4.17 ROTAVIRUS

4.17.1 Virology

Rotaviruses are non-enveloped RNA viruses that are classified according to the two surface proteins they contain: VP7, the ‘G’ glycoprotein, and VP4, the protease-cleaved ‘P’ protein. The G and P proteins are targets for the neutralising antibodies that contribute to protection against reinfection and disease.1,2 The two gene segments that encode these proteins can segregate independently, and a binary typing system, consisting of both P and G types, has been developed. Rotavirus strains are most commonly referred to by their G serotype, with G1, G2, G3, G4 and G9 accounting for around 90% of serotypes, both globally and in Australia.3,4 The most common P types found in combination with these G types are P1A[8] (found with all common G types except G2) and P1B[4], usually found in combination with G2.5

4.17.2 Clinical features

Rotavirus is the predominant agent of severe dehydrating gastroenteritis in infants and young children in both developed and developing countries.1,2 The spectrum of rotavirus infection ranges from asymptomatic infection, to mild, watery diarrhea of limited duration, to severe dehydrating diarrhea with vomiting, fever, electrolyte imbalance, shock and death. Rotavirus infections are often more severe than other common causes of diarrhea, and are more likely to result in dehydration and hospitalisation.1,6 The incubation period is 1 to 3 days, after which illness can begin abruptly, with vomiting often preceding the onset of diarrhea.7 Up to one-third of patients have a temperature of >39°C in the first few days of illness. Symptoms generally resolve in 3 to 7 days.

4.17.3 Epidemiology

Rotaviruses are shed in high concentrations in the stools of infected children and are transmitted by the faecal–oral route, both through close person-to-person contact and via fomites.7 In some instances, rotaviruses might also be transmitted by other modes, such as faecally contaminated food, water and respiratory droplets.6,8

Infection in early childhood is thought to be universal. Although individuals can be infected several times during their lives, the first infection, typically between 3 and 36 months of age, is most likely to cause severe diarrhea and dehydration.9,10 The degree of protection following natural infection varies. After a single natural infection, 40% of children are protected against any subsequent infection with rotavirus, 75% are protected against diarrhea from a subsequent rotavirus infection, and 88% are protected against severe diarrhea.10 Repeat infections provide even greater protection. Prior to the introduction of rotavirus vaccines in Australia, the best available estimates were that approximately 10 000 hospitalisations due to rotavirus occurred each year in children <5 years of age,11 equating to around half the hospitalisations for acute gastroenteritis in this age group11,12 and affecting 3.8% of all children (1 in 27) by the age of 5 years. In addition to hospitalisations, an estimated 115 000 children <5 years of age visited a GP, and 22 000 children required an emergency department visit due to rotavirus.11,13 On average, there was 1 death attributed to rotavirus each year in Australia, but this is likely to be a minimum estimate.13 Following the introduction of rotavirus vaccines to the NIP in 2007, substantial reductions (>70%) in both rotavirus-specific and all-cause hospital presentations for gastroenteritis have been reported (Figure 4.17.1).14-17 Emergency department visits for acute gastroenteritis have also declined, as have rotavirus notifications.18,19

In temperate Australia, rotavirus infections follow a seasonal pattern, with the peak incidence being in mid to late winter. In the northern tropical and arid regions, there is no consistent seasonal pattern – disease peaks are unpredictable20 and widespread epidemics cause severe strain on healthcare services.21,22 Overall, Indigenous infants and children are hospitalised with rotavirus gastroenteritis about 3 to 5 times more commonly than their non-Indigenous peers, are younger at hospitalisation, and have a longer duration of stay (an average of 5 days, compared with 2 days for non-Indigenous infants).12,20,21,23

Immunocompromised children and adults, such as those with congenital immunodeficiency, or post haematopoietic or solid organ transplantation, are at increased risk of severe, prolonged and even fatal rotavirus gastroenteritis.1,24,25 Rotavirus is an important cause of nosocomial gastroenteritis,26-30 and can also cause disease in adults, especially among those caring for children and those residing in aged care facilities.1,31,32
4.17.4 Vaccines

