

## APPENDIX 5: COMMONLY ASKED QUESTIONS ABOUT VACCINATION

This chapter contains information for providers to refer to when responding to questions and concerns about immunisation. It covers general questions on adult and childhood vaccination, including contraindications and precautions. In addition, a discussion on some of the more recent concerns about vaccination is included, covering issues relating to vaccine safety, vaccine content, immunisation as a possible cause of some illnesses of uncertain origin, and the need for vaccination.

This appendix is divided into 4 sections:

1. General questions
2. Contraindication and precautions
3. Responding to questions and concerns about immunisation
4. Where can I get more information about vaccination?

### 1. General questions

#### (i) How does vaccination work?

When a healthy person becomes infected with a virus, eg. measles, the body recognises the virus as an invader, produces antibodies which eventually destroy the virus and recovery occurs. If contact with the measles virus occurs again in the future, the body's immune system 'remembers' the measles virus and produces an increase in antibodies to destroy the virus.

Vaccination is the process that is used to stimulate the body's immune system in the same way as the real disease would, but without causing the symptoms of the disease. Most vaccines provide the body with 'memory' so that an individual doesn't get the disease if exposed to it.

Vaccination conveys immunity to diseases by a process called active immunity, which can be achieved by administration of either inactivated (ie. not live) or live attenuated organisms or their products. Live vaccines are attenuated, or weakened, by growing the organism through serial culturing (or passaging) steps in various tissue culture media. Inactivation is usually done using heat or formalin (sometimes both). Inactivated vaccines may include the whole organism (such as oral cholera vaccine), the toxin produced by the organism (such as tetanus and diphtheria vaccines), or specific antigens (such as Hib and pneumococcal vaccines). In some cases, the antigen is conjugated (ie. chemically linked) with proteins to facilitate the immune response. Inactivated viral vaccines may include whole viruses (such as IPV and hepatitis A vaccines) or specific antigens (such as influenza and hepatitis B vaccines). Live attenuated viral vaccines include MMR, rubella, varicella and yellow fever vaccines.

Immunity can also be acquired passively by the administration of immunoglobulins. Such immunity is immediate and is dose-related and transient. For example, measles or hepatitis B immunoglobulin can be used promptly after exposure in an unimmunised person to help reduce the chance of catching measles or hepatitis B from the exposure.

#### (ii) What is the correct site for vaccination of children?

The top, outer part of the thigh (the vastus lateralis muscle) is the recommended site for injections for infants <12 months of age. The deltoid region of the upper arm is the recommended site for vaccination of children ≥12 months of age because it is associated with fewer local reactions and has sufficient muscle bulk to facilitate the injection. However, the vastus lateralis muscle can also be used. The ventrogluteal area is an alternative site. (See Section 1.4.6, *Recommended injection sites* and Section 1.4.8, *Identifying the injection site*).

Rotavirus vaccines are administered by the oral route and must *never* be injected.

#### (iii) How many injections can be given into the same limb in a child aged <12 months?

More than 1 vaccine can be safely given into a limb at the same immunisation visit. Most States and Territories have routine immunisation schedules that include 3 injections during the primary course for children <12 months of age. In this case, 2 injections can be given into the same leg into the vastus lateralis muscle and the third injection in the other vastus lateralis muscle (or an alternative is the ventrogluteal site). The injections should be given at least 25 mm (2.5 cm) apart. Use separate sterile injection equipment for each vaccine administered. The accompanying documentation should indicate clearly which vaccines were given into which site (eg. left leg upper/left leg lower).

#### (iv) When should preterm infants be vaccinated?

Babies born at <32 weeks' gestation or <2000 g birth weight should receive their first dose of hepatitis B vaccine either at birth (within the first few days of life) or at 2 months of age. Immunisation schedules differ in different areas of Australia according to which combination vaccines are routinely used in that State or Territory. The routine 2-month vaccines containing the antigens DTPa-IPV-Hib-hepB, 7vPCV and rotavirus should be given 2 months after birth as normal, unless an infant is very unwell. 'Very unwell' can be interpreted in many ways but, in general, reflects that the premature neonate is particularly unstable. Delaying the 2-month vaccines is rarely required. If any preterm infant has the 2-month vaccines delayed, it should be remembered that the infant doses can be given 1 month apart rather than 2 months. Hence, if an infant receives the 2-month vaccines at 3 months then the 4 month vaccines should still be given at 4 months of age.

