Myths and Realities

Responding to arguments against immunisation

A GUIDE FOR PROVIDERS

Australian Government

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IMMUNISATION

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1 INTRODUCTION

Immunisation has been repeatedly demonstrated to be one of the most effective medical interventions to prevent disease. It has been estimated that immunisations currently save 3 million lives per year throughout the world and are one of the most cost effective health interventions that exist.

Modern vaccines provide high levels of protection against several diseases, and the consequent disability and death that can occur with these diseases. Furthermore, serious reactions to immunisation are rare.

Vaccines are administered to healthy people to prevent diseases which have become rare, largely thanks to vaccination. These factors contribute to concerns about vaccine safety.

In some instances, unwarranted concerns about the safety of certain vaccines have led to downturns in immunisation rates and outbreaks of disease.

Most of the arguments against immunisation appeal to parents' understandable deep-seated concerns for the health of their children. Unfounded allegations regarding adverse effects from vaccines typically target feared diseases, syndromes or conditions of unknown or uncertain cause such as autism, sudden infant death syndrome or multiple sclerosis.

In discussing concerns about immunisation, with parents or adults, it is important to recognise that a logical demonstration of the weaknesses in arguments against immunisation needs to be combined with listening and other good communication skills.

This publication gives health professionals information to address some of the most commonly held myths about immunisation.

2 BELIEFS ABOUT IMMUNISATION

The public may come across mixed and often confusing messages that can leave them feeling ambivalent about immunisation.

The majority of Australians are supportive of immunisation. Among parents, only a minority refuse vaccines for their children. Their rejection of immunisation is often combined with a wider scepticism of orthodox medical intervention and support for alternative approaches to health. Others may have had a personal experience where they or their child may have experienced an adverse event following immunisation. Some people can become vocal opponents of immunisation, spreading messages against immunisation in the mass media, internet and through grassroots lobbying. The theories espoused frequently have no sound scientific basis or misrepresent the scientific literature. However, they may be difficult to totally *dis*prove.

The most common concerns about immunisation centre on an intuitive belief that vaccines adversely affect the immune system. For new parents, an added factor is that babies are seen as vulnerable and as having an immature immune system. Multiple vaccines are often given at the one visit to children and this can also generate concerns about how a child's immune system can respond.

3 RESPONDING TO CONCERNS

Health professionals are the single most important influence on individuals making a decision to immunise themselves or their children.

It is important that immunisation service providers be well informed about immunisation and are a good source of authoritative and scientifically valid advice. To obtain valid consent, it is important that immunisation service providers honestly discuss the benefits and risks of vaccination. With the increasing number of vaccines on the immunisation schedule, there may be insufficient time to address each vaccine-preventable disease in detail. In such circumstances, resources like this one and the booklet *Understanding Childhood Immunisation* can help.

It is important to remember that there is no need to be defensive about immunisation. If parents raise arguments against immunisation, immunisation service providers should explore their reasons for doing so, then tailor appropriate information to the person's individual circumstances and education levels. They should treat decision making as a partnership between themselves and their patient or client. Immunisation service providers should emphasise the benefits of immunisation and, to the extent required, also explain the risks of disease and complications which result from withholding immunisation.

Information about expected adverse events which commonly occur following immunisation, such as pain at the injection site, fever and fussiness, should also be provided. Immunisation providers should think carefully before offering their own personal opinions and present the risks and benefits of vaccines objectively.

Immunisation service providers should respect differences of opinion about immunisation. It is also helpful to understand the personal, cultural and religious background that may influence a person's decision.

MYTHS AND CONCERNS ABOUT IMMUNISATION

Vaccine Manufacture and Testing

The safety of vaccines is very important as they are given to *prevent* disease, and target 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 of toxic or harmful substances being contained in them or to 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 "Vaccine Composition".

1. 'Vaccines are unsafe'

The Facts

In general, no pharmacologic agent, including vaccines, can be considered 100% safe. However, all vaccines currently available in Australia must pass stringent safety testing before being approved for use by the Therapeutic Goods Administration (TGA). 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 monitored once they are in use, by the Adverse Drug Reactions Advisory Committee (ADRAC) and other organisations.

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 be linked in time to immunisation. This is particularly the case in the first year of a child's life, when immunisation occurs so regularly that many events that occur will coincide with the time after which a vaccine has just 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. However, most reactions are mild and resolve quickly. It is usually not possible to predict which individuals may have a mild or a more rare, serious reaction to a vaccine. However, by following guidelines regarding when vaccines should and shouldn't be used, the risk of adverse effects can be minimised.

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Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics* 2003; 112:1394-7.

2. '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. These trials are strictly monitored for safety.
All vaccines registered in Australia by the Therapeutic Goods Administration (TGA) are manufactured and tested according to strict safety guidelines and are evaluated to ensure they are efficacious, 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 that failed in these early tests 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. In Australia, there are regional and national surveillance systems that collect reports of any adverse events following immunisation (AEFI). Each year, there are reports of AEFI published in the journal *Communicable Diseases Intelligence*, which is freely accessible via the Australian Government Department of Health and Ageing website.

An example of a vaccine that was withdrawn after marketing because of concerns regarding its safety was the rotavirus vaccine called Rotashield®, which was licensed in the USA in August 1998. In pre-licensure trials, the vaccine appeared to be safe, but post-licensure surveillance found it was associated with an 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 each new rotavirus vaccine has undergone testing in around 70,000 young children to rule out a risk of bowel obstruction.

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3. '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 which are 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 vaccines, the yellow fever vaccine and one rabies vaccine, are grown in eggs and must not be given to a person with known egg allergy. However, the measles and mumps vaccine viruses are grown in chick embryo cell cultures *not* actual eggs, and it is now recognised that measles-mumps-rubella (MMR) vaccine contains negligible amounts of egg protein. Children with egg allergy, even anaphylaxis to egg, can be safely given MMR vaccine by their usual provider. However, if reassurance regarding the vaccination of a child with egg or other allergies is required, they may be referred to a specialist immunisation clinic, paediatrician or infectious diseases specialist with a specific interest in immunisation. Information regarding specialist immunisation services is available via the Immunise Australia website http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-reactions.

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Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics* 2003; 112:1394-7.

4. '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 vaccine viruses can be grown. The viruses in current viral vaccines are propagated in either the cells of chicken eggs (flu vaccines) or continuous cell lines, which are thoroughly screened for adventitious (foreign) 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 known contaminants.

See also "Vaccines cause cancer" and "Polio vaccines cause HIV/AIDS".

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5. 'Vaccines contain toxic additives'

The Facts

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

Adjuvants, most commonly aluminium salts, are added to some vaccines to enhance the immune response. Aluminium from vaccines is lower than everyday exposure from 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 recent 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 alumimium, but this is usually mild.

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 as some antibiotics, most commonly penicillins and sulphonamides, can cause systemic allergic reactions. However, penicillins and sulphonamides are *not* contained in any vaccines used in Australia. For the antibiotic-containing vaccines used in Australia, the occurrence of immediate type-hypersensitivity to the trace quantities of neomycin has not been noted and previous skin reactions to neomycin are not a contraindication for use of neomycin-containing vaccines.

Other preservatives are used to prevent bacterial and fungal contamination of some vaccines. One preservative that is occasionally used is a mercury-based product, thiomersal (or thimerosal). Thiomersal has been used in very small amounts in vaccines for about 60 years, and is discussed further in the section "Safety Concerns: General".

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6. ‘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. ‘Cell lines’ are a specific population of cells that are maintained in culture for extended periods. They have an unlimited lifespan and represent a renewable and predictable system for growing the viruses used in the production of vaccines.
The best cell type in which to grow human-specific viruses are often cell lines derived originally from a sample of human tissue. It is very hard for some viruses that infect humans to be grown 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. The vaccines manufactured using cell lines originally derived from fetal tissue include: rubella vaccine and MMR vaccine, hepatitis A vaccines, varicella vaccines, rabies vaccine, and oral polio (Sabin) vaccine (no longer available in Australia).

Some individuals 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]”.

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Immune System

1. 'Vaccines weaken or overwhelm the immune system'

The Facts

Some worry that vaccines weaken or overwhelm the immune system, particularly when given to babies or when multiple vaccines are given at the same time. Vaccines do not weaken the immune system. They strengthen it by inducing protection against specific diseases of children and adults.

Children are exposed to many foreign antigens on a daily basis through activities such as routine eating, drinking and playing. Providers can therefore be confident in reassuring parents that their infant's immune system is very robust and designed to respond to multiple challenges. Vaccines only contain a small number of antigens in comparison to what children encounter every day in their environment and do not overwhelm or 'use up' the immune system.

The only situation where a vaccine has been found to temporarily suppress, rather than enhance, the immune system was immune suppression following the use of a particular high-titre measles vaccine. This immune suppression is less than that following natural measles and these vaccines have *never* been used in countries such as Australia. There is no evidence of this effect with other vaccines.

