

Myths and concerns about vaccination

Vaccine manufacture and testing

The safety of vaccines is very important as they are given to *prevent* disease, and immunisation programs are targeted at all or many members of the population, most of whom are healthy. Concerns about the manufacture and testing of vaccines mostly relate to the possibility that vaccines may contain toxic or harmful substances or biologic agents used in the manufacturing process. The most common questions and facts relating to these are summarised below. The components of vaccines are discussed further in the section ‘Realities of vaccination’.

‘Vaccines are unsafe’

The facts

In general, no pharmacologic agent, including vaccines, can be considered 100 per cent safe. However, all vaccines currently available in Australia must pass stringent safety testing before being approved for use by the Therapeutic Goods Administration (TGA), Australia’s regulatory authority for therapeutic goods. This testing is required by law and is usually done over many years during the vaccine’s development. In addition, the safety of vaccines is continually monitored once they are in use, by the TGA and other organisations. Immunisation providers play an important role in reporting adverse events following immunisation which assists in safety surveillance after a vaccine is registered for use in Australia.

The majority of problems thought to be related to the administration of a vaccine are actually not due to the vaccine itself. Many are coincidental events that just happen to occur at the same time as vaccination. This is particularly the case in the first year of a child’s life, when vaccines are given regularly. Events that occur in the child’s first year of life may therefore coincide with the time that a vaccine has been received. A good example of this is a six-month-old infant having a seizure. If the seizure started one hour

after a vaccination, it would be natural to think differently about why it may have occurred than if it commenced one hour before the vaccination.

Vaccines may produce some undesirable side effects, such as pain and redness at the injection site or fever, but most reactions are mild and resolve quickly. It is usually not possible to predict who may have a mild reaction and who may have a rarer, serious reaction to a vaccine. However, the risk of adverse effects can be minimised by following guidelines regarding when vaccines should and shouldn't be used.

Further reading

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'Vaccines are not adequately tested'

The facts

Before vaccines are made available for use they are rigorously tested in thousands of people in progressively larger clinical trials which are strictly monitored for safety. All vaccines registered in Australia by the TGA are manufactured and tested according to strict safety guidelines and are evaluated to ensure they are effective, comply with strict manufacturing and production standards, and have a good safety record.

The approval process can take up to 10 years. As a result of such detailed testing, a number of vaccines have failed in these early tests and have never been released.

After the introduction of a vaccine into general use, there is ongoing review of vaccine efficacy and safety through a variety of mechanisms, such as further clinical trials and surveillance of disease and vaccine adverse events (i.e. post-registration surveillance). In Australia, there are regional and national surveillance systems that collect reports of any adverse events following immunisation (AEFI). These AEFI reports include any untoward medical occurrence that follows immunisation. The occurrence may not necessarily have a causal relationship with the vaccine but may occur by chance (i.e. it would have occurred regardless of vaccination). These reports are regularly reviewed by the TGA and referred to expert committees, as required, if potential safety issues arise.

Each year, a summary of AEFI reports made to the TGA, including analyses of AEFI reporting rates, is published in the journal *Communicable Diseases Intelligence* which is freely accessible via the Australian Government Department of Health and Ageing website (see further reading list below). In 2012, the TGA made available on its website a searchable database, the Database of Adverse Event Notifications (DAEN), that lists all adverse event reports for medicines (including vaccines), irrespective of whether causality has been established.

In response to the continual review of vaccine safety after a vaccine program is introduced, the registration of a vaccine can change. For example, a rotavirus vaccine licensed in the United States in August 1998, Rotashield[®], was withdrawn from the market because of concerns regarding its safety. In pre-licensure trials, the vaccine appeared to be safe, but post-licensure surveillance found it was associated with a large increased risk of intussusception (a rare form of bowel obstruction occurring in infants). 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 are different in composition to Rotashield[®]. The current vaccines underwent testing in around 70,000 young children prior to licensure and have been monitored in post-licensure studies to assess the potential risk of intussusception. This is discussed further under 'Safety concerns: Specific vaccines'.

Further reading

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Mahajan D, Cook J, Dey A, Macartney K, Menzies RI. Annual report: surveillance of adverse events following immunisation in Australia, 2011. *Communicable Diseases Intelligence* 2012;36:E315-32. www.health.gov.au/internet/main/publishing.nsf/Content/cda-aeifi-anrep.htm (accessed Mar 2013).

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'Vaccines contain foreign proteins'**The facts**

Depending on their purpose and specific composition, vaccines can contain live viruses, killed viruses, purified viral proteins, inactivated bacterial toxins or bacterial polysaccharides. Vaccines are complex pharmaceutical products which need to withstand transport, storage and environmental factors. To ensure they are stable over time, vaccines can contain additives, such as gelatin or albumin. Furthermore, some vaccines contain tiny residual quantities of substances used during the manufacturing process, such as formaldehyde, antibiotics, egg proteins or yeast proteins.

An example of a question which arises relating to vaccines containing foreign material is the presence of egg proteins. Some vaccines, such as influenza, yellow fever and Q fever vaccines and one rabies vaccine, are grown in eggs and need to be given with caution to people with known egg allergy. The risk of an allergic reaction to these vaccines depends on the amount of egg protein (ovalbumin) in the vaccine and the extent of a person's allergy.

The majority of influenza vaccines in use in Australia have only trace amounts of ovalbumin (less than 1 microgram) per dose and can be safely given to most people with an egg allergy. However, individuals with a severe allergy to eggs should still seek specialist advice.

Yellow fever, Q fever and one of the rabies vaccines contain a higher amount of ovalbumin and generally should not be given to people with known severe allergy to eggs.

The measles and mumps viruses for vaccines are grown in chick embryo cell lines, *not* in eggs. It is now recognised that measles- and mumps-containing vaccines (MMR and MMRV) contain negligible amounts of egg protein and can be given to children with egg allergy, even those with anaphylaxis to egg. If reassurance regarding the vaccination of a child with egg or other allergies is required, the child can be referred to a specialist immunisation clinic, paediatrician or infectious diseases specialist with a specific interest in immunisation. Specialist immunisation advice can be obtained from state or territory health authorities.

Further reading

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'Vaccines are contaminated with foreign viruses'

The facts

While bacterial vaccines are not grown in cells, viruses cannot survive outside of cells. Therefore, viral vaccines require cells in which the attenuated (weakened) vaccine viruses can be grown. The viruses in current viral vaccines are grown in either the cells of chicken eggs (flu vaccines) or in cell lines (populations of a specific cell type which are grown continuously in the laboratory). These cells are thoroughly screened for foreign (adventitious) agents such as other viruses or bacteria. Any other materials or reagents used in the production of vaccines are also thoroughly tested for purity, sterility and for the absence of possible contaminants.

Concerns about the presence of foreign viruses in vaccines are discussed further in the sections on 'Safety concerns: General' and 'Safety concerns: Specific vaccines'.

