

Australian Government

Department of Health

Questions about vaccination



A joint Australian, State and Territory Government Initiative

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Questions about vaccination

Vaccination is one of the most successful and cost-effective advances in global public health. Vaccines are given to many millions of people in Australia and billions worldwide to prevent disease. Vaccines prevent an estimated 2 to 3 million deaths every year.

Australia has one of the world's most comprehensive national immunisation programs. About 94% of Australian children aged under 5 are fully immunised against 15 diseases.

But even though most Australian parents vaccinate their children, it's normal to have questions about vaccination. Misinformation on the internet and social media about the safety of vaccines has also caused concern for some people.

We want you to feel confident in your decision to vaccinate your child. To help parents get the facts, we asked researchers from the National Centre for Immunisation Research and Surveillance, the University of Sydney and the University of Melbourne to help. They collected parents' questions and searched through the research literature to find answers.

This document provides clear answers to many common questions about vaccination. It is designed:

- to help parents find out more about vaccines and the most recent evidence about their safety and effectiveness.
- to help doctors answer questions from their patients.

Each chapter is also provided as a PDF that can be downloaded and printed out.

More information is available in the 'Further reading' links.

Acknowledgements

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Why do we need vaccines?

Why do all children need vaccines?

Children need vaccines to protect them from serious infectious diseases. An estimated 2 to 3 million deaths are prevented every year because of vaccination.

Vaccinating all children in Australia is important to protect their health and the health of the communities they live in. If people are vaccinated or immune to a disease, then non-immune people are much less likely to meet an infected person and catch the disease (this is often called 'community immunity'). Non-immune people include people who can't be vaccinated because of their age (too young or too old) or because their immune systems don't work as well (see **If the diseases are rarely seen, why do we still need vaccines?** and **Why is 'community immunity' important?**).

Also, everyone needs to be vaccinated against diseases that aren't passed from human to human. An example is tetanus. Tetanus is not 'caught' from other people tetanus spores are present throughout the environment (for example, in soil) and anyone can catch the disease from these spores through a break in their skin. Vaccines against tetanus do not provide community immunity, and the only way for individuals to be protected against tetanus is to receive the vaccine.

Further reading

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Davidkin I, Kontio M, Paunio M, Peltola H. MMR vaccination and disease elimination: the Finnish experience. Expert Review of Vaccines 2010;9:1045–53.

The Immunisation Advisory Centre. <u>Efficacy and effectiveness.</u> (2017). (www.immune.org.nz/vaccines/efficiency-effectiveness) (2017). (www.ncirs.edu.au/research/social-research/skai-project)

Are the diseases we vaccinate against really serious?

Yes. Vaccines target infectious diseases that can be serious and even fatal.

Some people believe that the childhood diseases that vaccines target are a normal and healthy part of growing up. These diseases were much more common in Australia and other countries before vaccines were introduced. But vaccines have been so successful, and the number of cases of these diseases has decreased so much, that most parents haven't seen the effects of these diseases.

These effects were often life-threatening or caused long-term damage. For example:

- Diphtheria is an infection that causes an abnormal membrane to grow in the throat, which can block breathing. One in 10 diphtheria patients died.
- Poliomyelitis (polio) can cause paralysis of the arms, legs or diaphragm (breathing muscles). One in 20 polio patients died. Half of those who survived were permanently paralysed. If their diaphragm was paralysed, patients had to live in an 'iron lung' to help them breathe.
- Measles can cause pneumonia or brain swelling. About 9 in every 100 measles patients develop pneumonia, and 1 or 2 in every 1,000 develop brain swelling, which often causes brain damage.
- Varicella (chickenpox) can cause pneumonia, brain swelling and even death, particularly in children and adults whose immune systems aren't working properly.
- Mumps can affect the brain causing meningitis or deafness, and can cause infertility.

Even common infections, such as influenza, can have serious effects. Influenza is often dismissed as minor, but every year children who were previously healthy require intensive care or die from influenza.

Vaccines give children protection without causing disease. They are always much safer than getting the disease itself (see Is immunity from vaccination as good as natural immunity?).

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If the diseases are rarely seen, why do we still need vaccines?

Vaccines are still needed to protect us, even if we don't often see the diseases they protect against.

Some people believe that the diseases that can be prevented by vaccines have been almost entirely eliminated. They think that this means we won't be exposed to infectious diseases, so we don't need to be vaccinated.

But the diseases that we vaccinate against are becoming rare because we keep vaccinating against them. Just because diseases like poliomyelitis (polio) and diphtheria are now rarely seen in our communities (see **Do vaccines prevent death?**), this doesn't mean that we can start to relax vaccination.

It is important that we keep vaccination rates as high as possible for three reasons:

- We need to make sure people who can't be vaccinated are still protected. Some people can't be vaccinated, such as very young babies or people with particular medical problems. We need to protect them by making sure that the chance of them meeting an infected person is very low. This can be achieved if most of us are immunised—this effect is called 'community immunity'. (see Why is 'community immunity' important?).

- We need to make sure diseases don't return.

If vaccination rates decrease, diseases can return very rapidly. In 1974, Japan had a high vaccination rate (80% of the population) for pertussis (whooping cough) and had under 400 cases. But rumours began that the vaccine was no longer needed and that the vaccine was unsafe, and people stopped vaccinating. In 1979, Japan had a pertussis epidemic, with more than 13,000 cases and 41 deaths. In 1981, the government introduced a new pertussis vaccine, and the number of cases decreased again.

We need to protect ourselves from diseases that are still common in other countries.

Because diseases are still common in many other countries around the world, travellers can bring such diseases to Australia. If more of us aren't immunised, it's more likely that there will be an outbreak of disease. In Australia in 2011, a 22-year-old woman died of diphtheria, a disease which is now extremely rare because of vaccination. She was unvaccinated and got the disease from a friend who had returned from overseas travel.

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Kim TH, Johnstone J, Loeb M. Vaccine herd effect. Scandinavian Journal of Infectious Diseases 2011;43:683–9.

World Health Organization. <u>Six common misconceptions about immunization.</u> (www.who.int/vaccine_safety/initiative/detection/immunization_misconceptions/en/index1.html)

Why is 'community immunity' important?

Community immunity protects the people in our community who can't be vaccinated.

If most people within a community are immune to a disease, then community immunity protects those people who aren't immune by reducing their risk of infection. Diseases spread when people catch them from each other. If people are vaccinated or immune to a disease, then non-immune people are much less likely to meet an infected person—so it's much less likely that the disease will be transmitted. Community immunity is also known as 'herd immunity'.

People who can't protect themselves with vaccination include some of the most vulnerable in our community—for example, babies who are too young to have vaccines, and people whose immune systems are weakened by medical conditions or who are having treatments like a bone marrow transplant.

Vaccination is the best way to establish community immunity to protect these people. To achieve community immunity for infectious diseases, coverage needs to be high. For example, measles is highly infectious so it needs a coverage rate of about 92 to 94 per cent.

Some people believe that community immunity eliminates disease, so vaccines are no longer needed. But if vaccination rates decrease, diseases can return very rapidly. This will threaten every person who is not immunised (see also **If the diseases are rarely seen, why do we still need vaccines?)**.

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Centers for Disease Control and Prevention. <u>Why immunize?</u> (2017). (http://www.immune.org. nz/vaccines/efficiency-effectiveness)

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The Immunisation Advisory Centre. <u>Efficacy and effectiveness.</u> (2017). (www.immune.org.nz/vaccines/efficiency-effectiveness)

Do vaccines prevent death?

Yes. We know vaccines prevent death because far fewer people die from diseases after we start vaccinating against them. Deaths from diphtheria, pertussis (whooping cough), tetanus, poliomyelitis (polio) and measles all dropped rapidly after vaccination programs began in Australia in 1926 (see *Figure 1*).

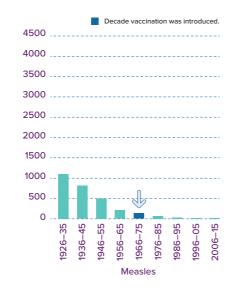
The biggest change we can see since that time is that deaths due to diphtheria have gone. This was one of the main causes of death in children before vaccines were available—1 in 10 children who got diphtheria died (see **Are the diseases we vaccinate against really serious?**).

In some cases, better living standards had begun to reduce deaths before vaccines were available. For example, deaths due to measles were falling before the vaccine was introduced in 1968, because of improved hospital care and new antibiotics to treat the bacterial pneumonia that sometimes followed measles. But vaccines brought the number of deaths to zero in 1996.

In some cases though, better living standards actually increased disease (see **Can our improved standard of living explain the reduction in disease?**). For example, improvements in hygiene meant that adults were not being exposed to polio as children, and did not develop immunity. This led to increased polio cases and deaths from the 1940s. After the vaccine was introduced in 1956, the number of cases fell to almost zero.