If vaccines overwhelmed or weakened the immune system, then one would expect lesser immune responses when vaccines are given at the same time as compared with when they are given at different times. When vaccines are developed, they are studied to see if the new vaccine gives the same immune response and safety profile when used together (at separate sites) with other vaccines on the immunisation schedule. In addition, combination vaccines, such as the five- or six-in-one DTPa-containing vaccines and the combination measles, mumps, rubella and varicella (MMRV) vaccine, are all rigorously tested during the research and development phase to ensure that the immune responses to each vaccine antigen are adequate.

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World Health Organization (WHO). Immune overload. 2006. Available at: http://www.who.int/vaccine_safety/topics/immune_overload/en/ (accessed Mar 2007).

2. 'Immunisation is unnatural'

The Facts

Some believe that immunisation is unnatural and that allowing nature to 'run its course' will provide optimal protection against the disease as well as benefits to overall health.
One reason often given for vaccination refusal is 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. It is therefore important to reinforce the concept that vaccines provide the same stimulus to the immune system as an infection but, most importantly, avoid the complications associated with disease.

Vaccines use a person's natural response to disease to stimulate the immune system so that if someone is exposed to that specific virus or bacteria 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.

Homoeopathic 'immunisation' has not been proven to give protection against infectious diseases; only conventional vaccination produces a measurable immune response (see "Homoeopathic preparations are an alternative to conventional vaccines").

Further Reading

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3. 'Specific immunity is not important for protection from disease'

The Facts

Some believe that factors such as having a healthy lifestyle and good nutrition can replace the need for the specific immunity provided by vaccines. Immunisation is the only proven means of protection against vaccine-preventable diseases, 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.

Maternal antibodies alone, such as those provided through breastfeeding, are also 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 pass on only minimal protection against pertussis (whooping cough) to the baby and the little protection that is transferred rapidly wanes during the first weeks, leaving the infant vulnerable to infection if exposed to pertussis. On the other hand, maternal antibodies against measles may provide protection to the infant for 6 to 12 months. These factors are taken into account when vaccine schedules are planned.

4. '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, whereas the effectiveness of conventional vaccines is well established through large scale studies of their safety and efficacy.

There are very few studies where homoeopathic preparations have been subjected to any scientific scrutiny. None of these studies is of a preparation against a disease on the current immunisation schedule recommended by the National Health and Medical Research Council, so the efficacy of these preparations is not established.

Many homoeopathic practitioners support traditional immunisation to protect against vaccine-preventable diseases. The United Kingdom Medical Association for Homoeopathy recommends orthodox immunisation with standard vaccines. The Society of Homeopaths in the United Kingdom does not encourage its members to advise patients against vaccination.

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 to the diluting water. Many of the schedules to administer these preparations are complex, extending over a period of years with multiple doses.

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

5. 'Vaccines cause or worsen asthma and allergies'

The Facts

Overall, the evidence supports the fact that vaccination does not cause or worsen asthma. There are many studies that have examined whether wheezing occurs more commonly after children receive vaccines, and it is clear that this is not the case. It is especially important that children with asthma be vaccinated, as catching a disease like whooping cough can make an asthma attack worse. In Australia, influenza vaccination is also recommended for children with asthma.

Vaccines or their components can cause allergic reactions. However, allergy and anaphylaxis are extremely rare in response to immunisation. The chance of anaphylaxis in children and adolescents has been reported as less than one per one million doses. The vaccine components that are rarely associated with allergic reactions are gelatin and yeast. Persons allergic to eggs should not receive influenza or yellow fever vaccines. 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.

The only exception to this is where a person has an allergy to any specific component in a vaccine. Vaccination is *contraindicated* where a person has experienced:

- anaphylaxis or severe hypersensitivity following a previous dose of a particular vaccine, or

- anaphylaxis or severe hypersensitivity following any vaccine components.

If a healthcare provider is unsure about vaccinating a person with a history of an allergic reaction following a vaccine or any vaccine components, immunisation specialists and immunisation clinics are available for advice. Information regarding specialist immunisation services is available via the Immunise Australia website http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-reactions.

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Need for Vaccination

1. 'Infectious diseases are not serious'

The Facts

Some argue that infections are a normal and healthy part of growing up. Vaccines target serious infectious diseases which can be fatal and have been common in Australia and other countries prior to vaccination. Only very recently, and with very high immunisation rates in the community, has the number of cases of these diseases 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 benign 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. Between 2003 and 2005, 101 deaths related to influenza infection were reported in Australia. This is likely to be a large *underestimate* of the true number of deaths due to influenza, many of which are not recognised. Other diseases, while commonly seen, can be associated with serious consequences. See "The Realities: Diseases Preventable by Vaccines".

Further Reading

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2. 'Improved living standards, not immunisation, have reduced infectious diseases'

The Facts

Some argue that improved living standards 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. Improved socioeconomic and sanitary conditions have immensely contributed to improvements in the overall health status of the population in countries like Australia. Better treatment has also had an impact on death rates. However, the dramatic reductions in disease cases following the introduction of specific vaccines underlines their important contribution.

Some examples which demonstrate that improvements in living conditions/ sanitation alone have not impacted on disease:

- *Haemophilus influenzae* type b (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, only 22 cases were notified. Sanitation and living conditions have clearly not changed since 1993 and so can not be the cause of the marked fall in Hib cases and deaths.
- Varicella (or chickenpox) disease has not disappeared despite improved living standards and improved sanitation.

Often the best way to demonstrate the impact an immunisation program has had on the incidence of vaccine-preventable diseases (VPDs) is to examine the impact of a VPD in a community where immunisation rates are low but living standards are high.

Some examples:

- There have been two major epidemics of poliomyelitis in Holland (1984 and 1991) occurring in a religious group who refused immunisation. There was no spread to the rest of the population, whose immunisation coverage against poliomyelitis 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% and pertussis has declined. Similar epidemics occurred in Japan and Sweden at about the same time due to low acceptance of pertussis vaccine.

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 persons all around the world as a result of travel to or from areas where vaccine-preventable diseases are still very common.

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3. 'Diseases are virtually eliminated so vaccination is not needed'

The Facts

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

Although in Australia the majority of people have been fully vaccinated, resulting in a marked reduction in the targeted diseases, it is now important that the vaccination rate be kept as high as possible. High vaccination rates prevent diseases coming back as occurred with pertussis in the United Kingdom and diphtheria in the former Soviet Union.

Another important reason to maintain high vaccination rates in Australia is to protect vulnerable people with medical problems which mean that they cannot themselves be protected by vaccination. This effect is known as 'herd immunity'. However, for herd immunity to be effective, immunisation rates among the population have to be high.

Vaccination is also needed because of the ease of international travel. Travellers returning from countries where vaccine-preventable diseases are still common have been known to bring back diseases, such as measles. There have also been outbreaks of disease within communities where immunisation rates are low and have declined.

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World Health Organization (WHO). Six common misconceptions about immunization. 2006. Available at: http://www.who.int/immunization_safety/aefi/immunization_misconceptions/en/index5.html (accessed Mar 2007).

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

The Facts

Most vaccines do not cause the diseases they are designed to prevent. The majority of vaccines are inactivated or prepared from only part of the organism. The organism is no longer alive and can not cause disease.

Live attenuated viral vaccines, such as measles-mumps-rubella (MMR) vaccine and others, do replicate in the host to create an immune response, but they do not cause disease, except on very rare occasions.

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. In contrast to this is the virus that causes varicella (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, some people vaccinated with the live attenuated varicella vaccine will reactivate the vaccine virus 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 at the site of a varicella vaccine occurs (which can happen in up to 5% of vaccinated persons), there is the potential to transmit the vaccine virus via direct contact with the rash. However, transmission of vaccine virus to contacts of vaccinated persons is extremely rare. In the USA, 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-type virus from healthy vaccinees. The MMR vaccine can also cause a transient rash 7–10 days after vaccination, but it is non-infectious.

Another rare exception is the oral polio vaccine. Oral polio vaccine very rarely causes vaccine associated paralytic polio (VAPP) in vaccine recipients or their close contacts. The overall risk of VAPP was estimated at one per 2.4 million distributed doses overall and one per 750,000 in those receiving their first dose. In 2005, oral polio vaccine was replaced on the Australian immunisation schedule with inactivated polio vaccine (IPV) to eliminate this rare side effect.

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5. ‘Many cases of disease for which vaccines are given occur among the vaccinated’

The Facts

Some people argue that since cases of vaccine-preventable disease occur in children who have been vaccinated, vaccines are not effective.

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 the vaccinated

can appear to be high in relation to the number of cases amongst the unvaccinated. This apparent paradox is explained by two factors:

- First, no vaccine is 100% effective. To make vaccines safer than the disease, the bacteria or virus is killed or weakened (attenuated). For reasons related to the individual, not all vaccinated persons develop immunity. Most routine childhood vaccines are effective for 85% to 95% of recipients. That means 5–15% of vaccine recipients 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.

The following hypothetical scenario shows how these two factors work together to result in a situation in which the majority of cases have been vaccinated in outbreaks.

