



Fundamentals of immunisation

Information about active and passive immunisation, key concepts in vaccine safety and effectiveness, and information about adverse events.

Summary

- Active immunisation uses vaccines to induce an immune response in the person receiving the vaccine. Passive immunisation is the direct transfer of antibodies to a non-immune person to provide temporary protection. This Handbook focuses on active immunisation.
- Vaccines are complex biological products. They contain one or more antigens (also called immunogens) that stimulate an active immune response. Vaccines also contain other components, such as adjuvants and stabilisers.
- Children and adults may need several doses of a vaccine to induce a protective immune response.
- Vaccine immunogenicity (<https://immunisationhandbook.health.gov.au/technical-terms#immunogenicity>) is a measure of antibody or cellular immune response to a vaccine.
- Vaccine efficacy (<https://immunisationhandbook.health.gov.au/technical-terms#efficacy>) and vaccine effectiveness are measures of how well a vaccine protects against the disease.
- Sometimes people may get the disease even though they have been vaccinated. This can happen for a variety of reasons.
- Rigorous processes ensure vaccine safety and effectiveness. By law, vaccines must meet strict manufacturing and production standards. Vaccine safety is tested at all stages of development and after vaccines are registered for use in people.
- Once vaccines are in use in the population, the Therapeutic Goods Administration and other organisations monitor their safety and effectiveness. Safety monitoring includes passive and active surveillance for adverse events following immunisation.
- Some vaccines have contraindications or precautions for their use. This helps ensure that they are not given to people who have a high risk of serious adverse events.
- Passive immunisation can use normal human immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) or immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>).

[ndbook.health.gov.au/technical-terms#immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin)) with a high concentration of antibody specific to a particular disease.

- Normal human [immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin) (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) can be used as pre- or post-exposure prophylaxis (<https://immunisationhandbook.health.gov.au/technical-terms#post-exposure-prophylaxis>) against hepatitis A and measles.
- Specific immunoglobulins can protect against hepatitis B, rabies, varicella, tetanus, diphtheria, botulism, and disease caused by cytomegalovirus and respiratory syncytial [virus](https://immunisationhandbook.health.gov.au/technical-terms#virus) (<https://immunisationhandbook.health.gov.au/technical-terms#virus>).

Active immunisation

Active immunisation uses vaccines to stimulate the immune system to produce a protective immune response. This usually mimics the host's response to natural [infection](https://immunisationhandbook.health.gov.au/technical-terms#infection) (<https://immunisationhandbook.health.gov.au/technical-terms#infection>), but avoids the disease that is the harmful consequence of [infection](https://immunisationhandbook.health.gov.au/technical-terms#infection) (<https://immunisationhandbook.health.gov.au/technical-terms#infection>). On average, an immune response takes around 10 to 14 days.¹

Most vaccines work by inducing B-cells to produce antibodies that bind to a specific pathogen or toxin. This is also called '[humoral immunity](https://immunisationhandbook.health.gov.au/technical-terms#humoral-immunity)' (<https://immunisationhandbook.health.gov.au/technical-terms#humoral-immunity>). Some vaccines also generate T-cell-mediated immunity (also called 'cellular immunity').

Immunity after active immunisation generally lasts for months to many years. This depends on the nature of the vaccine, the type of immune response (antibody or T-cell) and host factors.^{1,2}

Types of vaccines

Antigen(s) in the vaccine induce protective immunity against a particular pathogen and the disease it causes. The number and derivation of antigens vary across vaccines.^{1,2} Antigens may be:

- live attenuated viruses, such as measles, mumps and rubella vaccines
- live attenuated [bacteria](https://immunisationhandbook.health.gov.au/technical-terms#bacteria) (<https://immunisationhandbook.health.gov.au/technical-terms#bacteria>), such as in BCG (bacille Calmette-Guérin) (bacille Calmette–Guérin) vaccine for tuberculosis
- killed or inactivated viruses, such as hepatitis A vaccines
- killed or inactivated [bacteria](https://immunisationhandbook.health.gov.au/technical-terms#bacteria) (<https://immunisationhandbook.health.gov.au/technical-terms#bacteria>), such as Q fever vaccine

- subunit components of a pathogen that only contain the antigen (<https://immunisationhandbook.health.gov.au/technical-terms#antigen>)(s) of interest, such as hepatitis B vaccine
- toxoids (bacterial toxins that have been made non-toxigenic), such as in tetanus and diphtheria vaccines

Live vaccines

Live attenuated vaccines contain a weakened form of the pathogen that replicates more slowly and is less virulent than the original pathogen.