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Can our improved standard of living explain the reduction in disease?

Some people believe that the number of cases of infectious diseases have decreased because of improvements in our health, hygiene and healthcare, not because of vaccines. Improvements in our standard of living have reduced deaths from all diseases. But it's clear that vaccines have had a separate effect.

There are now almost no deaths from the main diseases we vaccinate against diphtheria, tetanus, pertussis (whooping cough), poliomyelitis (polio) and measles. Deaths often decreased only a very short time after vaccination was introduced in a community (see **Do vaccines prevent death?**). This would not have happened just because of improvements in our standard of living, which happen more slowly.

It's easy to see the separate effects of vaccination when vaccination rates fall in communities or countries with high living standards. In such cases, diseases return very rapidly. For example:

- In the 1970s, vaccination for pertussis decreased in Britain. Between 1977 and 1979, there was an epidemic of 102,500 cases of pertussis; 27 children died and 17 developed permanent brain damage. Pertussis vaccination has now increased again and the number of cases has decreased.
- There were two major epidemics of polio in the Netherlands in 1984 and 1991.
 These occurred in a religious group who refused vaccination. The diseases did not spread to the rest of the population, which had a high rate of vaccination.
- In 2017, falling rates of vaccination in Europe led to over 21,000 cases of measles with 35 deaths.

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Why do children get more vaccines now than they did when I was young?

Children get more vaccines now because there are more vaccines available. As technologies continue to evolve, so has our ability to prevent disease. The results of some of these advancements are new vaccines. These include vaccines for human papillomavirus (HPV), meningococcal disease, pneumococcal disease, rotavirus and varicella (chickenpox).

These vaccines have already reduced death and disease in Australia.

Human papillomavirus (HPV)

Human papillomavirus (HPV) vaccines protect people from HPV, which is a common sexually transmitted infection. HPV infection is very contagious and most people will be infected within a few years of becoming sexually active. In most cases, it's a minor illness and most people will be free of infection after 1–2 years.

But HPV infection can cause cancer. The main cancers associated with HPV are cervical and vaginal cancers in women. HPV is also associated with penile cancer in men, and anal and head and neck cancers which can affect both men and women.

Australia was the first country in the world to implement a National HPV Vaccination Program, which started in April 2007. The National Immunisation Program provides free HPV vaccination through schools to children aged 12–13 years.

Cervical cancer rates have decreased significantly since the vaccine was introduced (see *Figure 2*). It was recently reported that Australia is on track to be the first country in the world to eliminate cervical cancer.

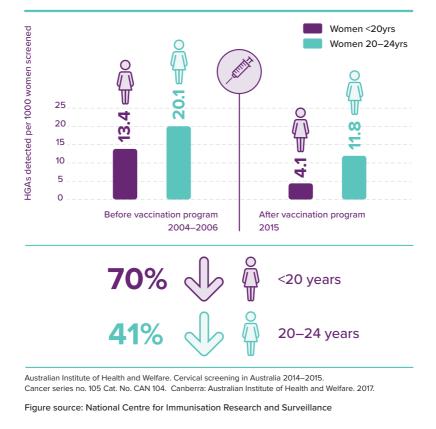
Further reading

9 News. <u>Australia on track to become first country to completely eliminate cervical cancer</u> (video). (2018). (www.9news.com.au/national/2018/03/04/07/30/australia-on-track-to-become-first-country-to-completely-eliminate-cervical-cancer)

Figure 2 High-grade cervical abnormalities detected by screening programs in Australian women before and after the vaccination program

HPV VACCINATION PROGRAM APRIL 2007

High-grade cervical abnormalities (HGAs) detected in women screened in Australia before and after vaccination program



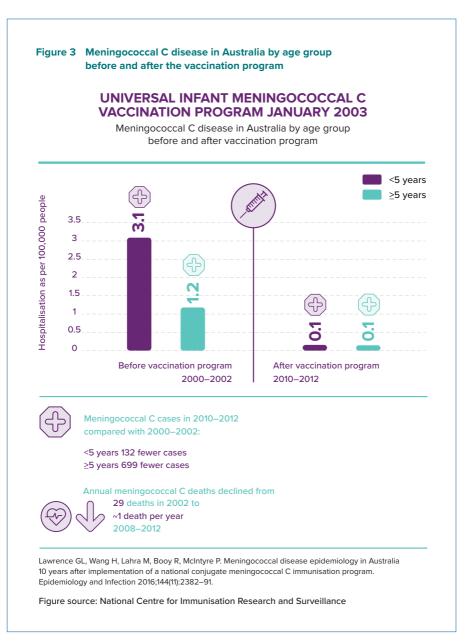
Meningococcal disease

The bacteria *Neisseria meningitidis*, also known as meningococcus, can cause meningitis (an inflammation of the protective membranes covering the brain and spinal cord) and septicaemia (blood poisoning). About 10% of cases are fatal, even with early treatment.

There are 13 known types of meningococcus bacteria. Five of these can be prevented by vaccines (A, B, C, W and Y).

After a vaccine against meningococcal C was introduced in Australia's National Immunisation Program in 2003, there was a dramatic decrease in the number of meningococcal C cases among the age groups that received vaccination (up to 19 years; see *Figure 3*). There were also fewer cases in older age groups because of community immunity (see **Why is 'community immunity' important?**).

In response to increased rates of the W and Y types of meningococcal disease, the combined ACWY meningococcal vaccine replaced meningococcal C vaccine on the National Immunisation Program for infants at 12 months of age in 2018. Vaccines against meningococcal B are also available. They aren't provided through the National Immunisation Program, but are available for purchase.



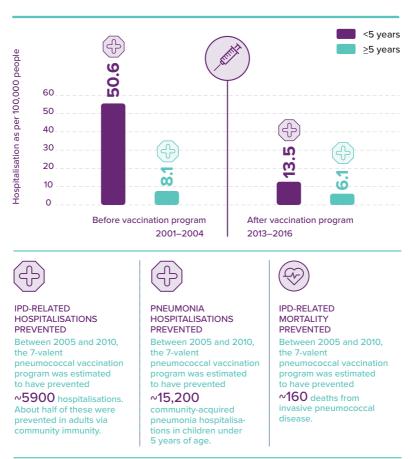
Pneumococcal disease

The bacteria *Streptococcus pneumoniae*, also known as pneumococcus, has over 80 types and causes pneumonia, sepsis and meningitis as well as other infections. If the bacteria gets into the bloodstream, the fluid in the brain or spinal cord, or the fluid around the lungs, it is called 'invasive pneumococcal disease' (IPD) which can be fatal. Children under 2 years of age and the elderly are most susceptible to IPD.

In Australia, a pneumococcal vaccine protecting against the 13 most common types is offered to all infants through the National Immunisation Program. Over 90% of infants are immunised against IPD. The vaccine was first offered on the National Immunisation Program in 2005. By 2016, rates of IPD in children under 5 years of age reduced by about 75% (see *Figure 4*). A different pneumococcal vaccine is also available for people aged over 65.

Figure 4 Invasive pneumococcal disease hospitalisations in Australia by age group before and after the vaccination program

UNIVERSAL INFANT CONJUGATE PNEUMOCOCCAL VACCINATION PROGRAM JANUARY 2005



Invasive pneumococcal disease (IPD) hospitalisations in Australia by age group before and after conjugate vaccination program

Newall AT, Reyes JF, McIntyre P, Menzies R, Beutels P, Wood JG. Retrospective economic evaluation of childhood 7-valent pneumococcal conjugate vaccination in Australia: uncertain herd impact on pneumonia critical. Vaccine 2016;34:320–7.

Figure source: National Centre for Immunisation Research and Surveillance

Rotavirus

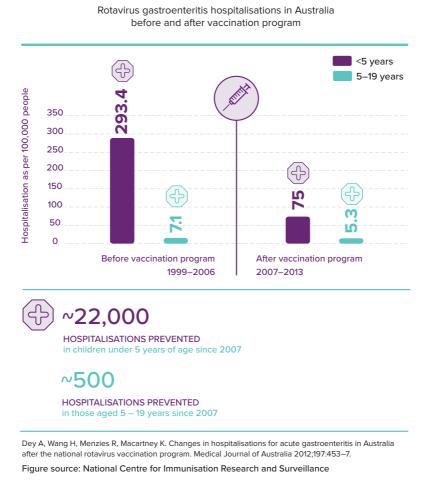
Rotavirus is the most common cause of severe diarrhoea in young children worldwide. Rotavirus infection can also cause vomiting, fever and acute dehydration.

Rotavirus kills about 500,000 children worldwide every year. Before the introduction of the rotavirus vaccine, around 10,000 children under 5 years of age were hospitalised with rotavirus each year in Australia.