In a high school of 1000 students, none has ever had measles. 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 not to respond to the vaccine. The efficacy rate for two doses of measles vaccine can be as high as 99%; so in this school, seven students do not respond, and they too become infected. Therefore, seven of 12, or about 58%, of the cases occur in students who have been fully vaccinated.

As you can see, 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% of the children who had not been vaccinated got measles, compared with less than 1% 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 1000 cases of measles.

Further Reading

Jacobson RM, Poland GA. The genetic basis for measles vaccine failure. *Acta Paediatrica* 2004;93 (Suppl 445):43-7.

Poland GA, Jacobson RM. Failure to reach the goal of measles elimination. Apparent paradox of measles infections in immunized persons. *Archives of Internal Medicine* 1994;154:1815-20.

6. '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, which is partially hydrolysed collagen, is 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, even if the vaccines contain porcine-derived gelatin. Likewise, leaders of the Jewish faith have also indicated that pork-derived additives to medicines are permitted.

See also “Vaccines are cultured on cell lines from aborted fetuses”.

Further Reading

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Johns Hopkins Bloomberg School of Public Health. Religious leaders approval of use of vaccines containing porcine gelatin. 2003. Available at: http://www.vaccinesafety.edu/Porcine-vaccineapproval.htm (accessed Jul 2007).

World Health Organization (WHO), Regional Office for the Eastern Mediterranean. Statement arising from a seminar held by the Islamic Organization for Medical Sciences on ‘The judicially prohibited and impure substances in foodstuff and drugs’. 2001. Available at: http://www.immunize.org/concerns/porcine.pdf (accessed Mar 2007).

Safety Concerns: General

1. ‘Mercury in vaccines can cause autism’

The Facts

There is no evidence that thiomersal in vaccines has caused any health problems, except perhaps minor reactions, such as redness at the injection site. Thiomersal (also known as thimerosal) is a mercury-based preservative that has been used in very small amounts in some vaccines since the 1930s to prevent bacterial and fungal contamination.

Mercury occurs naturally in the environment in the air, earth, ocean, and in fish. It is also used in industrial processes, dental fillings, and thermometers. It is harmful only after it reaches a certain level in the body, and the toxicity depends on the amount of mercury consumed, body weight and the time period of exposure. When thiomersal was in vaccines, infants with a low birth weight were more likely to have temporarily higher concentrations of mercury because of their size. However, 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.

Thiomersal has been removed from childhood vaccines since the year 2000 as a precautionary measure. This also reduces the total exposure of young children to 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 and other live attenuated viral vaccines, never contained thiomersal. With regards to adults, the exposure to mercury from thiomersal-containing vaccines is so low that experts do not recommend removal of thiomersal from vaccines for adolescents or adults. There are certain vaccines available in Australia that still contain very small amounts of thiomersal, such as some influenza vaccines.

Further Reading

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine. Stratton K, Gable A, McCormick MC, eds. Immunization safety review. Thimerosal-containing vaccines and neurodevelopmental disorders. Washington, D.C.: National Academy Press, 2001.

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Thiomersal fact sheet. 2007. Available at: http://www.ncirs.usyd.edu.au/facts/thiomersal.pdf (accessed Jul 2007).

2. 'Vaccines can cause diabetes'

The Facts

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

The incidence of type 1 diabetes is increasing in developed countries including Australia. This increase was noted to occur at a similar time to the introduction of widespread childhood immunisations. One study postulated that early immunisation (at less than two months of age) protected against type 1 diabetes, whereas immunisation after this date increased the risk of developing type 1 diabetes. Originally, these claims implicated the *Haemophilus influenzae* type b (Hib) vaccine, but later included the BCG (Bacille Calmette-Guérin, for tuberculosis) and, more recently, the MMR (measles-mumps-rubella) and pertussis vaccines.

Following the reports described above, many large, well-conducted studies have been conducted and 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 immunisations have not been shown to alter the risk of developing diabetes.

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

Further Reading

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Diabetes and vaccines fact sheet. 2007. Available at: http://www.ncirs.usyd.edu.au/facts/diabetes_and_vaccines.pdf (accessed Mar 2007).

The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood immunizations and type 1 diabetes: summary of an Institute for Vaccine Safety Workshop. *Pediatric Infectious Disease Journal* 1999;18:217-22.

3. 'Vaccines cause cancer'

The Facts

Vaccines actually prevent some cancers, such as liver cancer (associated with hepatitis B infection) and cervical cancer (associated with human papillomavirus infection).

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 USA was unknowingly contaminated

with SV40. The virus came from the monkey kidney cell cultures 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. In 2002, an independent Immunization Safety Review Committee considered that the available data was inadequate. However, 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 Therapeutic Goods Administration (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.

Further Reading

Cossart Y. Review of the health consequences of SV40 contamination of poliomyelitis vaccines, and in particular a possible association with cancers. Canberra: Australian Government Department of Health and Ageing, Therapeutic Goods Administration, 2004. Available at: http://www.tga.gov.au/alerts/sv40.htm (accessed Mar 2007).

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies. Stratton K, Almario DA, McCormick MC, eds. Immunization safety review. SV40 contamination of polio vaccine and cancer. Washington, D.C.: The National Academies Press, 2003.

4. '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 that were received between 1996 and 1999. There have been no cases of vCJD reported among persons in the United Kingdom 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.

In Australia, the Therapeutic Goods Administration (TGA) has confirmed that all vaccines available in this country 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.

Further Reading

Australian Government Department of Health and Ageing, Therapeutic Goods Administration. BSE risk associated with the use of materials of bovine origin during the manufacture of vaccines: questions and answers. 2004. Available at: http://www.tga.gov.au/docs/html/bsefaq.htm (accessed Mar 2007).

The European Agency for the Evaluation of Medicinal Products. Questions and answers on Bovine Spongiform Encephalopathies (BSE) and vaccines. 2001. Available at: http://www.emea.europa.eu/pdfs/human/bwp/081901en.pdf (accessed Jul 2007).

5. 'Vaccines are linked to Guillain-Barré syndrome'

The Facts

Guillain-Barré syndrome (GBS) is a rare neurologic disorder, involving inflammatory demyelination of peripheral nerves, with an estimated annual incidence of 1–2 cases per 100,000 persons. 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 which causes gastroenteritis.

In 1976, vaccination with the swine flu vaccine was associated with an increased risk of getting GBS. This vaccine is no longer used. Several studies have been done to evaluate if other flu vaccines since 1976 were associated with GBS. None of the studies conducted using influenza vaccines other than the 1976 swine influenza vaccine have demonstrated a substantial increase in GBS associated with influenza vaccines.

Isolated case reports and epidemiological studies have drawn attention to a possible association of Guillain-Barré syndrome with several other vaccines including oral polio, measles-mumps-rubella (MMR), tetanus toxoid-containing vaccines, and hepatitis B. In Australia, there have been no cases of GBS that have been causally linked to these vaccines. In 2005, a possible association between GBS and a meningococcal conjugate vaccine (MCV4) used in teenagers in the USA, but not in Australia, was reported to the USA Vaccine Adverse Events Reporting System (VAERS). However, it is still yet to be determined if this vaccine increases the risk of GBS.

Further Reading

Haber P, DeStefano F, Angulo FJ, et al. Guillain-Barré syndrome following influenza vaccination. *JAMA* 2004;292:2478-81.

Juurlink DN, Stukel TA, Kwong J, et al. Guillain-Barré syndrome after influenza vaccination in adults: a population-based study. *Archives of Internal Medicine* 2006;166:2217-21.

6. ‘Vaccines cause sudden infant death syndrome’

The Facts

A comprehensive review of relevant studies has shown that immunisation does not increase the risk of sudden infant death syndrome (SIDS) and may even lower the risk.

SIDS is defined as the sudden and otherwise unexplained death of an infant less than one year of age. The incidence of SIDS peaks at two months of age, the age at which Australian children are recommended to receive vaccinations. 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 conducted over 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. A recent study using Australian data calculated that, by chance alone, one or two of the SIDS cases per year in Australia would be expected to occur within 24 hours after vaccination.

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 focussed on reducing these risk factors.

Further Reading

Brotherton JM, Hull BP, Hayen A, Gidding HF, Burgess MA. Probability of coincident vaccination in the 24 or 48 hours preceding sudden infant death syndrome death in Australia. *Pediatrics* 2005;115:e643-e646.

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies. Stratton K, Almario DA, Wizemann TM, McCormick MC, eds. Immunization safety review. Vaccinations and sudden unexpected death in infancy. Washington, D.C.: The National Academies Press, 2003.

7. ‘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 bleeding around the brain (subdural/subarachnoid haemorrhage), brain swelling, and bleeding in the back of the eye (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 bleeding and retinal haemorrhages can be caused by shaking of young infants and 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, vaccines seldom cause febrile convulsions and children who have febrile seizures do not develop cerebral haemorrhage or fractures. The third contention is that since thrombocytopenia (low platelets) is a well-established, though rare, serious reaction to MMR vaccine, bleeding disorders following vaccination could cause retinal haemorrhages similar to SBS. However, MMR vaccine is not given until 12 months of age, intracranial bleeding is rare with thrombocytopenia, and the other effects are not seen.