Live vaccines generate a strong immune response because they mimic natural infection (<https://immunisationhandbook.health.gov.au/technical-terms#infection>). They stimulate both the humoral and cellular immune responses, leading to high-affinity antibodies and long-term immune memory.

Live vaccines can sometimes cause a weakened disease pattern in a small proportion of vaccine recipients. This may cause some people to experience mild disease symptoms after they receive the vaccine.

There is a theoretical risk that the live attenuated pathogen in the vaccine could revert to the wild-type virulent pathogen and cause disease in the vaccine recipient. This is more often an issue for people who are immunocompromised.

Because of this, people who are significantly immunocompromised should not receive live vaccines. Their weakened immune systems may not be able to control the replication of the pathogen in the vaccine.

Killed, subunit and toxoid vaccines

Killed vaccines contain an inactivated version of the pathogen. These vaccines do not usually induce as strong an immune response as live attenuated vaccines, because the pathogen cannot replicate. People often need multiple doses of killed vaccines to induce protective immune responses.

Subunit and toxoid vaccines contain only select components of the pathogen.

Killed, subunit and toxoid vaccines primarily induce humoral immunity (<https://immunisationhandbook.health.gov.au/technical-terms#humoral-immunity>). Antibody levels against these vaccines generally decrease over time, and revaccination is needed to boost the immune response. Non-live vaccines present no risk of reverting back to a virulent wild-type form. People who are immunocompromised can safely receive these vaccines. An exception to this is the Q fever vaccine, which is contraindicated in people who are immunocompromised.

Polysaccharide and conjugate vaccines for bacterial diseases

For many diseases, the antigen (<https://immunisationhandbook.health.gov.au/technical-terms#antigen>) in the vaccine is a protein-based substance. For others, the antigen (<https://immunisationhandbook.health.gov.au/technical-terms#antigen>) is a sugar-based (polysaccharide) substance. The type of antigen (<https://immunisationhandbook.health.gov.au/technical-terms#antigen>) used in a vaccine can affect the extent and duration of protection.

Polysaccharide vaccines provide protection for a few years only. This is because polysaccharide antigens (sugars) induce antibodies without involving T-cells. This is called a T-cell-independent response. An example is the pneumococcal polysaccharide vaccine (<https://immunisationhandbook.health.gov.au/technical-terms#polysaccharide-vaccine>).

T-cells need to be involved for long-term immune memory. If they are not, protection is relatively short-lived, immunity wanes, and revaccination may be needed. Repeated doses of polysaccharide vaccines can actually reduce the immune response rather than boost it — this is called hyporesponsiveness. Polysaccharide vaccines are poorly immunogenic in children aged <2 years.¹

Vaccines that conjugate (or link) a bacterial capsular polysaccharide to a protein carrier produce higher-quality and longer-term immunity than vaccines that use polysaccharides, particularly in young children.¹ This can induce antibody production with help from T-cells, which is called a T-cell-dependent response. Conjugated vaccines are available for:

- *Haemophilus influenzae* type b
- *Neisseria meningitidis* (serogroups A, C, W-135 and Y)
- *Streptococcus pneumoniae*

Vaccine components

Vaccines may also contain:

- adjuvants, which increase the immune response to an antigen (<https://immunisationhandbook.health.gov.au/technical-terms#antigen>) — an example is aluminium hydroxide (alum), which has been included in many vaccines for almost 100 years
- preservatives, which reduce the risk of contamination — an example is 2-phenoxyethanol (also used in many cosmetics and pharmaceuticals)
- stabilisers, which improve shelf-life and help to protect the vaccine from adverse conditions — examples are sucrose, mannitol, lactose and gelatin (most types of confectionery and many pharmaceuticals contain stabilisers)

- emulsifiers or surfactants, which alter the surface tension of the liquid vaccine — examples are polysorbate 80 and sorbitol (most ice creams and many pharmaceuticals contain emulsifiers)
- residuals, which are minute or trace amounts of substances that remain after making the vaccine — examples are formaldehyde, antibiotics such as neomycin or polymyxin, and egg proteins

The product information (PI) and the consumer medicines information (CMI) for each vaccine list the vaccine's components. The Therapeutic Goods Administration website provides the current versions of the PI and the CMI (<https://www.tga.gov.au/picmi-search-facility>).

Vaccine components are also listed in:

- disease-specific chapters (<https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases>) of this Handbook
- Table. Components of vaccines used in Australia (<https://immunisationhandbook.health.gov.au/node/122>) in Preparing for vaccination (<https://immunisationhandbook.health.gov.au/node/181>).