Rotavirus vaccine first became available in Australia in 2006 and became part of the National Immunisation Program in 2007. Since then, hospitalisations due to rotavirus in Australia have decreased by about 75% (see *Figure 5*).

Figure 5 Rotavirus gastroenteritis hospitalisations in Australia before and after the vaccination program

UNIVERSAL INFANT ROTAVIRUS VACCINATION PROGRAM JULY 2007



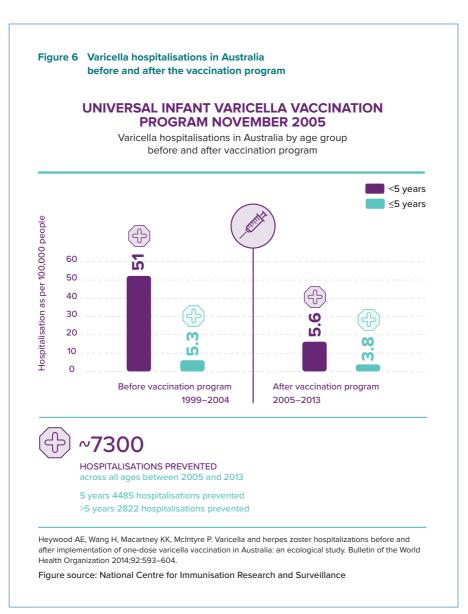
Varicella (chickenpox)

Varicella (chickenpox) is a highly infectious disease caused by the varicella-zoster virus (VZV). Before varicella vaccine became available, almost all children got varicella. This means that even if only a small percentage of these children had complications, that added up to a large number of children who needed to be hospitalised. Some needed intensive care and, although this was rare, some died. Complications include bacterial infection of the chickenpox sores, pneumonia, and brain inflammation and swelling (meningitis/encephalitis).

Vaccination of children against varicella prevents these complications. Varicella vaccine was included on Australia's National Immunisation Program in late 2005. Since then, varicella hospitalisations in children between 18 months and 4 years of age decreased by about 70% (see *Figure 6*).

Vaccination also ensures that children become immune before they grow to be teenagers and adults. Complications from varicella are much more common in people who get varicella as a teenager or an adult, and they are more likely to require hospitalisation.

Since July 2013, varicella vaccine has been available as both a single vaccine and as part of the combined measles–mumps–rubella–varicella (MMRV) vaccine. The flow on benefit of varicella vaccination is anticipated prevention of shingles.



Why should I be vaccinated while I'm pregnant?

Women should be vaccinated while they are pregnant to protect themselves and their babies against two serious infections:

- Pertussis (whooping cough)

Babies can die from pertussis if they get it before they can receive protection from vaccination. Vaccination during pregnancy is the most effective way to prevent pertussis in newborn babies.

A single dose of pertussis vaccine, given as a combination vaccine with tetanus and diphtheria, is strongly recommended for pregnant women in the third trimester of every pregnancy (preferably between 28 and 32 weeks).

Pregnant women are vaccinated against pertussis in many countries, including Australia, the United States, England and New Zealand. There is now evidence from hundreds of thousands of women in these countries that pertussis vaccination in pregnancy does not increase the risk of problems with pregnancy or any harm to the baby.

- Influenza (the flu)

If the mother gets influenza during pregnancy, it can cause premature delivery or death of the baby. Influenza can also be much more severe for pregnant women. Pregnant women are more than twice as likely to be admitted to hospital as other people with influenza.

Babies under 6 months of age have the highest risk of hospitalisation or death from influenza, much higher than older children.

Babies of mothers who receive an influenza vaccine during pregnancy have been shown to be 50–90% less likely to have confirmed influenza infection in the first six months of life. Babies can receive influenza vaccine themselves from 6 months of age.

Studies have shown that influenza vaccination during pregnancy doesn't increase problems for the mother or baby.

Both pertussis and influenza vaccines are inactivated vaccines, which are safe for pregnant women (see **How are vaccines made?**).

Other inactivated vaccines aren't usually used during pregnancy, but may be considered in special circumstances. Live attenuated vaccines aren't given during pregnancy, to avoid any possibility of passing the live virus to the baby, although follow-up of women who have received them by mistake show no problems.

Further reading

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What do vaccines do?

How do vaccines work?

Vaccines trigger a protective immune response in the body to the infection they target, without causing the disease itself.

When an organism that might cause disease—such as a bacteria or virus—enters the body, the body responds to fight the organism and make the body immune to that organism in the future.

This is called an 'immune response'.

The immune response to vaccines has two parts:

 Vaccines stimulate cells in the immune system to produce antibodies to help fight disease.

Vaccines contain 'antigens' (or antibody generator), which are parts of the diseasecausing organism that the immune system can recognise. After vaccination, the body's B-cells (a type of white blood cell) produce antibodies against these antigens.

Each type of antibody targets a specific disease—for example, measles antibodies specifically target the measles virus. If the measles virus enters the body of a vaccinated person, the antibodies that were produced in response to the vaccine attach to the virus. This allows other cells in the immune system to kill the virus before it can cause symptoms or be transmitted to someone else.

– Vaccines teach the immune system to 'remember' the specific organism. Specialised 'memory' cells in the immune system recognise the disease's antigen if the organism is encountered in the future. This means that even if the level of specific 'targeted' antibodies in the body has decreased, the body can quickly produce more of them—a lot more quickly than for someone who is not vaccinated.

How well do vaccines work?

Vaccines have been one of the most successful public health advances in history. An estimated 2 to 3 million deaths are prevented every year because of vaccination.

Most routine childhood vaccines are effective in 85–95% of people. This means that in every 100 people who receive a vaccine, between 5 and 15 of them may not develop their own protective immunity (see **How do vaccines work?**).

But if vaccination rates are high, then these people are still protected. If most of us are immunised, it means that a person without protective immunity has a much lower chance of meeting an infected person. This is why vaccination for everyone is important (see also **If the diseases are rarely seen, why do we still need vaccines?**).

Further reading

Chain of Protection. Herd immunity (video). (2014). (https://vimeo.com/11641261)

Davidkin I, Kontio M, Paunio M, Peltola H. MMR vaccination and disease elimination: the Finnish experience. Expert Review of Vaccines 2010;9:1045–53.

The Immunisation Advisory Centre. <u>Efficacy and effectiveness</u>. (2017). (www.immune.org.nz/vaccines/efficiency-effectiveness)

Can vaccines cause or spread disease?

Almost never. Most vaccines available in Australia are either inactivated (which means the components of the vaccine are dead) or attenuated (which means the components of the vaccine are alive but weakened) (see also **How are vaccines made?**).

It is not possible for inactivated vaccines to cause disease. Attenuated viruses can only cause disease in people who have immune systems that don't work as well, such as after a bone marrow transplant. This means it is important that live attenuated vaccines are not given to people with weakened immune systems. Examples of attenuated vaccines are measles, mumps, rubella, varicella (chickenpox) and rotavirus.

In people with normal immune systems, live attenuated vaccines can sometimes cause mild symptoms of the disease they target:

- About a week after receiving measles vaccine, about 1 in 20 children will develop a mild case of measles with fever and/or a rash. Children who develop measles-like disease due to the vaccine virus have never transmitted it to anyone else.
- There has been 1 case of mumps transmitted from a mumps vaccine, but it was a different strain of the virus to the ones used in Australian vaccines.
- Mild cases of rubella have been reported after coming into contact with the faeces (poo) of someone who has recently had a live attenuated rubella vaccine.
 Good hygiene (washing your hands after changing babies' nappies) prevents disease being spread in this way.
- The vaccine strain of rubella has also been found in mothers' breastmilk and the noses of babies being breastfed, but no cases of it causing disease in mothers, babies or anyone else have been reported.
- Sometimes, people who get a varicella (chickenpox) vaccine get a skin rash at the injection site (in 5 out of every 100 people who receive the vaccine). It is then possible for someone else to be infected if they come into contact with the rash. However, being infected in this way is extremely rare.
- Varicella (chickenpox) vaccine virus can reactivate later in life and cause shingles.
 This is the same as for natural varicella infection. But shingles occurs much less often and less severely after varicella vaccination than after natural varicella infection.

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Is immunity from vaccination as good as natural immunity?

Yes. In fact, immunity from vaccination is better than 'natural' immunity because vaccines cause immunity without causing disease. Vaccination is the safest way of developing immunity.

It is true that the immunity produced by vaccines doesn't last as long as natural immunity for some diseases, such as pertussis (whooping cough), measles and mumps. But vaccination is still better than getting the disease.

There are five key reasons that immunity from vaccines is better than natural immunity:

- Catching diseases is not a safe way to develop immunity.

Catching a disease can protect a child from catching it again. But it can make them seriously ill in the process. Many diseases that are prevented by vaccines have serious effects, including death.

Vaccines cause immunity without causing the disease. The side effects of vaccination are usually mild (like getting a sore arm or a mild rash) and pass quickly.