Further Reading

Harding B, Risdon RA, Krous HF. Shaken baby syndrome. *BMJ* 2004;328:720-1.

Moran KT. National Australian conference on shaken baby syndrome. *Medical Journal of Australia* 2002;176:310-1.

Safety Concerns: Specific Vaccines

1. 'MMR vaccine causes autism and inflammatory bowel disease (IBD)'

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 in 1998. They suggested that measles virus in the gut caused a new syndrome of IBD which 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 many significant weaknesses. 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 concluded that current scientific data do not show any causal link between the measles virus and autism or IBD. An extensive review published in 2004 by the Institute of Medicine, 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.

In 2004, 10 of the 13 authors of the original 1998 study (published in *The Lancet*) published a statement retracting the paper's interpretation, stating that the data were insufficient to establish a causal link between MMR vaccine and autism. *The Lancet* subsequently retracted the original paper.

It was also suggested that giving each vaccine component of MMR 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 population susceptible to outbreaks of these diseases. National and international expert bodies all recommend that MMR should continue to be used. Only the rubella vaccine is available as a separate vaccine in Australia.

Further Reading

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Measles, mumps, rubella vaccine, inflammatory bowel disease and autism (fact sheet). 2006. Available at: http://www.ncirs.usyd.edu.au/facts/mmr_autism.pdf (accessed Mar 2007).

The Children's Hospital of Philadelphia, Vaccine Education Center. Thimerosal and autism. 2006. Available at: http://www.chop.edu/consumer/jsp/division/generic.jsp?id=75751 (accessed Mar 2007).

2. '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, DTPw. These DTPw ('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. All DTP vaccines used in Australia are now manufactured from purified components of the pertussis bacterium, and are referred to as acellular pertussis vaccines, DTPa. These newer DTPa vaccines cause a much lower incidence of fever and local reactions than DTPw vaccines.

With respect to the whole cell vaccines, a large British study (the National Childhood Encephalopathy Study) in the 1970s showed that, if brain damage occurred, it was very rare. With respect to the current acellular vaccines, a study of all suspected cases in Canada over a 10 year period concluded that it was not the vaccine but pre-existing conditions that were responsible for the encephalopathy.

Further Reading

Jefferson T, Rudin M, DiPietrantonj C. Systematic review of the effects of pertussis vaccines in children. *Vaccine* 2003;21:2003-14.

Moore DL, Le Saux N, Scheifele D, Halperin SA, Members of the Canadian Paediatric Society/Health Canada Immunization Monitoring Program Active (IMPACT). Lack of evidence of encephalopathy related to pertussis vaccine: active surveillance by IMPACT, Canada, 1993-2002. *Pediatric Infectious Disease Journal* 2004;23:568-71.

3. '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, thus causing HIV-1 in humans and the earliest cases of AIDS. Recent testing of the Koprowski vaccine found no contamination with SIV or HIV.

The vaccine-HIV argument is now thoroughly discredited.

In addition, there are no recordings of earliest AIDS cases receiving the Koprowski vaccine. Despite this vaccine being given to people in Europe and Africa, early AIDS cases were only seen 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.

Further Reading

Keele BF, Van Heuverswyn F, Li Y, et al. Chimpanzee reservoirs of pandemic and nonpandemic HIV-1. *Science* 2006;313:523-6.

Koprowski H. First decade (1950-1960) of studies and trials with the polio vaccine. *Biologicals* 2006;34:81-6.

Worobey M, Santiago ML, Keele BF, et al. Origin of AIDS: contaminated polio vaccine theory refuted. *Nature* 2004;428:820.

4. 'Hepatitis B vaccine causes multiple sclerosis'

The Facts

There is no evidence that hepatitis B vaccine, or any other vaccine, causes multiple sclerosis (MS). There is also evidence that vaccination does not worsen the symptoms or cause relapses of 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 after administering 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 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 (WHO), the Institute of Medicine (IOM) and the Centers for Disease Control and Prevention (CDC) in the USA, agree that there is no evidence to support the theory that immunisation with hepatitis B vaccine, or any other vaccine, is associated with an increased risk of multiple sclerosis.

Further Reading

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine of the National Academies. Stratton K, Almario DA, McCormick MC, eds. Immunization safety review. Hepatitis B vaccine and demyelinating neurological disorders. Washington, D.C.: The National Academies Press, 2002.

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Hepatitis B vaccine and multiple sclerosis (fact sheet). 2007. Available at: http://www.ncirs.usyd.edu.au/facts/hepB_and%20multiple%20sclerosis.pdf (accessed Mar 2007).

5. 'Flu vaccines cause the flu'

The Facts

Influenza vaccines can not give a person the flu. None of the influenza vaccines used in Australia contain live virus. The vaccines used are either

split-virion or sub-unit (inactivated) vaccines, which only contain the surface structures of the virus, not infectious particles.

The belief that the vaccine has resulted in '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 24–72 hours, and the vaccine takes 7–14 days to produce protection, so occasionally a vaccine recipient 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 them 'the flu', these side effects may occur with many different types of vaccines.

Further Reading

National Health and Medical Research Council (NHMRC). The Australian Immunisation Handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

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

The Facts

Human papillomavirus (HPV) vaccines have been developed to prevent cervical cancer. These 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 USA, the Therapeutic Goods Administration (TGA) in Australia and the European Medicines Agency (EMEA) have concluded that HPV vaccines are safe and effective.

The main side effect of the vaccines is a local reaction at the injection site (pain, redness and swelling) which occurs in about 80% of those who receive the injection. Fever, headache and fatigue have also been reported in clinical trials but these are no more common than in placebo recipients. The studies found very few serious adverse events reported following vaccination (<0.1%) and they were no more frequent than in those receiving the placebo vaccine. From the clinical studies, those vaccinated have been evaluated for at least four years after the vaccine was given to determine if higher rates of new medical conditions, including autoimmune diseases, occur. 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, reports of adverse events following vaccination are monitored. (See also "Vaccine Manufacture and Testing" for further information.)

It is not possible for the HPV vaccine to cause infertility. HPV infection,

unlike some other sexually transmitted infections, such as chlamydia, is not a cause of infertility. Studies of high doses of the vaccine in female rats showed no effect on fertility. While it is recommended that vaccination be avoided during pregnancy, there is no indication that inadvertent administration of the vaccine to a pregnant woman will result in an increased risk of adverse pregnancy outcomes.

Further Reading:

National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Human papillomavirus vaccines for Australians: information for GPs and immunisation providers (fact sheet). 2007. Available at: http://www.ncirs.usyd.edu.au/facts/hpv_jan_2007.pdf (accessed Mar 2007).

THE REALITIES: DISEASES PREVENTABLE BY VACCINES

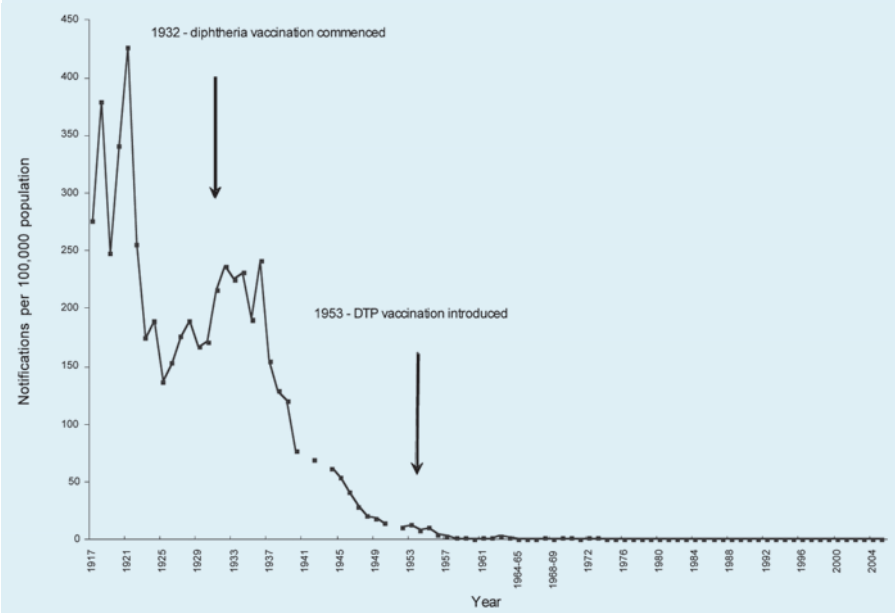
The following section shows the decline in vaccine-preventable diseases over time.

1. Diphtheria

Diphtheria is a serious communicable disease caused by toxigenic strains of *Corynebacterium diphtheriae*. The case-fatality rate is 5% to 10% with the highest death rates occurring in the very young and the elderly.

Although diphtheria has become rare in Australia as a result of vaccination, the potential to encounter the disease remains, especially for travellers. For example, outbreaks of diphtheria have occurred in areas in the former USSR in the last 10 years due to a decline in immunisation rates.