Dosage and administration

The recommended number of doses and the age of administration vary for each vaccine.

Recommendations are based on:

- the type of vaccine
- the disease epidemiology (the age-specific risk for infection (<https://immunisationhandbook.health.gov.au/technical-terms#infection>), and complications)
- the recipient's anticipated immune response, including whether transplacental transfer of maternal antibodies will inhibit an infant's immune response^{1,2}

Children and adults may need several doses of a vaccine to induce protective immunity, particularly in younger children.

Homeopathic preparations do not induce immunity and are never an alternative to vaccination.

The disease-specific chapters (<https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases>) in this Handbook include details on available vaccines and recommendations for their use.

Vaccine efficacy and vaccine effectiveness

Vaccine efficacy (<https://immunisationhandbook.health.gov.au/technical-terms#efficacy>) refers to estimates of protection under ideal conditions in a randomised controlled trial. It is expressed as the percentage reduction in a person's risk of disease if they were vaccinated compared with the risk if they were not vaccinated.

Vaccine effectiveness refers to estimates of protection under 'real world' rather than trial conditions. This is usually when using the vaccine in immunisation programs after the vaccine has been registered. Vaccine effectiveness can be assessed in a number of ways, with different outcome measures, including by assessing:

- how effective the vaccine is at preventing infection (<https://immunisationhandbook.health.gov.au/technical-terms#infection>)
- how effective the vaccine is at preventing hospitalisation for the disease
- the impact of a vaccination program on disease incidence in the population

In studies that involve the whole population, this estimation can include any herd protection or 'community immunity' that occurs in unvaccinated people.^{1,3}

Vaccine failure

Vaccine failure is when a disease occurs in a person even though they have had a recommended number of vaccines.

It can be categorised as primary or secondary.

Primary vaccine failure occurs when a fully vaccinated person does not produce an adequate immune response to the vaccine. This might be because:

- the vaccine was not stored properly (for example, there was a cold chain (<https://immunisationhandbook.health.gov.au/technical-terms#cold-chain>), breach)
- the vaccine had passed its expiry date and was not potent enough to stimulate a protective immune response
- the vaccine was defective as a result of a manufacturing fault
- the person's immune response was ineffective, either specifically to that vaccine or because of a broader immunodeficiency

Secondary vaccine failure occurs when a fully vaccinated person later becomes susceptible to the disease. This is usually because immunity after vaccination wanes with time. Duration of protection varies, depending on:

- the nature of the vaccine
- the type of immune response elicited
- the number of doses received
- host factors

Infections in vaccinated people usually involve a milder form of the disease. Examples are:

- mild chickenpox in people who have been vaccinated against varicella
- mild pertussis in people who have been vaccinated against pertussis

Natural [infection](https://immunisationhandbook.health.gov.au/technical-terms#infection) (when a pathogen grows on or in body sites) in vaccinated people can stimulate the immune system even more, which helps to maintain protection. For example, nasal colonisation with meningococcus can stimulate the production of specific antibodies.

Vaccine safety

The Therapeutic Goods Administration (TGA) regulates all medicines in Australia, including vaccines. Vaccines are rigorously tested in human clinical trials to confirm that they are safe and effective before they can be used.

Vaccine safety is important. Many medicines are used to treat illness in relatively few people. But vaccines are given to many people (or even the entire population), most of whom are healthy. Very high safety standards are essential to minimise the risk of harm to people who are otherwise healthy.

Before a vaccine is used in Australia, the TGA assesses its safety and effectiveness. The TGA also seeks input from experts, such as the Advisory Committee on Vaccines. Vaccine manufacturers must have a risk management plan that details any potential safety risks and how they will be dealt with if they arise. Manufacturers must report information from worldwide vaccine safety monitoring to the TGA.

After a vaccine comes into use in the population, its safety and effectiveness continue to be monitored using a variety of mechanisms. These may include:

- further clinical trials
- surveillance of the impact of the vaccine on the disease it aims to prevent
- surveillance of adverse events following immunisation



An adverse event following immunisation (<https://immunisationhandbook.health.gov.au/technical-terms#adverse-event-following-immunisation>) (AEFI) is any untoward medical occurrence that follows immunisation. It does not necessarily have a causal relationship with the vaccine.