 Vaccines can make the disease less severe, even if immunity wears off.
 If immunity produced by a vaccine has decreased over time, you might catch a disease you are vaccinated against. But usually the disease will be much less severe than it would be if you were not vaccinated.

 Some vaccines provide stronger, longer-lasting immunity than getting the disease itself.

Vaccines that provide stronger immunity than the disease itself include the human papillomavirus (HPV), hepatitis B and tetanus vaccines.

- Vaccination provides community immunity.

Vaccinations can reach more people in the community (and make them immune) than disease. Currently, about 94% of Australian children under 5 years of age are fully immunised against 15 diseases. This high vaccination rate means that people who can't be immunised are still protected because they are unlikely to meet someone with the disease (see Why is 'community immunity' important?).

Vaccines can often protect against multiple strains of a virus or bacteria. For some diseases, natural infection may only protect you against the one strain that you catch. Examples of vaccines that protect against several strains include HPV, poliomyelitis (polio) and pneumococcal vaccines.

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Can immunity that comes from vaccination wear off?

Yes. Infection or vaccination causes the production of antibodies in the body that can fight the disease (see also **How do vaccines work?**). The level of these antibodies naturally decreases over time.

But even though antibody levels developed after vaccination will gradually decrease, the immune system 'remembers' antigens that it has previously seen for a very long time. This means that if you are exposed to a disease you've been vaccinated against, the immune system will respond much more rapidly and effectively than if you had not been vaccinated (see also **How do vaccines work?**).

How long protective immunity lasts depends on the type of vaccine and the specific disease. Vaccines that are made from weakened whole live viruses (see **How are vaccines made?**), like measles, can protect for many years, perhaps for life, after two doses. Vaccines made from parts of a virus or bacteria, such as pertussis (whooping cough), pneumococcal and meningococcal vaccines, or a modified toxin produced by an organism (such as diphtheria and tetanus), aren't as long-lasting. Getting booster doses of these vaccines at the recommended ages maintains protection against the disease.

How long immunity lasts also depends on patient factors such as age—immune responses are lower in infants and the elderly. But even these lower responses provide useful protection, and further doses are given to build stronger immunity.

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Does the influenza vaccine cause influenza?

The influenza vaccine can't cause an influenza infection. This is because all influenza vaccines in use in Australia are made with a virus that has been inactivated or killed. It is not alive or functioning like a whole virus and can't cause disease.

Sometimes, the normal responses the body has after getting the vaccine can be like the early signs of influenza. People may experience swelling, redness and pain at the injection site, and also fever, tiredness and muscle aches. This can make people think they have developed influenza from the vaccine. But these symptoms are a sign that the vaccine is causing an immune response, which is what it's designed to do (see also **How do vaccines work?**).

The symptoms can start within a few hours of being vaccinated and sometimes last 1–2 days. They go away on their own once your body has successfully made an immune response to the vaccine, which will protect you from influenza. Lots of infections circulate during the influenza season, including respiratory infections that are not related to influenza, and are often an alternate cause of symptoms.

No vaccine is 100% effective at preventing disease, and it's possible to get influenza after being vaccinated. How well the influenza vaccine works can vary. It depends on several factors including your age and health, and how well the strain of influenza in the vaccine matches the strain of influenza circulating in the community that year.

But even a small reduction in the chance of getting influenza is worthwhile. Australian studies have shown that influenza vaccines reduce the chances of the most severe complications of influenza. Getting an influenza vaccine also helps to stop you from passing influenza on to unvaccinated people—for example, if there is a new baby in the family, vaccinating other family members can help to protect the baby from influenza.

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Do homeopathic vaccines work?

Although some people find homeopathic preparations helpful for a range of health concerns, homeopathic immunisation (also called homeoprophylaxis) doesn't protect people from infectious diseases such as diphtheria, pertussis (whooping cough), tetanus, poliomyelitis (polio) and measles.

Several homeopathic substances marketed as homeopathic 'vaccines' are available. These don't have any ingredients that work in the way that vaccines work, and they haven't been scientifically tested or proven. By contrast, all vaccines recommended in Australia have been proven to be effective in many studies and many thousands of people (see also **How do vaccines work?** and **Are vaccines properly tested and monitored?**).

The Australian Homoeopathic Association and the United Kingdom Medical Association for Homeopathy recommend that children are vaccinated with standard vaccines to protect them against disease. Most homeopathic practitioners in Australia support vaccination to protect against vaccine-preventable diseases.

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Are vaccines safe for my child?

What side effects might occur with vaccines?

Vaccines are given to many millions of people in Australia and billions worldwide. Almost all side effects are minor. Being vaccinated is less harmful than getting the disease—many of the diseases we vaccinate against can be fatal or have long-term health effects.

Common reactions

Most of the side effects associated with vaccines are minor, and usually go away within a few days. The most common side effects of vaccines are redness, swelling and tenderness at the injection site. These happen within hours of the injection.

Other less common effects are fever, headache, tiredness or nausea. Up to 10 people in every 100 who are vaccinated will experience these minor effects. Even fewer people experience vomiting, diarrhoea, or muscle or joint pain.

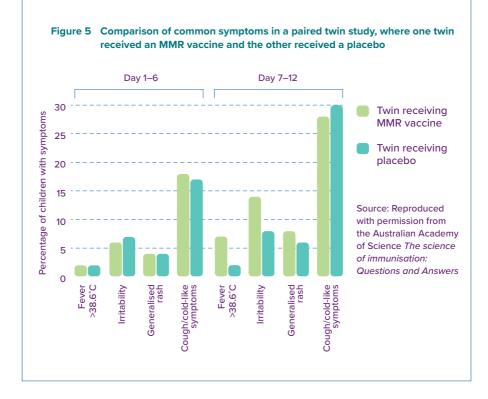
These symptoms could be happening by chance (unrelated to the vaccine) or simply indicate that the vaccine is working in the body to generate an immune response, which is what it's designed to do (see **How do vaccines work?**).

Other causes of reactions

Children often experience fevers, rashes or irritability for many reasons. So even if a child has these symptoms just after they receive a vaccine, it doesn't always mean that the vaccine caused them.

A study of identical twins was used to investigate whether measles–mumps–rubella (MMR) vaccine caused fevers, rashes, irritability or cold-like symptoms. For each pair of twins, one was given MMR vaccine and the other was given a placebo (an injection with no vaccine in it). In the first week after the injection, the twins who got the placebo experienced these symptoms just as often as children who got the vaccine (see *Figure 7*). In the second week after the injection, the twins who got the vaccine were more likely to have fever, irritability or a rash because the virus strains from the vaccine had time to multiply. But they didn't have any more cold-like symptoms, which are not caused by the measles vaccine virus, than twins who got the placebo.

This study showed how difficult it is to know which symptoms are due to a vaccine and which are due to something else.



Serious side effects

Serious reactions to vaccines are extremely rare. It is usually not possible to predict who may have a mild reaction and who may have a rarer, more serious reaction to a vaccine.

Sometimes, children can have a fit or seizure if their temperature rises suddenly (called a 'febrile seizure'). If the vaccine causes a fever, this can sometimes in turn cause a febrile seizure. These seizures might alarm parents, but they don't usually cause any long-term health effects (see **Do vaccines cause seizures**?).

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Do vaccines cause or worsen asthma and allergies?

There is no evidence that vaccines cause or worsen asthma or allergies. It is very important that people with asthma or allergies are vaccinated to reduce their chance of getting a serious infection, which could make their existing condition worse.

The number of people affected by asthma or allergies has increased significantly in the last few decades. The reasons for this aren't known.

But some people think that this increase may be due to vaccines.

Their theory is that improved standards of living, higher levels of hygiene and the use of vaccines have decreased our exposure to antigens (substances that might cause disease, like bacteria or viruses) early in life. This exposure usually causes a non-allergic immune response (called a Th1 response). These people think that because our exposure is reduced, our bodies are instead prone to an allergic response instead (called a Th2 response), including to ordinary foods.

But this theory is wrong. Vaccines have targeted some of the most serious and common diseases. But there are still many thousands of other diseases. We are still exposed to a vast number of infections, and our normal non-allergic immune response is intact. Vaccines do not disrupt the normal Th1–Th2 balance.

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Do vaccines cause autoimmune diseases (like type 1 diabetes, Guillain–Barré syndrome, multiple sclerosis and rheumatoid arthritis)?

There is no evidence that vaccines cause autoimmune diseases. Autoimmune diseases include type 1 diabetes, Guillain–Barré syndrome, multiple sclerosis and rheumatoid arthritis.

It is very important that people who have autoimmune diseases are vaccinated to reduce their chance of getting a serious infection, which could make their condition worse. People with autoimmune diseases should be vaccinated according to Australia's National Immunisation Program schedule. It's strongly recommended that people with autoimmune diseases have the influenza vaccine every year, because developing influenza can make their symptoms worse.