Further reading

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Finn TM, Egan W. Vaccine additives and manufacturing residuals in the United States: licensed vaccines. In: Plotkin SA, Orenstein WA, Offit PA, eds. *Vaccines*. 6th ed. Philadelphia: Elsevier Saunders; 2013.

'Vaccines contain toxic additives'

The facts

All vaccines marketed in Australia are assessed by the TGA to ensure they meet strict safety guidelines prior to being registered for use. This includes stringent testing for all vaccine components, including adjuvants, preservatives, additives and any manufacturing residuals.

Adjuvants, most commonly aluminium salts (known as alum), are added to some vaccines to enhance the immune response to the vaccine. Aluminium intake from vaccines is lower than everyday intake from diet or medications, such as antacids, and is well below the levels recommended by organisations such as the United States Agency for Toxic Substances and Disease Registry. A review of all available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) found that there was no evidence that aluminium salts in vaccines cause any serious or long-term adverse events. More redness and swelling at the injection site is associated with aluminium-containing vaccines compared to those not containing aluminium, but this is usually mild.

Preservatives are used in some vaccines to prevent bacterial and fungal growth. In practice, preservatives are no longer used in most vaccines available in Australia as the vaccines are now produced in single-use sealed vials. However, preservatives are required when vaccines are produced in multi-dose vials for mass vaccination, usually as an emergency measure, for example, during a pandemic. In the past, a preservative occasionally used was thiomersal (or thimerosal), a mercury-based product. Thiomersal contains a form of mercury called ethyl mercury which has not been associated with any of the toxic effects linked to the related compound, methyl mercury, a known neurotoxin. Thiomersal has been used in very small amounts in vaccines for about 80 years with no evidence of it being harmful. Thiomersal is discussed further in the section 'Safety concerns: General'.

Antibiotics, such as neomycin and polymyxin B, are used in some vaccines to prevent bacterial contamination during manufacturing. There are concerns that antibiotics in vaccines may be harmful on the basis that, sometimes when antibiotics (most commonly penicillins and sulphonamides) are given

to people to treat infections, they can cause systemic allergic reactions. However, penicillins and sulphonamides are *not* contained in any vaccines used in Australia. Immediate-type hypersensitivity reactions to the trace quantities of neomycin used in some vaccines have not been reported in Australia. Previous skin reactions to neomycin are not a contraindication for use of neomycin-containing vaccines.

Further reading

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Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics* 2003;112:1394-401.

Orenstein WA, Paulson JA, Brady MT, Cooper LZ, Seib K. Global vaccination recommendations and thimerosal. *Pediatrics* 2013;131:149-51.

'Vaccines are cultured on cell lines from aborted fetuses'

The facts

There has been concern about the morality of receiving vaccines when the cells in which the vaccine virus is grown may have been originally obtained from an aborted fetus.

Although bacteria can, under the right supportive conditions, survive and replicate on their own, viruses require cells in order to replicate and can only be grown in the laboratory in cells or 'cell lines'. A cell line is a specific population of cells that is maintained in culture for extended periods. Cell lines have an unlimited lifespan and represent a renewable and predictable system for growing viruses used in the production of vaccines. The best cell types in which to grow human-specific viruses are often cell lines derived originally from a sample of human tissue. It is very hard to grow some viruses that infect humans in any other type of cell.

Certain cell lines (human diploid cell lines WI-38 and MRC-5) originated from fetal tissue obtained from three elective abortions indicated for medical reasons in the 1960s. These cell lines have been growing under laboratory conditions for more than 40 years. There has been no further tissue obtained from fetuses since the 1960s. Abortions have not been conducted specifically for the purpose of harvesting cell lines. Vaccines available in Australia which are manufactured using cell lines originally derived from fetal tissue include rubella-containing vaccines (MMR and MMRV), hepatitis A vaccines, varicella vaccines and rabies vaccine.

Some people with religious objections to abortion have questioned the use of these vaccines. In response, a statement by The Vatican includes the comment that “as regards the disease against which there is no alternative... if the latter [population as a whole] are exposed to considerable dangers to their health, vaccines with moral problems pertaining to them may also be used on a temporary basis ... this is particularly true in the case of vaccination against German measles [rubella]”.

Further reading

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Immune system

'Vaccines weaken or overwhelm the immune system'

The facts

Healthy people have the capacity to mount a response to every infection they could possibly encounter. Vaccines do not weaken the immune system but strengthen it by stimulating defence mechanisms that provide protection against specific diseases.

The body's immune system begins developing before birth. In the period during and soon after birth, when the functions of the immune system are still maturing, newborns are protected against many, but not all, serious infections by antibodies from their mothers (maternal antibodies). This protection usually lasts for about four months. National immunisation programs are designed to balance the capacity of the baby's immune system to respond to the vaccine, against the risk of infection. Vaccines only contain a small number of antigens in comparison to what children encounter every day in their environment, through routine eating, drinking and playing, and they do not overwhelm or 'use up' the immune system.

If giving multiple vaccines overwhelmed the immune system, then one might expect much lesser immune responses when many vaccines are given at the same time compared with when they are given at different times. However, when vaccines are developed, they are studied to confirm that the addition of a new vaccine (and the existing vaccines given at the same time) still have the same immune response and safety profile. In addition, combination vaccines (such as the five- or six-in-one DTPa-containing vaccines and the combination measles-mumps-rubella-varicella (MMRV) vaccine) are all rigorously tested during the vaccine's research and development phase to ensure that the immune responses to each vaccine antigen are adequate.

Further reading

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'Immunisation is unnatural'

The facts

Vaccines use a person's natural response to disease to stimulate the immune system so that if someone is exposed to that specific pathogen in the future, their immune system can 'remember it' and mount an effective response to either stop disease developing or reduce the severity of disease.

Some believe that vaccination is unnatural and that contracting the disease will provide optimal protection against it, as well as benefits to overall health. Tied with this is the belief that vaccination interferes with the body's natural processes. However, choosing to remain unvaccinated, and have the disease rather than prevent it, can have serious consequences. Diseases such as tetanus and meningitis can kill and maim, whereas the vaccines against these diseases are generally well tolerated with minor side effects. Vaccines provide the same stimulus to the immune system as an infection and can potentially offer more effective protection against certain pathogens. Most importantly, protection through vaccination avoids the complications associated with having the disease. The benefits of vaccination far outweigh those of infection with a vaccine-preventable disease.

Homoeopathic ‘immunisation’ has not been proven to give protection against infectious diseases; only conventional vaccination produces a measurable immune response. Homoeopathic preparations are discussed below.

Further reading

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‘Homoeopathic preparations are an alternative to conventional vaccines’

The facts

There is no scientific basis to support the use of any homoeopathic preparation in preventing diseases targeted by conventional vaccines. However, the effectiveness of conventional vaccines is well established through large-scale studies of their safety and efficacy.