When Liquid PedvaxHIB is used in an extremely preterm baby (<28 weeks' gestation or <1500 g birth weight), an additional dose should be given at 6 months of age.

Further explanation of the special immunisation needs of premature babies is provided in Section 2.3.2 *Vaccination of women planning pregnancy, pregnant or breastfeeding women, and preterm infants*.

**(v) Do elderly people (>65 years) who have no chronic illnesses need the influenza vaccine?**

Yes. Age is an independent risk factor for influenza. Vaccination of those aged >65 years, regardless of the presence or absence of chronic illness, reduces mortality by up to 50% in the winter period in this age group (see Chapter 3.9, *Influenza*).<sup>1,2</sup> The healthy elderly should also receive the 23-valent pneumococcal polysaccharide vaccine (see Chapter 3.15, *Pneumococcal disease*).

**(vi) Should adults receive pertussis (whooping cough) vaccine boosters?**

Yes. Two brands of acellular pertussis vaccines, both combined with tetanus and diphtheria antigens, are now available for adolescents and adults. dTpa vaccines are recommended in Australia for booster vaccination of individuals ≥8 years of age who have previously had a primary course of diphtheria-tetanus-pertussis vaccine. dTpa vaccines have a lower content of diphtheria and pertussis antigens than DTPa formulations for young children.

A recent study showed that adults can be protected against pertussis after a single dose of dTpa. No recommendations about the need for further boosters using adolescent/adult formulation dTpa have been made at this time.

A single dose of dTpa is recommended for the following groups (unless contraindicated or they have already received a previous dose of dTpa):

- adults working with young children. Vaccination is especially recommended for childcare workers;
- all healthcare workers;
- adults planning a pregnancy, or for both parents as soon as possible after delivery of an infant (preferably before hospital discharge), unless contraindicated.<sup>3</sup> Other adult household members, grandparents and carers of young children should also be vaccinated. This recommendation is based on evidence from several studies of infant pertussis cases, which indicated that family members, particularly parents, were identified as the source of infection in more than 50% of cases and were the presumed source in a higher proportion;
- any adult expressing an interest in receiving a booster dose of dTpa.

Adults ≥50 years of age who have not previously received dTpa vaccine should also be offered vaccination. See Chapter 3.3, *Diphtheria*, Chapter 3.14, *Pertussis* or Chapter 3.21, *Tetanus* in this *Handbook*.

Contraindications to adolescent/adult formulation dTpa are discussed in Chapter 3.3, *Diphtheria*, Chapter 3.14, *Pertussis* and Chapter 3.21, *Tetanus* in this *Handbook* and include previous anaphylactic reaction to any vaccine component.

If the patient has never received a primary course of dT, see Chapter 3.3, *Diphtheria*, Chapter 3.14, *Pertussis* or Chapter 3.21, *Tetanus* in this *Handbook*.

**(vii) A parent wants a child to receive his/her vaccines separately. Why can't they do this?**

There is no scientific evidence or data to suggest that there are any benefits in receiving vaccines such as MMR or DTPa as separate monovalent vaccines. Using the example of MMR vaccine, there is no individual mumps or measles vaccine licensed for use in Australia. If these vaccines were to be administered individually it would require 3 separate vaccines which would unnecessarily increase discomfort for the child. In addition, if these monovalent vaccines were not given on the same day, they would need to be spaced 1 month or more apart which would increase the risk of that child being exposed to serious vaccine-preventable diseases. A policy of providing separate vaccines would cause some children to not receive the entire course, and combination vaccines can offer a reduced amount of vaccine stabiliser and adjuvant compared to 3 individual vaccine doses.

**(viii) Is vaccination compulsory? What happens if children do not get vaccinated?**

Vaccination is not compulsory in Australia.

The Maternity Immunisation Allowance and Child Care Benefit are parent incentive payments that are paid where a child is up-to-date with his/her immunisations or the parent has obtained an appropriate medical or philosophical exemption.

If a parent decides not to have a child vaccinated and, if cases of certain vaccine-preventable diseases occur at that child's day-care centre or school, the parent may, in some circumstances, be required to keep the unvaccinated child at home until the incubation period for that particular disease has passed or no further cases have occurred in that setting.

## **2. Contraindications and precautions**

**If you have any concerns about whether to proceed with vaccination, please seek expert advice. See Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control.***

**(i) What are the absolute contraindications to childhood vaccination?**

True contraindications to the childhood vaccines are extremely rare (see relevant chapters), and include only anaphylaxis to any of the particular vaccine's components, and anaphylaxis following a previous dose of that vaccine.