Figure 1 Diphtheria notifications, Australia, 1917–2005



Source: Brotherton J, Wang H, Schaffer A, et al. Vaccine preventable diseases and vaccination coverage in Australia, 2003 to 2005. Communicable Diseases Intelligence 2007;31(Suppl):viii-S152.

Further Reading

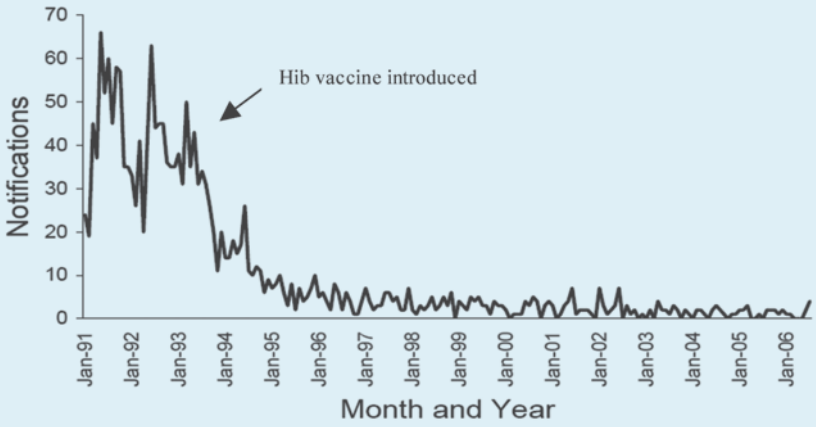
National Health and Medical Research Council (NHMRC). The Australian Immunisation Handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

2. *Haemophilus influenzae* type b (Hib)

Hib is a bacterium which causes bloodstream infection, meningitis, epiglottitis, and pneumonia. Even with early treatment, meningitis has a case-fatality rate of 5% with many survivors having long-term disabilities. In Australia, before the introduction of Hib immunisation, there were approximately 500 cases each year, with 10–15 deaths.

Since Hib vaccine has been widely used in Australia from 1993 there has been a greater than 95% reduction in Hib cases in children less than five years of age, with less than 10 cases per year (see Figure 2). Of the few cases reported, most are in unimmunised children.

Figure 2 *Haemophilus influenzae* type b (Hib) notifications, Australia, 1991–2006



Source: Australian Government Department of Health and Ageing. Immunise Australia Program disease notifications. *Haemophilus influenzae* type b notifications, 1991-2006. 2007. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/program-disnotif (accessed Jul 2007).

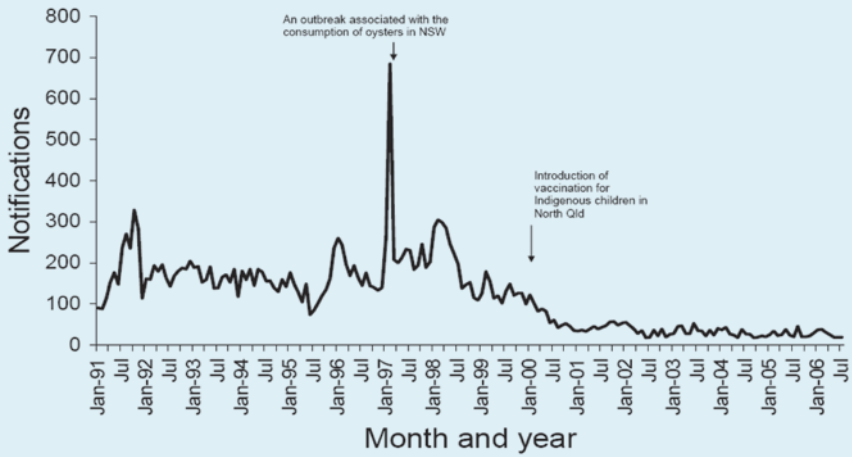
Further Reading

National Health and Medical Research Council (NHMRC). The Australian Immunisation Handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

3. Hepatitis A

Hepatitis A is a virus which causes an acute hepatitis. It is transmitted by the faecal-oral route and is easily transmitted from person to person. Hepatitis A cases are highly infectious about one week before the symptoms become apparent and remain infectious for a further two weeks, generally following the appearance of jaundice. Infected people can unwittingly spread the disease to others living in the same household before the disease is diagnosed. The majority of notified cases of hepatitis A in Australia are seen in travellers returning from overseas, particularly from areas in the Middle East, south-east Asia and eastern Europe. Routine hepatitis A immunisation is now recommended for all Aboriginal and Torres Strait Islander children in Queensland, the Northern Territory, Western Australia and South Australia where there are the highest population rates of disease.

Figure 3 Hepatitis A notifications, Australia, 1991–2006



Source: Australian Government Department of Health and Ageing. Immunise Australia Program disease notifications. Hepatitis A notifications, 1991-2006. 2007. Available at: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/program-disnotif (accessed Jul 2007).

Further Reading

National Health and Medical Research Council (NHMRC). The Australian Immunisation Handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

4. Hepatitis B

Hepatitis B is a virus which can cause acute or chronic hepatitis, liver cirrhosis (scarring) and liver cancer. It is transmitted by contact with blood and body fluids, for example by sexual intercourse, intravenous drug use or blood transfusion (which is now very rare because of routine blood screening procedures). In approximately 15% of cases, a readily identifiable risk factor for the infection is not found. Hepatitis B can also be transmitted from an infected mother to her baby around the time of birth. This is particularly serious as babies infected at birth usually become chronically infected, known as 'carriers'. Chronic infection may lead to cirrhosis or cancer of the liver. All children born in Australia are offered hepatitis B vaccine at birth and have another three doses in the first year of life.

Further Reading

National Health and Medical Research Council (NHMRC). The Australian Immunisation Handbook. 9th ed. Canberra: Australian Government Department of Health and Ageing, 2008.

5. Human papillomavirus (HPV)

Human papillomavirus (HPV) causes a common and usually asymptomatic viral infection of the genital mucosa. HPV infection is highly contagious and most people will be infected within

a few years of becoming sexually active. HPV infection rates vary greatly between geographic regions, but it is estimated that up to 79% of women worldwide will be infected with HPV at some point in their lives.

Most people clear HPV infection within 12–24 months. However, of the 40 genital HPV types, 15 of these are known as 'high-risk' types. These high-risk types can establish persistent cervical infection (in about 3–10% of infected women) which in turn can result in cervical abnormalities that, in some cases, will progress to cervical cancer. HPV types 16 and 18 cause 70% of cervical cancers. HPV types 6 and 11 cause 90% of genital warts. The subtypes that cause warts do not also cause cancer.

HPV vaccines act to prevent infection and disease associated with some of the high-risk HPV types. Vaccination will not treat or alter existing HPV infection or disease. Because the vaccine does not provide protection against all HPV types, women who have received a HPV vaccine still require two yearly cervical Pap screening, and Pap screening remains the most important preventive strategy against cervical cancer for women who are sexually active.

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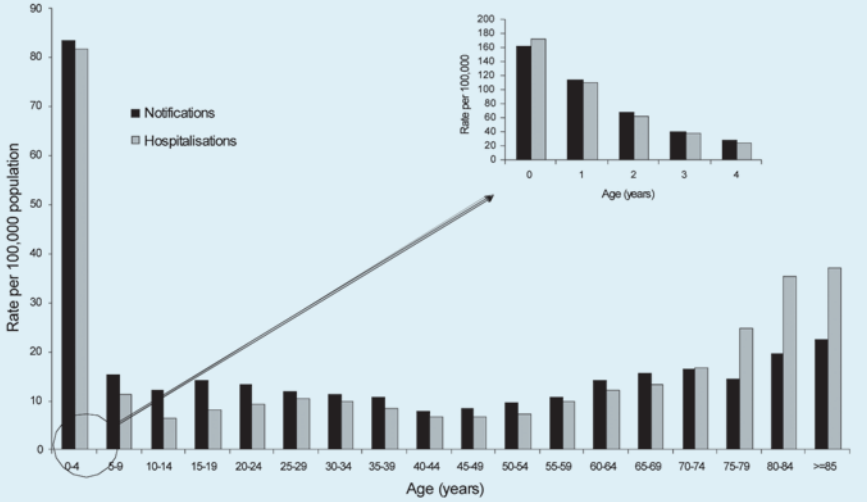
6. Influenza ('flu')

Influenza (flu) is an infectious disease caused by influenza virus. The symptoms of flu include sudden fever, headache, muscle aches and pains, fatigue, cough, sore throat, stuffy or runny nose. The virus can cause a mild or severe illness depending on the type of influenza virus and the age and general health of the affected person. The incubation period is around 24–72 hours followed by symptoms which may last up to a week.

People of all ages can become severely ill with influenza but, particularly in the elderly and persons with an underlying medical condition, complications following influenza can be fatal. There were 101 influenza-related deaths reported between 2002 and 2005 and over 9000 hospitalisations (see Figure 4). It is likely that influenza notifications are underestimated and as the figure below demonstrates, the greatest number of hospitalisations due to influenza actually occurs in children aged less than four years.