There have been very few studies where homoeopathic preparations have been subjected to any scientific scrutiny. None of these studies have been on a preparation for use against a disease on the current national immunisation schedule. Therefore, the efficacy of homoeopathic preparations against these diseases has not been established.

Several homoeopathic substances marketed as ‘vaccines’ are available. Most of these preparations are manufactured by making successive dilutions of disease, tissue or plant extracts, to the point where none of the original material is contained within the preparation. This process of ‘succussion’ is said to transfer the protective activity of the original material to the diluting water. However, there is no biologically plausible mechanism for how the ingestion of homoeopathic preparations could prevent infections and/or their related diseases.

Many homoeopathic practitioners support conventional vaccination to protect against vaccine-preventable diseases. The Australian Homoeopathic Association and the United Kingdom Medical Association for Homoeopathy recommend conventional vaccination with standard vaccines. The Society of Homeopaths in the United Kingdom does not encourage its members to advise patients against vaccination.

Further reading

Australian Homoeopathic Association. Vaccination issues. www.homeopathyoz.org (accessed Jan 2013).

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Sulfaro F, Fasher B, Burgess MA (on behalf of The Immunisation Interest Group of the Royal Alexandra Hospital for Children). Homoeopathic vaccination: what does it mean? *Medical Journal of Australia* 1994;161:305-7.

'Specific immunity is not important for protection from disease'

The facts

The immune system comprises two major sections: the 'non-specific' (innate) and the 'specific' (adaptive). The non-specific immune system is the first line of defence against invading pathogens and includes physical, chemical, molecular and cellular defences. The specific immune system is a second line of defence acting against specific pathogens; through developing immune memory, it provides protection against future re-exposure to the same pathogen. Specific immunity is primed when individuals are vaccinated against a specific pathogen, for example, measles.

Some believe that factors such as having a healthy lifestyle and good nutrition can replace the need for the specific immunity provided by vaccines. While having a healthy lifestyle may increase the immune system's general

capacity, exposure to a specific disease antigen through vaccination is the only means (other than getting the disease itself) of stimulating an immune response specifically against that disease, irrespective of diet and lifestyle factors. Factors such as diet, healthy lifestyle and stress avoidance can be important for general well-being; however, this alone will not protect against specific diseases.

There is also a belief that breastfeeding children means they do not need to be vaccinated. Maternal antibodies alone, such as those provided through breastfeeding, are not sufficient to protect a baby against all infections. Maternal antibodies do provide some protection to the newborn but the amount of protection varies with different diseases and the presence of maternal antibodies is dependent on the mother's prior exposure to the actual disease or antigen. For example, mothers who have not recently been immunised or infected with pertussis (whooping cough) generally only pass on minimal protection against pertussis to their baby. In addition, the low amount of antibody that is transferred rapidly wanes during the first weeks, leaving the infant vulnerable to infection if they are exposed to pertussis. On the other hand, maternal antibodies against measles may provide protection to the infant for up to 12 months. These factors are taken into account when vaccine schedules are planned. Importantly, for certain diseases, such as influenza, vaccination of a woman during her pregnancy protects her against this disease, as well as protecting her baby in the baby's first few months of life (due to the passage of high levels of maternal antibodies across the placenta prior to birth).

Further reading

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‘Vaccines cause or worsen asthma and allergies’

The facts

There is no evidence that vaccines cause or worsen allergic diseases such as asthma or eczema. There are many studies that have examined whether wheezing occurs more commonly in children after they have received vaccines, and it is clear that this is not the case. It is especially important that children with asthma be given all recommended vaccines, as catching a disease like pertussis or influenza can worsen asthma. In Australia, influenza vaccination is particularly recommended for children with asthma because of this risk.

In some people vaccines or their components can cause allergic reactions; however, the risk of this is low. For example, the risk of anaphylaxis (a rapid and life-threatening form of allergic reaction) after a single vaccine dose has been estimated as less than one in a million. However, this risk varies depending on the vaccine type. Components of vaccines which can trigger allergic reactions include gelatin, yeast and egg protein. Vaccination of people who are allergic to eggs is discussed further in the section ‘Vaccine manufacture and testing’. It is important to elicit the presence of particular allergies and the exact nature of the allergic response if present. Children or adults with most food or environmental allergies, such as dust mite or hayfever, can be safely vaccinated.

Vaccination is *contraindicated* where a person has experienced:

- anaphylaxis following a previous dose of a particular vaccine, or
- anaphylaxis following any vaccine component.

If a healthcare provider is unsure about vaccinating a person with a history of an allergic reaction following a vaccine or vaccine component, they should contact a specialist immunisation clinic, paediatrician or infectious diseases specialist with a specific interest in immunisation. Specialist immunisation advice can be obtained from state or territory health authorities.

Further reading

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Need for vaccination

'Infectious diseases are not serious'

The facts

Some argue that infections are a normal and healthy part of growing up. However, the infectious diseases that vaccines target can be serious and even fatal. These diseases were common in Australia and other countries prior to vaccination, but with the introduction of vaccines and very high vaccination rates in the community, the number of cases of these diseases has been reduced. Current generations of parents are unlikely to have seen a child paralysed by poliomyelitis who requires an 'iron-lung' to assist with breathing, a child with obstructed breathing due to diphtheria, or someone with brain damage due to measles. Other diseases like varicella (chickenpox) are generally considered as mild childhood diseases. However, varicella can be severe or fatal, particularly in immunocompromised children and adults.

Influenza is sometimes dismissed as not being a serious illness. Many people will refer to the common cold as 'the flu'. However, influenza is not the same as the common cold and is a serious infection, particularly in the elderly. In Australia, there are dozens of deaths every year where influenza is officially reported as the cause of death. However, this is a large *underestimate* of the true number of deaths due to influenza as many are not recognised. It is estimated that, in Australia, there are over 3,000 deaths due to influenza per year in people aged over 50 years alone.

Other vaccine-preventable diseases, such as meningitis from *Haemophilus influenzae* type b (Hib), meningococcus or pneumococcus, while not very commonly seen, can also be associated with serious health consequences. See 'Realities of vaccination' for further information.

Further reading

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Newall AT, Wood JG, MacIntyre CR. Influenza-related hospitalisation and death in Australians aged 50 years and older. *Vaccine* 2008;26:2135-41.

‘Improved living standards, not vaccination, have reduced infectious diseases’

The facts

Some argue that improved health and hygiene have caused the dramatic decline in infectious diseases over the last century, not vaccines. To support this argument, graphs are used to depict declining disease death rates before the introduction of vaccines and no visible impact from vaccination. These graphs always show death rates overall rather than disease incidence and hide the true effect of vaccines.

While overall improvements in living standards, healthcare and treatment have reduced deaths from all diseases, the additional impact of vaccines themselves is illustrated by the near disappearance of deaths from diphtheria, tetanus, pertussis, polio and measles (see ‘Deaths from vaccine-preventable diseases’). Such a dramatic decline in deaths after vaccine introduction, often in short periods of time, could not possibly be attributed to improvements in living conditions or medical treatment alone.