NB. Anaphylaxis following ingestion of eggs does not contraindicate MMR vaccine, as the vaccine viruses are not grown in eggs and the vaccine does not contain any egg protein<sup>4</sup> (see Chapter 3.11, *Measles*).

**(ii) What are the contraindications to further doses of pertussis-containing vaccines?**

Further doses of DTPa are contraindicated in those who have had a previous immediate severe allergic or anaphylactic reaction to vaccination with DTPa.

A previous simple febrile convulsion or pre-existing neurological disease is *not* a contraindication to pertussis-containing vaccines.

**(iii) What are the precautions to childhood vaccination?**

In general, children with impaired immunity or on immunosuppressive therapy should not be given live vaccines (see (vii) to (ix) below).

**(iv) Should a child with an intercurrent illness be vaccinated?**

A child with a minor illness (without systemic illness and with a temperature <38.5°C) may be safely vaccinated. Infants and children with minor coughs and colds without fever, or those receiving antibiotics in the recovery phase of an acute illness, can be vaccinated safely and effectively. In a child with a major illness or high fever ≥38.5°C, vaccination should be postponed until the child is well. If vaccination were to be carried out during such an illness, the fever might be confused with vaccine side effects and might also increase discomfort to the child. In such cases, it is advisable to defer vaccination and arrange for the child to return for vaccination when well again.

**(v) Should children with epilepsy be vaccinated?**

Yes. Stable neurological disease (such as epilepsy) is not a reason to avoid giving vaccines like pertussis (whooping cough). Children who are prone to fits should have paracetamol before and for 48 hours after vaccination to reduce the chance of a fever after vaccination bringing on a convulsion. A family history of fits or epilepsy is not a reason to avoid vaccination.

**(vi) Should children with neurological disease receive the normal vaccination schedule?**

Yes. Children with neurological disease are often at increased risk of complications from diseases like measles, influenza and whooping cough, as they can be more prone to respiratory infections and chest problems. It is important that these children be immunised, on time, as recommended in the National Immunisation Program schedule.

**(vii) Are steroids a contraindication to vaccination?**

Live vaccines such as MMR, BCG and varicella-zoster vaccines, should *not* be given to children or adults receiving high dose oral or parenteral corticosteroid therapy for more than 2 weeks. High dose oral corticosteroid

therapy is defined as more than 2 mg/kg per day prednisolone for more than 1 week. This is because steroids, in large doses, greatly suppress the immune system which means that, not only is the vaccine unlikely to be effective, but there is an increased chance of an adverse event occurring as a result of the immunosuppression.

Inactivated vaccines, eg. DTPa-hepB-IPV, may be less effective in this group but are not contraindicated. Therapy with inhaled steroids is not a contraindication to vaccination.

(viii) Should vaccines be given to children who have problems with their immune systems?

Children with impaired immunity or those on immunosuppressive therapy should not be given live viral vaccines such as MMR, varicella, and rotavirus vaccines.<sup>5</sup>

HIV-infected children may be given MMR vaccine provided they do not have severely impaired immunity (see Table 2.3.4 *Immunological categories based on age-specific CD4 counts and percentage of total lymphocytes*). The contacts of children with impaired immunity can be given MMR without any risk of transmission. The rash seen in a small percentage of MMR vaccine recipients, usually between days 5 to 12 post vaccination, is not infectious.

It is highly recommended that non-immune household contacts of children with impaired immunity receive varicella vaccine. There is an almost negligible risk of transmitting varicella vaccine virus from a vaccine-related vesicular rash to contacts. However, vaccine-related rash occurs in 3 to 5% of vaccinees either locally at the injection site or generalised, with a median of only 25 lesions. This small infection risk of the less virulent attenuated vaccine strain is far outweighed by the high risk of non-immune contacts catching wild varicella infection and transmitting the virus to the household member with impaired immunity via respiratory droplets or from the large number of skin lesions that occur with wild varicella infection (a median of 300 to 500 lesions).

Live viral vaccines can be given to children with leukaemia and other malignancies who have been on chemotherapy at least 3 months after they have completed chemotherapy, provided there are no concerns about their immune status. Such measures would normally be carried out under the supervision of the child's oncologist (see Section 2.3.3, *Vaccination of individuals with impaired immunity due to disease or treatment*).

(ix) What vaccines should children with HIV infection receive?

