

## 2.3 GROUPS WITH SPECIAL VACCINATION REQUIREMENTS

This chapter considers the use of vaccines in people who have special vaccination requirements, those who may experience more frequent adverse events, and those who may have a suboptimal response to vaccination. Recommendations for vaccination of those at occupational risk are also included.

### 2.3.1 Vaccination of children who have had a serious adverse event following immunisation (AEFI)

Children who have had a serious AEFI (other than a contraindication, such as anaphylaxis) may be subsequently vaccinated under close medical supervision (see Appendix 6, *Definitions of adverse events following immunisation*). Not all States and Territories offer an adverse event immunisation clinic. However, in States or Territories where there are no clinics, there is often a paediatrician or infectious diseases specialist who will review families who have concerns regarding future vaccinations following a previous adverse event.

To make an enquiry, or for more information about making a referral to a vaccination serious adverse events service, please go to the website below:

<http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-reactions>.

### 2.3.2 Vaccination of women planning pregnancy, pregnant or breastfeeding women, and preterm infants

#### (i) Women planning pregnancy

The need for measles, mumps, rubella, varicella, diphtheria, tetanus and pertussis vaccination should be assessed as part of any pre-conception health check. Where previous vaccination history or infection is uncertain, relevant serological testing should be undertaken to ascertain immunity. Influenza vaccine is recommended routinely and pneumococcal vaccination is recommended for women with risk factors, including smokers. Women receiving live viral vaccines must be advised against falling pregnant within 28 days of vaccination. Please refer to individual disease chapters for more information about primary vaccination for these diseases.

## (ii) Pregnancy

Although the use of most vaccines during pregnancy is not usually recommended on precautionary grounds, there is no convincing evidence that pregnancy should be an absolute contraindication to the use of any vaccine, particularly inactivated vaccines. The only exception is vaccinia virus (smallpox vaccination), which has been shown to cause fetal malformation. There is some evidence, however, that fever *per se* is teratogenic.<sup>1,2</sup> With the exception of the use of influenza vaccine, the NHMRC takes the conservative position that the use of vaccines during pregnancy might cause fever and should be avoided other than in situations of increased risk, where the benefits of protection from vaccination outweigh the risks. Eliminating the risk of exposure to vaccine-preventable diseases during pregnancy (eg. by changing travel plans, avoiding high-risk behaviours or occupational exposures) is an alternative to vaccination.

Live attenuated vaccines are contraindicated for pregnant women because of the hypothetical risk of harm to the fetus should transmission occur. If a live attenuated vaccine is inadvertently given to a pregnant woman, or if a woman becomes pregnant within 4 weeks of vaccination, she should be counselled about the potential transmission, albeit extremely unlikely, to the fetus. There is, however, no indication to consider termination of a pregnancy in this situation.

The following table may be used as a guide to the recommended use of vaccinations in pregnancy. Information regarding pregnancy status in women of reproductive age should be part of the routine pre-vaccination screening checklist (see Section 1.3.4, *Pre-vaccination screening*).

