immmunisation

Myths & Realities

Responding to arguments against immunisation

A GUIDE FOR PROVIDERS

THIRD EDITION

Commonwealth Department of Health and Aged Care

IMMUNISE AUSTRALIA PROGRAM

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Health and Aged Care

IMMUNISE AUSTRALIA PROGRAM

IMMUNISATION

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1 Introduction

Immunisation has been repeatedly demonstrated in both research trials and in the field to be one of the most effective medical interventions we have to prevent disease. It has been estimated that immunisations currently save 3 million lives per year throughout the world while remaining one of the most cost effective health interventions.

Modern vaccines provide high levels of protection against several diseases, and protection against consequent disability and death. Further, serious adverse events following immunisation are rare. But despite a very good record of effectiveness and safety there are people who have reservations about immunisation. There are small groups in the community who oppose immunisation and who are vocal in expressing their opposition.

This publication examines some arguments frequently raised by opponents of immunisation, and examines the scientific evidence in order to assist practitioners and parents in making an informed choice about the benefits and risks of vaccination. The vaccine-preventable diseases of childhood are still with us and continue to cause substantial distress, disability and even death. Immunisation remains a cornerstone of child health and no child should be denied the benefits of immunisation unless there is a scientifically demonstrated reason to do so.

For the success of the immunisation program it is important that practitioners be well-informed about immunisation and be seen to be a good source of authoritative and scientifically justified advice. It is important that practitioners honestly discuss the benefits and risks of vaccination, and that parents have as full an understanding of both as possible. They should also understand the risks and benefits of not immunising their child. Parents cannot consent to immunisation without this understanding. They

have a right to know the facts and honesty is important to maintain the credibility of immunisation as an effective means of preventing disease. Practitioners should be positive about immunisation, as practitioners' attitudes have been found to be a major influence on patients.

Opponents of immunisation are often vocal and attract media coverage with their sensational stories. This may be partly the result of the ready acceptance of immunisation by most of the community, so that people with arguments against immunisation feel a need to present their arguments strongly. Parents who are undecided about immunisation for their children may receive medical advice which is hesitant and uninformed, while receiving strongly argued and apparently well-researched information from those opposed to immunisation.

Most of the arguments against immunisation appeal to parents' deep-seated concerns for the health of their children and their fear particularly of injections. Parents may find it difficult to express their concerns to medical practitioners, and these concerns may make parents sympathetic to arguments against immunisation. Such arguments provide a rationale for parents who have doubts about immunisation to decide against vaccinating their children. In countering anti-immunisation arguments it is important to recognise this. Mere logical demonstration of the weakness of arguments against immunisation will not be sufficient, and a positive, caring attitude is essential. For this reason it is helpful to have a broad overview of what parents think of immunisation.

References: (1-4)

2 Immunisation myths: Common arguments against immunisation

Arguments put forward against immunisation are generally based on either a rejection of evidence supporting immunisation or are based on alternative views of health and health care. Because these arguments are frequently based on anecdotes, and appeal to emotional concerns about vaccines it may be difficult to respond to them in a way that fully satisfies parents.

Further, the scientific presentation of immunisation is not without controversy. There have been shifts of scientific opinion, technological development which has rendered some vaccines obsolete, and the epidemiology of diseases has changed. This has resulted in ongoing changes to the immunisation schedule. With the development of new vaccines such changes will continue.

2.1

Immunisation myths: Rejection of evidence supporting immunisation

'Infectious diseases are not serious and are a normal part of growing up'

Parents may believe that the vaccine-preventable diseases of childhood do not cause serious illness and are a normal part of a child's growth. In Australia, in the ten years between 1989 and 1998 there were 581 recorded deaths from diseases preventable by vaccines on the current childhood immunisation schedule, with 440 deaths from hepatitis B, 88 deaths from *Haemophilus influenzae* type b, 1 death from diphtheria, 19 from measles and its late complication (subacute sclerosing panencephalitis - SSPE), 14 from pertussis, 3 from mumps, and 16 from tetanus.

References: (5, 6)

REALITIES OF PERTUSSIS *(WHOOPING COUGH)*

Pertussis causes significant morbidity. The cough of pertussis may persist for 6 months or more and post-tussive vomiting may lead to significant weight loss. Neurological complications of pertussis include cerebral hypoxia, seizures, stupor, weakness and cranial nerve abnormalities.

Seizures occur in 2% of cases and encephalopathy in 0.7%. In the USA in 1990 to 1996, 32% of notified cases of pertussis were hospitalised, 10% developed pneumonia, 1.4% experienced seizures, and 0.2% developed encephalopathy. A total of 0.2% of these cases died. During this seven year period, 57 deaths attributed to pertussis were reported to the United States Centers for Disease Control and Prevention.

Pertussis is an extremely infectious disease. Up to 90% of unimmunised contacts in households where there is a case of pertussis contract the disease. In Sweden routine pertussis immunisation was stopped in 1979, subsequently there was a resurgence of epidemic pertussis, and by age 4 years 75% of unimmunised Swedish children had been infected, rising to 90% by adulthood. Sweden recommenced nationwide vaccination against pertussis in 1996.

Since whooping cough is not only highly infectious but also causes severe disease, the risks of complications or even death for each unimmunised child are high.

Between 1993 and 1998 there were 9 deaths from pertussis in Australia; 6 of these were in 1997 during an epidemic.

References: (6–15)

REALITIES OF MEASLES

Measles is one of the most severe and infectious diseases of childhood. In the 1990s, one in every 5–10,000 measles cases died from the acute effects of the disease, despite the best modern medical care. Additionally, deaths from the late effects of the disease may continue to occur several months or years after the acute illness. Measles is still a leading cause of death worldwide. In 1998, there were 888,000 deaths due to measles, more than for breast or skin cancer, or homicide and violence. 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 0.1% of cases, convulsions in 0.5%, and subacute sclerosing panencephalitis (SSPE) in 0.001% of cases. SSPE is a

delayed response to wild measles infection with severe encephalopathy occurring years after wild measles infection, and has a uniformly fatal outcome. SSPE does not occur as a result of administration of measles vaccines. Immunosuppression, which can last for several weeks, with consequent secondary infection, is a further complication of wild measles.

Measles is virtually universal amongst unimmunised children in all countries. Eventually, 99.9% of people who have not been immunised will contract measles, and 90% will do so before the age of 20.

