# APPENDIX 4: COMMONLY ASKED QUESTIONS ABOUT VACCINATION



This appendix 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 six sections:

- General questions
- Questions about contraindication and precautions
- Questions about vaccine safety
- Questions about vaccine content
- Questions about the need for immunisation
- Further information about vaccination

## A.4.1 General questions

### How does vaccination work?

When a healthy person becomes infected with a virus or bacteria (also known as a pathogen), for example, the measles virus, the body recognises the virus as an invader, produces antibodies that 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 this pathogen.

Vaccination is the process that is used to stimulate the body's immune system in the same way as the real pathogen or disease would, but without causing the symptoms of the disease. Most vaccines provide the body with 'memory' so that an individual does not get the disease if exposed to it (see 1.5 *Fundamentals of immunisation*).

Vaccination conveys immunity to diseases by a process called active immunity, which can be achieved by administration of either inactivated (i.e. not live) or live attenuated pathogens 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 pathogen (such as oral cholera vaccine), the toxin produced by the pathogen (such as tetanus and diphtheria vaccines), or specific antigens (such as *Haemophilus influenzae* type b [Hib], meningococcal and pneumococcal

vaccines). In some cases, the antigen is conjugated (i.e. chemically linked) with proteins to facilitate the immune response. Inactivated viral vaccines may include whole viruses (such as inactivated poliomyelitis vaccine [IPV] and hepatitis A vaccines) or specific antigens (such as influenza and hepatitis B vaccines). Live attenuated viral vaccines include measles-mumps-rubella (MMR), varicella and yellow fever vaccines.

Immunity can also be acquired passively by the administration of immunoglobulins, which are the same as antibodies (see 1.5 *Fundamentals of immunisation*). 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 getting measles or hepatitis B disease from the exposure.

### What is the correct site for vaccination?

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 all persons aged ≥12 months, because it is associated with fewer local reactions and, in younger children, has sufficient muscle bulk to facilitate the injection. However, the vastus lateralis muscle can also be used in both young children and, where absolutely necessary, adults.

The ventrogluteal area is an alternative site in children. (See 2.2.6 *Recommended injection sites* and 2.2.8 *Identifying the injection site*).

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

### How many injections can be given into the same limb, particularly in a child aged <12 months?

More than one vaccine can be safely administered into a limb at the same immunisation visit in either children or adults (See 2.2.9 *Administering multiple vaccine injections at the same visit*).

Where more than one injection is required into the one limb, 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 (e.g. left arm upper / left arm lower).

Most Australian states and territories have routine immunisation schedules that include at least two injections during the primary course for children <12 months of age. In this case, injections can be given into either the same leg, into the vastus lateralis muscle, or the second injection can be given into the other vastus lateralis muscle; an alternative is the ventrogluteal site.

### When should preterm infants be vaccinated?

Babies born at <32 weeks gestation or <2000 g birth weight should receive their 1st dose of hepatitis B vaccine either at birth (within the first few days of life) or at 2 months of age. The routine 2-month vaccines containing the antigens diphtheria-tetanus-acellular pertussis-hepatitis B-inactivated poliovirus-*Haemophilus influenzae* type b (DTPa-hepB-IPV-Hib), *Streptococcus pneumoniae* (13vPCV) 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 medically 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 subsequent infant doses can be given 1 month apart rather than 2 months. Hence, if an infant receives the 2-month vaccines at 3 months of age then the 4-month vaccines should still be given at 4 months of age. However, the 3rd dose of DTPa-hepB-IPV-Hib should not be given before 6 months of age. Further explanation of the special immunisation needs of premature babies is provided in 3.3.2 *Vaccination of women who are planning pregnancy, pregnant or breastfeeding, and preterm infants.*

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

Yes. Age is an independent risk factor for severe influenza. Vaccination of those aged >65 years, regardless of the presence or absence of chronic illness, reduces mortality during the winter period in this age group (see 4.7 *Influenza*). The healthy elderly should also receive the 23-valent pneumococcal polysaccharide vaccine (see 4.13 *Pneumococcal disease).*

### 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 ≥10 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 reduced antigen content formulation dTpa have been made at this time.