Table 2.3.1: Vaccinations in pregnancy

Live attenuated vaccines		
Bacterial	Recommendation	Comments
BCG vaccine (Live attenuated strain <i>M. bovis</i> )	Contraindicated.	Hypothetical risk only. BCG has not been shown to cause fetal damage.
Rotavirus vaccine	Contraindicated. Not registered for use in adults.	Rotavirus vaccine can be safely administered to household contacts of pregnant women.
Oral typhoid vaccine	Contraindicated.	Studies in animals are inadequate but available data show no evidence of an increased occurrence of fetal damage with oral live attenuated vaccine. Inactivated typhoid Vi polysaccharide vaccine is preferred.
Live attenuated vaccines		
Viral	Recommendation	Comments
Measles-mumps-rubella (MMR) vaccine	Contraindicated.	Hypothetical risk only. Despite concerns that attenuated rubella vaccine virus might cause congenital abnormalities, rubella vaccine (either monovalent or as MMR) has been given to pregnant women (usually inadvertently) without harm to the fetus. Even though the rubella vaccine virus can infect the fetus if given in early pregnancy, there is no evidence that it causes congenital rubella syndrome in infants born to susceptible mothers vaccinated during pregnancy and, in particular, rubella vaccination during pregnancy is not an indication for termination. <sup>3</sup>  Women of child-bearing age should avoid pregnancy for 28 days after vaccination.  It is standard practice to test all pregnant women for immunity to rubella, and to vaccinate susceptible women as soon as possible after delivery (preferably using MMR).
Smallpox vaccine	Contraindicated.	Should not be given to women who are pregnant or considering becoming pregnant. Pregnancy should be avoided for 3 months after vaccination.
Varicella vaccine	Contraindicated.	Hypothetical risk only. Congenital varicella syndrome has (to date) not been identified in women who have been inadvertently vaccinated in early pregnancy. <sup>4</sup> This provides some reassurance of the safety of the vaccine.  Women of child-bearing age should avoid becoming pregnant for 28 days after vaccination.
Yellow fever vaccine	Contraindicated, unless travelling to yellow fever endemic area.	Hypothetical risk only. Yellow fever vaccine has been given to a large number of pregnant women with no adverse outcomes. <sup>5</sup> Pregnant women who travel to a yellow fever-endemic area against medical advice should receive yellow fever vaccine.  The administration of yellow fever vaccine in early pregnancy is not an indication for termination.

Inactivated vaccines		
Bacterial	Recommendation	Comments
Cholera (oral) vaccine	Not recommended.	Inadequate information on safety of oral cholera vaccine in pregnancy.
Adolescent/adult formulation dTpa vaccine	Recommended for pregnant women who work in close contact with infants eg. childcare, neonatal units.	Data on use of adolescent/adult formulation dTpa during pregnancy are not available, so it should be given in pregnancy only when the possible advantages outweigh the possible risks to the fetus. All women who are planning pregnancy should be encouraged to receive a single dose of dTpa before pregnancy; if not given before pregnancy, it should be given as soon as possible after delivery.
<i>Haemophilus influenzae</i> type b (Hib) vaccine	Recommended for pregnant women at increased risk of Hib disease (eg. hyposplenia, asplenia).	Available clinical data suggest that it is unlikely that use of Hib vaccine in pregnant women would have any deleterious effects on the pregnancy.
Meningococcal C conjugate vaccine (MenCCV)	Recommended for pregnant women at increased risk of meningococcal disease (eg. hyposplenia, asplenia), or possible exposure to serogroup C.	Although no clinical study data are available on the use of MenCCV in pregnant women, it is unlikely that it would have any deleterious effects on the pregnancy.
Meningococcal polysaccharide vaccine (4vMenPV)	Recommended for pregnant women at increased risk of meningococcal disease who have not been vaccinated with 4vMenPV in the past 3 years (eg. hyposplenia, asplenia), or possible exposure to serogroup A, W <sub>135</sub> or Y.	No documented adverse events in either pregnant women or their newborns when vaccinated with 4vMenPV administered in the second and third trimesters of pregnancy. The number of pregnant vaccinees reported in the literature is small.
7-valent pneumococcal conjugate vaccine (7vPCV)	Not recommended.	Vaccination during pregnancy has not been evaluated for potential harmful effects to mother or fetus. Although unlikely to result in adverse effects, the vaccine is currently only registered for use in children $\leq 9$ years of age.
23-valent pneumococcal polysaccharide vaccine (23vPPV)	Recommended for pregnant women at increased risk of invasive pneumococcal disease (IPD) (eg. asplenia, impaired immunity, chronic illness, CSF leak) who have not received 23vPPV in the past 5 years (and provided they have not received 2 previous doses).	No adverse effects when administered in pregnancy. Data are limited to clinical trials and deferral of vaccine is recommended unless there is an increased risk of IPD. Women of reproductive age with known risk factors for IPD (including smokers) should be vaccinated before planned pregnancy.
Q fever vaccine	Not recommended.	Safety of use in pregnancy has not been established.
Typhoid Vi polysaccharide vaccine	In pregnant women travelling to endemic countries where water quality and sanitation is poor.	There is no evidence of risk to the fetus from vaccination with Vi polysaccharide vaccine.