Some examples which demonstrate that vaccines have had a marked impact on the incidence of infectious diseases include:

- Hib vaccine was introduced into the Australian standard vaccination schedule in 1993. In 1992, there were 560 cases of Hib disease notified but in 2006–2007, only 39 cases were notified. Sanitation and living conditions have clearly not changed since 1993 and so cannot be the cause of the marked fall in Hib cases and deaths.

- A rise in invasive meningococcal disease due to serogroup C occurred in Australia during the late 1990s. In early 2003, a conjugate vaccine against meningococcal C was introduced and the number of meningococcal C cases dropped from 225 cases in the year prior to vaccine introduction to less than 15 cases per year in recent years.

Often the best way to demonstrate the impact a vaccination program has had on the incidence of vaccine-preventable diseases is to examine the impact of the disease in a community where vaccination rates are low but living standards are high.

For example:

- There have been two major epidemics of poliomyelitis in Holland (1984 and 1991) occurring in a religious group who refused vaccination. There was no spread to the rest of the population, whose uptake of polio vaccine was very high.
- There was a decline in the acceptance of pertussis vaccine in Britain in the mid-1970s. Between 1977 and 1979, there was an epidemic of 102,500 cases of pertussis during which 27 children died from the direct consequences of pertussis and 17 developed permanent neurological damage. Acceptance of pertussis vaccine has now improved to about 93 per cent and pertussis has declined. Similar large epidemics occurred in Japan and Sweden at about the same time due to low acceptance of pertussis vaccine.
- There was a resurgence of measles in Britain following falls in measles immunisation rates in the wake of the now discredited claims of links between MMR vaccine and autism (discussed in the section 'Safety concerns: Specific vaccines'). This resulted in thousands of cases of measles, including some deaths, and loss of the United Kingdom's previously obtained measles elimination status. In contrast, Australia continues to have no 'home grown' measles (i.e. has eliminated measles), but there have been recent measles outbreaks, arising from imported measles cases, in small areas in Australia where measles vaccine coverage rates have been low.

Higher standards of living and sanitation alone unfortunately do not ensure protection from infectious diseases. With short travel times over large distances, infectious diseases can be carried from countries with greater

disease prevalence. Cases have occurred in unimmunised people all around the world as a result of travel to or from areas where vaccine-preventable diseases are still very common.

Further reading

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‘Diseases are virtually eliminated so vaccination is not needed’

The facts

Some people believe that vaccine-preventable diseases have been almost entirely eliminated and that, in Australia, the risk of exposure to infectious disease is minimal so no vaccination program is needed.

Although the majority of people in Australia have been fully vaccinated, resulting in a marked reduction in targeted diseases, it is now important that vaccination rates be kept as high as possible.

One important reason to maintain high vaccination rates in Australia is to protect the wider community, particularly vulnerable people with medical problems that mean they cannot be vaccinated themselves. When a significant proportion of individuals in a population are protected against a disease through vaccination, people who are still susceptible to the disease are indirectly protected as they are less likely to come into contact with someone with the disease or infection. This effect is known as ‘herd immunity’. However, for herd immunity to be effective, vaccination rates among the population have to be high.

Although many vaccine-preventable diseases are rarely seen in Australia today, they are still common in many other countries around the world.

Travellers returning from countries where vaccine-preventable diseases are still common have been known to bring home diseases such as measles. In this situation, there is greater potential for an outbreak of disease to occur in communities where vaccination rates are low or have declined.

Reductions in vaccination rates can lead to diseases coming back. This has happened in the past with polio in many developed countries, with diphtheria in the former Soviet Union and, more recently, with measles in the United Kingdom.

Further reading

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‘Vaccines cause or spread the diseases they are supposed to prevent’

The facts

The majority of vaccines available in Australia are inactivated or prepared from only part of the pathogen. This means the components of the vaccine are not living and therefore cannot cause disease.

An exception to this is live attenuated viral vaccines which contain weakened (or ‘attenuated’) forms of the virus that the vaccine aims to protect against. The weakened virus does replicate in the host to create an immune response, but cannot cause disease, except on very rare occasions. There are also other types of live vaccines which contain a naturally occurring organism that does not itself cause disease in humans but which is closely related to (and can therefore induce protection against) the human pathogen which can cause disease. Some of the live vaccines available in Australia include

measles-, mumps- and rubella-containing vaccines (MMR and MMRV), varicella (chickenpox) vaccine and BCG (bacille Calmette-Guérin, for tuberculosis and leprosy) vaccine.

After most natural infections and most vaccines, the infecting organism or antigens do not persist in the body because they are eliminated by the immune response they induce. An exception to this is the virus that causes chickenpox and then remains dormant in sensory nerves to (sometimes) reactivate later in life and cause herpes zoster (shingles). Similar to what happens following natural infection, in some people vaccinated with the live attenuated varicella vaccine, the vaccine virus will reactivate later in life to cause shingles. However, this occurs at a much lower rate than following natural varicella infection, and reported cases have been mild.

Similarly, if a vesicular skin rash occurs at the injection site of a varicella vaccine (which occurs in five people out of every 100 people who receive the vaccine), there is the potential to transmit the vaccine virus to someone else through direct contact with the rash. However, transmission of vaccine virus in this way is extremely rare. In the United States, where more than 56 million doses of varicella vaccine have been distributed over 10 years, there have been only six documented cases of transmission of the vaccine virus from an immunocompetent vaccinated person to others. The MMR vaccine can also cause a transient rash 7 to 10 days after vaccination, but it is non-infectious.

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'People who are vaccinated can still get the disease'

The facts

Some people argue that since cases of vaccine-preventable disease occur in those who have been vaccinated, vaccines are not effective. However, this is not completely true.

There is a relationship between vaccination rates, vaccine effectiveness and apparent vaccine failures. Where vaccination rates are high and an outbreak of disease occurs, the numbers of cases in vaccinated people can appear to be high in relation to the number of cases among those who are unvaccinated. This apparent paradox is because of two factors:

- First, no vaccine is 100 per cent effective. To make vaccines safer than the disease, the bacteria or virus is killed or weakened (attenuated). For reasons related to individuals' genetics, not all vaccinated people develop immunity. Most routine childhood vaccines are effective in 85 to 95 per cent of recipients. That means that in every 100 people who receive a vaccine, between 5 and 15 of them may not develop protective immunity.
- Second, in a country such as Australia, the people who have been vaccinated against the common childhood vaccine-preventable diseases vastly outnumber those who have not.

How these two factors work together to bring about a situation where the majority of cases in an outbreak occur in those who have been vaccinated is explained using the following hypothetical scenario.