Children with HIV (human immunodeficiency virus) infection should have all routine *inactivated* vaccines on the National Immunisation Program schedule. Varicella vaccine is generally contraindicated in children with HIV, as it can cause disseminated varicella infection. However, it may be considered for asymptomatic or mildly symptomatic HIV-infected children, after weighing up the potential risks and benefits. This should be discussed with the child's specialist.

MMR vaccine can be given to children with HIV, depending on their CD4 counts (see point (viii) above). Children with HIV infection should also be vaccinated against pneumococcal disease (see Chapter 3.15, *Pneumococcal disease*). Influenza vaccine is also recommended for HIV-infected children. They should *not* be given BCG, due to the risk of disseminated infection (see Section 2.3.3, *Vaccination of individuals with impaired immunity due to disease or treatment*).

#### (x) Should chronically ill children be vaccinated?

In general, children with chronic diseases should be vaccinated as a matter of priority because they are often more at risk from complications from vaccine-preventable diseases. Annual influenza vaccine is highly recommended for chronically ill children and their household contacts.

Care is needed with the use of live attenuated viral vaccines in situations where the child's illness, or its treatment, may result in impaired immunity. Advice may need to be sought on these patients to clarify the safety of live viral vaccine doses.

#### (xi) Should children be vaccinated while the child's mother is pregnant?

There is no problem with giving routine vaccinations to a child whose mother is pregnant. MMR vaccine viruses are not transmissible. Administration of varicella vaccine to household contacts of non-immune pregnant women is safe. Transmission of varicella vaccine virus is very rare. There is an almost negligible risk of transmitting varicella vaccine virus from a vaccine-related vesicular rash to contacts. However, vaccine-related rash occurs in 3 to 5% of vaccinees either locally at the injection site or generalised, with a median of only 25 lesions. Furthermore, vaccinating the child of a pregnant mother will reduce the risk of her being infected by her offspring with the more virulent wild virus strain if she is not immune.

#### (xii) Should children with allergies be vaccinated? What precautions are required for atopic or egg-sensitive children?

Asthma, eczema and hay fever are not contraindications to any vaccine on the childhood schedule unless the child is receiving high-dose steroid treatment (see point (vii) above). For other allergies, see Appendix 4, *Components of vaccines used in the National Immunisation Program*, and the relevant vaccine product information (PI) enclosed in the vaccine package. Unless the child (or person being vaccinated) has an allergy to a specific constituent of a vaccine (or has another contraindication) there is no reason not to vaccinate.

An important exception is anaphylactic sensitivity to eggs, characterised by generalised hives, swelling of the mouth or throat, difficulty breathing, wheeze, low blood pressure, and shock. If a person has a history of severe egg allergy, influenza, yellow fever and Q fever vaccines should *not* be given. Because MMR vaccine viruses are not cultured in eggs and the vaccine does not contain egg protein, MMR can be given safely to those with anaphylactic sensitivity to eggs.<sup>4</sup>

Simple dislike of eggs or having diarrhoea or stomach pains after eating eggs are not reasons to avoid MMR and these children require no special precautions. These children can also have all other routine vaccines without special precautions.<sup>4</sup>

*Families with questions about allergies and vaccines are encouraged to discuss this with their immunisation service provider to have any questions promptly answered to avoid unnecessary delays of vaccine doses.*

### **3. Responding to questions and concerns about immunisation**

Some people express concerns about immunisation. These mostly relate to whether the vaccine is safe and whether vaccines weaken the immune system of the child. Providers should listen to and acknowledge people's concerns. Providers should discuss the risks and benefits of immunisation with parents/carers honestly and in a non-defensive manner. Parents/carers and adult vaccine recipients should receive accurate information on the risks from vaccine-preventable diseases and information about vaccine side effects and adverse events (see table inside the front cover *Comparison of the effects of diseases and the side effects of vaccines*). The following section responds to some concerns raised about the safety of immunisation, and examines the scientific evidence in order to assist providers and parents in making an informed choice about the risks and benefits of vaccination.

#### **a) Vaccine safety**

##### **(i) How safe are vaccines?**

Before vaccines are made available for general use they are tested for safety and efficacy in clinical trials and then in large trials, otherwise known as Phase 2 and 3 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 before marketing approval is granted.