Annual influenza vaccination is provided free for all people over 65 years of age and for Aboriginal and Torres Strait Islander people over 50 years of age. In addition, adults and children with underlying medical conditions and pregnant women are recommended to receive annual influenza vaccination.

Figure 4 Influenza notification rates 2003–2005 and hospitalisation rates 2002/03–2004/05, Australia, by age group



Source: Brotherton J, Wang H, Schaffer A, et al. Vaccine preventable diseases and vaccination coverage in Australia, 2003 to 2005. Communicable Diseases Intelligence 2007;31(Suppl):viii-S152.

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7. Measles

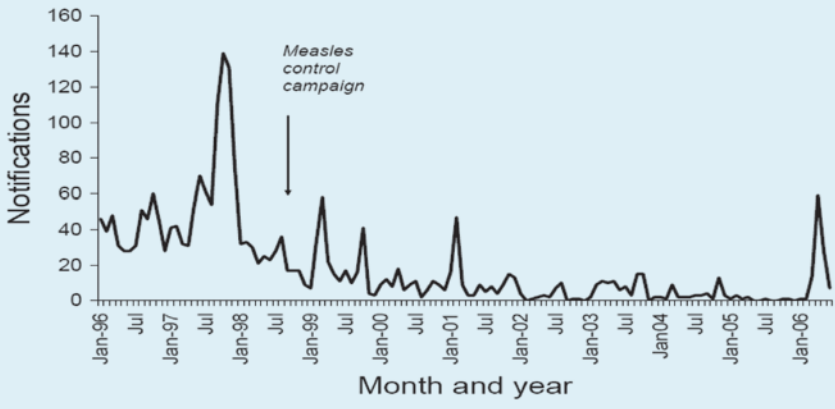
Measles is one of the most severe and highly infectious diseases of childhood and is virtually universal amongst unimmunised children in many countries. There has been a marked reduction in measles incidence in countries where vaccine has been widely used, but it remains a serious and common disease in many parts of the world, including popular holiday destination spots for Australians, such as Fiji and Indonesia.

One measles case in 70 requires hospital admission. Measles is complicated by otitis media in 5–9% of cases, pneumonia in 1–7% of cases, encephalitis in 1 in 1000 cases, convulsions in 0.5% of cases, and subacute sclerosing panencephalitis (SSPE) in 1 in 100,000 cases. SSPE is a delayed response to wild measles infection, occurring years afterwards, with severe encephalopathy and a uniformly fatal outcome. SSPE does not occur as a result of administration of measles vaccines.

Local transmission of measles has not occurred within Australia for some time now and recent cases have involved contact with a person(s) who has acquired measles from overseas.

In 2006, an increase in measles occurred which was linked to a national tour by a spiritual group (see Figure 5 below). Over 60 cases of measles occurred amongst people attending these meetings in several Australian cities, most of whom were unimmunised.

Figure 5 Measles notifications, Australia, 1996–2006



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8. Meningococcal disease

Neisseria meningitidis (meningococcus) is a bacterium that can cause meningitis and septicaemia and only infects humans. The overall case-fatality rate is high, at about 10%, despite early and appropriate treatment. Asymptomatic carriage of meningococci in the upper respiratory tract is present in about 10% of the population at any given time. Factors associated with an increased risk of carriage include smoking and living in crowded conditions.

Most cases of meningococcal disease in Australia are now due to serogroup B organisms for which no vaccine is available. However, prior to vaccination, most of the clusters of meningococcal disease were due to serogroup C. Effective vaccines, which only protect against this serogroup, have been used in Australia since 2003 and have resulted in dramatic decreases in serogroup C cases.

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9. Mumps

Mumps is a viral disease that causes a febrile illness, often with swelling of the parotid glands, and sometimes with complications such as oophoritis (inflammation of the testes), pancreatitis, hepatitis, and inflammation of other organs or glands. Nerve deafness is a serious but rare complication. Since 2004 in Australia, there has been an increase in mumps cases in young adults who have received no doses or only one dose of MMR vaccine. In the USA and the United Kingdom, there have recently been very large outbreaks of mumps, where the peak rates of disease have also been in the 18–24 year age group, many of whom have not been fully vaccinated.

Two doses of mumps-containing vaccine, usually given as MMR, are highly effective at preventing mumps infection, and are recommended for all persons who are not immune or previously vaccinated.

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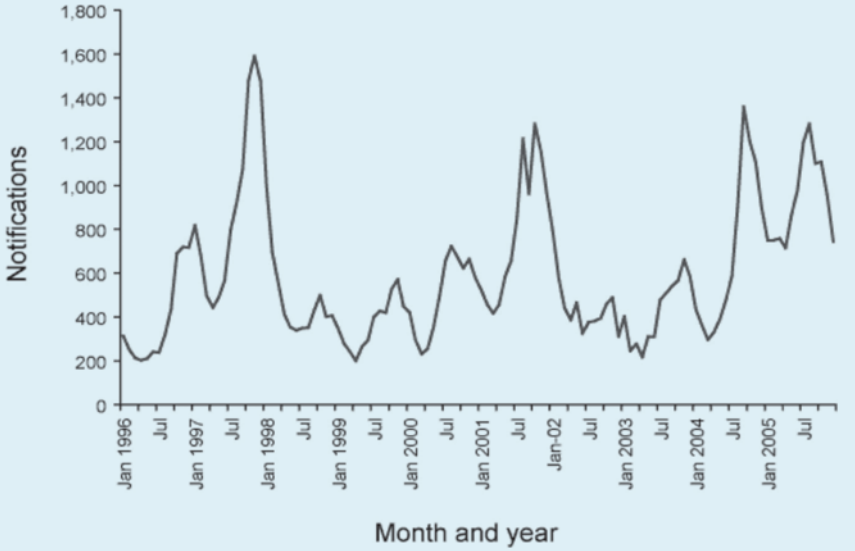
10. Pertussis ('whooping cough')

Pertussis is a very infectious disease; up to 90% of unimmunised contacts in a household where there is a case will acquire the disease. The overall mortality from pertussis is 0.03% but the mortality in babies under six months of age is substantially higher (3.5%). Young infants also have the highest rates of hospitalisation and complications.

Pertussis causes significant morbidity. The cough may persist for six months or more and lead to sleep disturbance and significant weight loss. Severe complications, which occur almost exclusively in unimmunised people, include seizures and pneumonia. Increasing vaccination coverage has been associated with big reductions in disease in immunised children. However, large numbers of cases

continue to occur in older people. Figure 6 below demonstrates the seasonal fluctuations along with periodic increases in the number of cases every 2–3 years. In Australia, a booster dose of pertussis vaccine for adolescents has been recommended since 2003. Receipt of a booster dose of pertussis vaccine is also recommended for certain adults, such as health care workers or those in contact with young children.

Figure 6 Pertussis notifications, Australia, 1996–2005



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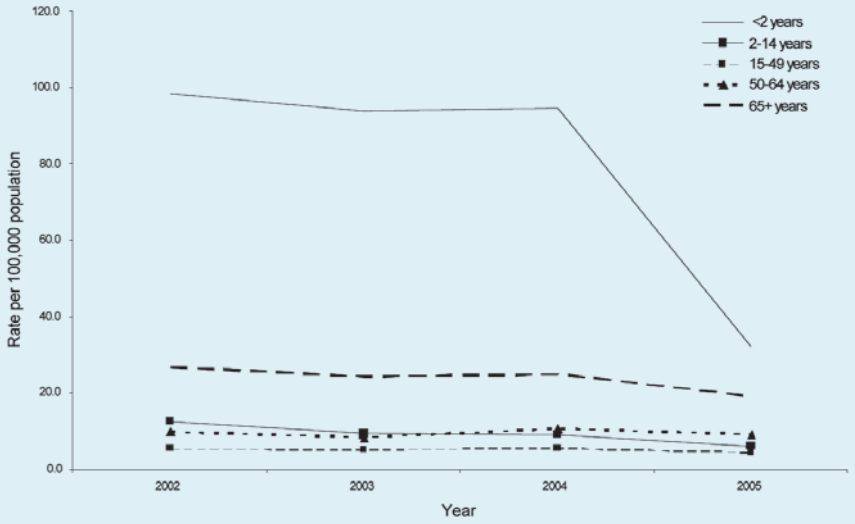
11. Pneumococcal disease

The bacteria *Streptococcus pneumoniae*, also known as the pneumococcus, causes a range of infections including pneumonia, bacteraemia, sepsis, meningitis, and middle ear infections. The most severe infections, bacteraemia and meningitis, are jointly referred to as invasive pneumococcal disease (IPD) and are the primary outcome that vaccination aims to prevent. Children under two years of age and the elderly are most susceptible to IPD.

All children are offered a conjugate pneumococcal vaccine (containing seven of the most common serotypes) at 2, 4 and 6 months of age and children with specific medical conditions are offered an extra dose at 12 months of age plus the polysaccharide pneumococcal vaccine (containing 23 serotypes) at 4–5 years of age. Figure 7 below demonstrates the impact the childhood vaccination program has had on pneumococcal disease notifications. All persons aged 65 years of age are eligible to receive a dose of the polysaccharide pneumococcal vaccine.