A single dose of dTpa is recommended for the following groups, unless contraindicated or if they have already received a previous dose of dTpa in the last 10 years (or 5 years when specifically indicated, see 4.12 *Pertussis*):

- adults working with young children; vaccination is especially recommended for those working in early childhood education and care
- all healthcare workers

- adults planning a pregnancy, or both parents as soon as possible after delivery of an infant (preferably before hospital discharge)

  Pregnant women can also be vaccinated during the last trimester of pregnancy, as an alternative to getting vaccinated straight after delivery. This allows for antibodies to be transferred to the infant during the pregnancy – this particularly helps to protect the infant against pertussis. 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, in which 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 4.2 *Diphtheria*, 4.12 *Pertussis* or 4.19 *Tetanus* in this *Handbook*).

Contraindications to the reduced antigen content formulation dTpa are discussed in 4.2 *Diphtheria*, 4.12 *Pertussis* and 4.19 *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 4.2 *Diphtheria*, 4.12 *Pertussis* or 4.19 *Tetanus* in this *Handbook*.

### A person wants 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 as separate monovalent vaccines. Using the example of MMR vaccine, there is no individual mumps, measles or rubella vaccine approved for use in Australia. If these vaccines were to be administered individually, it would require three 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 person being exposed to serious vaccine-preventable diseases. A policy of providing separate vaccines would cause some people to not receive the entire course. Combination vaccines can offer a reduced amount of vaccine preparation to be injected overall, compared to three individual vaccine doses.

### Is vaccination compulsory? What happens if children do not get vaccinated?

Vaccination is not compulsory in Australia.

Eligibility for the Family Tax Benefit Part A supplement will require either that children are assessed as fully immunised or that the parent has obtained an appropriate medical or philosophical exemption. This replaced the Maternity Immunisation Allowance on 1 July 2012.

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.

## A4.2 Questions about contraindications and precautions

If a person has any concerns about whether to proceed with vaccination, they should be provided with appropriate information and encouraged to obtain expert advice from their usual immunisation provider or an immunisation specialist, if necessary. See Appendix 1 *Contact details for Australian, state and territory government health authorities and communicable disease control* for contact details.

### What are the absolute contraindications to childhood vaccination?

True contraindications to 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. Follow-up specialist medical advice should always be sought if any severe reaction or anaphylaxis has occurred following the administration of any vaccine(s).

*Note*: 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 (see 4.9 *Measles*). Many persons who have a history of a severe allergic reaction to eggs can also be vaccinated with influenza vaccine (see 4.7 *Influenza*).

### Can someone who has had whooping cough (pertussis) still be vaccinated?

Vaccination with pertussis vaccine in children, adolescents or adults who have had laboratory-confirmed pertussis infection is safe and is necessary, as natural immunity does not confer life-long protection. In particular, incompletely vaccinated infants <6 months of age who develop pertussis may not mount an adequate immune response following infection and should receive all routinely scheduled vaccines, including pertussis-containing vaccines (see 4.12 *Pertussis*).

### What are the precautions to vaccination?

In general, persons with impaired immunity or on immunosuppressive therapy, or pregnant women, should not be given live vaccines. However, any general concerns that the person to be vaccinated or the parent/carer holds should always be fully discussed prior to the administration of any vaccine.

### Should a person with an intercurrent illness be vaccinated?

A child or adult with a minor illness (without systemic illness and with a temperature <38.5°C) may be safely vaccinated. People, including infants, toddlers and teenagers 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 person with a major illness or high fever ≥38.5°C, vaccination should be postponed until they are 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 person. In such cases, it is advisable to defer vaccination and arrange for the person to return for vaccination when well again (see Table 2.1.2 *Responses to relevant conditions or circumstances identified by the pre-vaccination screening checklist*).