Diabetes

There is no evidence that vaccines cause diabetes.

It has been suggested that vaccinations in early childhood might play a role in the development of type 1 diabetes. Because some infections might trigger type 1 diabetes in susceptible people, some people think that vaccines for those infections could also cause the disease. But thorough research hasn't found any evidence of this:

- Large studies haven't shown any link between type 1 diabetes and vaccines for pertussis (whooping cough), measles-mumps-rubella (MMR), *Haemophilus influenzae* type b (Hib), hepatitis B or varicella (chickenpox).
- A review published in 2015 looked at 23 studies worldwide investigating 16 vaccines. The review found no evidence of a link between any childhood vaccines and type 1 diabetes.
- Expert groups, including the National Institutes of Health in the United States, have reviewed the evidence and found no link between vaccines and type 1 diabetes.
- In 1997, one research group found that vaccines given after 2 months of age increased the risk of diabetes, but these results haven't been confirmed by any other researchers.

Guillain–Barré syndrome

Overall, there is no evidence that vaccines cause Guillain–Barré syndrome (GBS). But, in the case of influenza vaccines, there is evidence of a possible, though tiny, increase in risk in some years. The risk of GBS after influenza infection is much higher than the risk of GBS after influenza vaccination. GBS is a rare disorder in which the body's immune system attacks part of the nervous system. GBS can cause muscle weakness and, in severe cases, paralysis.

It is estimated that each year there are 1–2 cases of GBS diagnosed in every 100,000 people. GBS can occur spontaneously (without any identified cause). Because it can occur without an identified cause, it is understandable that people who have been recently vaccinated who develop GBS might blame the vaccine. But there is no evidence of a link.

GBS can occur after certain events such as infections, including with influenza or *Campylobacter jejuni* which causes gastroenteritis (gastro).

In the United States in 1976, that year's seasonal influenza vaccine formulation was associated with an increased risk of developing GBS. Several studies have assessed whether other influenza vaccines since then have been associated with GBS. Some studies have found no increased risk at all. Other studies have found only a very small increase in GBS following influenza vaccination. The increase is about 1 additional case of GBS for every million people vaccinated against influenza. The influenza vaccine changes every year, and the increase only appears in some years.

There have been some vaccines where initial reports suggested a possible link with GBS, including oral polio, measles-mumps-rubella (MMR), tetanus, hepatitis B and meningococcal vaccines. However, in each case, subsequent large, well-conducted studies have not shown any evidence of a link. For example, in the United States, a possible link between GBS and a meningococcal vaccine used in teenagers was reported. Later research, including over 12 million people, found that this vaccine was not associated with an increased risk of GBS.

Multiple sclerosis

There is no evidence that vaccines cause multiple sclerosis (MS).

MS is a disease of the central nervous system that can affect the brain, spinal cord and optic nerves. It can cause problems with vision, balance, muscle control and other basic body functions.

It has been suggested that vaccines might cause MS through 'molecular mimicry'. This means that the body reacts to ingredients in vaccines that are like the body's own proteins, and in turn attacks these proteins in the body. There is no evidence that this is true.

The hepatitis B and influenza vaccines have been the target of these suggestions:

- The hepatitis B vaccine was first proposed to cause MS in 1985, when a study seemed to suggest that the hepatitis B vaccine triggered an autoimmune disease in rabbits. There were also reports of some MS diagnoses after hepatitis B vaccination. But more than 10 careful studies have consistently shown no link between hepatitis B vaccine and MS.
- The influenza vaccine contains a protein that is like the human myelin basic protein, so the process of 'molecular mimicry' is plausible. But several large studies have shown that the influenza vaccine doesn't cause or worsen symptoms of MS.

There is also evidence that vaccination doesn't worsen the symptoms or cause relapses of MS in people who already have the disease.

Rheumatoid arthritis

There is no evidence that vaccines cause rheumatoid arthritis.

Rheumatoid arthritis causes chronic joint inflammation and other problems. It has been suggested that the hepatitis B and human papillomavirus (HPV) vaccines could cause the disease. But there is no evidence of this.

A Swedish study of almost 2000 cases of rheumatoid arthritis found no link between any type of vaccine and the disease.

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Do vaccines cause seizures?

Yes, occasionally. This is because vaccines can cause fevers, and when fevers develop suddenly some children can have seizures. These are known as febrile seizures and they are usually very mild. Children who have them usually recover on their own, without any ongoing effects or permanent brain damage. Febrile seizures do not increase the risk of developing epilepsy.

By the age of 5, about 3 in every 100 children will have had a febrile seizure, but these aren't usually associated with a vaccination. Febrile seizures are more commonly triggered by fever from gastroenteritis (gastro) or influenza.

Measles-mumps-rubella (MMR) vaccines

Measles–mumps–rubella (MMR) and measles–mumps–rubella–varicella (MMRV) vaccines are associated with a small increased risk of a febrile seizure 7 to 12 days after the first dose of vaccine. It is estimated that 1 extra child out of every 3,000 who receive an MMR vaccine will have a febrile seizure during this time.

But seizures occur much less often than they would if the person caught the disease:

- In children who receive the MMR vaccine, about 3 in every 10,000 will develop a fever that is high enough to cause seizures.
- In children who get measles, about 100 in every 10,000 will develop a fever that is high enough to cause seizures.

When the MMRV vaccine is given as the first dose of MMR-containing vaccine, the risk of fever and febrile convulsions during this time is about two times greater than if MMR and varicella (chickenpox) vaccines are given separately. MMRV vaccine is therefore not recommended as the first dose of MMR-containing vaccine in young children in Australia.

Influenza vaccines

Influenza itself usually causes fever, which may result in febrile seizures. Influenza vaccines have been shown to be safe in children from 6 months of age. Febrile seizures related to fever after influenza vaccination are uncommon and occur in less than 1 in every 1,000 children who receive the vaccine.

However, in 2010, one brand of influenza vaccine (Fluvax[®] and Fluvax[®] Junior, CSL Limited) caused higher rates than expected of fevers and febrile seizures in children under 5 years of age. The rates were also higher than for other influenza vaccines. Fluvax[®] is no longer used for children in this age group. Other brands of influenza vaccine are available for use in young children.

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Do vaccines cause sudden infant death syndrome (SIDS)?

There is no evidence that vaccines cause sudden infant death syndrome (SIDS).

SIDS is the sudden and otherwise unexplained death of an infant under 1 year of age. Most cases of SIDS happen in the first 3 months of a baby's life. It is also recommended that Australian children receive their second set of childhood vaccinations at 2 months of age. This coincidence has led to suggestions that vaccination may cause SIDS. This idea has been thoroughly researched and shown to be incorrect:

- In the last 20–30 years, several well-conducted studies have shown a link between SIDS and several risk factors. Risks include the prone and side sleeping positions for infants, infant overheating and maternal smoking. None of these studies has shown a link between vaccination and SIDS.
- In 2017, a review of the risk factors associated with SIDS was published in the journal JAMA Pediatrics (one of the journals of the American Medical Association). This review found that many studies and analyses of the Vaccine Adverse Event Reporting System in the United States haven't found a link between vaccination and SIDS.
- One review even found that the risk of SIDS was halved in vaccinated children, although this result hasn't been found in other studies.

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Does the human papillomavirus (HPV) vaccine cause rare syndromes or problems with fertility or pregnancy?

There is no evidence that the human papillomavirus (HPV) vaccine causes any rare syndromes or problems with fertility or pregnancy.

The World Health Organization, the Australian Technical Advisory Group on Immunisation, the Centers for Disease Control and Prevention in the United States, and many other experts recommend that HPV vaccine be used to prevent HPV-related disease and death.

Rare syndromes

People who have had HPV vaccines are no more likely than others to develop rare syndromes including demyelinating syndromes, venous thromboembolism, autoimmune disease or neurological conditions such as complex regional pain syndrome (CRPS) or postural orthostatic tachycardia syndrome (POTS).

Many reviews by expert groups have found no evidence that HPV vaccines cause any disorders, including CRPS and POTS. In 2015, a review by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee found no evidence that the rates of these syndromes in vaccinated girls were more than the expected rates in this age group.

Problems with fertility or pregnancy

There is no evidence that HPV vaccines cause infertility or adverse pregnancy outcomes.

Some people think that HPV may affect fertility because it's a sexually transmissible disease. But HPV infection, unlike some other sexually transmissible infections such as chlamydia, doesn't cause infertility. So it doesn't make sense that the HPV vaccine could cause infertility in women or men.

Studies of high doses of HPV vaccine in female and male rats show no effect on fertility.