Figure 7 Pneumococcal disease notifications, Australia, 2002–2005, by age group



Source: Brotherton J, Wang H, Schaffer A, et al. Vaccine preventable diseases and vaccination coverage in Australia, 2003 to 2005. Communicable Diseases Intelligence 2007;31(Suppl):viii-S152.

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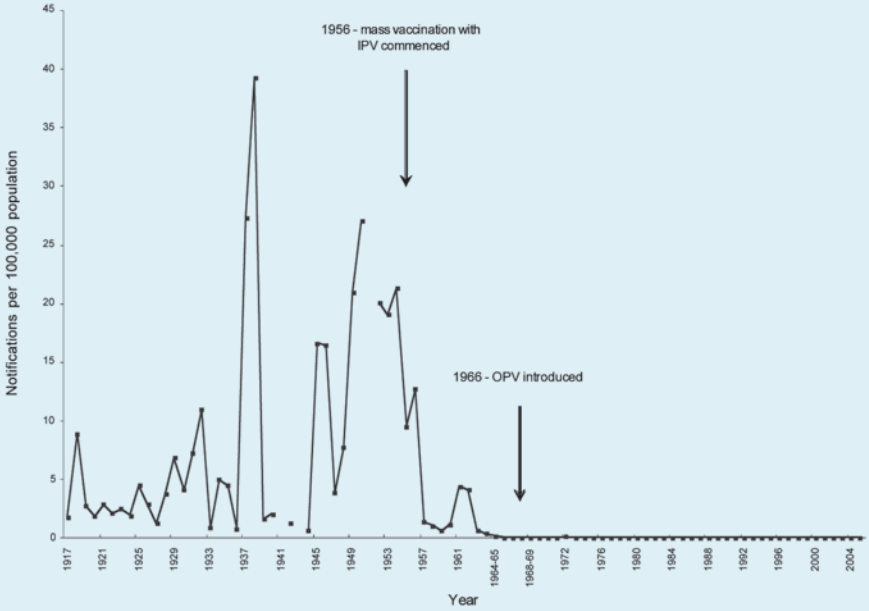
12. Poliomyelitis ('polio')

Poliomyelitis is caused by an enterovirus which commonly causes mild or asymptomatic illness but, in approximately 1% of cases, results in acute flaccid paralysis due to a specific effect on the anterior horn cells of the motor nerves in the spinal cord. There may be as many as 75–1000 cases of asymptomatic infections for each paralytic case, depending on the virus type, age of the population and environmental conditions. Australia has had only one case of wild-type paralytic poliomyelitis since 1978, but continues to be at risk of importation of the disease from overseas.

The World Health Organization planned global eradication of polio by the year 2005, but recent outbreaks in Africa and several south-east Asian countries have delayed this plan. In 2007, a person returning back to Australia from Pakistan flew whilst ill with poliomyelitis. The patient subsequently recovered from mild paralytic poliomyelitis. However, as a precautionary measure, persons on the same flight were notified and offered vaccination. This illustrates the importance of maintaining high coverage with polio vaccine, now given to all children as IPV (inactivated poliomyelitis vaccine).

Figure 8 Polio notifications, Australia, 1917–2005



Source: Brotherton J, Wang H, Schaffer A, et al. Vaccine preventable diseases and vaccination coverage in Australia, 2003 to 2005. Communicable Diseases Intelligence 2007;31(Suppl):viii-S152.

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13. Rotavirus

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

Rotaviruses are transmitted by the faecal-oral route. Large numbers of viral particles are shed in the faeces and the virus is stable in the environment, so contamination of hands and objects (fomites) commonly helps spread the virus. Rotavirus infection occurs despite very high standards of hygiene.

In Australia, it is estimated that there are approximately 10,000 hospitalisations due to rotavirus in children less than five years of age each year. This translates to approximately one in 27 children being hospitalised with rotavirus gastroenteritis by the age of five years. On average, there is one death due to rotavirus each year in Australia.

Rotavirus vaccine is recommended for infants and is given orally in the first few months of life. Those who receive rotavirus vaccine are less likely to

be hospitalised, visit the Emergency Department, or see a doctor for gastroenteritis.

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National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Rotavirus vaccines for Australian children: information for GPs and immunisation providers (fact sheet). 2007. Available at: http://www.ncirs.usyd.edu.au/facts/rotavirus_vaccine_for_children_june_2007.pdf (accessed Jul 2007).

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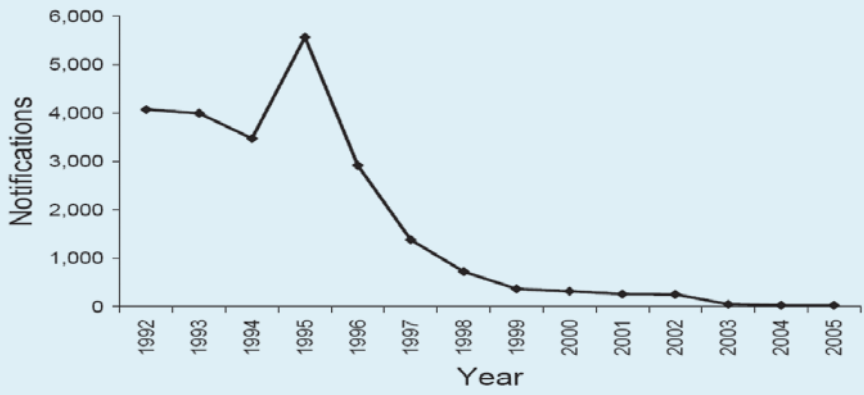
14. Rubella

Rubella is a viral illness that is generally mild with fever, rash and lymphadenopathy. Some adults who develop rubella can also develop severe arthritis. The greatest risk from rubella is due to infection occurring early in pregnancy. Maternal rubella infection during the first 8–10 weeks of pregnancy results in fetal damage in up to 90% of pregnancies.

There has been a steady fall in rubella cases due to increased immunisation rates, as most persons have received two doses of rubella-containing vaccine, given as MMR. However, it is important that women considering becoming pregnant should be checked for rubella immunity and vaccinated if necessary. Vaccination of both males and females is important to provide ongoing herd immunity against rubella.

Figure 9 Rubella notifications, Australia, 1992–2005



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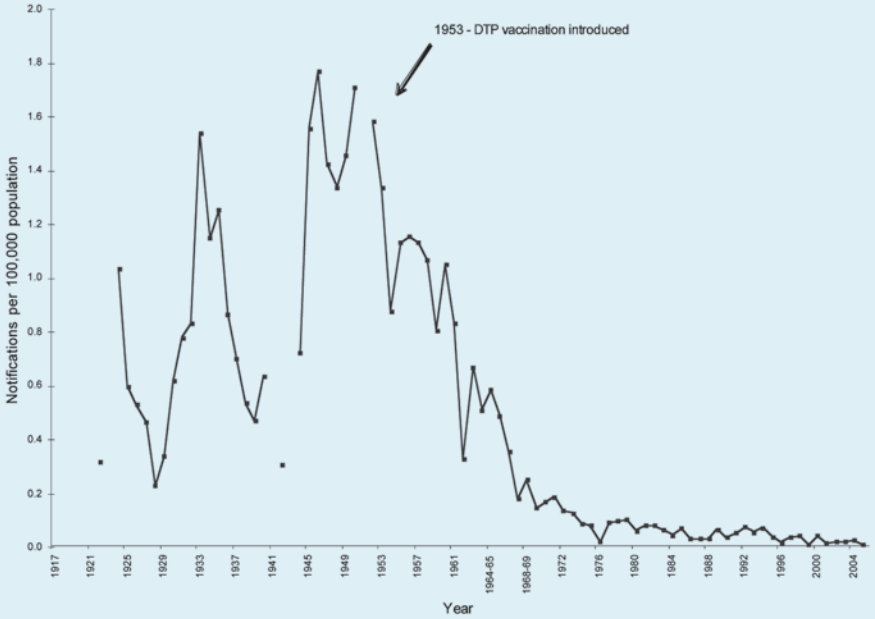
15. Tetanus

Tetanus is an acute, often fatal, disease caused by the toxin produced by the bacterium *Clostridium tetani*. This neurotoxin acts on the central nervous system causing muscle rigidity with painful spasms. The disease usually occurs after an incubation period of 3–21 days (range one day to several months), with a median time of onset after injury of 10 days. Death may result from respiratory failure, hypertension, hypotension or cardiac arrhythmia. Tetanus only affects the individual and cannot be passed from person to person. The bacterium is found in soil everywhere and the only means of protection available to an individual is through immunisation.

In Australia, tetanus is now rare, occurring primarily in older adults who have never been vaccinated or who were vaccinated many years previously. During 2001–2002, there was one death from tetanus, in a person aged over 60 years.

Effective protection against tetanus is only provided by active immunisation, and even people who have had tetanus disease previously can remain susceptible. As tetanus can follow apparently trivial, even unnoticed, wounds, immunisation is the only certain protection.

