Wales	NSW Public Health Units	Contact your local Public Health Unit, found under '**Health**' in the White Pages
*Northern Territory	NT Department of Health and Community Services	08 8922 8044
*Queensland	Queensland Health	07 3234 1500
*South Australia	Department of Health In SA, parents can also report adverse events by calling	08 8226 7177 1300 364 100 (24 hours)
Tasmania	ADRAC	Use blue card
*Victoria	Department of Human Services, SAEFVIC	1300 822 924
*Western Australia	State Health Department	08 9321 1312

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

1.5.3 Documentation of vaccination

A personal health record should be established for each vaccinee and newborn infant, and kept by that person or the parent/carer. The parent/carer should be urged to present the record every time a child is seen by a health professional.

The following details should be recorded in the personal health record, and in the clinical file:

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

If the vaccinee is a child <7 years of age, the Australian Childhood Immunisation Register (ACIR) must also be notified of the vaccination details (see 'The Australian Childhood Immunisation Register' below).

1.5.4 The Australian Childhood Immunisation Register

The Australian Childhood Immunisation Register (ACIR) is a national database for recording details of vaccinations given to children <7 years of age who live in Australia. It commenced on 1 January 1996 and is administered by Medicare Australia 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 implemented and managed. Section 46E sets out the provisions for giving both de-identified and identified information to recognised immunisation service providers and other specified agencies.

Children enrolled in Medicare are automatically included on the ACIR. Children not enrolled in Medicare will be included when an immunisation service provider sends details of a vaccination to the ACIR. No vaccination information is recorded on the ACIR after a child turns 7 years of age, but any information already held is retained. The information will relate only to vaccines received between the ages of birth and the 7th birthday. The ACIR Enquiry Line can be contacted on 1800 653 809 (free call) and any record held for an individual who is ≥7 years of age can also be made available to an immunisation service provider or parent/carer.

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

Reporting to ACIR

Immunisation service providers should send to the ACIR details of all NIP and private vaccinations given to children <7 years of age. Vaccination details may be submitted by sending data electronically via Medicare Australia's on-line claiming facility, Electronic Data Interchange (EDI) on the Internet, or by using a paper form. Providers in Queensland and the Northern Territory currently sending data to the ACIR via their State/Territory Health Department should continue to do so. Providers in all other States/Territories should send data directly to the ACIR.

A child's vaccination record can also be updated with vaccination details where the vaccination was performed by another immunisation service provider, including those given while the child was overseas, by completing and sending an Immunisation History form to Medicare Australia. Forms are available on the ACIR website at www.medicareaustralia.gov.au/providers/forms/acir.htm.

When relevant, immunisation service providers should complete the Conscientious Objection and Medical Contraindication forms and forward to the ACIR.

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 Enquiry Line, 1800 653 809 (free call).

Immunisation History Statement

Immunisation History Statements, which contain details of all vaccines administered to the child and recorded on the ACIR, and those that may be missing, are automatically generated when a child turns 12 months, 2 and 5 years of age and on completion of the childhood vaccination schedule. Statements will be mailed to the address most recently recorded on the ACIR for that child.

Parent/carers can also get a Statement at any other time:

- on-line at www.medicareaustralia.gov.au,
- from their local Medicare office,
- by calling 1800 653 809 (free call).

Immunisation History Statements can be used when proof of vaccination is needed. For example, Statements can be used to meet vaccination requirements for:

- primary school enrolment – a sentence will be displayed at the bottom of the statement that says the child has received all the vaccinations required by 5 years of age, and/or
- eligibility for the Child Care Benefit and Maternity Immunisation Allowance; an up-to-date status for the Family Assistance Office will be displayed.

Recording details of a deceased child

The ACIR should be notified of a deceased child to prevent an Immunisation History Statement being sent to bereaved parents/carers. 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 the child's name, address, date of birth, Medicare number and date of death.

Children who have moved to live overseas

A child who has moved overseas can be removed from the ACIR by sending details to the ACIR by fax, phone or secure site email. This prevents the child's name continuing to appear on ACIR reports of overdue children.

Ascertaining individual vaccination status

Parents/carers can telephone the ACIR on 1800 653 809 (free call) for information about their child's vaccination status, regardless of where the child's vaccination was given. Immunisation service providers can also request a child's vaccination status by telephone.

Vaccination 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) scheme can receive quarterly reports on vaccination coverage for children within that practice. Other reports, including those that identify a child's vaccinations and due/overdue details, are available through the secure area of the ACIR Internet site to approved immunisation service providers.

The ACIR Internet site

The ACIR Internet site has 2 main parts, a general information area and a secure area. The Internet address for the ACIR is www.medicareaustralia.gov.au. Any person with Internet access may view the ACIR site for general vaccination information and statistics.

Approved immunisation service 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 for access to the secure area of the ACIR Internet site, providers should complete the online request form at http://www.medicareaustralia.gov.au/providers/programs_services/acir/index.htm. Further information or assistance may be obtained by calling the ACIR Internet Helpline on 1300 650 039 (free call).

References

Full reference list available on the electronic *Handbook* or website http://immunise.health.gov.au.