### Should persons with epilepsy be vaccinated?

Yes. Stable neurological conditions (such as epilepsy) are not a reason to avoid giving any vaccines, including pertussis (whooping cough). Children and adults 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.

### Should persons with a neurological disease or conditions receive the normal vaccination schedule?

Yes. Persons with a 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.

### Are steroids a contraindication to vaccination?

Live vaccines, such as MMR, measles-mumps-rubella-varicella (MMRV), bacille Calmette-Guérin (BCG) and varicella-zoster vaccines, should *not* be given to children or adults receiving high-dose oral or parenteral corticosteroid therapy for more than 1 week. High-dose oral corticosteroid therapy is defined as more than 2 mg/kg per day prednisolone for more than 1 week in children, or more than 60 mg per day for more than 1 week in adults. 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 (see 3.3.3 *Vaccination of immunocompromised persons*).

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

### Should vaccines be given to persons who have problems with their immune systems?

Persons who are immunocompromised (from either a disease or medical treatment) should generally *not* be given live viral vaccines such as MMR, MMRV, varicella, zoster or rotavirus vaccines (see 4.9 *Measles*, 4.22 *Varicella*, 4.24 *Zoster* and 4.17 *Rotavirus*).

HIV-infected persons may be given MMR, varicella and zoster vaccines, provided they do not have severe immunocompromise (see 3.3 *Groups with special vaccination requirements* and Table 3.3.4 *Categories of immunocompromise in HIV-infected persons, based on age-specific CD4⁺ counts and percentage of total lymphocytes*). The close contacts of persons who are immunocompromised can be given live viral vaccines, except oral polio vaccine, which is no longer used in Australia.

The rash seen in a small percentage of MMR vaccine recipients, usually between 5 and 12 days after vaccination, is not infectious. Non-immune household contacts of persons who are immunocompromised should 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 vaccinated persons, 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 immunocompromised household member 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 persons with leukaemia and other malignancies 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 person's oncologist (see 3.3.3 *Vaccination of immunocompromised persons*).

### What vaccines should someone with HIV infection receive?

Persons with HIV (human immunodeficiency virus) infection, especially children, should have all routine *inactivated* vaccines on the National Immunisation Program schedule. Varicella vaccine is contraindicated in persons with HIV who are significantly immunocompromised, 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 'Should vaccines be given to persons who have problems with their immune systems?' above). Persons with HIV infection should also be vaccinated against pneumococcal disease (see 4.13 *Pneumococcal disease*). Influenza vaccine is also recommended for HIV-infected persons. They should

*not* be given BCG, due to the risk of disseminated infection. More detailed information on the use of vaccines in persons with HIV is included in 3.3.3 *Vaccination of immunocompromised persons*.

### Should chronically ill persons be vaccinated?

In general, persons 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 persons and their household contacts.

Care is needed with the use of live attenuated viral vaccines in situations where the person'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.

### Should children or household contacts be vaccinated while the child's mother is pregnant?

There is no problem with giving routine vaccinations to a child, or others, living in the same household with a pregnant woman. 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 vaccinated persons, 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 (see 3.3.2 *Vaccination of women who are planning pregnancy, pregnant or breastfeeding, and preterm infants*).

### Should persons with allergies be vaccinated? What precautions are required for atopic or egg-sensitive children or adults?

Depending on the allergy identified, there often may *not* be a contraindication to vaccination. Specialist medical advice should always be sought in order to determine which vaccinations can be safely given. For example, a history of an allergy to antibiotics most commonly relates to β-lactam, or related antibiotics, and is not a contraindication to vaccines that contain neomycin, polymyxin B or gentamicin. Previous reactions to neomycin that only involved the skin are not considered a risk factor for a severe allergic reaction or anaphylaxis to vaccines manufactured with neomycin, since there are only trace amounts of this antibiotic in the final product (see 3.3.1 *Vaccination of persons who have had an adverse event following immunisation*).