In a high school of 1,000 students, none has ever had measles disease. All but five of the students have had two doses of measles vaccine, and so are fully immunised. The entire student body is exposed to measles, and every susceptible student becomes infected. The five unvaccinated students will be infected, of course. But of the 995 who have been vaccinated, we would expect several to have not responded to the vaccine. The efficacy rate for two doses of measles vaccine can be as high as 99 per cent so, in this school, ten students will have not responded to the vaccine, and they too become infected. Therefore, 10 of 15, or about 67 per cent, of the cases will be in students who have been fully vaccinated.

However, this doesn't prove the vaccine didn't work – only that most of the children in the school had been vaccinated, so those who were vaccinated and did not respond outnumbered those who had not been vaccinated. Looking at it another way, 100 per cent of the children who had not been vaccinated got measles, compared with around one per cent of those who had been vaccinated. Measles vaccine protected most of the students. If nobody in the school had been vaccinated, there would probably have been 1,000 cases of measles.

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'Some people have objections to vaccines based on religious beliefs'

The facts

Some religious groups have concerns about the origin or characteristics of some vaccine ingredients, for example, gelatin (partially hydrolysed collagen, usually of bovine or porcine origin). Gelatin is added to some vaccines to act as a stabiliser against adverse conditions, such as temperature extremes, which may affect the vaccine quality. Some members of the Islamic and Jewish faiths may object to vaccination arguing that vaccines can contain pork products. However, scholars of the Islamic Organization for Medical Sciences have determined that the transformation of the original pork product into gelatin alters it sufficiently to make it permissible for observant Muslims to receive vaccines. Likewise, leaders of the Jewish faith have also indicated that pork-derived (but transformed) additives to medicines are permitted.

The concern about vaccines being cultured on cell lines from aborted fetuses is discussed in the section on 'Vaccine manufacture and testing'.

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Safety concerns: General

‘Mercury in vaccines can cause autism’

The facts

There is no evidence that thiomersal (a mercury-based preservative) in vaccines has caused any health problems, except perhaps minor reactions such as redness at the injection site.

Thiomersal (also known as thimerosal) has been used in very small amounts in some vaccines since the 1930s to prevent bacterial and fungal contamination. The form of organic mercury contained within thiomersal is ‘ethyl mercury’ which doesn’t accumulate in the body, unlike the closely related ‘methyl mercury’ which does accumulate and is neurotoxic. The different forms of mercury occur naturally in the environment (in the air, earth and ocean) and in fish. Mercury is also used in industrial processes, dental fillings and thermometers. Mercury is harmful only after it reaches a certain level in the body, and the toxicity depends on the amount of mercury consumed, the form of mercury consumed, body weight and the time period of exposure. Although there are clear neurotoxic effects of methyl mercury absorption in humans, well-designed toxicity studies examining ethyl mercury accumulation suggest that a relationship between ethyl mercury in vaccines and neurologic toxicity is biologically implausible. Many well-conducted studies and reviews by expert panels have shown that there is no evidence of developmental or neurologic abnormalities, such as autism, having resulted from the use of vaccines containing thiomersal.

Since 2000, vaccines available on Australia’s National Immunisation Program have not contained thiomersal as they are now produced in single-use sealed vials that do not require the use of a preservative. This reduces the total exposure of young children to any form of mercury in a world where other environmental sources (particularly food such as fish) may be more difficult to eliminate. Some vaccines, such as pneumococcal vaccines, MMR vaccine and other live attenuated viral vaccines, never contained thiomersal. When vaccines are produced in multi-dose vials, for example, as an emergency measure during a pandemic, thiomersal may be used as a preservative to prevent the growth of bacteria after the vial has been opened for the first time.

There has also been a proposed theory linking the MMR vaccine and autism specifically. However, this was due to one published study that has since been retracted due to the data being fraudulent. All epidemiological studies since have disproven this theory. The concern about the relationship between MMR vaccine and autism is further discussed in the section 'Safety concerns: Specific vaccines'.

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'Vaccines can cause diabetes'

The facts

Worldwide, there has been much research that has searched for a link between diabetes and immunisations, but there is no evidence that vaccines cause diabetes.

The incidence of type 1 diabetes is increasing in developed countries including Australia. This increase was noted to have begun at a similar time to the introduction of widespread childhood vaccination. One study postulated that vaccination at an early age (younger than two months) protected against type 1 diabetes, whereas vaccination after this date increased the risk of developing type 1 diabetes. Originally, these claims implicated the Hib vaccine but later included the BCG vaccine for tuberculosis and, more recently, the MMR and pertussis-containing vaccines.

Following the reports described above, many large well-conducted studies have found *no* link between any of the recommended childhood vaccines and type 1 diabetes, nor have they been able to verify the findings of the earlier studies. Changes in the timing of vaccination have not been shown to alter

the risk of developing diabetes.

It is recommended that people with diabetes should be vaccinated according to the Australian National Immunisation Program schedule. The influenza vaccine is currently recommended annually for people with diabetes.

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'Vaccines can cause cancer'

The facts

Two vaccines, hepatitis B vaccine and human papillomavirus (HPV) vaccine, actually act to directly *prevent* cancer, as opposed to modifying the risk of cancer by attention to factors such as diet, exposure to tobacco smoke and lifestyle behaviours. The hepatitis B vaccine prevents liver cancer (associated with hepatitis B infection) and the HPV vaccine prevents cervical and other anogenital cancers (associated with HPV infection). Both of these vaccines are inactivated vaccines which means they are not made of live virus and there is no biological way that these vaccines could cause cancer.

However, some people believe that vaccines can cause cancer because some batches of injectable polio vaccines produced between 1957 and 1963 were contaminated with a simian virus (called SV40) that may be linked to the development of some cancers.

Simian virus 40 (SV40) is a virus found in some species of monkey and

thought to be possibly involved in cancer. Between 1955 and 1963, some of the polio vaccine administered in the United States was unknowingly contaminated with SV40. The virus came from the monkey kidney cell lines used to produce the vaccine. Because SV40 was not even discovered until 1960, no one was aware that polio vaccines made in the 1950s could have been contaminated. However, all polio vaccines since the early 1960s have been screened for SV40.

None of the current poliomyelitis vaccines used in Australia contain SV40.

It is known that SV40 can be found in certain types of human cancer, such as mesotheliomas (rare tumours located in the lungs), brain and bone tumours, and some types of non-Hodgkin's lymphoma. However, the possible role that SV40 plays in human cancers is not fully understood and is the topic of continued research. Most information, including many large studies done in Europe and the United States, strongly suggests that there is no increased risk of cancer in people who were given vaccine containing SV40 between 1955 and 1963 compared with people who never received polio vaccine at that time.

A similar review commissioned by the Australian TGA found that, while there is some concern that there could be a link between SV40-contaminated vaccine and some cancers, studies of groups of people who received polio vaccine between 1955 and 1963 do not show an increased cancer risk.