The adverse event may be any:

- unfavourable or unintended sign
- unfavourable or unintended symptom
- disease
- abnormal laboratory finding

These events may be caused by the vaccine(s) or may occur by chance (that is, the event would have occurred regardless of vaccination).^{4,5}

AEFIs should be reported promptly, either according to relevant state or territory protocols, or directly to the Therapeutic Goods Administration. For details on reporting and managing AEFIs, see After vaccination (<https://immunisationhandbook.health.gov.au/node/188>).

Monitoring adverse events following immunisation

In Australia, regional and national surveillance systems collect reports of any AEFI. These reports are added to the Therapeutic Goods Administration's (TGA's) national Adverse Drug Reactions System (ADRS) database. See also After vaccination (<https://immunisationhandbook.health.gov.au/node/188>).

Each year, the journal Communicable Diseases Intelligence (<http://www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-cdiintro.htm>) publishes data and analysis of AEFIs in Australia. The TGA also has a Database of Adverse Event Notifications that provides publicly available information on adverse events.

Australia has a national, collaborative active vaccine safety surveillance initiative called AusVaxSafety. AusVaxSafety collects reports of AEFIs directly from the general public. Software programs installed in sentinel surveillance sites (such as general practices and community immunisation clinics) send SMSs after a vaccination asking about the person's experience. The system monitors de-identified information to detect possible safety signals for vaccines.

In some cases, extra studies are conducted specifically to ensure that vaccine safety is closely monitored once a new vaccine is in use. For example, the risk of intussusception (<https://immunisationhandbook.health.gov.au/technical-terms#intussusception>) after rotavirus vaccination has been closely monitored in Australia and elsewhere because a previously licensed vaccine was associated with a high risk of intussusception (<https://immunisationhandbook.health.gov.au/techni>

cal-terms#intussusception). Another example is specific studies of Guillain–Barré syndrome (<https://immunisationhandbook.health.gov.au/technical-terms#guillain%E2%80%93barr%C3%A9-syndrome>) after the 2009 pandemic influenza (<https://immunisationhandbook.health.gov.au/technical-terms#pandemic-influenza>) A (H1N1) vaccine.^{6,7}

Types of adverse events

Serious AEFIs are rare. Some of these events are coincidental — that is, they are not caused by the vaccine. It is even rarer that AEFIs are caused by a vaccine. It is usually not possible to predict which people may have a mild or serious AEFI.

The risk of adverse events can be minimised by following guidelines for when and when not to use vaccines.

Vaccine adverse events can be local or systemic:

- Injection site reactions, which occur at the site of vaccine administration, are the most frequent AEFI. Common injection site reactions include pain, redness and swelling. Most of these reactions are only mild and resolve without treatment within a few days.
- Systemic adverse events most commonly include fever, headache and lethargy.⁸ Allergic reactions can also occur. Vaccination rarely causes anaphylaxis (<https://immunisationhandbook.health.gov.au/technical-terms#anaphylaxis>) (the most severe form of an allergic response — see After vaccination (<https://immunisationhandbook.health.gov.au/node/188>)).

Association and causation

If an adverse event occurs soon after vaccination, the vaccine is often blamed. However, just because an adverse event occurs after vaccination, this does not prove that the vaccine caused the event. A causal association is more likely when:

- the adverse event is typical of, or previously reported for, that vaccine (even if very rare)
- there is a direct relationship — for example, an injection site reaction occurring immediately after vaccination⁹
- the same adverse event occurs when the same person receives repeated doses

Many AEFI have plausible alternative explanations, or are events or illnesses for which a cause is not identified. These events may be only coincidental and not caused by the vaccine. Large-scale epidemiological studies and specific tests can be used to assess these associations. For example, in some cases, vaccine allergy can be assessed by allergy testing or a vaccine challenge (which may involve giving part or whole of a vaccine dose under medical supervision). Even when an adverse event is typical, it may be unrelated to vaccination (see After vaccination (<https://immunisationhandbook.health.gov.au/node/188>)).

Vaccine contraindications and precautions

A contraindication (<https://immunisationhandbook.health.gov.au/technical-terms#contraindication>) is a reason a vaccine should not be given. This might be when a person has a pre-existing condition that significantly increases their chance of having a serious adverse event after a specific vaccine.

Insufficient safety data about a vaccine may also be a contraindication (<https://immunisationhandbook.health.gov.au/technical-terms#contraindication>), if there is a theoretical but significant risk of harm in a particular age group or group of people. An example might be use of a particular vaccine in people with specific medical conditions.