Figure 10 Tetanus notifications, Australia, 1917–2005



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16. Varicella ('chickenpox')

Varicella or chickenpox is a highly infectious disease caused by the varicella-zoster virus (VZV) which is one of eight herpes viruses that cause illness in humans. Like other herpes viruses, such as the virus that causes cold sores (HSV), VZV has the unusual ability to establish a latent infection in nerve ganglions, which can later reactivate to cause shingles (herpes zoster).

Varicella is generally a benign, self-limiting illness in children but as almost all children develop chickenpox, even a small proportion with complications results in a large number of hospitalisations. Complications, such as secondary bacterial infection (most commonly cellulitis and bacteraemia), meningitis, encephalitis and pneumonia, can occur and result in hospitalisation. Prior to widespread vaccination, there were approximately 1500 hospitalisations and approximately eight deaths per year due to chickenpox.

Vaccination of children against chickenpox prevents serious or complicated disease and also ensures

that immunity is provided prior to reaching adolescence and adulthood when complications from the disease occur more commonly.

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National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS). Varicella-zoster (chickenpox) vaccines for Australian children: information for GPs and immunisation providers (fact sheet). 2005. Available at: http://www.ncirs.usyd.edu.au/facts/varicella_zoster_for_children_sep_05.pdf (accessed Mar 2007).

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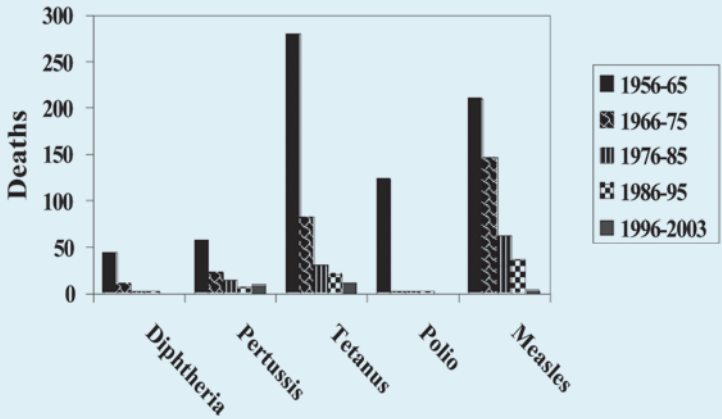
Deaths from vaccine-preventable diseases

The figure below shows the substantial decline in deaths from diphtheria, pertussis, tetanus, polio and measles in Australia between 1956 and 2003.

Figure 11 Deaths in Australia from diphtheria, pertussis, tetanus, polio and measles, 1956–2003



THE REALITIES: VACCINES

Vaccine Composition

Vaccines are designed to provide protection against a disease without the risks or complications of the disease itself. The composition of the vaccine may vary from a weakened strain of an otherwise infective agent, such as an attenuated virus, to a non-infectious component of the infective agent, as described in Section 1 below. In addition to containing a modified form of the bacteria, virus or toxin that induces immunity against a specific disease, some vaccines contain other substances that are either added during the manufacturing process or are residual components that remain as a result of the way in which the vaccine is manufactured. These are described below in Sections 2 and 3.

1. Bacteria and viruses

The great majority of current vaccines protect against either viruses or bacteria and are made in the following ways:

Attenuate the virus

The live viruses used in vaccines are weakened (or attenuated) so that they reproduce themselves in only a very limited way inside the body. Examples of live attenuated viral vaccines are the measles, mumps, rubella, varicella and rotavirus vaccines. Fully potent viruses (known as natural or 'wild type' viruses) cause disease by reproducing themselves many thousands or millions of times in the body's cells. However, vaccine viruses usually reproduce fewer than 20 times. Vaccine viruses replicate just well enough to induce the immune system to produce protective antibodies and to make very long-lived 'memory B cells' that remember the infection and produce more antibodies if the natural infectious virus is subsequently encountered.

The advantage of live, attenuated vaccines is that only one or two doses usually provide immunity that is lifelong. The limitation of this approach is that these vaccines cannot be given to people with *severely* impaired immunity, as a greatly weakened immune system may not be able to limit the reproduction of the vaccine virus.

Inactivate the virus

Some viruses in vaccines are completely inactivated (or killed) with a chemical, often formaldehyde. The virus or part of the virus that is killed cannot possibly reproduce itself or cause disease. The inactivated polio and hepatitis A vaccines are made this way. The advantage is that the virus is still recognised by the body's immune system.

The strength of this approach is that the vaccine does not cause even a mild form of the disease that it prevents, and therefore these vaccines can be given to people with impaired immunity. The limitation of this approach is that sometimes several doses must be given to achieve immunity, and persons with impaired immunity may not respond to even multiple doses.

Use part of the virus or bacterium

The part of the virus or bacterium required to 'induce immunity' is identified and separated from the part which causes disease symptoms. The hepatitis B, *Haemophilus influenzae* type b (Hib), and human papillomavirus (HPV) vaccines are examples. In the case of hepatitis B, the vaccine is composed of a protein that resides on the surface of the virus. In the case of the Hib vaccine, only the outer coat or polysaccharide is used, joined on to a protein so that the immune system responds to it.

These vaccines can be given to people with impaired immunity, although this is not always recommended if the person's immune system is too weak to develop a good response.

Use a toxin produced by the bacteria

Some vaccines are manufactured by taking specific bacterial toxins and inactivating them with a chemical. The toxin, chosen because it causes the most serious manifestations of the particular disease, is called a toxoid once it is inactivated in the vaccine. Diphtheria and tetanus vaccines are made from toxoids. In the case of tetanus, very little toxin is sufficient to cause disease and even having tetanus disease does not induce protective antibody. The only way to be protected against tetanus is to be vaccinated using several doses of tetanus toxoid.

2. Additives

Additives are used to stabilise vaccines in adverse conditions (temperature extremes of heat and freeze drying) and to prevent the vaccine components adhering to the side of the vial. Examples of additives include lactose and sucrose (both sugars), glycine and monosodium glutamate (both are amino acids or salts of amino acids), human or bovine serum albumin (both are examples of proteins), and gelatin. They are required to ensure that safe and effective doses of the vaccine are available.

Stabilisers

Some vaccines contain stabilisers to keep them safe and effective under different conditions or different temperatures. Gelatin and lactose-sorbitol are examples of stabilisers.

Adjuvants

Adjuvants are chemicals added to vaccines to enhance immunity. Various forms of aluminium salts are commonly used as adjuvants in vaccines. A recent 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.

Diluents

A diluent is a liquid used to dilute a vaccine to the proper concentration. In vaccines, this is usually saline or sterile water.

Preservatives

Preservatives are included in some vaccines to prevent fungal or bacterial contamination of the vaccine. Preservatives are mostly used in vaccines that are manufactured as multidose vials. However, in Australia, multidose vials are not routinely used. Examples of preservatives are thiomersal (also spelt thimerosal), phenoxyethanol, and phenol. Thiomersal is a mercury-containing compound and is discussed in more detail in the section "Safety Concerns: General". Phenoxyethanol (a thiomersal alternative) is an aromatic ether alcohol and is also used as a preservative in cosmetics.

3. Remnants from manufacturing

Chemicals are often used during the vaccine manufacturing process and then removed from the final product. For example, formaldehyde might be used to kill a vaccine virus, or antibiotics might be used to prevent bacterial contamination while growing viruses in the laboratory. When these chemicals are removed, sometimes a trace amount may remain. While some of these chemicals might be harmful in large doses, the trace amounts left in vaccines are too small to have a toxic effect.

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Abbreviations

ADRAC	Adverse Drug Reactions Advisory Committee (Australia)
AEFI	Adverse event following immunisation
AIDS	Acquired immunodeficiency syndrome
BCG	Bacille Calmette-Guérin
BSE	Bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention (United States)
DTPa	Diphtheria-tetanus-acellular pertussis combination vaccine
DTPw	Diphtheria-tetanus-pertussis combination vaccine containing whole (but inactivated) pertussis organism
EMEA	European Medicines Agency
FDA	Food and Drug Administration (United States)
GBS	Guillain-Barré syndrome
Hib	*Haemophilus influenzae* type b
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IBD	Inflammatory bowel disease
IOM	Institute of Medicine (United States)
IPD	Invasive pneumococcal disease
IPV	Inactivated poliomyelitis vaccine
MCV4	Quadrivalent meningococcal conjugate vaccine (Note: not used in Australia)
MMR	Measles-mumps-rubella vaccine
MMRV	Measles-mumps-rubella-varicella vaccine
NCIRS	National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (Australia)
SBS	Shaken baby syndrome
SIDS	Sudden infant death syndrome
SIV	Simian immunodeficiency virus
SSPE	Subacute sclerosing panencephalitis
SV40	Simian virus 40
TGA	Therapeutic Goods Administration (Australia)
VAERS	Vaccine Adverse Events Reporting System (United States)
VAPP	Vaccine associated paralytic poliomyelitis
vCJD	Variant Creutzfeldt-Jakob disease
VPD	Vaccine-preventable disease
VZV	Varicella-zoster virus