Measles is highly infectious and causes severe disease, with the result that the risks of complications or even death for each unimmunised child are high.

References: (9, 15–26)

REALITIES OF *HAEMOPHILUS INFLUENZAE* TYPE B (HIB) INFECTION

Hib is a bacterium which causes invasive disease, particularly meningitis, epiglottitis, septicaemia, cellulitis, pneumonia, septic arthritis, osteomyelitis and pericarditis. Meningitis accounts for 60% of invasive Hib infections and has a case-fatality risk of 5%. It causes long-term disability, including cerebral palsy, deafness, convulsions and permanent intellectual impairment in about 15–45% of survivors despite modern treatment.

In Australia before the introduction of Hib immunisation, there were about 700 cases each year, with 10–15 deaths, and 20–40 children left with significant disabilities.

Before immunisation was available, Hib was the major cause of meningitis and invasive infection in children under the age of 5 years, with 1 in 200 children suffering invasive disease before age 5.

The first conjugate Hib vaccine became available in Australia in 1992, several more followed in 1993 and Hib vaccines became free to all children under the age of 5 years from April 1993. There was a 95% reduction in the number of Hib cases in children under 5 years of age between 1992 and 1999. The total number of cases (all age groups) declined from 502 in 1992 to 41 in 1999, a reduction of 92% (Figure 1).

References: (15, 16, 27–33)

REALITIES OF POLIO

Polio is caused by an enterovirus and infection may result in paralysis, aseptic meningitis, or mild or inapparent illness. There may be as many as 75–1,000 cases of inapparent infections for each paralytic case, depending on the virus type, age of the population and environmental conditions. In developed countries, such as Australia, the risk of paralysis tends to be higher. The fatality risk varies from 2–10% for paralytic cases and also increases with age.

On 29 October 2000 the World Health Organisation (WHO) announced the Western Pacific Region, including Australia, had stopped the circulation of the indigenous wild poliovirus and as a result, the Region has been certified as polio-free. Further, the WHO plans global eradication of polio by the year 2005.

The last known wild polio case in Australia was reported in 1972. However, importation of the disease from overseas continues to be a risk. Therefore Australia needs to maintain coverage with polio vaccine for the present time. After eradication of the disease and the containment of poliovirus, it can be dropped from the recommended immunisation schedule as has already been done for smallpox.

References: (9, 15, 16)

REALITIES OF DIPHTHERIA

Although relatively small numbers of cases of diphtheria have occurred in Australia in recent years the potential for an outbreak remains. Following the break up of the former Soviet Union, social disruption led to various problems including a decrease in immunisation programs. Tens of thousands of cases of diphtheria followed and more than a thousand people died from the disease. Prior to that outbreak, diphtheria had been controlled in the Soviet Union by immunisation for approximately 30 years.

References: (15, 34–36)

REALITIES OF HEPATITIS B

Hepatitis B is a viral infection which can cause acute or chronic hepatitis. It is transmitted by contact with blood and body fluids, for example by sexual intercourse, intravenous drug use and blood transfusion. It can also be transmitted from an infected mother to her baby around the time of birth. There is some evidence that

children may transmit it to each other through contact that occurs while playing together. Some people may become 'carriers' due to chronic infection. Chronic infection may lead to cirrhosis (scarring) of the liver or cancer of the liver. Infants and young children are much more likely to develop chronic infection than adults. This means that infant vaccination is more effective at reducing chronic carriage of the virus. From 1993 to 1998 there were 1,645 notifications of hepatitis B and 1,414 hospitalisations for hepatitis B in Australia. Notification rates were highest in the age group 20-24 years. Rates of hepatitis B are higher in indigenous Australians, with carriage rates ranging from 3–22% in various communities.

The vaccine for hepatitis B is made by recombinant DNA technology, which produces inactive (non-infectious) subunits of the virus. When injected into non-immune people, the vaccine gives a high level of protection against hepatitis B infection. In 2000, a birth dose of hepatitis B vaccine (with boosters at 2,4 and 6 or 12 months) was introduced into the childhood schedule in Australia. An adolescent hepatitis B schedule is available for children who have not received hepatitis B vaccination as an infant.

Routine antenatal screening for HBsAg is essential to minimise carriage in high-risk families. Infants born to HBsAg positive mothers should be given hepatitis B immunoglobulin within 12 hours of birth. They should also be vaccinated with the first dose of monovalent hepatitis B vaccine within 24 hours of birth. If this is not possible, vaccination should not be delayed beyond 7 days after birth. Three subsequent doses of the vaccine should be given at 2, 4 and either 6 or 12 months according to the instructions for the particular vaccine, so that the infant is given a total of four doses of hepatitis B containing vaccines.

References: (15, 37–39)

'Immunisation is not responsible for the decline in communicable diseases as improved living standards and sanitation have reduced the incidence of infectious diseases'

It is often said that factors other than immunisation are responsible for the decline in the importance of

communicable diseases. The decline in communicable diseases is multifactorial, and living standards do play an important role. However, vaccination has also had a clear and significant impact.

Measles and pertussis are spread via the respiratory route and attack rates are not affected by living standards or standards of sanitation. The attack rate for both of these diseases is almost 100% irrespective of social and sanitary conditions. Both affect virtually all people eventually, in all countries. Polio is caused by an enteric virus which spreads more easily under conditions of poor hygiene, but has caused epidemics in countries like Holland, Finland and Israel, all of which have high standards of hygiene. All the vaccine-preventable diseases have shown dramatic reductions in incidence after the introduction of vaccination.

Hib vaccine was introduced into the standard vaccination schedule in 1993. Figure 1 (page 10) shows the dramatic impact Hib vaccination has had on lessening disease. Sanitation and living conditions have not changed since 1993 and so can not be the cause of the marked fall in Hib cases and deaths. The improvement is clearly due to immunisation.

Reference: (9)

LIVING STANDARDS AND THE DECLINE IN MORTALITY FROM VACCINE-PREVENTABLE DISEASES

Opponents of immunisation frequently state that mortality from vaccine-preventable diseases declined before the introduction of immunisation.