Vaccines should not be given if there is a contraindication (<https://immunisationhandbook.health.gov.au/technical-terms#contraindication>), except under expert medical advice from an immunisation specialist (<https://www.health.gov.au/health-topics/immunisation/immunisation-contacts>). This advice would consider both the benefits and the risks of giving the vaccine, in consultation with the person to be vaccinated, or their parent or carer.

A precaution is a condition that may increase the chance of an adverse event following immunisation (<https://immunisationhandbook.health.gov.au/technical-terms#adverse-event-following-immunisation>) or compromise the vaccine's ability to produce immunity.

If there is a precaution, sometimes the benefits of giving the vaccine outweigh the potential risks. Consulting with an immunisation specialist (<https://www.health.gov.au/health-topics/immunisation/immunisation-contacts>) or a specialist clinic may be helpful.

Contact your state or territory health department (<https://www.health.gov.au/health-topics/immunisation/immunisation-contacts>) for more details about services for immunisation adverse events. See Vaccination for people who have had an adverse event following immunisation (<https://immunisationhandbook.health.gov.au/node/437>).

Each disease-specific chapter (<https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases>) in the Handbook indicates whether there are contraindications or precautions for administering vaccines.

Passive immunisation

This section of the Handbook is about passive immunisation using immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) preparations.

Passive immunity is the direct transfer or administration of antibodies to a non-immune person. Examples are:

- natural transfer of maternal antibodies across the placenta to the fetus during the 2nd half of pregnancy — this helps to protect the newborn against certain infections for a short time after birth^{10,11}
- administration of IgG antibodies (immunoglobulins) pooled from blood donors to a non-immune person¹² — protection is immediate, but lasts for only a few weeks (because the half-life of IgG is around 3–4 weeks)

Immunoglobulins used for passive immunisation are generally given intramuscularly. However, if a person has a specific immunodeficiency that is routinely treated with intravenous immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>), this also provides passive protection against many vaccine-preventable diseases.

The way immunoglobulins are used varies. Some immunoglobulins are given when a non-immune person has been exposed to the disease. This is called post-exposure prophylaxis (<https://immunisationhandbook.health.gov.au/technical-terms#post-exposure-prophylaxis>) and aims to prevent disease or reduce the severity of the disease.

In some cases, specific immunoglobulins are also available to help treat a disease. This therapeutic use of immunoglobulins is discussed in the National Blood Authority's Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia (<https://www.criteria.blood.gov.au/>).¹³

Types of immunoglobulin

There are 3 types of immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) preparations:

- normal human immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) (NHIG (normal human immunoglobulin))
- specific immunoglobulins
- intravenous immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) (IVIG (intravenous immunoglobulin))

NHIG (normal human immunoglobulin) is derived from the pooled plasma of blood donors. It contains antibodies to microbial agents that are common in the general population.

NHIG (normal human immunoglobulin) can be used as post-exposure prophylaxis (<https://immunisationhandbook.health.gov.au/technical-terms#post-exposure-prophylaxis>) for 2 vaccine-preventable diseases if the exposed person is not already immune:

- measles (see Measles (<https://immunisationhandbook.health.gov.au/node/151>))
- hepatitis A (see Hepatitis A (<https://immunisationhandbook.health.gov.au/node/146>))

Specific [immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin) (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) preparations come from pooled blood donations from:

- patients who are recovering from the relevant [infection](https://immunisationhandbook.health.gov.au/technical-terms#infection) (<https://immunisationhandbook.health.gov.au/technical-terms#infection>)
- donors who have recently received the relevant vaccine
- people who have been screened and have sufficiently high antibody concentrations

These blood-derived specific immunoglobulins contain higher titres of antibody to a particular organism or toxin than normal [immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin) (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>). They can protect against the specific pathogen.

Specific immunoglobulins that are available in Australia for [post-exposure prophylaxis](https://immunisationhandbook.health.gov.au/technical-terms#post-exposure-prophylaxis) (<https://immunisationhandbook.health.gov.au/technical-terms#post-exposure-prophylaxis>) against vaccine-preventable diseases include:

- hepatitis B (see [Hepatitis B](https://immunisationhandbook.health.gov.au/node/147) (<https://immunisationhandbook.health.gov.au/node/147>))
- rabies (see [Rabies](https://immunisationhandbook.health.gov.au/node/157) (<https://immunisationhandbook.health.gov.au/node/157>))
- varicella (see [Varicella](https://immunisationhandbook.health.gov.au/node/163) (<https://immunisationhandbook.health.gov.au/node/163>))
- tetanus (see [Tetanus](https://immunisationhandbook.health.gov.au/node/160) (<https://immunisationhandbook.health.gov.au/node/160>))
- diphtheria (see [Diphtheria](https://immunisationhandbook.health.gov.au/node/144) (<https://immunisationhandbook.health.gov.au/node/144>))

The use of disease-specific and NHIG (normal human immunoglobulin) is described briefly in each disease-specific chapter in this Handbook.