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'Vaccines cause mad cow disease'

The facts

Bovine spongiform encephalopathy (BSE) is a rare neurodegenerative, and ultimately fatal, brain disease of cattle with an incubation period of more than four years. It is also known as a 'spongiform encephalopathy'. It was only discovered in 1986 that some humans had developed a form of 'mad cow disease', known as variant Creutzfeldt-Jakob disease (vCJD), from eating beef from infected cattle. Most cases of BSE and vCJD have been reported in the United Kingdom (UK) or Europe. In the UK there have also been four known cases of vCJD associated with blood transfusions received between 1996 and 1999. There have been no cases of vCJD reported among people in the UK who received other blood-derived products or vaccines. Despite many millions of doses of vaccines being administered worldwide, there have been no reported cases of vCJD associated with vaccines.

The Australian TGA has confirmed that all vaccines available in Australia have been manufactured using materials from BSE-free areas and comply with Australian guidelines for minimising the risk of transmission of agents causing spongiform encephalopathies.

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'Vaccines are linked to Guillain-Barré syndrome'

The facts

Guillain-Barré syndrome (GBS) is a rare neurologic disorder involving inflammatory demyelination of peripheral nerves. It is estimated that every year there are one to two newly diagnosed cases of GBS for every 100,000 people in the population (0.001–0.002%). The most severe cases of GBS result in paralysis, sometimes requiring respiratory support if the chest wall muscles are affected. GBS can occur spontaneously (without any identified cause) or after certain events such as infections, including infection with *Campylobacter jejuni*, a bacterium that causes gastroenteritis.

In the United States in 1976, receipt of that year's seasonal influenza vaccine formulation was associated with an increased risk of getting GBS. Several studies have been done to evaluate if other influenza vaccines since 1976 have been associated with GBS. These long-term studies have only found a very small increase in GBS following influenza vaccination of approximately one additional case for every one million people vaccinated against influenza (above the number that would have occurred anyway without vaccination).

Isolated case reports have suggested a possible association of GBS with several other vaccines including oral polio, MMR, tetanus toxoid-containing and hepatitis B vaccines. However, robust epidemiologic studies have not demonstrated any link. In the United States, a possible association between GBS and a quadrivalent meningococcal conjugate vaccine used in teenagers was reported to the United States Vaccine Adverse Events Reporting System (VAERS). However, a subsequent investigation found that this vaccine was not associated with an increased risk of GBS.

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'Vaccines cause sudden infant death syndrome'

The facts

Sudden infant death syndrome (SIDS) is defined as the sudden and otherwise unexplained death of an infant under one year of age. The incidence of SIDS peaks at two months of age, the age at which Australian children are recommended to receive their first vaccines. This apparent 'association' between the timing of vaccination and SIDS deaths has been examined to determine whether there is a causal link.

A number of well-controlled studies in the last 20 years have found, almost unanimously, that the number of SIDS deaths associated in time with DTP vaccination was within the range expected to occur by chance and irrespective of vaccination. This data is important to highlight when chance associations do occur. For example, a study using Australian data from 1997–2001 calculated that, by chance alone, approximately two of the 130 SIDS cases per year would have occurred within the 24-hour period after vaccination. To date all of the published evidence suggests that vaccination does not increase the risk of SIDS, and some studies have suggested that vaccination may lower the risk.

There are several well-established risk factors for SIDS, such as putting the baby into bed in a prone (face-down) position and smoking by the parents. Major reductions in SIDS deaths in Australia and internationally can be attributed to successful campaigns that have focused on reducing these risk factors.

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'Vaccines cause shaken baby syndrome'

The facts

The claim that shaken baby syndrome (SBS) can be due to vaccines has been primarily made in the context of mounting a defence in prosecutions for the death or injury of infants.

Shaken baby syndrome is caused by non-accidental shaking of young infants and is characterised by certain types of intracranial haemorrhages (subdural/subarachnoid), brain swelling, and retinal haemorrhages. The theory that vaccines are associated with SBS is not supported by detailed consideration of the pathophysiology of SBS, well-conducted vaccine safety studies or surveillance for vaccine-related adverse events.

There is *strong* scientific evidence that intracranial and retinal haemorrhages can be caused by shaking of young infants but no credible evidence of any link with vaccination. The vaccine theory rests on three misconstrued

assumptions. The first assumption is that vaccines cause encephalitis which leads to brain swelling similar to that of SBS. However, encephalitis is rarely, if ever, caused by vaccines. The second assumption is that convulsions from fever following vaccination can be violent enough to cause the bleeding and fractures seen in SBS. However, children who experience febrile seizures do not develop intracranial haemorrhages or fractures from the seizure alone. The third contention is that since thrombocytopenia is a well-established, though rare, serious reaction to MMR vaccine, bleeding following vaccination could cause retinal haemorrhages similar to SBS. However, infants with SBS do not usually have thrombocytopenia, MMR vaccine is not given until 12 months of age, and intracranial bleeding is rare with thrombocytopenia of any cause.

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Safety concerns: Specific vaccines

‘MMR vaccine causes inflammatory bowel disease and autism’

The facts

The MMR vaccine does not cause autism or inflammatory bowel disease (IBD). This theory was proposed by a group of researchers in the United Kingdom (UK) in 1998. They suggested that measles virus in the gut caused a new syndrome of IBD that resulted in decreased absorption of essential vitamins and nutrients through the intestinal tract. It was suggested that this, in turn, caused developmental disorders such as autism, or worsening of symptoms in children already diagnosed with autism, so-called ‘regressive autism’.

Although this theory generated a lot of media attention, the few studies on which it is based have a number of significant weaknesses and have since been retracted. Ten of the 13 authors of the original 1998 study (published in *The Lancet*) published a statement in 2004 retracting the paper’s findings, stating that the data were insufficient to establish a causal link between MMR vaccine and autism. *The Lancet* subsequently retracted the original paper and an investigation into the original data has shown it to be fraudulent.

Numerous well-conducted studies and expert panel reviews since 1998 have now produced conclusive evidence that there is no link between MMR vaccine and autism or IBD. A review by the World Health Organization (WHO) concluded that current scientific data do not show any causal link between the measles virus and autism or IBD. Extensive reviews published by the Institute of Medicine (IOM), an independent expert body in the United States, also concluded that there is no association between the MMR vaccine and the development of autism. Other reviews by the American Academy of Paediatrics, the British Chief Medical Officer, the UK Medical Research Council, and Canadian experts have also found no link between autism or IBD and measles-containing vaccines.

It has also been suggested that giving each component of MMR vaccine separately over time would be better than giving MMR as a combination

vaccine. However, there is no scientific evidence to support this suggestion. In fact, giving each component separately may be harmful because vaccination for each disease would be delayed, leaving the child susceptible to these diseases and, in turn, leaving the population susceptible to disease outbreaks. National and international expert bodies all recommend that MMR vaccine should continue to be used.

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'Pertussis vaccine causes brain damage'

The facts

The pertussis vaccine does not cause brain damage.