This is due to other factors such as improved living standards, improved nutrition, and higher standards of medical care. However, vaccination has also contributed significantly to the reduction in vaccine-preventable diseases. In the case of measles and pertussis, there has been a considerable reduction in the mortality risk from measles and pertussis over time, but there was no reduction in the incidence of these diseases before the introduction of vaccines (Figures 2 & 3). Despite the very considerable reduction in mortality, there is still a substantial risk of death from vaccine-preventable disease, making immunisation a program of ongoing public health importance.

References: (40, 41)

IMMUNISATION AND THE DECLINE IN INCIDENCE OF VACCINE-PREVENTABLE DISEASES

Following the introduction of measles immunisation in the USA in 1962 there was a prompt reduction in the incidence of measles of over 99%.

In Britain a similar fall was observed following the introduction of the measles immunisation program in 1968 (Figure 2).

There have been major epidemics of polio in the Netherlands occurring in a religious group who refused immunisation.

There was no spread to the rest of the population, whose immunisation coverage against polio 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, 27 children died from the direct consequences of pertussis and 17 developed permanent neurological damage as a result of the infection. Acceptance of pertussis vaccine has now improved to about 93% and pertussis has declined (Figure 3).

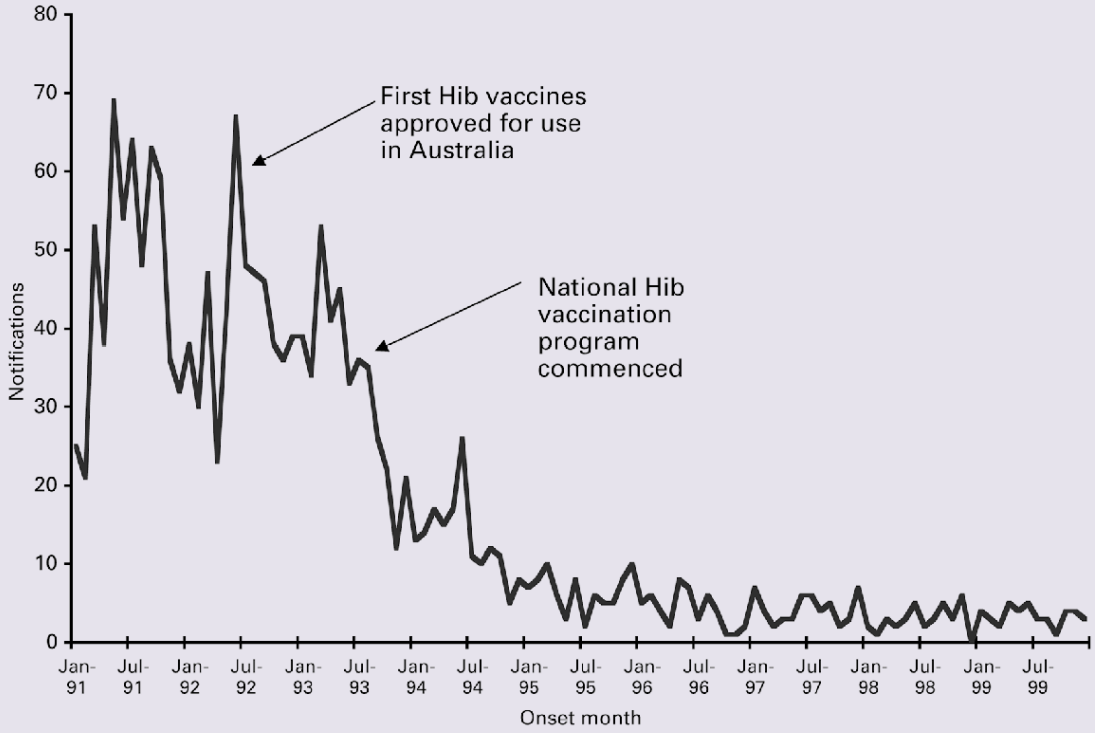
Similar epidemics occurred in Japan and Sweden at about the same time due to low acceptance of pertussis vaccine.

In most Western countries the incidence of Hib had been increasing since the 1940s. This was true in Finland until 1990, when the trend was dramatically reversed after introduction of a comprehensive Hib immunisation program. Similar results have been reported in Australia, the USA, Iceland, and the UK (Figure 1).

References: (7, 17, 23, 40–49)

Figure 1 Notifications of invasive Hib disease in Australia, 1991–1999

(source: Communicable Diseases Network—Australia New Zealand—National Notifiable Diseases Surveillance System, Personal Communication)



'The vaccines do not protect against disease as many cases of disease occur in immunised children'

Some parents believe that, since many of the cases of vaccine-preventable disease occur in children who have been immunised, vaccines are not effective in preventing disease.

There is an apparent paradox, in that as immunisation coverage increases, there are increasing proportions of cases of vaccine-preventable diseases in immunised children. There is a simple relationship between vaccine efficacy, immunisation coverage and the apparent proportion of vaccine failures. The number of cases of measles (where the efficacy of the vaccine is 95% and the attack rate of the disease is 100% in susceptible persons) which will occur in a group of children and the proportions of cases which occur in immunised children are illustrated in Table 1. It is important to note the dramatic effect of immunisation on the total number of cases.

Figure 2 Measles notifications, deaths and vaccination coverage in England and Wales, 1940–1999

(data source: PHLS Communicable Diseases Surveillance Centre and the Department of Health).