For other allergies, see Appendix 3, *Components of vaccines used in the National Immunisation Program*, and the relevant vaccine product information (PI) enclosed in the vaccine package. Unless the person being vaccinated has an allergy to a specific constituent of a vaccine (or has another contraindication), there is no

reason not to vaccinate. Asthma, eczema and hay fever are not contraindications to any vaccine, unless the child/adult is receiving high-dose oral steroid therapy.

Persons with egg allergies can receive MMR vaccines because the measles and mumps components of MMR vaccine do not contain sufficient amounts of egg ovalbumin to contraindicate MMR vaccination of people with egg allergy (even anaphylaxis) (see 3.3.1 *Vaccination of persons who have had an adverse event following immunisation* and 4.9 *Measles*). A simple dislike of eggs, or having diarrhoea or stomach pains after eating eggs, are not reasons to avoid MMR vaccination, and no special precautions are required in these circumstances. These persons can also have all other routine vaccines without special precautions.

A history of anaphylaxis or allergy to egg had previously been considered an absolute contraindication to influenza vaccination, but there have now been a number of studies indicating that the majority of such persons can be safely vaccinated.[1,2] Given that there is still a small risk of anaphylaxis, it is essential that such persons are vaccinated in facilities with staff able to recognise and treat anaphylaxis. (See also 4.7 *Influenza*.)

Yellow fever, Q fever and one of the available rabies vaccines contain a higher amount of egg albumin than is present in the currently available influenza vaccines. Persons with egg allergy requiring vaccination with either yellow fever, rabies or Q fever vaccines, should seek specialist immunisation advice from their state or territory health department. See also relevant chapters of this *Handbook*.

Families with questions about allergies and vaccines are encouraged to discuss this with their immunisation service provider and, where necessary, seek referral to an immunologist to have any questions promptly answered to avoid unnecessary delays of vaccine doses or referral to a specialist immunisation clinic. Information on specialist immunisation clinics is available from your local state or territory health department. (See Appendix 1 for further details.)

## A4.3 Questions about vaccine safety

Some people have concerns about immunisation. These mostly relate to whether the vaccine is safe and whether vaccines weaken the immune system. Providers should always 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 *Comparison of the effects of diseases and the side effects of NIP vaccines* inside the back cover of this *Handbook*). 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.

## 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 II (2) and III (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 vaccines are introduced into vaccination schedules, they are subjected to 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 unexpected side effects occur after vaccines are registered for use. Australian reports on adverse events that occur following immunisation are published on a 6-monthly basis in the journal *Communicable Diseases Intelligence* (www.health.gov.au/internet/main/publishing.nsf/content/cda-pubs-cdi-cdiintro.htm).

## Can too many vaccines overload or suppress the natural immune system?

No. Although the increase in the number of vaccines and vaccine doses given to children has led to concerns about the possibility of adverse effects of the aggregate vaccine exposure, especially on the developing immune system, there is not a problem. 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 two 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.[3]

## 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 questions 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 creating 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?

No.

In 1998, Wakefield et al. (Royal Free Hospital, London) 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. *The Lancet* retracted this publication in 2010 and the British Medical Council struck off the lead author in 2010, following the British General Medical Council's Fitness to Practice Panel finding the author 'guilty of serious professional misconduct'.

An extensive review published in 2004 by the Institute of Medicine (IOM), an independent expert body in the United States, concluded that there is no association between the MMR vaccine and the development of autism. A 2011 update by the IOM continues to reject any causal association between MMR vaccine and autism (see www.iom.edu/vaccineadverseeffects).

See 4.9 *Measles* for further information. There is also an MMR vaccine decision aid designed for parents available at www.ncirs.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 (see 4.7 *Influenza*).

### Does influenza vaccine cause flu?

No. It is not possible for influenza vaccine to cause 'flu' as it is not a live viral vaccine. (*Note*: a live attenuated influenza vaccine is used in some countries, but not in Australia.) 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.