Some websites suggest that one ingredient of the vaccine, polysorbate 80, causes infertility in rats. This is based on one study of newborn rats given extremely large doses of polysorbate 80—up to 200 times the amount in HPV vaccines. The Australian Therapeutic Goods Administration has reviewed all the available data about polysorbate 80 and fertility. They found no evidence that polysorbate 80 at the levels in HPV vaccines affects human reproduction or fertility. Polysorbate 80 is already found in many medications, foods and cosmetics.

There is no reason to think that HPV vaccine could cause problems during pregnancy. Although there is no reason to give it then, HPV vaccine should not be given during pregnancy because there isn't enough data yet on the effects of HPV vaccine when given during pregnancy. However, the available data are reassuring. During clinical trials of Gardasil[®] HPV vaccine, 1,796 women who received Gardasil[®], and 1,824 women who received a placebo, became pregnant. There was no difference in the outcomes of these pregnancies, so it's unlikely that receiving HPV vaccine while pregnant causes harm to women or their unborn babies.

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Does the measles-mumps-rubella (MMR) vaccine cause autism?

The measles–mumps–rubella (MMR) vaccine doesn't cause autism. Many studies and reviews over almost 20 years have found no link between MMR vaccine and autism.

The potential link between the MMR vaccine and autism was originally suggested by a group of researchers led by Dr Andrew Wakefield in the United Kingdom in 1999. Wakefield's studies suggested that measles virus in the gut caused a specific type of inflammatory bowel disease (IBD). This syndrome decreased absorption of essential vitamins and nutrients. It was suggested that this in turn caused developmental disorders such as autism or made symptoms worse in children already diagnosed with autism. This theory generated a lot of media attention and research.

The Wakefield study was shown to be fake. Investigations by the British Medical Council found that Wakefield had been hired to attack the MMR vaccine and that the research group had made up their results. The published paper about their research was withdrawn by the journal and Wakefield was struck off the medical register in the United Kingdom and is no longer allowed to practice medicine.

More than 20 studies, and many expert reviews since then, have shown that children who get the MMR vaccine are no more likely to have autism or IBD.

National and international expert groups all recommend that the MMR vaccine should be used to protect children and communities from these diseases.

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Does the pertussis (whooping cough) vaccine cause damage to the brain or nervous system?

There is no evidence that the pertussis (whooping cough) vaccine causes damage to the brain or nervous system.

Pertussis vaccine is usually given as the combination diphtheria–tetanus–pertussis (DTP) vaccine.

The pertussis part of the DTP vaccine was originally made from inactivated whole pertussis organisms (called the DTPw vaccine; see **How are vaccines made?**). DTPw vaccines were associated with injection site reactions, fever, and sometimes drowsiness, irritability and loss of appetite.

DTPw vaccines are no longer used in Australia. All pertussis vaccines used in Australia now contain purified components of the pertussis organism (called 'acellular' or DTPa vaccines). These newer vaccines have a much lower rate of side effects than the old DTPw vaccines.

Studies of current DTPa vaccines, including a study of all suspected cases of brain damage in Canada over 10 years, concluded that cases of brain damage were not caused by vaccination but by pre-existing medical conditions or infections.

Some babies can have a rare reaction to the DTPa vaccine, which looks like fainting. Babies who have this reaction go limp and pale and don't respond to people around them for a short time. This is called a hypotonic–hyporesponsive episode (HHE). HHE is rare—in 2012, it was estimated that only 22 babies out of every million who receive DTPa vaccines in Australia experience an HHE. HHEs can be very frightening for parents, but studies have shown that children don't have any long-term brain or nerve disorders after an HHE. It is safe for these children to receive further doses of DTPa vaccines.

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Does the rotavirus vaccine cause intussusception?

Yes, rarely. There is a very small increased risk of intussusception following vaccination against rotavirus.

Rotavirus is a virus that causes severe inflammation of the stomach and bowel (gastroenteritis or gastro). Rotavirus is the most common cause of severe diarrhoea among infants and children throughout the world. It kills about 500,000 children worldwide every year. Intussusception is a rare form of bowel obstruction. It affects about 1 in 1,000 children, usually between 4 and 10 months of age.

The benefits of preventing gastroenteritis from rotavirus are much greater than the small risk of intussusception. Each year, the vaccine prevents about 7,000 children in Australia from being hospitalised because of rotavirus gastroenteritis. Because the benefits of rotavirus vaccination are high, and the occurrence of intussusception is extremely low, the World Health Organization, the Australian Technical Advisory Group on Immunisation and advisory bodies in other countries recommend that rotavirus vaccine is used for preventing rotavirus gastroenteritis in infants.

Two rotavirus vaccines are currently used in Australia—Rotarix® and RotaTeq®. They were tested in some of the largest and most stringent clinical trials ever conducted for any vaccine. The clinical trials found that the new vaccines had much less risk of intussusception than a previous vaccine called RotaShield®. RotaShield® was used in the United States in 1998 but withdrawn when safety monitoring found that it was associated with an increased risk of intussusception.

The new vaccines have been monitored since their release in Australia, the United States and other countries. The studies show that there may be a small increased risk of intussusception in infants in the first week after the first vaccine dose (for both Rotarix[®] and RotaTeq[®]). The increased risk is about 6 additional cases of intussusception in every 100,000 infants vaccinated. This is much lower than the risk of RotaShield[®]. Studies are continuing to see whether the vaccine really increases the risk, or just triggers an episode that children were prone to developing anyway.

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Can my child be vaccinated and when should they be vaccinated?

Can my child still be vaccinated if they have allergies?

Yes. Children with hayfever, eczema, or dustmite or food allergies can usually still be vaccinated with all of the vaccines on the Australian National Immunisation Program. In fact, it's very important that people with allergies are vaccinated to reduce their chance of getting a serious infection, which could make their existing condition worse.

Some vaccines contain ingredients that can be allergens (see **What ingredients are in vaccines?**). So, if you or your child are allergic to any foods or medicines, you should tell your doctor or nurse so they can check that the vaccines they plan to give you are safe.

But it's very rare for vaccines to either trigger an allergic response or anaphylaxis (a rapid and severe form of allergic reaction), or to worsen common allergies (see also **Do vaccines cause or worsen asthma and allergies?**). The risk of vaccine-related anaphylaxis following vaccination has been found to be less than 1 case per 1 million doses.

Common substances in vaccines that can be allergens are:

 Egg—Some vaccines may contain traces of egg proteins because the virus to be used for the vaccine is grown in chicken eggs. Vaccine viruses that are grown in eggs include measles, mumps and influenza.

People with an egg allergy, even an anaphylactic egg allergy, can safely havesuch vaccines. Measles-mumps-rubella (MMR) vaccines contain no egg protein and influenza vaccines contain only minute traces of egg protein. Studies have shown that people with an egg allergy don't need special precautions (such as split dosing, allergy testing with the vaccine or review by an allergy specialist) before vaccination.

However, yellow fever and Q fever vaccines might contain higher amounts of egg protein. People who have an egg allergy should seek expert advice before receiving these vaccines.

 Gelatin—Gelatin is a form of collagen (a protein) that usually comes from cows or pigs. It is added to some vaccines as a stabiliser (see What ingredients are in vaccines?).

The risk of allergic reaction to the gelatin used in vaccines is extremely low (1 case per 2 million vaccine doses). But people who have a gelatin allergy should seek expert advice before receiving vaccines containing gelatin. In Australia's National Immunisation Program, gelatin is found in the M-M-R II (MMR), Proquad (measles–mumps–rubella–varicella) Varivax Refrigerated (varicella) and Zostavax (varicella–zoster) vaccines.

Yeast—Some vaccines are manufactured using yeast. These include hepatitis B vaccines and human papillomavirus (HPV) vaccines.

Yeast is found in breads and bread products and some people have an intolerance to such products. This has caused some people to be concerned about a possible allergic response to yeast in vaccines. But there is no evidence that the trace amount of yeast in vaccines causes any harm.

 Antibiotics—Antibiotics that may be found in vaccines include neomycin, polymyxin B and gentamicin. These are a different class of antibiotics to penicillin and other similar antibiotics, which can sometimes cause allergic reactions. Reactions to the trace amounts of antibiotics in vaccines are extremely rare and mild.

People who are allergic to latex may be at risk during vaccination. This is because of the vaccination equipment, rather than the vaccine. People who have a latex allergy should tell the doctor or nurse and check the product information sheets to see whether latex is present in the vaccination equipment. If there are any doubts, they should consult a specialist clinic for further advice and management.

Further reading

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Can my child still be vaccinated if they have a genetic polymorphism?

Yes. There is no evidence that vaccination is not safe for people with a genetic polymorphism.

A genetic polymorphism is a change to a gene that is considered harmless to our health. (It is different from a gene mutation, which is a change that severely disrupts the functioning of a gene.)

MTHFR (methylenetetrahydrofolate reductase) gene polymorphisms have gained public attention in recent years. MTHFR polymorphisms are very common—almost 85% of the population has one or two, and there is no evidence that these cause any increased risk of health problems.