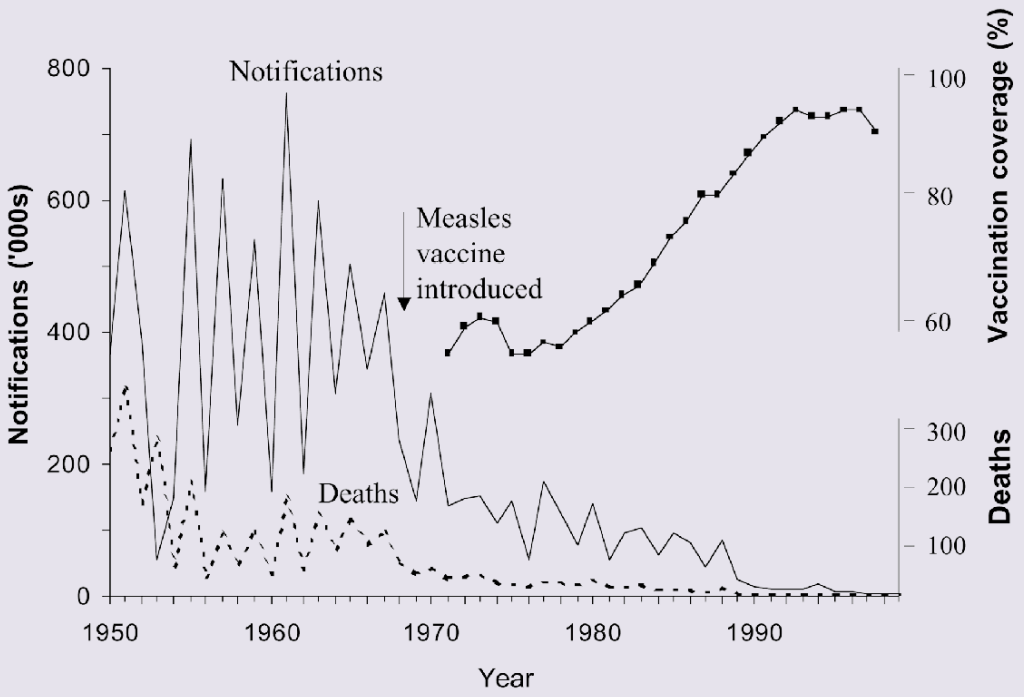


Table 1 The effect of measles immunisation on an outbreak of measles in a hypothetical school of 2,000 students (source: reference (50))

No. (%) vaccinated	No. immune from vaccine	No. (%) who become infected	% of cases in vaccinated
0 (0)	0	2000 (100)	0
1000 (50)	950	1050 (53)	5
1500 (75)	1425	575 (29)	13
1800 (90)	1710	290 (15)	31
1900 (95)	1805	195 (10)	49
1960 (98)	1862	138 (7)	71
1980 (99)	1892	108 (5.4)	94
2000 (100)	1900	100 (5)	100

Reference: (50)

Figure 3

Pertussis notifications, deaths and vaccination coverage in England and Wales, 1940–1999

(data source: PHLS Communicable Diseases Surveillance Centre and the Department of Health).

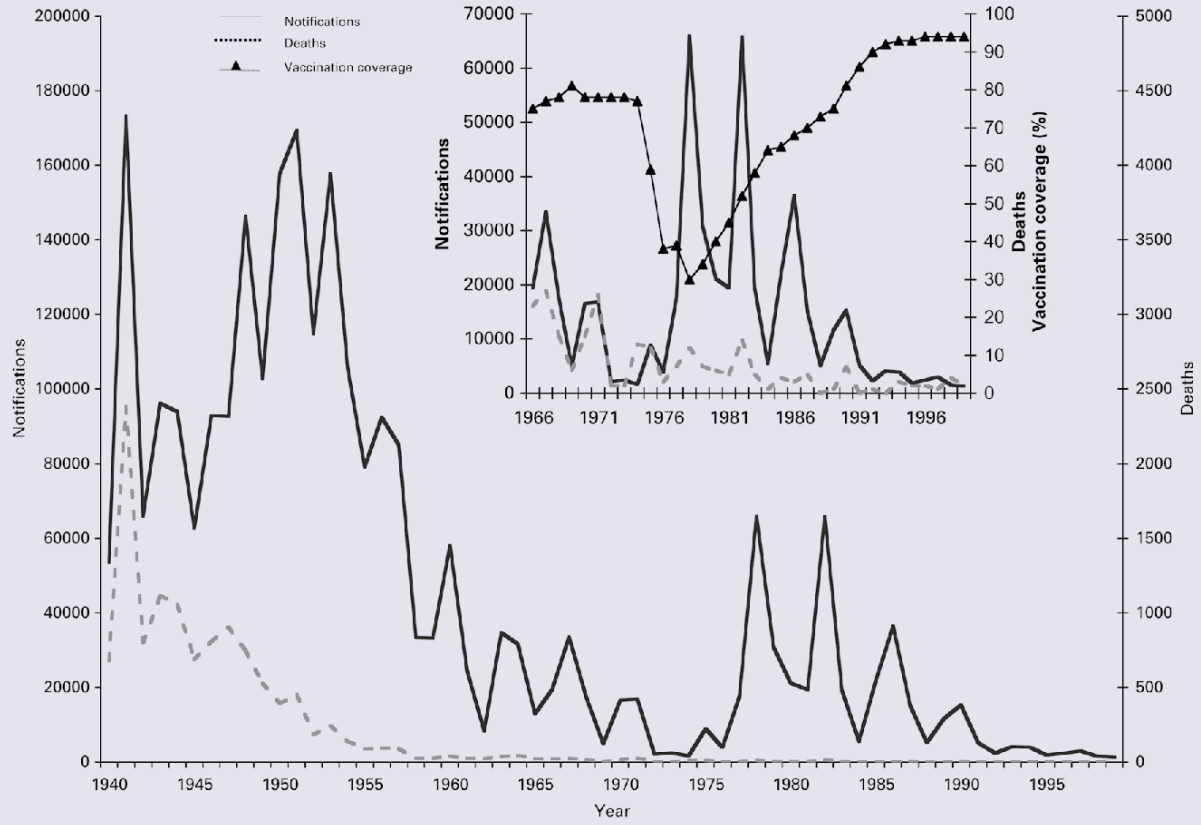


Table 2

Vaccine efficacies of some vaccines used in the Australian immunisation program (sources: references quoted)

Vaccine	Efficacy	Reference
diphtheria	84%	(51)
acellular pertussis	76-90% against disease, >90% against severe disease	(52, 53)
polio	95%	(16)
Hib	95%	(31, 54)
measles	95%	(24, 55)

VACCINE EFFICACY

Vaccine efficacy is a measure of the level of protection against a disease in children who have been vaccinated compared with the attack rate in children who have not been vaccinated. A vaccine efficacy of 100% indicates perfect protection, 0% indicates no protective effect. There are many good controlled trials and field studies to show the efficacy of vaccines. The protective efficacies of several vaccines are given in Table 2.

Acellular pertussis containing vaccines were funded for use in both primary and booster vaccination schedules in Australia in February 1999. The pertussis component of this vaccine has been shown to have an efficacy of between 76% and 90%.

No vaccine (or, for that matter, any other treatment or preventive strategy) is 100% effective. As the vaccine coverage increases, so inevitably does the proportion of cases that are due to vaccine failures. If all children have been immunised against a disease, all cases of the disease will be regarded as due to 'vaccine failures'.