Inactivated vaccines		
Viral	Recommendation	Comments
Hepatitis A vaccine	Recommended for susceptible pregnant women travelling to areas of moderate to high endemicity or who are at increased risk of exposure through lifestyle factors, or where severe outcomes may be expected (eg. pre-existing liver disease).	Hepatitis A vaccine should only be given to pregnant women who are non-immune and where there is a clear indication. As for any inactivated viral vaccines, although data are limited, no adverse effects on the developing fetus are expected.
Hepatitis B vaccine	Recommended for susceptible pregnant women for whom this vaccine would otherwise be recommended.	Hepatitis B vaccine should only be given to pregnant women who are non-immune and where there is a clear indication. As for any inactivated viral vaccines, although data are limited, no adverse effects on the developing fetus are expected.
Human papillomavirus (HPV) vaccine	Not recommended.	There are no concerns that HPV vaccines are teratogenic and animal studies have found no evidence of teratogenicity or adverse fetal outcomes. However, where vaccine has inadvertently been administered during pregnancy, further doses should be deferred until after delivery.
Influenza vaccine	Recommended for all pregnant women who will be in the second or third trimester during the influenza season, including those in the first trimester at the time of vaccination.	There is no evidence of congenital defects or adverse effects on the fetus of women who are vaccinated against influenza in pregnancy.
Japanese encephalitis (JE) vaccine	Recommended for pregnant women at risk of acquiring JE.	No adverse effects on pregnancy have been attributed to JE vaccine, whereas JE infection is associated with miscarriage.
Inactivated polio vaccine (IPV)	Recommended for pregnant women at risk of poliovirus exposure (eg. travel to endemic countries).	IPV should only be given to pregnant women when clearly indicated. There is no convincing evidence of risk to the fetus from IPV administered in pregnancy.
Rabies vaccine	Recommended for pregnant women for whom this vaccine would otherwise be recommended (eg. travellers to rabies endemic countries).	Pregnancy is never a contraindication to rabies vaccination in situations where there is a significant risk of exposure (related to occupation or travel), or where there has been a possible exposure to rabies virus or Australian bat lyssavirus.
Toxoids and immunoglobulins		
Tetanus/diphtheria toxoid	Recommended for pregnant women.	Toxoids are safe in pregnancy.
Pooled or hyperimmune immunoglobulins	Recommended for susceptible pregnant women exposed to: measles, hepatitis A, hepatitis B, rabies or Australian bat lyssavirus, varicella viruses and tetanus.	There is no known risk to the fetus from passive immunisation of pregnant women with immunoglobulins.

### Contact between pregnant women and individuals who have recently received live vaccines

Although there is no risk of transmission of the MMR vaccine viruses (MMR vaccine viruses are not transmissible), and an almost negligible risk of transmission of varicella vaccine virus, there is a very small risk of transmission of the rotavirus vaccine viruses to a susceptible pregnant woman. However, there is no evidence that there is any risk to the fetus if pregnant women are in contact with recently vaccinated individuals. Therefore, it is safe to administer varicella vaccine and rotavirus vaccine to household contacts of pregnant women.

#### (iii) Breastfeeding and vaccination

The rubella vaccine virus may be secreted in human breast milk and transmitted to breastfed infants but, where infection has occurred in an infant, it has been mild. Otherwise, there is no evidence of risk to the breastfeeding baby if the mother is vaccinated with any of the live or inactivated vaccines described in this *Handbook*. Breastfeeding does not adversely affect immunisation and is not a contraindication for the administration of any vaccine to the baby.