After introduction into vaccination 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 occur after vaccines are registered for use. Regular Australian surveillance reports are published in the journal *Communicable Diseases Intelligence*.<sup>6</sup>

##### **(ii) Can too many vaccines overload or suppress the natural immune system?**

No. The increase in the number of vaccines and vaccine doses given to children has led to concerns about the possible adverse effects of the aggregate vaccine exposure, especially on the developing immune system. In day-to-day life, all children and adults confront enormous numbers of antigens and the immune system responds to each of these in various ways to protect the body. Studies of

the diversity of antigen receptors indicate that the immune system can respond to an extremely large number of antigens. In addition, the number of antigens received by children during routine childhood vaccination has actually decreased compared with several decades ago. This has occurred in spite of the increase in the total number of vaccines given, and can be accounted for by the removal of 2 vaccines – smallpox vaccine (which contained about 200 different proteins), and whole-cell pertussis vaccine (about 3000 distinct antigenic components) from routine vaccination schedules. In comparison, the acellular pertussis vaccine currently used in Australia has only 3 to 5 pertussis antigens.<sup>7</sup>

### (iii) Do vaccines cause disease?

Some studies have suggested a temporal link between vaccinations and certain medical conditions, such as asthma, multiple sclerosis, and diabetes. The allegations of a link are often made for a disease of unknown cause. The appearance of a certain medical condition after vaccination does not necessarily imply that they are causally related. Importantly, however, once an issue is raised it needs prompt research, discussion and then education to avoid propagating a myth. In many cases, subsequent epidemiological studies have indicated that the association is due to chance alone. The following is a list of concerns that have been raised.

- **Does MMR vaccine cause inflammatory bowel disease or autistic spectrum disorder?**<sup>8</sup>

In 1998, Wakefield et al (Royal Free Hospital, London)<sup>9</sup> published a case series study with 12 children suggesting that MMR vaccine caused inflammatory bowel disease (IBD), which then resulted in decreased absorption of essential vitamins and nutrients through the intestinal tract. They proposed that this could result in developmental disorders such as autism.

Following the study's publication, Wakefield suggested that it may be 3 live viruses in the 1 vaccine which was causing the development of the subsequent disorders. He suggested it was preferable to provide MMR vaccination as 3 separate vaccines, a suggestion with no supportive evidence.<sup>9</sup>

This study had several weaknesses. First, finding out whether or not MMR causes autism is best determined by comparing the incidence of autism in vaccinated versus unvaccinated children. However, the researcher included only vaccinated children. Second, the author claimed that gastrointestinal inflammation contributes to autism. However, in several of the children, their behavioural problems appeared before the onset of bowel disease.<sup>10,11</sup> Furthermore, the study was primarily based on parental recall of when the bowel disease and developmental disorders first appeared, and people are more likely to have linked changes in behaviour with memorable events such as vaccination. The Royal Free Hospital study was conducted on a very selective group of patients, all referred to the hospital for gastrointestinal ailments, and such a case series analysis is unable to determine causal links.

The onset of autism and MMR vaccination may coincide because the average age at which parents report concerns about child development is 18 to 19 months, and more than 90% of children in the UK receive MMR vaccine before their 2<sup>nd</sup> birthday.<sup>12</sup> More rigorous and larger epidemiological studies have found no evidence of an association.<sup>13-16</sup>

A review by the World Health Organization concluded that current scientific data do not permit a causal link to be drawn between the measles virus and autism or IBD.<sup>17</sup> An extensive review published in 2004 by the Institute of Medicine, an independent expert body in the United States, concluded that there is no association between the MMR vaccine and the development of autism.<sup>18</sup> Reviews by the American Academy of Pediatrics, The British Chief Medical Officer, the UK Medical Research Council, Canadian experts, and numerous other scientific experts have stated that there is no link between autism or IBD and the measles vaccine.<sup>14,19-21</sup>

See Chapter 3.11, *Measles* for further information. There is also an MMR vaccine decision aid designed for parents available at <http://www.ncirs.usyd.edu.au/decisionaid/index.html>.