References: (52, 56–58)

'Vaccines are unsafe'

A major concern of opponents of immunisation is that they consider vaccines to cause harm, whether or not they prevent disease. In general, no biological product can be considered 100% safe. However, all vaccines available in Australia are required to pass stringent quality, safety and efficacy requirements before being approved by the Australian Therapeutic Goods Administration.

'The side effects of DTP include brain damage'

DTP vaccine contains components to induce immunity to tetanus, diphtheria and pertussis. The pertussis component of the vaccine that was available for many years was manufactured from whole-cell pertussis organisms. These whole-cell DTP vaccines were commonly associated with several local adverse events (eg redness, swelling and pain at the injection site), fever, and other mild systemic events (eg drowsiness, fretfulness and loss of appetite). More severe systemic events (eg convulsions, with or without fever, and hypotonic hyporesponsive episodes) occurred less frequently (about 1 case in 1,750 doses

administered). There was concern in the 1970s that pertussis vaccine caused encephalopathy and brain damage. Despite it being studied extensively, there is no conclusive scientific evidence that pertussis vaccines of that time caused acute encephalopathy or brain damage. In fact, the US Institute of Medicine stated that pertussis vaccine did not cause permanent brain damage. Acellular pertussis vaccines cause a much lower incidence of fever and local reactions than whole-cell vaccines. The incidence of other adverse events with acellular vaccines has not been as extensively documented as it has with whole-cell vaccines.

References: (52, 53, 59, 60)

'Vaccines cause the diseases they are supposed to prevent'

Oral polio vaccine (OPV) is often said by opponents of immunisation to be the major cause of paralytic polio in developed countries like Australia and the USA. Live oral polio vaccine may cause paralysis in 1 per 2.5 million distributed doses, particularly in those receiving their first dose. In the USA there were about 8 cases of paralysis per year following the use of OPV. Because OPV virus is shed for about 6 weeks after administration there are occasional cases of paralysis in contacts of vaccine recipients. In the UK there were 9 cases of paralysis in contacts of children immunised with oral polio vaccine from 1985 to 1997. In Australia, there have only been 2 cases of vaccine–associated paralytic poliomyelitis in the last 13 years.

First generation Hib vaccine (PRP) was associated with a transiently increased risk of invasive Hib infection after vaccination. This vaccine is no longer used, and was never used in Australia. Current Hib vaccines do not have this effect.

References: (16, 61–68)

'Vaccines suppress the immune system'

It is sometimes argued that vaccines suppress, rather than enhance, the immune system. The only situation where this may occur appears to be immune suppression following the use of high-titre measles vaccines, which were proposed at one time as the preferred vaccines for some developing countries. As a consequence, these vaccines are no longer used. They have never been used in developed countries, such as

Australia. There is no evidence of this effect with other vaccines.
References: (24, 69)

'Additives in vaccines are toxic'

Additives in many vaccines are said to be 'toxic', for example formaldehyde (used in the preparation of several vaccines), thiomersal (used as a preservative in several vaccines) and aluminium (used in some vaccine adjuvants). It is an exaggeration and misleading to say that vaccines contain many toxic ingredients.

The newer generation vaccines (eg recombinant hepatitis B vaccine, conjugated Hib vaccine, acellular pertussis vaccine) are highly purified subunit components of the organisms causing disease, and are virtually free of toxic components often associated with the whole organism (eg bacterial endotoxin).

Formaldehyde is a chemical agent that is used in the manufacture of certain vaccines made from components of bacteria or viruses. For example, formaldehyde is used to detoxify the tetanus toxin protein produced during the manufacture of tetanus vaccine. The non-toxic protein which becomes the active ingredient of the vaccine is further purified to remove contaminants and any excess (unreacted or unbound) formaldehyde.

The current standard applicable to vaccines for human use in Australia is the British Pharmacopoeia (BP) 1993 and subsequent amendments. The BP contains a general requirement for all vaccines which includes limits on residual free formaldehyde. The BP dictates that vaccines should not contain more than 0.02% weight for volume (w/v) of free formaldehyde. The maximum amount of free formaldehyde detected by the Therapeutic Goods Administration during testing of vaccines registered in Australia has been 0.004% w/v - well below the standard limit.

The adjuvant in DTP vaccine (usually very small amounts of aluminium salts) improves the protective response to immunisation. Diphtheria and tetanus toxoids are weak immunogens and they are adsorbed onto adjuvants to strengthen the immune response. The main functions of adjuvants is to keep antigens near the injection site and to activate antigen-presenting cells.

Preservative is added to some

vaccines. Live measles vaccine contains trace amounts of neomycin and polio vaccine is stabilised with sucrose or magnesium chloride. In killed and toxoid vaccines thiomersal is usually used.

Thiomersal is a compound which contains 49.6% mercury and it has been used in very small amounts in vaccines since the 1930s, as it prevents bacterial and fungal contamination. There is no scientific evidence that thiomersal in vaccines causes any adverse health effects in children. However, the possibility exists that vaccination of newborn babies, particularly those who have a low birth weight, with repeated doses of thiomersal-containing vaccines, may result in levels of mercury that are above the recommended guidelines. Theoretically, such infants may therefore be at risk of adverse effects from mercury. A recent US study measured blood mercury levels before and after a dose of hepatitis B vaccine given at birth. This study found raised blood mercury levels after hepatitis B vaccination in babies, particularly premature babies, but the levels were within the "normal" range defined by the US Department of Health & Human Services.

The current National Health and Medical Research Council (NHMRC) Australian Standard Vaccination Schedule for children under the age of 5 years includes only one vaccine that contains thiomersal. This vaccine is monovalent hepatitis B vaccine, which contains 25 micrograms of thiomersal per dose.

In July 1999, the US Food and Drug Authority (FDA) issued a directive to all vaccine manufacturers to remove thiomersal from all vaccines, or to justify its continued use. The Australian Therapeutic Goods Administration (TGA) has written to sponsors of all vaccines included in the Australian Standard Vaccination Schedule, requesting removal of thiomersal or minimisation of thiomersal content. In response, a thiomersal-free monovalent hepatitis B vaccine was introduced in May 2000, and an equivalent product was introduced in August 2000 that does not contain thiomersal as a preservative.