For more details about managing these diseases and obtaining [immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin) (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>):

- refer to the Communicable Diseases Network Australia [Series of National Guidelines](http://www.health.gov.au/cdnasongs) (<http://www.health.gov.au/cdnasongs>).
- contact your [state or territory public health authority](https://www.health.gov.au/health-topics/immunisation/immunisation-contacts) (<https://www.health.gov.au/health-topics/immunisation/immunisation-contacts>), or the [Australian Red Cross Blood Service](https://transfusion.com.au/) (<https://transfusion.com.au/>).

IVIG (intravenous immunoglobulin) is only used in an immunisation context when NHIG (normal human immunoglobulin) or specific [immunoglobulin](https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin) (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) preparations are not available.

Some people who have antibody deficiencies may have regular IVIG (intravenous immunoglobulin) infusions.

IVIG (intravenous immunoglobulin) can also be used to treat specific immune-mediated conditions. For more details, see [Criteria for the Clinical Use of Intravenous Immunoglobulin in Australia \(https://www.blood.gov.au/ivig-criteria\)](https://www.blood.gov.au/ivig-criteria).¹³

Safety of passive immunisation

Immunoglobulin products are manufactured by:

- screening blood donors
- treating the blood products to minimise the risk of viruses such as HIV, hepatitis A virus (<https://immunisationhandbook.health.gov.au/technical-terms#virus>), hepatitis B virus (<https://immunisationhandbook.health.gov.au/technical-terms#virus>), hepatitis C virus (<https://immunisationhandbook.health.gov.au/technical-terms#virus>) and parvovirus

The Therapeutic Goods Administration requirement for 2 pathogen removal steps means that the [risk of transfusion-transmissible infections is very low \(https://transfusion.com.au/adverse_events/risks/estimates\)](https://transfusion.com.au/adverse_events/risks/estimates).¹⁴ There is a theoretical risk of prion transmission.

Potential interaction between immunoglobulin preparations and vaccines

Live attenuated viral vaccines

Immunoglobulin preparations can interfere with the response to some live attenuated viral vaccines that are given parenterally. This is because the immunoglobulins prevent vaccine [virus \(https://immunisationhandbook.health.gov.au/technical-terms#virus\)](https://immunisationhandbook.health.gov.au/technical-terms#virus) replication.

Vaccines that are affected by immunoglobulins are:

- measles-mumps-rubella-containing vaccines
- varicella-containing vaccines

Depending on the person's clinical status, do not give these vaccines for:¹⁵

- at least 3 months after the person has received intramuscular [NHIG \(normal human immunoglobulin\)](#)
- at least 8 months after the person has received intravenous [NHIG \(normal human immunoglobulin\)](#)

The following vaccines are not affected by immunoglobulins and can be given at any time:

- rotavirus

- zoster
- yellow fever

For details on recommended intervals, see [Table. Recommended intervals between immunoglobulins or blood products, and measles-mumps-rubella, measles-mumps-rubella-varicella or varicella vaccination \(https://immunisationhandbook.health.gov.au/node/532\)](https://immunisationhandbook.health.gov.au/node/532) in [Vaccination for people who have recently received normal human immunoglobulin and other blood products \(https://immunisationhandbook.health.gov.au/node/438\)](https://immunisationhandbook.health.gov.au/node/438).

For the same reason, if a person has received a measles-containing or varicella-containing vaccine, do not give immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) products for at least 3 weeks, unless it is essential that the person receives the immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) within a shorter time frame.

Rh (D) immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>) (anti-D) does not interfere with the antibody response to measles-containing or varicella-containing vaccines. People can receive anti-D immunoglobulin (<https://immunisationhandbook.health.gov.au/technical-terms#immunoglobulin>), and measles-containing or varicella-containing vaccines either:

- at the same time in different sites with separate syringes, or
- at any time in relation to each other

See [Table. Recommended intervals between immunoglobulins or blood products, and measles-mumps-rubella, measles-mumps-rubella-varicella or varicella vaccination \(https://immunisationhandbook.health.gov.au/node/532\)](https://immunisationhandbook.health.gov.au/node/532).

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