Two studies suggested that there may be a link between an MTHFR gene polymorphism and adverse reactions to a vaccine that is not used any more (live attenuated smallpox vaccine). These findings haven't been confirmed by any further studies.

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Are vaccines permitted (kosher) for observant Jewish children?

Yes. Vaccines are permitted for observant Jewish children.

Gelatin is added to some vaccines to act as a stabiliser to make sure the vaccine can be stored safely. Some people of the Jewish faith have questions about the use of gelatin from pork in the production of vaccines, because pork products aren't kosher.

Leaders of the Jewish faith have declared that pork-derived additives to medicines are permitted (see **What ingredients are in vaccines?**).

Rabbi Abraham Adler, from the Kashrus and Medicines Information Service in the United Kingdom, advises on kashrut issues. He released a statement in 2003 that said:

It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, injections, suppositories, creams and ointments.

Rabbi Adler's statement can be found on the **Institute for Vaccine Safety website** (www.vaccinesafety.edu/Porcine-vaccineapproval.htm).

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Are vaccines permitted (halal) for observant Muslim children?

Yes. Vaccines are permitted for observant Muslim children.

Gelatin is added to some vaccines to act as a stabiliser to make sure the vaccine can be stored safely (see **What ingredients are in vaccines?**). Some people of the Muslim faith have questions about the use of gelatin from pork in the production of vaccines, because pork products aren't halal.

Scholars of the Islamic Organization for Medical Sciences have determined that the transformation of the original pork product into gelatin alters it enough to make it permitted for observant Muslims to receive vaccines.

In 2001, a letter from the World Health Organization Regional Office for the Eastern Mediterranean reported on the findings of over 100 Islamic scholars who met to clarify Islamic purity laws. The letter stated that

...the gelatin formed as a result of the transformation of the bones, skin and tendons of a judicially impure animal is pure, and it is judicially permissible to eat it.

This ruling was applied to the use of gelatin in vaccines and medicine capsules. The letter can be found on the **Institute for Vaccine Safety website** (www.vaccinesafety.edu/Porcine-vaccineapproval.htm).

The Grand Mufti of Australia also released a letter in 2013 stating that the use of vaccines containing gelatin derived from pork was permitted.

Further reading

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Is it safe to give my child more than one vaccine at the same time?

Yes. Thorough research has shown that giving children several vaccines at the same time is safe.

Vaccines given at the same time can be either:

- combination vaccines, when two or more vaccines (that could be given separately) are given together in the one shot.
- concomitant vaccines, when two or more vaccines are given at the same time but as separate injections.

Both forms of multiple vaccines have been shown to be safe and to induce the same immune response as if given separately (see **How do vaccines work?**). This means that children receive the same protection as if they were given the vaccines separately, but with fewer injections. This means less pain and stress for the child.

Some parents may worry that infants receive too many vaccines, and that giving multiple vaccines at the same time might 'overwhelm' the child's immune system. But infants' immune systems are very strong. When babies are born, they encounter many thousands of different types of antigens (parts of organisms that cause disease, such as bacteria or viruses). Vaccines contain only a very small number of antigens compared with the large number that children encounter every day in their environment. Vaccines will actually strengthen your baby's immunity to protect them from some of the most dangerous infectious diseases (see **Do vaccines prevent death?** and **Why do children get more vaccines now than they did when I was young?**).

Further reading

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Can I space out or delay some vaccines given to my child?

No. It is not safe to space out or delay vaccines until your child is older, because babies are at greatest risk from disease while they are very young. The first dose of vaccine is recommended for the youngest age that a baby's immune system is mature enough to give a good response and thus good protection. So it is best to follow the National Immunisation Program schedule for all vaccinations.

When vaccines are delayed or spaced out, children are unprotected for longer than they need to be at the age when disease is most common or most serious. Small babies are more likely to catch a vaccine-preventable disease, and if they catch a disease they are more likely to get seriously ill or die.

The timing of each dose of every vaccine given to babies and children is carefully chosen and based on many decades of research. The timing considers:

- which diseases Australian children are likely to be exposed to and how early in life.
- how serious the diseases can be for children at different ages.
- which vaccines are safest and most effective.
- how many doses are needed to give full protection.
- the age at which vaccines give the best protection.

Some vaccines are only available in combinations and can't be separated or spaced out. These combination vaccines have been thoroughly tested and proven to be safe and effective.

Spacing out vaccines would also mean that a child is likely to need more vaccination appointments and injections. This would mean more stress for the child. Research has shown that children experience just as much stress when they get one needle as they do when they get more than one.

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How are vaccines made and tested?

How are vaccines made?

Vaccines are made from whole bacteria or viruses or their parts, or from toxins (poisons) produced by bacteria. In each case, these are changed so that they can't cause disease, but will still cause an immune response that will protect people from disease (see **How do vaccines work?**).

Every vaccine is made differently. There are four main methods:

- Live attenuated (weakened) viruses—In this method, viruses are weakened so that they can't reproduce well inside the human body. A natural virus may reproduce thousands of times to cause disease, but a weakened virus will reproduce fewer than 20 times. The advantage of live attenuated vaccines is that one or two doses are usually enough to give long-lasting immunity. However, people with weakened immune systems usually can't have these vaccines because even a few copies of a virus can make them very sick. Examples of these vaccines include measles—mumps—rubella (MMR), rotavirus and varicella (chickenpox) vaccines.
- Inactivated viruses—In this method, a virus or bacteria is completely killed using a chemical. The killed virus causes an immune response in our bodies, even though it can't reproduce or cause disease. The advantage of inactivated vaccines is that they can be given to people with weakened immune systems. However, several doses may be needed and people with weakened immunity may not respond. Examples of these vaccines include influenza, poliomyelitis (polio) and rabies vaccines.
- Inactivated bacterial toxins (toxoids)—In this method, toxins produced by the tetanus and diphtheria bacteria are inactivated using chemicals into harmless 'toxoids' that still cause an immune response. The advantage of toxoid vaccines is that they produce much stronger protective immunity than the disease itself (although boosters may be needed). People with weakened immune systems can safely have diphtheria and tetanus vaccines, but they may not respond adequately.
- Using only part of the virus or bacteria—In this method, the part of the virus or bacteria that causes an immune response is separated from the parts that cause disease symptoms. This part is then used in the vaccine. These vaccines can be safely given to people with weakened immune systems. But if the person's immune system is too weak, they may not develop an immune response that is strong enough to protect them from getting the disease if they are exposed to it in future. Examples of these vaccines include both bacterial (*Haemophilus influenzae* type b [Hib], pneumococcal, meningococcal) and viral (hepatitis B and human papillomavirus [HPV]) vaccines.

Further reading

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What ingredients are in vaccines?

There are six main ingredients that may be present in vaccines. All vaccines and their ingredients are fully tested for safety before they can be used in Australia (see **Are vaccines properly tested and monitored?**)

Two ingredients are in all vaccines:

- Active components (or antigens)—Antigens are a modified form of the virus, bacteria or toxin that causes the disease. Antigens are the most important part of a vaccine because they are the part that the body's immune system recognises and then responds to by producing antibodies (see How do vaccines work?). These antibodies then provide protection against the virus, bacteria or toxin. Vaccine antigens are modified so they cannot cause disease, but will still produce protective immunity (see How do vaccines work?).
- Diluents—These are liquids used to dilute vaccines so that they contain the right dose of antigen. Sterile saline (salt water) or water are usually used as diluents in vaccines.

Four other ingredients may be present, depending on the vaccine and how it's made. (see **How are vaccines made?**):

 Adjuvants—These are chemicals that increase our bodies' immune response to an antigen, making it more effective (see How do vaccines work?). Using adjuvants can reduce the amount of antigen that is needed in each dose of a vaccine and the number of doses needed to protect us from diseases. Not all vaccines contain adjuvants. For example, live vaccines don't contain adjuvants. (see How are vaccines made?).

Common adjuvants include aluminium salts such as aluminium hydroxide, aluminium phosphate and potassium aluminium sulfate. There is no evidence that the small amount of aluminium salts contained in vaccines causes any harm (see **Do vaccines contain aluminium or mercury?**).