- **Do childhood immunisations cause asthma?**

There is no evidence that vaccination causes or worsens asthma. It is especially important that children with asthma be vaccinated like other children, as catching a disease like whooping cough can make an asthma attack worse. Although influenza vaccine is not routinely recommended for all asthmatics, it is recommended for severe asthmatics, such as those requiring frequent hospitalisation.<sup>22</sup>

- **Does hepatitis B vaccine cause multiple sclerosis?**

There is no reliable evidence that the hepatitis B vaccine causes multiple sclerosis (MS). With millions of hepatitis B 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 reports, however, they suggest only the possibility of an association. Subsequent studies have found no increase in incidence of MS, or even relapse of MS, after hepatitis B vaccination.<sup>23-27</sup>

In response to a single study by Hernán et al,<sup>28</sup> the World Health Organization Global Advisory Committee on Vaccine Safety released the following statement: “multiple studies and review panels have concluded that there is no link between MS and hepatitis B vaccination”.<sup>29</sup>

In addition, a review by the Institute of Medicine Immunization Safety Review Committee in 2003 found no link between hepatitis B vaccine and certain neurological disorders such as MS.<sup>30</sup> A systematic review from the Cochrane Vaccines Field in 2003 also found no evidence of an association between hepatitis B vaccine and MS.<sup>31</sup> Recent statements by the World Health Organization and the US Centers for Disease Control and Prevention support this position.<sup>29,32,33</sup>

- **Do some vaccines cause ‘Mad Cow Disease’?**

Variant Creutzfeldt-Jakob disease (vCJD) is considered to be the human equivalent of bovine spongiform encephalopathy (BSE, also known as ‘mad cow disease’). There is no evidence that any case of vCJD has resulted from the administration of any vaccine product, despite millions of doses of vaccine being administered worldwide. Concerns about the risk of transmission of this disease arose because the production of some vaccines requires bovine derivatives such as fetal bovine serum. In Australia, the Therapeutic Goods Administration has confirmed that the vaccines available in this country contain bovine materials preferentially sourced from BSE-free areas, and that they undergo appropriate purification treatment. Therefore, although some vaccines carry a theoretical risk of transmissible spongiform encephalopathies, this risk is infinitesimally small (estimated at less than 1 in a billion).<sup>34</sup> The benefits of vaccination are considered to far outweigh any theoretical risk of BSE transmission.<sup>35</sup>

- **Is there a link between vaccination and Sudden Infant Death Syndrome (SIDS)?**

Despite extensive studies, there is no evidence that vaccination causes SIDS (cot death). Deaths do occasionally occur shortly after vaccination but the relationship is a chance association, since SIDS tends to happen in babies of 2–6 months of age, whether they are vaccinated or not.<sup>36</sup> Many studies have conclusively shown that SIDS is not caused by immunisation. In addition, some studies have found a lower rate of SIDS in immunised children.<sup>37-39</sup>

- **Does immunisation cause diabetes?**

In 1997, a study from Finland suggested a link between Hib vaccination and type 1 diabetes.<sup>40</sup> However, subsequent reanalysis of the data did not support such a link.<sup>41,42</sup> The conclusion that there is no causal link between any of the childhood vaccines and diabetes has also been supported by a subsequent review of the literature, and the conclusions of 2 workshops held in the USA in 1998.<sup>8,41-43</sup>

- **Does influenza vaccine cause flu?**

No. It is not possible for influenza vaccine to cause ‘flu’ as it is not a live viral vaccine. As some people experience side effects such as a mild fever after the vaccine, it is understandable that they may confuse these symptoms with actually having the flu. In addition, the influenza vaccine is recommended to be given at the commencement of the flu season. Hence, it is possible that a person who has contracted, and is incubating, influenza during vaccination will mistakenly believe the vaccine to be causal. In addition, influenza vaccine is given at the very time of year when there are a lot of upper respiratory tract infections (URTIs) around. It is not uncommon for someone to attribute an URTI within a week of an influenza vaccine to the vaccine dose. Importantly, URTI symptoms occurring after influenza vaccine should not put people off having the vaccine the following year.

## b) Vaccine content<sup>44</sup>

(See also Appendix 4 for a list of vaccines used in the NIP which contain these compounds and refer to the relevant vaccine product information (PI) enclosed in the vaccine package.)

- **Preservatives**

Preservatives are used to prevent fungal and or bacterial contamination of the vaccine. They include thiomersal, phenoxyethanol, and phenol.

### (i) Thiomersal

Thiomersal (or thimerosal) is a compound which is partly composed of mercury, ethylmercury. It has been used in very small amounts in vaccines for about 60 years, to prevent bacterial and fungal contamination of vaccines. In the past, the small amount of thiomersal in vaccines was one of several potential sources of mercury. Diet (such as some seafood) and other environmental sources are also possible sources of mercury. Vaccines used in the past, such as DTP, contained only 25 µg of thiomersal per dose.