DTP vaccine includes components to induce immunity to diphtheria (D), tetanus (T) and pertussis (P). The pertussis component of DTP vaccine was originally manufactured from inactivated whole pertussis organisms (designated as DTPw). These DTPw (or 'whole-cell') vaccines were commonly associated with local reactions (such as redness, swelling and pain at the injection site), fever, and mild to moderate systemic side effects (such as drowsiness, fretfulness and loss of appetite). Whole-cell vaccines are no longer used in Australia. All DTP vaccines used in Australia now contain purified components of the pertussis bacterium and are referred to as

'acellular' pertussis vaccines, or DTPa. These newer DTPa vaccines have a much lower incidence of fever and local reactions than DTPw vaccines.

With respect to the whole-cell vaccines, in a study of more than 2 million children in the United States, administration of DTPw was not associated with increased risk of encephalopathy. With respect to the current acellular vaccines, a study of all suspected cases of encephalopathy in Canada over a 10-year period concluded that, in all cases, the encephalopathy was related to a pre-existing medical condition or infection and was not caused by vaccination.

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'Polio vaccines cause HIV/AIDS'

The facts

Some have argued that an oral polio vaccine used in the 1950s (developed by Dr Hilary Koprowski) was contaminated with simian immunodeficiency virus (SIV), a primate virus that gave rise to the human immunodeficiency virus (HIV)-1 that infects humans and which causes acquired immunodeficiency syndrome (AIDS).

However, there are a number of factors that counter this argument:

- Testing of the Koprowski vaccine found no contamination with either SIV or HIV.
- There are no recordings of the Koprowski vaccine being given to the people in whom AIDS was first identified.
- The vaccine was given to people in Europe and Africa, but early AIDS cases were only seen in people in Central Africa.
- The Koprowski vaccine was documented as being produced in cells from Asian monkeys which do not carry the viruses thought to be responsible for HIV.

Even if a theory about unofficial use of cells from local (Belgian Congo) chimps were true, more recent molecular epidemiological research demonstrates that the wild chimps from the Belgian Congo had a form of SIV that did not match any HIV-1 strains that affect humans.

The vaccine–HIV argument is now thoroughly discredited.

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'Hepatitis B vaccine causes multiple sclerosis'

The facts

There is no evidence that hepatitis B vaccine, or any other vaccine, causes multiple sclerosis (MS). MS is a chronic illness resulting from inflammation of myelin, a protective covering over nerves in the brain and spinal cord. The cause of MS is unknown, but genetic and environmental factors appear important.

There was concern about hepatitis B vaccination and MS in France in the 1990s. There were reports of MS or MS-like illness occurring after administration of hepatitis B vaccines in a large-scale vaccination program of adolescents/young adults, an age group where MS often first presents. The French government initially stopped the vaccination program. However, on further study, the rate of MS in vaccinated people was found to be the same as the usual rate of MS in the population.

Numerous other studies performed around the world, and expert panels from the World Health Organization, the Institute of Medicine and the Centers for Disease Control and Prevention in the United States, agree that there is no evidence to support the theory that vaccination with hepatitis B vaccine, or any other vaccine, is associated with an increased risk of multiple sclerosis.

There is also evidence that vaccination does not worsen the symptoms or cause relapses of MS.

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'Flu vaccines cause the flu'

The facts

It is impossible for the influenza vaccine to cause 'the flu' (influenza disease). The vaccines registered for use in Australia are all inactivated, which means they do not contain live virus. The vaccines used are either 'split-virion' or 'sub-unit' vaccines which only contain the surface structures of the virus, not infectious particles.

The belief that the vaccine causes the flu could result from misinterpretation of either mild vaccine side effects or coincidental infection from other respiratory viruses, both of which can cause 'flu-like' symptoms. The incubation period for influenza is between 24 and 72 hours, and the vaccine takes 7 to 14 days to produce protection, so occasionally a vaccinated person may contract the influenza virus during this period.

All vaccines elicit an immune response. Some of these responses can include a mild fever and headache, amounting to flu-like symptoms. This could result in the mistaken belief that the vaccine has given someone the flu. These side effects may occur with many different types of vaccines.

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'Vaccination of young children can cause seizures'

The facts

Febrile convulsions (sometimes referred to as seizures) are a relatively common response to fever of any cause in young children. In most cases, these seizures are mild and improve on their own. Overall, by the age of five years, approximately three in every 100 children will have experienced a febrile convulsion, irrespective of whether a vaccine is given. As fever is a well-documented adverse event following the administration of many common childhood vaccines, it is not unexpected that febrile convulsions may occur following vaccination, although it is still very rare. The risk is higher following administration of certain vaccines, such as influenza, MMR and MMRV vaccines.

For example, MMR and MMRV vaccines are associated with an increased risk of a febrile convulsion between 7 and 12 days after the first dose of vaccine, compared with other periods. It is estimated that one extra child out of every 3,000 who receive MMR vaccine will experience a febrile convulsion during this period. When the MMRV vaccine is given as the first dose of MMR-containing vaccine, the risk of fever and febrile convulsions during this period is approximately two times greater than if MMR and varicella vaccines are given separately. It is for this reason that MMRV vaccines are not recommended as the first dose of MMR-containing vaccine in children under four years of age. Children in this age group are more likely to experience convulsions when they have a high fever.

Seasonal (inactivated trivalent) influenza vaccines are considered safe in children from six months of age. However, in 2010, one brand of seasonal influenza vaccine (Fluvax[®] and Fluvax[®] Junior, CSL Limited) resulted in higher rates of fevers and febrile convulsions in children under five years of age than other influenza vaccines. Fluvax[®] is no longer registered for use in children under five years and must not be used in this age group. The risk of febrile convulsions following influenza vaccination is discussed in more detail below.

Further reading

Kohl KS, Marcy SM, Blum M, et al. Fever after immunization: current concepts and improved future scientific understanding. *Clinical Infectious Diseases* 2004;39:389-94.

Australian Technical Advisory Group on Immunisation. *The Australian Immunisation Handbook*. 10th ed. Canberra: Australian Government Department of Health and Ageing; 2013.

'The flu vaccine causes febrile convulsions in young children'**The facts**

Overall, seasonal influenza (flu) vaccines are generally safe in children from six months of age and febrile convulsions following vaccination are rare. However, in 2010, one brand of seasonal influenza vaccine (Fluvax® and Fluvax® Junior, CSL Limited) resulted in higher rates of adverse events, particularly fevers and febrile convulsions in children under five years of age, than other influenza vaccines. Following an extensive review of the evidence around the use of seasonal influenza vaccines in children, by the TGA and the Australian Technical Advisory Group on Immunisation (ATAGI), it was advised that this specific brand of vaccine be no longer used in children. This was because the risk of febrile convulsions after this vaccine was up to one in 100 in children under five years of age, while the acceptable background rate of febrile convulsions in this age group is less than one in 1,000. There was no excess risk of fever and febrile convulsions identified in children in this age group following vaccination with any of the other brands of influenza vaccine. Fluvax® is now not registered for use in children under five years of age in Australia, and an alternative brand of influenza vaccine is recommended for vaccination of children up to 10 years of age.