- Stabilisers—These are substances that may be added to vaccines to make sure the vaccine can be stored and transported safely.
 Common stabilisers include sugars (such as lactose and sucrose), amino acids (glycine and monosodium glutamate), and proteins (such as serum albumin and gelatin). In some cases, the gelatin used in vaccines comes from pork. Jewish and Muslim leaders have said that such pork-derived additives to vaccines are permitted (see Are vaccines permitted (kosher) for observant Jewish children? and Are vaccines permitted (halal) for observant Muslim children?).
 People who have a gelatin allergy should seek expert advice before receiving vaccines containing gelatin.
- Preservatives These prevent contamination of the vaccine. Preservatives are only used in vaccines that come in containers with more than one dose in them (multidose vials), to protect against contamination. Multidose vials aren't used for any vaccines given in Australia's National Immunisation Program.
 Common preservatives are thiomersal (also known as thimerosal), phenoxyethanol and phenol. Thiomersal (a mercury-based preservative) is not used in vaccines in the National Immunisation Program any more, and there is no evidence that thiomersal has caused any health problems (see Do vaccines contain aluminium or mercury?).
- Trace components (or residues)—These are tiny amounts of substances used during manufacturing that might still be present in the vaccine. Depending on the manufacturing process used, this may include:
 - egg proteins—some vaccines may contain traces of egg proteins because the virus to be used for the vaccine is grown in chicken eggs. Vaccine viruses grown in eggs include measles, mumps and influenza (flu). People with an egg allergy, even an anaphylactic egg allergy, can safely be given such vaccines.
 - yeast—some vaccines are manufactured using yeast. Vaccine viruses grown in yeast include hepatitis B and human papillomavirus (HPV). There is no evidence that trace amounts of yeast in vaccines causes any harm.
 - antibiotics—these are sometimes used to ensure that vaccines aren't contaminated by bacteria during manufacturing. Common antibiotics used in vaccines include neomycin, polymyxin B and gentamicin. These are a different class of antibiotics to penicillin and similar antibiotics, which can sometimes cause allergic reactions. Reactions to trace amounts of antibiotics in vaccines are extremely rare and mild.
 - inactivating agents—these are used to inactivate the bacteria or toxin (see How are vaccines made?). Common inactivating agents are formaldehyde or glutaraldehyde. There is no evidence that the trace amount of these agents in vaccines causes any harm.

(See also Can my child still be vaccinated if they have allergies?)

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Do vaccines contain aluminium or mercury?

Some vaccines used in Australia contain aluminium, but no Australian vaccines contain mercury. There is no evidence that aluminium or mercury in vaccines causes harm.

(See also What ingredients are in vaccines?)

Aluminium

Some vaccines given to children in Australia's National Immunisation Program contain aluminium salts, such as aluminium hydroxide, aluminium phosphate and potassium aluminium sulfate. Aluminium salts are used in hepatitis A, hepatitis B, diphtheria– tetanus–pertussis (DTP), *Haemophilus influenzae* type b (Hib), human papillomavirus (HPV), meningococcal and pneumococcal vaccines.

There is no evidence that the small amount of aluminium salts contained in vaccines causes any long-term harm.

Aluminium salts are included in vaccines as adjuvants, which are chemicals used to increase the immune response to the vaccine (see **What ingredients are in vaccines?**).

Vaccines containing aluminium salts can increase the chance of swelling or inflammation (redness) at the injection site. They can also increase the chance of developing subcutaneous nodules (bumps under the skin) at the site, but this is rare.

But the amount of aluminium in vaccines is too small to cause any long-term health effects. The exposure to aluminium from vaccines is far less than we get from our diet or medicines. In the first 6 months of life, a baby would receive more than twice the amount of aluminium contained in vaccines through breast milk, or more than 10 times the amount through infant formula.

Aluminium salts have been added to some vaccines, in small amounts, for about 60 years. A recent review of all the available studies of diphtheria, tetanus and pertussis (whooping cough) vaccines that contain aluminium found no evidence that the aluminium salts cause any serious or long-term harm.

Mercury

None of the vaccines given to children in Australia's National Immunisation Program contain mercury. Some vaccines that are used overseas contain thiomersal (also known as thimerosal), which is a compound containing ethyl mercury. Thiomersal is a preservative which was used to prevent bacteria from contaminating vaccines that come in containers with more than one dose in them (multidose vials).

Thiomersal is now only rarely used in vaccines because new technologies and cheaper packaging have made it unnecessary. Most vaccines used in developed

countries are now given from single-dose vials or syringes, so a preservative is no longer needed in the vaccine.

There is no evidence that the mercury in vaccines has caused any long-term harm.

Some people worry that the ethyl mercury in vaccines could harm children or adults because they have been warned to avoid eating fish and other foods than can contain methyl mercury. Methyl mercury can be harmful because it can build up in our bodies and damage the nervous system. However, thimerosal is a different compound with a similar name. Ethyl mercury doesn't build up in people's bodies and does no long-term harm.

All the scientific evidence shows that vaccines that contain thiomersal are safe:

- A review published in the journal *Pediatrics* in 2004 assessed all the published studies of vaccines that contain thiomersal. The review found that vaccines with thiomersal in them don't cause autism or increase the chances that a child will develop autism.
- A review of research studies published by the Institute of Medicine in the United States in 2004 also found that vaccines with thiomersal in them don't cause autism or increase the chances that a child will develop autism.

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Are vaccines properly tested and monitored?

Yes. Vaccines must meet the highest possible safety standards. All vaccines used in Australia are tested before they are released for use in the community. Once vaccines are in use in the community, each batch is monitored for safety during manufacture and for any unanticipated problems during use.

Before use

All vaccines must be tested to make sure they are safe before they can be used.

Vaccines are first tested on animals to check if they could cause harm. Then, if a vaccine is found to be safe in animal trials, it's thoroughly tested in humans in three phases of clinical trials:

- Phase 1 trials test the new vaccine in a small number (25–50) of healthy adults.
 The main aim of these trials is to assess safety that is, that the vaccine doesn't cause any harm to patients.
- Phase 2 trials test the vaccine in more people (usually hundreds). The main aims
 of these trials are to see if the vaccine is effective, how much vaccine or how
 many doses are needed to give adequate immune responses, and whether
 there are any side effects.
- Phase 3 trials test the vaccine in thousands of people. The main aims of these trials are to establish whether the vaccine is effective in large numbers of people and to detect uncommon or serious side effects.

Every vaccine given to Australians must pass all three phases before it can be used in Australia. The approval process from discovery to use can take up to 10 years and sometimes even longer.

During manufacture

Rules around the safe manufacturing of vaccines ensure that every vaccine dose is safe. Every manufacturer must be accredited and meet strict manufacturing and production standards.

During use

Vaccines used in Australia are constantly monitored for safety and effectiveness. If people who have recently been vaccinated experience an adverse event (an adverse event is an unintended and sometimes harmful occurrence associated with the use of a vaccine or medicine), this should be reported. All reports received are reviewed by Australia's Therapeutic Goods Administration. Vaccines can be withdrawn from use if problems are found. For example, a rotavirus vaccine licensed in the United States in 1998, RotaShield[®], was quickly withdrawn when there were safety concerns. The vaccine appeared to be safe in clinical trials, but surveillance (monitoring) during use in millions of children found it was associated with an increased risk of intussusception (a rare form of bowel obstruction). As soon as this problem was discovered, the vaccine was withdrawn from the market. Rotashield[®] was never released in Australia, and the two currently available rotavirus vaccines have a different composition to RotaShield[®] (see also **Can rotavirus vaccines cause intussusception?**).

Australia also has a system called AusVaxSafety, which monitors the safety of vaccines. This system uses a short SMS survey to ask patients, or parents of children, in a large number of general practices around Australia, how they felt in the first few days after vaccination. AusVaxSafety has now captured information from hundreds of thousands of people and this shows that the rates of adverse effects after vaccination are extremely low in Australia (see also **What side effects might occur with vaccines?**).

Further reading

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Are some vaccines made using fetal tissue?

Yes, but the connection is remote because the tissue was taken once in the 1960s, and no new tissue has been taken since then.

Viruses need living cells to replicate. Viruses that are needed to produce vaccines are grown in the laboratory in cells or 'cell lines'. A cell line is a population of cells that is grown continuously in the laboratory for extended periods. Once established, cell lines have an unlimited lifespan and so are a renewable and predictable system for growing viruses.

The best cell types in which to grow human viruses originally came from a sample of human tissue. It is very hard to grow some viruses that infect humans in any other type of cell.

Some cell lines (called human diploid cell lines WI-38 and MRC-5) used to produce vaccines came from fetal tissue. The tissue came from 3 abortions performed for medical reasons in the 1960s. These cell lines have been growing under laboratory conditions since then. There has been no new tissue taken from fetuses for cell lines since the 1960s.

Vaccines available in Australia that are manufactured using cell lines that originally came from fetal tissue include rubella, hepatitis A, varicella (chickenpox) and rabies.

The world's major religions (Bahá'í Faith, Buddhism, the major denominations of Christianity, Confucianism, Daoism, Hinduism, Islam, Jainism, Judaism, Shinto and Sikhism) consider that the use of vaccines with remote fetal origins is permitted and ethical when there are no alternative products available. An expert report from the Vatican in 2005 said that the use of vaccines with remote fetal origins was acceptable to protect the health of children and pregnant women.

Further reading

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For more information visit the website www.health.gov.au/immunisation



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