Mercury causes a toxic effect after it reaches a certain level in the body. Whether or not it reaches a toxic level depends on the amount of mercury consumed and the person's body weight; individuals with very low body weight are usually more susceptible to toxic effects from a certain intake of mercury. Thus, the possibility existed that vaccination of newborn babies, particularly those of very low birth weight, with repeated doses of thiomersal-containing vaccines, might have resulted in levels of mercury above the recommended guidelines. Thiomersal was removed from vaccines in response to the above theoretical concern and to reduce total exposure to mercury in babies and young children in a world where other environmental sources may be more difficult to eliminate.<sup>45-47</sup>

Currently, all vaccines on the NIP for children <5 years of age are now either free of thiomersal, or contain a reduced (trace) amount of thiomersal.

There are certain vaccines that are still most effectively manufactured using a trace amount of thiomersal as the preservative, eg. influenza vaccine. Infants from 6 months of age can be given influenza vaccine safely.

### (ii) Phenoxyethanol

2-Phenoxyethanol is an aromatic ether alcohol used as a preservative in many vaccines. It is also used as a preservative in cosmetics. 2-Phenoxyethanol is used in vaccines as an alternative preservative to thiomersal.

### (iii) Phenol

Phenol is an aromatic alcohol used as a preservative in a few vaccines.

#### • Adjuvants

Adjuvants are compounds used to enhance the immune response to vaccination and include various aluminium salts such as aluminium hydroxide, aluminium phosphate and potassium aluminium sulphate (alum). A recent review of all available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) found no evidence that aluminium salts in vaccines cause any serious or long-term adverse events.<sup>48</sup>

### Aluminium

A small amount of aluminium salts has been added to some vaccines for about 60 years. Aluminium acts as an adjuvant, which improves the protective response to vaccination by keeping antigens near the injection site so they can be readily accessed by cells responsible for inducing an immune response. The use of aluminium in vaccines means that, for a given immune response, less antigen is needed per dose of vaccine, and a lower number of total doses are required. Although aluminium-containing vaccines have been associated with local reactions and, less often, with the development of subcutaneous nodules at the injection site, other studies have reported fewer reactions with aluminium-adsorbed vaccines than with unadsorbed vaccines. Concerns about the longer-term effects of aluminium in vaccines arose after some studies suggested a link between aluminium in the water supply and Alzheimer's disease, but this link has never been substantiated. The amount of aluminium in vaccines is very small and the intake from vaccines is far less than that received from diet or medications such as some antacids.<sup>49,50</sup>

#### • 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 or MSG (both are amino acids or salts of amino acids);
- gelatin, which is partially hydrolysed collagen usually of bovine or porcine origin. Some members of the Islamic and Jewish faiths may object to vaccination, arguing that vaccines can contain pork products. Scholars of the Islamic Organization for Medical Sciences have determined that the transformation of pork products into gelatin will sufficiently alter them thus making it permissible for observant Muslims to receive vaccines, even if the vaccines contain porcine gelatin. Likewise, leaders of the Jewish faith

have also indicated that pork-derived additives to medicines are permitted. Further information may be obtained from the following websites <http://vaccinesafety.edu/Porcine-vaccineapproval.htm> and <http://www.immunize.org/concerns/porcine.pdf>;

- human serum albumin (protein).
- **Manufacturing residuals**

Manufacturing residuals are residual quantities of reagents used in the manufacturing process of individual vaccines. They include antibiotics (such as neomycin or polymyxin), inactivating agents (eg. formaldehyde) as well as cellular residuals (egg and yeast proteins), traces of which may be present in the final vaccine. Antibiotics are used during the manufacturing process to ensure that bacterial contamination does not occur; traces of these antibiotics may remain in the final vaccine. Inactivating agents are used to ensure that the bacterial toxin or viral components of the vaccine are not harmful, but will result in an immune response. Cellular residuals are minimised by extensive filtering. However, trace amounts may be present in the final product. The most commonly found residual is formaldehyde.

### Formaldehyde

Formaldehyde is used during the manufacture of many vaccines. For example, with tetanus vaccines, formaldehyde is used to detoxify the tetanus toxin protein produced. 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 less than 0.02% 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, which is well below the standard limit.

- **Other**

Vaccines also may be made up in sterile water or sterile saline (salt-water).