Giving the seasonal influenza vaccine and 13-valent pneumococcal conjugate vaccine (13vPCV) at the same time may also be associated with an increased risk of febrile convulsions in young children, compared to when either vaccine is given separately. However, as this risk is still relatively low (18 additional cases for every 100,000 doses of these vaccines administered together),

13vPCV and seasonal influenza vaccine can still be given to children at the same visit. Health professionals should ensure that parents are aware of the risk and offer alternative vaccination options, such as vaccination on separate days, if parents are concerned.

Ensuring young children are vaccinated against influenza is important as they are at higher risk of getting influenza than other age groups and, if they do get the disease, they are more likely to experience severe complications. Children are also involved in the transmission of the influenza virus to others in the community.

Further reading

Armstrong PK, Dowse GK, Effler PV, et al. Epidemiological study of severe febrile reactions in young children in Western Australia caused by a 2010 trivalent inactivated influenza vaccine. *BMJ Open* 2011;1:e000016. doi:10.1136/bmjopen-2010-000016.

Australian Government Department of Health and Ageing. Review of data on the safety of seasonal influenza vaccines, particularly Fluvax (CSL Biotherapies) in adults and children >10 years. 2012. www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/review-fluvax (accessed Jan 2013).

'There is a link between rotavirus vaccine and intussusception'

The facts

Intussusception is a rare form of bowel blockage caused by telescoping of the intestine into itself. It is most common in young infants. About 200 cases per year occur in infants under 12 months of age, independent of vaccination. Intussusception usually resolves on its own or can be successfully treated with a specialised enema or surgical intervention. There have been no deaths due to intussusception in Australia in the last 15 years.

The risk of intussusception following rotavirus vaccines has been closely monitored in Australia and elsewhere because of the association of a previously licensed vaccine (Rotashield®) which had an unacceptably high risk of intussusception. This vaccine is discussed further in the section 'Vaccine manufacture and testing'. Clinical trials of the currently used

rotavirus vaccines did not identify an association between intussusception and vaccination. However, studies since the vaccines came into use have identified a nine-fold increased risk of intussusception in the first seven days after the first dose of vaccine and a two-fold increased risk in the first seven days after the second dose of vaccine. It is estimated that this increased risk would result in six additional cases of intussusception among every 100,000 infants vaccinated, or 18 additional cases per year in infants in Australia.

However, it is estimated that rotavirus vaccination prevents approximately one to two deaths and more than 7,000 hospitalisations each year in Australia. The ATAGI and TGA have reviewed available evidence and found that the benefits of rotavirus vaccination outweigh the risks associated with it, and a review of the risks and benefits carried out by the WHO reached the same conclusion. Rotavirus vaccines therefore continue to be recommended for use in Australia and globally on the basis of this positive benefit to risk profile.

Health professionals should ensure that rotavirus vaccine is not given to infants above specified upper age limits; the benefit and safety profile of vaccination in older children has not been established. They should also inform parents and carers of the rare risk of intussusception, how to be alert for the signs and symptoms of the condition, and what action to take. Parents can be directed to the Immunise Australia website for additional information.

Further reading

Buttery JP, Danchin MH, Lee KJ, et.al. Intussusception following rotavirus vaccine administration: post-marketing surveillance in the National Immunization Program in Australia. *Vaccine* 2011;29:3061-6.

Australian Technical Advisory Group on Immunisation. *The Australian Immunisation Handbook*. 10th ed. Canberra: Australian Government Department of Health and Ageing; 2013.

Dey A, Wang H, Menzies R, Macartney K. Changes in hospitalisations for acute gastroenteritis in Australia after the national rotavirus vaccination program. *Medical Journal of Australia* 2012;197:453-7.

'HPV vaccines are unsafe and cause infertility or problems with pregnancy'

The facts

HPV vaccines have been developed primarily to prevent cervical cancer. However, HPV vaccines also provide protection against other cancers in both men and women including anal cancer, penile cancer, and head and neck cancers. HPV vaccines have been evaluated for safety and efficacy in the same manner as for all other vaccines administered in Australia. The Food and Drug Administration (FDA) in the United States, the TGA in Australia and the European Medicines Agency (EMA) have concluded that HPV vaccines are safe and effective.

In clinical trials the main side effect of the HPV vaccines was a local reaction at the injection site (pain, redness and swelling) which occurred in about 80 per cent of those who received the vaccine. Other reported side effects were fever, headache and fatigue but these were no more common in vaccine recipients than in placebo recipients. Very few serious adverse events were reported following vaccination (in less than 0.1 per cent of vaccine recipients) and they were no more frequent than in those receiving the placebo vaccine. Participants vaccinated in the clinical studies have been evaluated for up to four years after the vaccine was given to determine if they experience higher rates of new medical conditions, including autoimmune diseases. No trends or patterns of new medical conditions or safety concerns have been identified during the follow-up period. As with all vaccines administered in Australia, adverse events following vaccination are still being monitored now that the vaccine is in use. (See also the section on 'Vaccine manufacture and testing' for further information.)

There is no biologically plausible way in which the HPV vaccine could cause infertility in either women or men. HPV infection, unlike some other sexually transmitted infections such as chlamydia, is not a cause of infertility. Studies of high doses of the HPV vaccine in female and male rats showed no effect on fertility. Some Internet sites report disturbing claims that one ingredient of the vaccine, polysorbate 80, causes infertility in rats. This is based on one study of newborn rats (weighing 10 to 17 grams) that were

injected in the abdomen with very large doses of polysorbate 80 (20 to 200 times the amount in Gardasil® HPV vaccine). However, the TGA has reviewed available data regarding polysorbate 80 and fertility and concluded that there is no evidence that polysorbate 80 at the level of 50 micrograms per 0.5 millilitre dose in Gardasil® poses a hazard to human reproduction or fertility. Polysorbate 80 is found in numerous medications, including other vaccines, and is used as an additive in foods and cosmetics.

While it is recommended that vaccination be avoided during pregnancy, there is no evidence that inadvertent administration of the HPV vaccine to a pregnant woman will result in an increased risk of adverse pregnancy outcomes. Although participants were requested to avoid pregnancy, during Phase 3 trials of Gardasil® there were 1,796 pregnancies in women who received Gardasil® and 1,824 pregnancies in women who received a placebo. The rate of adverse pregnancy outcomes was similar in both groups of women.

Further reading

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Human papillomavirus (HPV) vaccines for Australians: information for immunisation providers (fact sheet). 2013. www.ncirs.edu.au/immunisation/fact-sheets/index.php (accessed Mar 2013).

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Quadrivalent HPV vaccine: frequently asked questions (fact sheet). 2013. www.ncirs.edu.au/immunisation/fact-sheets/index.php (accessed Mar 2013).