#### (iv) Preterm babies

Preterm (premature) infants have a special need for protection and, despite their immunological immaturity, they generally respond well to vaccines. Provided they are well and there are no contraindications to vaccination they should be vaccinated according to the recommended schedule at the usual chronological age.<sup>6-14</sup>

Routine childhood vaccines can cause an increase in apnoea in preterm babies vaccinated in hospital, particularly babies still requiring special care, but these are generally self-limiting and do not affect the clinical course.<sup>8</sup> Preterm babies in hospital should be monitored for apnoea or bradycardia for up to 48 hours post vaccination.<sup>6-8</sup> Vaccinations have not caused an increase in apnoeas in babies at home, and are not associated with an increased risk of SIDS.<sup>6-8</sup>

- **Vaccines as recommended on the National Immunisation Program (NIP) schedule**

Preterm babies produce good antibody responses to most vaccines in the NIP. They should be vaccinated at the standard recommended ages without correction for prematurity.<sup>14</sup>

- **Pneumococcal vaccines**

All preterm babies born at less than 28 weeks' gestation or with chronic lung disease should be offered the 7-valent pneumococcal conjugate vaccine at 2, 4 and 6 months of age, with a fourth dose at 12 months of age, and a 23-valent pneumococcal polysaccharide vaccine booster at 4–5 years of age (see Chapter 3.15, *Pneumococcal disease*).

- ***Haemophilus influenzae* type b vaccine**

Some smaller preterm babies do not respond as well as term babies to PRP-OMP (Liquid PedvaxHIB or COMVAX) Hib vaccine.<sup>9-14</sup> When PRP-OMP is used in an extremely preterm baby (<28 weeks' gestation or <1500 g birth weight), an extra dose of vaccine should be given at 6 months of age (ie. doses should be given at 2, 4, 6 and 12 months of age) (see Chapter 3.4, *Haemophilus influenzae* type b).

- **Hepatitis B vaccine**

Preterm babies do not respond as well to hepatitis B-containing vaccines as term babies.<sup>7,12,13,15</sup> Thus, for babies born at <32 weeks' gestation or <2000 g birth weight, it is recommended to give vaccine at 0, 2, 4 and 6 months of age and either:

- (a) measure anti-HBs at 7 months of age and give a booster at 12 months of age if antibody titre is <10 mIU/mL, or
- (b) give a booster at 12 months of age without measuring the antibody titre.

(See Chapter 3.6, *Hepatitis B*.)

- **Influenza vaccine**

Preterm infants with ongoing problems at 6 months of age, particularly respiratory, cardiac or neurological disease, should receive influenza vaccine.

### **2.3.3 Vaccination of individuals with impaired immunity due to disease or treatment<sup>16-18</sup>**

The vaccination of individuals with impaired immune systems presents several problems. First, the immune response to vaccines may be inadequate and, second, there is a risk that some live vaccines may themselves cause progressive infection. Degrees of impaired immunity vary from insignificant to profound, and this should be taken into account when considering a vaccination schedule, as should the risk of acquiring the vaccine-preventable diseases.

Although it may seem logical to give higher or more frequent doses of vaccines to these patients, in many cases there are insufficient data to advocate such measures. Because of the uncertainty of the immune response in some patients with impaired immunity, it may be useful to measure post-vaccination antibody titres in groups such as children who have received haematopoietic stem cell transplants (see '2.3.3.3 Re-vaccination following haematopoietic stem cell transplantation (HSCT)' below).

Administration of certain vaccines is a priority for some patients with medical conditions that increase the risk from infectious diseases, even in the absence of specific immune defects. These include: the use of influenza vaccine in individuals with severe asthma, chronic lung disease, congenital heart disease, diabetes and Down syndrome; pneumococcal conjugate vaccine in children