## (c) The need for immunisation

### (i) Isn't natural immunity better than immunity from vaccination?

While vaccine-induced immunity may diminish with time without boosters (vaccine or contact with wild-type infection), 'natural' immunity, acquired by catching the disease, is usually life-long, with the exception of pertussis. The problem is that the wild or 'natural' disease has a higher risk of serious illness and occasionally death. Children or adults can be revaccinated (with some but not all vaccines) if their immunity from the vaccines falls to a low level or if previous research has shown that a booster vaccination is required for long-term protection. It is important to remember that vaccines are many times safer than the diseases they prevent.

(ii) Diseases like measles, polio, whooping cough and diphtheria have already disappeared from most parts of Australia. Why do we need to keep vaccinating children against these diseases?

Although these diseases are much less common now, they still exist. The potential problem of disease escalation is kept in check by routine vaccination programs. In countries where vaccination rates have declined, vaccine-preventable diseases have sometimes reappeared. For example, Holland has one of the highest rates of fully vaccinated people in the world. However, in the early 1990s, there was a large outbreak of polio among a group of Dutch people who belonged to a religious group that objected to vaccination. While many of these people suffered severe complications like paralysis, polio did not spread into the rest of the Dutch community. This was due to the high rate of vaccination against polio, which protected the rest of the Dutch community.

There have been recent outbreaks of whooping cough, measles and rubella in Australia, and a number of children have died. Cases of tetanus and diphtheria, although rare, still occur. Thus, even though these diseases are much less common now than in the past, it is necessary to continue to protect Australian children, so that the diseases cannot re-emerge to cause large epidemics and deaths.

Also, many of the diseases which we vaccinate our children against are still common in other areas of the world. For example, measles still occurs in many Asian countries and many people take holidays or travel for business to these areas. Therefore, it is possible for non-immune individuals to acquire measles overseas, and with the speed of air travel, arrive home and be able to pass measles onto those around them if they are unprotected. Measles is highly infectious and can infect others for several hours after an infected person has left a room. Vaccination, while not 100% effective, can minimise a person's chance of catching a disease. The more people who are vaccinated the less chance of a disease, such as measles, spreading widely in the community. This is referred to as herd immunity.

(iii) Why do some children get the disease despite being vaccinated?

This is possible, since no vaccine is 100% effective. A small proportion of those who are vaccinated will remain susceptible to the disease. However, in the cases in which illness does occur in vaccinated individuals, the illness is usually much less severe than in those who were not vaccinated. The protection provided by the same vaccine to different individuals can differ. For example, if 100 children are vaccinated with MMR, 5 to 10 of the fully vaccinated children might still catch measles, mumps or rubella (although the disease will often be less severe in vaccinated children). If 100 children are vaccinated with a full schedule of pertussis-containing vaccines, 20 of the children might still get whooping cough but, once again, the disease is often less severe in these vaccinated children. To put it another way, if you do not vaccinate 100 children with MMR vaccine, and the children are exposed to measles, all of them will catch the disease with a

risk of high rates of complications like pneumonia or encephalitis. The reason why fewer children become infected than these figures suggest is due to the high vaccine coverage rates in the community. If there are high coverage rates, there is less chance of contact with the infection and, although children may be susceptible, they have a low chance of contact with the infection.

#### (iv) What about homeopathic ‘immunisation’?

Homeopathic ‘immunisation’ has not been proved to give protection against infectious diseases; only conventional vaccination produces a measurable immune response. The Council of the Faculty of Homeopathy, London, issued a statement in 1993, which reads: “The Faculty of Homeopathy, London, strongly supports the conventional vaccination program and has stated that vaccination should be carried out in the normal way, using the conventional tested and proved vaccines, in the absence of medical contraindications”.<sup>51</sup>

## 4. Where can I get more information about vaccination?

More information about vaccination can be found in the following publications produced by the Australian Government Department of Health and Ageing:

- *Understanding childhood immunisation*
- *Immunisation myths and realities – responding to arguments against immunisation: a guide for providers*

The following two websites include further publications, fact sheets, etc. and are recommended for both immunisation service providers and the general public:

- Immunise Australia website <http://www.immunise.health.gov.au>
- The National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases (NCIRS) website [www.ncirs.usyd.edu.au](http://www.ncirs.usyd.edu.au)

Also, check with your local State or Territory public health unit or local council, maternal child health nurse, or public health vaccination clinic for more information (see Appendix 1, *Contact details for Australian, State and Territory Government health authorities and communicable disease control*).

## References

Full reference list available on the electronic *Handbook* or website <http://immunise.health.gov.au>.