References: (70–76)

'Vaccines cause Sudden Infant Death Syndrome (SIDS)'

This belief came about because a moderate proportion of children who die of SIDS have recently been vaccinated. On the surface this seems to indicate vaccination was the cause of death. However this logic is faulty, it confuses association with causality. Consider that many people who crash their cars have eaten bread in the 24 hours before a car crash. Eating bread may be shown to be associated with car crashes but it is not a cause.

SIDS deaths occur during the age range when many vaccinations are given and thus you would expect vaccinations to precede SIDS simply by chance. Several studies have shown that immunisation does not increase the risk of SIDS and may even lower the risk.

Some factors are known to be associated with SIDS, for example putting the baby into bed in a prone position and smoking by the parents. Concentrating on stopping these habits has been shown to do much to lessen deaths from this cause.

References: (77–79)

'Vaccines contain foreign proteins'

Foreign proteins, for example egg protein and gelatin, in vaccines may cause allergic reactions. Opponents of immunisation say that this is especially dangerous for very young infants who are said to be vulnerable by virtue of their immaturity. They claim that vaccines cause encephalitis, convulsions, brain damage, multiple sclerosis and other neurological syndromes.

The measles and mumps components of MMR vaccine are grown on chick embryo cell culture and truly egg-sensitive children may have severe reactions to the vaccine. MMR vaccines also contains small amounts of porcine or bovine gelatin, which can cause allergic reactions, including anaphylaxis. MMR vaccine is contraindicated in people with known allergy to gelatin. However egg allergy, even anaphylactic egg allergy, is not a contraindication to immunisation with measles vaccine or MMR. At the Royal Children's Hospital, Melbourne, Aikin et al administered MMR vaccine to 400 children who had both a history of egg allergy and a positive skin prick test. Only 4 children had minor reactions and none had any reaction

that required treatment. Children with egg allergy can safely be given MMR vaccine provided this is done under close supervision, with adrenaline ready for injection.

References: (16, 80–82)

'Some vaccines may cause Mad Cow Disease'

Bacteria for use in some vaccines are grown on a medium containing bovine heart and brain components. Thus there is a danger of transmitting Bovine Spongiform Encephalopathy (BSE) or 'mad cow disease' to the recipients of vaccines manufactured using this method.

In November 2000, Australia's Chief Medical Officer, Professor Richard Smallwood, announced that an expert committee had undertaken a review of vaccines in Australia that were 'grown' in calf serum originally sourced from UK cattle. Following a full review of all vaccines, the Committee considered the risk of exposure to variant Creutzfeldt-Jakob Disease (vCJD - the human equivalent of mad cow disease) through vaccines is negligible.

These findings follow a similar verdict from the American Food and Drug Administration which declared that the risk of contamination from calf serum, used to prepare master and working seed banks for some vaccines, to be negligible and the benefit of immunising children outweighed the remote theoretical risk of vCJD.

Despite millions of doses of vaccine being administered worldwide, there have been no reported cases of Creutzfeldt-Jakob Disease (CJD) associated with vaccines. In addition, there has been no known transmission of CJD via blood or blood products despite the relatively long history of use of these preparations. In one retrospective study, no cases of CJD have occurred in 158 recipients of blood components from 14 donors who subsequently developed CJD. Thus, the risk of transmission of CJD through vaccines and blood or blood products is considered to be theoretical only.

References: (83, 84)

'Vaccine viruses persist after immunisation'

Vaccine viruses are supposed by some opponents of immunisation to persist in the body leading to chronic disease. A variant of this view is the homeopathic 'Hering's law' which

states that immunisation drives viruses directly into the bloodstream and thus deep into the body, where they 'attack vital organs'.

For most vaccines, antigens do not persist after immunisation, since they are eliminated by the immune response they cause. The exception is varicella vaccine, which is capable of causing herpes zoster in vaccinees many years after vaccination, but at a much lower rate than natural varicella infection.

References: (85, 86)

'MMR vaccine causes inflammatory bowel disease and autism'

In 1993, a group of researchers led by Dr Wakefield at the Royal Free Hospital, London, suggested an association between both the natural and vaccine types of measles virus and inflammatory bowel disease (IBD) based on a study of 25 children with Crohn's disease (compared to 22 well children). In 1998 researchers from the same group reported the occurrence of an apparently new syndrome of an unusual type of IBD in association with developmental disorders such as autism. The researchers suggested that MMR vaccine caused IBD, which then resulted in decreased absorption of essential vitamins and nutrients through the intestinal tract. They suggested that this resulted in developmental disorders such as autism.

Reviews of these studies by expert groups around the world have found the suggested associations to be weak and the studies to have several flaws. Primarily the Royal Free Hospital studies have been conducted on very selective patients, all referred to the hospital for gastrointestinal ailments. Such a case series analysis is unable to determine causal links. In addition, there was no report of detection of vaccine viruses in the bowel or brain tissues of any of the patients. Furthermore, the association between vaccine and autism was primarily based on parental recall. Parents are likely to have linked changes in behaviour with memorable events such as vaccination. More thorough, large epidemiological studies, including an English population based study of the vaccination status of 498 children with autism, and rates of IBD and autism among 6,100 French school-aged children, have found no evidence of an association.

Laboratory studies using a similar methodology to Wakefield et al. did not find any measles virus in patients with IBD. Other groups using more sensitive testing methods have not found any evidence of measles virus in the gastrointestinal tract of patients with Crohn's disease or ulcerative colitis. Recently Wakefield and John O'Leary presented data of selected cases of autistic children suggesting that they may have isolated measles virus from some children. These data have not been published in the scientific literature, and no other laboratory has been able to reproduce these findings.

Reviews by Canadian and World Health Organization experts have concluded that 'current scientific data do not permit a causal link to be drawn between the measles virus and IBD'. In 1998 Sir Kenneth Calman, British Chief Medical Officer, convened a meeting of the Medical Research Council and a group of national and international experts, including the World Health Organization, to review the work of Wakefield and the Royal Free Hospital IBD study group. The meeting concluded that based on current evidence 'there is no link between measles, measles vaccine, and either Crohn's Disease or autism'.

The onset of autism and MMR vaccination may coincidentally appear associated in time because the average age at which parents report concerns about child development is 18 months to 19 months, and over 90% of children receive MMR vaccine before their second birthday in the UK.

References: (87–91)

'Vaccines are contaminated with adventitious viruses'

It has been said that vaccines are cultured on animal tissue and therefore, contain many bacteria and viruses other than the ones they are supposed to immunise against.

It is misleading and an exaggeration to state that vaccines are cultured on animal tissue and therefore contain many contaminants. Only viral vaccines are cultured in material derived from animal tissues. Bacterial vaccines are manufactured in cultures free of animal cells.

The viruses used in current viral vaccines are propagated in chicken eggs, primary cell cultures and continuous cell lines. These substrates are thoroughly screened for adventitious agents such as other viruses or bacteria. Any other materials or reagents used in the

production of vaccines are also thoroughly tested for purity, sterility and for absence of known contaminants.

Between 1955 and 1963 some batches of polio vaccine were inadvertently contaminated with a monkey virus called simian virus 40 (SV40), which has since been found to be capable of causing cancer in hamsters. This issue was reviewed at an international workshop on SV40 virus in the United States of America in January 1997.

The meeting concluded that there is no evidence of increased cancer risk in people who were given vaccine containing SV40. Since 1963, all polio vaccines have been demonstrated to be free of SV40 as well as other known possible contaminants such as simian immunodeficiency virus (SIV). It has also been suggested that polio vaccine may have been linked with the development of Acquired Immune Deficiency Syndrome (AIDS). This has recently been disproven when the development of AIDS was traced to the 1930s, long before polio vaccination. There is no scientific evidence linking AIDS to polio vaccines. In addition, polio vaccine stored in the 1950s has been tested with the latest technology for the presence of HIV, the virus which causes AIDS, and no HIV has been found.

References: (92–98)

'Hepatitis B vaccine causes multiple sclerosis (MS)'

There is no evidence that hepatitis B vaccine causes multiple sclerosis (MS). Concern about hepatitis B vaccination arose from France, which had a large-scale population hepatitis B vaccination program. Over one-third of the entire French population has been vaccinated against hepatitis B. A few recent case reports were made in France of MS or MS-like illness associated with hepatitis B vaccines. As a result of this, the French government stopped their school-based hepatitis B vaccination program. When the French data were examined, however, the rate of MS in vaccinated people was not significantly different from the expected population rate.

In addition, there is very little else in the medical literature suggesting that hepatitis B vaccine causes MS. Specifically, there have been no large-scale population-based studies or clinical trials which have shown this to be a real relationship. Because of

the large number of people vaccinated in France, it is possible that the MS case reports are purely coincidental to hepatitis B vaccination. Extensive pre-licensure clinical trials of hepatitis B vaccine did not document MS as a side effect. In addition, mass immunisation with hepatitis B vaccine in New Zealand, Taiwan and Alaska has not resulted in any serious adverse events or illnesses suggestive of MS. In the USA, surveillance of adverse events after hepatitis B vaccination has also not shown any clear association between hepatitis B vaccine and serious adverse events. These findings provide important negative evidence, and suggest that if vaccination does cause MS, it does so extremely rarely.

With millions of vaccinations administered worldwide, it is likely that surveillance systems in some countries will receive some reports of MS which seem to be related in time to vaccinations. As with all such case reports, however, they only suggest the possibility of an association. Four large studies designed to answer this question have found no increase in MS after hepatitis B vaccine. Further controlled studies (which compare large numbers of vaccinated people with unvaccinated people) are necessary to establish causation.

References: (99–102)

'The rubella and chicken pox vaccines are cultured on cell lines of aborted fetuses'

The anti-vaccination lobby appears to have recently revived this old story which gained prominence in the mid 1990s when the mass vaccination campaign against measles and rubella was planned and subsequently carried out in the United Kingdom.

Viruses are parasites and depend for their existence upon repeated invasion of other cells which are destroyed as the viruses utilise them in their life cycle. Moreover, viruses are generally specific as to the type of cells they inhabit. Rubella virus, for instance, can infect only human cells, so that rubella is a human disease only.

The rubella component of the measles, mumps and rubella vaccines used in Australia, is a live virus (Wistar RA 27/3 strain) which was adapted to and propagated in the WI-38 human diploid cell culture. This cell culture was derived originally

from human fetal lung tissue obtained from a fetus aborted at approximately 3 months gestation of a Caucasian female in about 1966.

By a process of repeated cultivation it is possible to produce an "immortal" self-replicating group of cells known as a "cell line". A cell line thus produced is not identical to the cells of the original species from which it is derived but has similar genetic characteristics. Cell lines are used widely in the culture of other organisms. No new tissue has been added since the original samples were taken over 30 years ago and the cells, although uniform, no longer resemble the originals. No other fetal tissue is used in any way in research or manufacture of rubella vaccine.

Press clippings from 1994 indicate that there appears to be no ethical problem to the use of rubella vaccine in the eyes of the Catholic church. Statements supporting the use of the vaccine are quoted from Mary Brogan, President, National Board of Catholic Women in the UK, who also indicates the support of the board's Episcopal Liaison, Bishop Vincent Malone. Also quoted as supporting use of the vaccine is Father Norman Ford, a lecturer in medical ethics at the Catholic Theological College at Clayton in Victoria.

Chicken pox (varicella) vaccine is also grown on a human diploid cell line originally derived from a fetus many years ago and the varicella virus used in the vaccine strain came from a young boy infected with chicken pox.

'Vaccines can cause diabetes'

There is no evidence that vaccines cause diabetes. There have been a number of studies which have searched for links between diabetes and immunisations. The only study suggesting a possible increase in risk has come from Dr John B Classen, who found that if the first vaccination in children is performed after 2 months of age, there is an increased risk of diabetes. His laboratory study in animals also found that certain vaccines, if given at birth, actually decrease the risk of diabetes. This study was based on experiments using anthrax vaccine, which is very rarely used in children or adults. Dr Classen also compared diabetes rates with vaccination schedules in different countries, and interpreted his results as meaning that

vaccination causes an increased risk of diabetes. This has been criticised because the comparison between countries included vaccines which are no longer used or used rarely, such as smallpox and the tuberculosis vaccine (BCG). The study also failed to consider many reasons other than vaccination which could influence rates of diabetes in different countries.

Other researchers who have studied the issue have not verified Dr Classen's findings. This includes a group from the highly respected international Cochrane Collaboration, which reviewed all the available studies and did not find an increased risk of diabetes associated with vaccination. Expert groups such as the National Institutes of Health in the USA have met and reviewed the evidence and conclude that there is no link between vaccines and diabetes.

References: (103–106)

VACCINE SAFETY

Before vaccines are made available they are tested for safety and efficacy in clinical trials and then in mass trials. All vaccines marketed in Australia are manufactured according to strict safety guidelines and are evaluated by the Therapeutic Goods Administration to ensure they are efficacious and are of adequate quality and safety prior to marketing approval being granted.

After introduction into immunisation schedules there is continuing surveillance of efficacy and safety through trials and post marketing surveillance. In Australia there are regional and national surveillance systems actively seeking any adverse events following immunisation. This is necessary, as sometimes problems do occur after vaccines are registered for use. An example is rotavirus vaccine, which was licensed in the USA in August 1998. In pre-licensure trials, the vaccine appeared to be safe, but post-licensure surveillance detected a risk of intussusception associated with the vaccine. As soon as this risk was discovered, the vaccine was withdrawn from the market. Rotavirus vaccine was never released in Australia.

References: (107–109)

2.2

Immunisation myths: Some alternative views of health and health care

'The germ theory of disease is false'

Under this hypothesis, infectious agents are not the cause of infection but merely one of its manifestations.

The germ theory of infectious disease is one of the bases of scientific medicine, which has had virtually universal support from at least the time of Pasteur and Koch's postulates in the late nineteenth century. Prior to that time transmission of disease was thought to be via toxic miasmata and effluvia.

'Immunisation is unnatural'

Immunisation is said to be an artificial stimulus to the immune system which is somehow harmful. A variant of this view is that the injection of vaccines is unnatural and that the natural portal of entry is usually via the respiratory or some other route. The 'large' dose of antigen directly injected then supposedly overwhelms the child's natural responses.

Vaccines provide the same stimulus to the immune system as infection, but without disease. In this sense immunisation is natural, and few drugs interact with the body in such a natural way as vaccines. Children are continually challenged with a large number of agents of communicable disease in the first few years of life (including, in the absence of immunisation, the vaccine-preventable diseases).

References: (71, 72)

'Specific immunity is not important for protection from disease'

Factors such as diet, healthy life-style (including a sense of well-being) and avoidance of stress are said to be the most important factors in preventing disease. Occasionally, specific factors are proposed, for example that lack of ascorbic acid is the main cause of infection. General 'strengthening of the immune system' is the proposed means of preventing infection.

Immunisation is the only tested and proven means of protection against the vaccine-preventable diseases. Immunisation is particularly important in conditions of stress and unhealthy life-style such as in refugee camps.

Some protection is provided by maternal antibodies, passed from the mother to the newborn baby and the amount of protection varies with different diseases. Effective protection is provided against measles infection for the first few months of the baby's life but the maternal antibodies disappear between six and twelve months of age. The amount of antibody passed on by a mother who has been vaccinated against measles is less than that passed by a mother who had recovered from measles disease. In contrast, mothers pass only minimal antibody protection against pertussis to the baby and the little protection that is passed, rapidly disappears during the first few weeks of life, putting babies at risk of infection when exposed to adults or older children with the disease.

The ability of an infant to mount an appropriate immune response to many vaccines is poor at birth but improves as the child's immune system matures. Hence the routine immunisation schedule commences at 2 months of age. An exception is hepatitis B vaccine which produces a high level of protection when given to newborn infants.

References: (110–114)

'Homeopathic vaccines'

There is a wide variation in the use of immunisation by homeopathic practitioners. The Medical Association for Homoeopathy recommends orthodox immunisation with standard vaccines.

Several homeopathic 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. By the process of 'succussion' the protective activity is supposed to be transferred to the diluting water. Some of the schedules to administer these preparations are of great complexity and extend over a period of years with multiple doses.

Few studies where homeopathic 'vaccines' have been subjected to scientific scrutiny are available. None of the studies which are available is of a 'vaccine' against a disease on the current immunisation schedule recommended by the National Health and Medical Research Council, and the efficacy of these 'vaccines' is therefore not established.

References: (115–117)

3 Parents' beliefs about immunisation

Parents often feel ambivalent about immunisation. Table 3 summarises parents' perceptions of immunisation and compares these perceptions with those of disease.

Parents are concerned about the risk of adverse events and about efficacy. They often perceive practitioners as uninformed, and unwilling to explain and discuss immunisation. When parents compare notes after consulting different doctors they often find they had been given conflicting explanations. Parents would like a single, authoritative and credible explanation. They often believe that 'natural' immunity is better and many parents believe that age 2 months is too young to begin to immunise a baby, thinking that this is a kind of 'assault' on the child and on the child's immune system. Parents do not usually understand how immunisation protects the child and the diseases are often not seen as serious. Few parents have direct experience of children who have suffered from the more severe complications of vaccine-preventable disease.

Table 3 A summary of parents' beliefs about immunisation

(source: research carried out for the Commonwealth Department of Human Services and Health, 1995)

Immunisation	Disease
Experience first hand	Often no, or distant experience
Fact	Chance
Palpable, adverse effects	Dangerous but unknown
Emotional, involving	Rational, distant

4 Responding to immunisation myths

Fear of immunisation is not uncommon and it is from this fear that arguments against immunisation derive much of their power. There is a need to respond both factually and empathically to these concerns.

The best approach is a combination of a caring attitude towards patients, up to date knowledge, and a positive attitude towards immunisation. There is no need to be defensive about immunisation. The vaccine-preventable diseases are severe and immunisation prevents them. If parents raise arguments against immunisation, practitioners should explore the reasons for doing so. Practitioners should emphasise the benefits of immunisation, but should themselves raise and discuss adverse events which may follow immunisation. Practitioners should also explain the risks of disease and complications which result from *withholding* immunisation.

Parents understand and value an attitude which results from a critical review of the evidence. The vaccine provider should allow time for a discussion with the individual to ensure the issue of risks and benefits of the vaccine and the disease has been addressed. As with any medical intervention, the doctor/nurse should make a note in the clinical records that such a discussion has taken place prior to the person giving consent. A stamp or sticker, signed by the provider, is acceptable.

'No child should be denied immunisation without serious thought as to the consequences, both for the child and the community' (World Health Organization)
Reference: (118)

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