Two oral rotavirus vaccines are available in Australia, and their efficacy and safety in the prevention of rotavirus gastroenteritis have been extensively evaluated.\textsuperscript{3,33-39} Both are live attenuated vaccines administered orally to infants, but the component vaccine viruses differ. The human rotavirus vaccine, Rotarix (GlaxoSmithKline), is a live attenuated vaccine containing one strain of attenuated human rotavirus (G1P1A[8] strain). Rotarix protects against non-G1 serotypes on the basis of other shared epitopes. A pentavalent vaccine, RotaTeq (CSL Limited/Merck & Co Inc), contains five human–bovine rotavirus reassortants with the human serotypes G1, G2, G3, G4 and P1A[8] and the bovine serotypes G6 and P7.

In middle- and high-income countries, a course of vaccination with either Rotarix or RotaTeq prevents rotavirus gastroenteritis of any severity in approximately 70% of recipients and prevents severe rotavirus gastroenteritis and rotavirus hospitalisation for 85 to 100% of recipients for up to 3 years.\textsuperscript{33,34,40} Vaccination is also highly effective in preventing emergency department and clinic/GP visits.\textsuperscript{33,40} Overall, in pre-market clinical trials, rotavirus vaccination prevented around half (42–58%) of hospital admissions for acute gastroenteritis of any cause in young children, suggesting that rotavirus is responsible for more gastroenteritis than detected using routine testing and admission practices.\textsuperscript{33,34,40} Post-marketing studies in the United States and Australia have confirmed high vaccine effectiveness and impressive reductions in both rotavirus-coded and all-cause gastroenteritis hospitalisations.\textsuperscript{15,19,42-46} Reductions have also been observed in age groups not eligible for vaccination, suggesting that herd protective effects are also likely to exist for rotavirus vaccines.\textsuperscript{15,19,45}

Although more modest estimates of efficacy have been reported in resource-poor settings,\textsuperscript{36,38,47} post-marketing evaluation in the middle income countries Mexico and Brazil have revealed substantial reductions in diarrhoea-related mortality since vaccine introduction.\textsuperscript{46,49} Studies of Rotarix during consecutive epidemics in Central Australia gave generally lower and wide-ranging vaccine effectiveness estimates, which require further investigation.\textsuperscript{36,50} Considering the uniqueness of the remote Australian setting, these results should not be extrapolated to elsewhere in Australia, where the weight of evidence indicates a substantial reduction in the burden of rotavirus disease following vaccine introduction. To date, there has been no convincing evidence of important differences between the two vaccines with regard to protective efficacy against different serotypes.\textsuperscript{33,34,39}

RotaShield, a tetravalent rhesus-reassortant vaccine, which was licensed in the United States (but not elsewhere) in 1998–99, was subsequently associated with intussusception (IS, an uncommon form of bowel obstruction in young children) in approximately 1 in 10 000 vaccine recipients.\textsuperscript{51} The pathogenesis of RotaShield-associated IS has not been determined. The greatest risk of IS occurred within 3 to 14 days after the 1st dose, with a smaller risk after the 2nd dose.\textsuperscript{31,52} There is evidence suggesting that when the 1st dose of RotaShield was given at >3 months of age, the risk of
IS was increased.52 The current rotavirus vaccines (Rotarix and RotaTeq) differ in composition to RotaShield, which was more reactogenic.53–55 The large-scale safety studies of Rotarix and RotaTeq included approximately 140,000 infants, and found the risk of IS in vaccine recipients to be similar to that of placebo recipients, and less than that estimated for RotaShield.33,34 A meta-analysis of clinical trial data also did not find evidence of an increased risk of IS among vaccine recipients.39 The clinical trials of Rotarix and RotaTeq limited administration of the 1st dose of vaccine to infants under 14 and 12 weeks of age, respectively, and did not give subsequent doses to infants beyond 24 weeks for Rotarix and 32 weeks for RotaTeq.33,34 There are no data from clinical trials on the use of rotavirus vaccines given outside the recommended dosing age ranges. While clinical trials excluded an association between Rotarix or RotaTeq and IS of the magnitude associated with RotaShield, post-marketing studies in Australia and in Mexico indicate that a smaller increase in the absolute risk of IS might exist, particularly post dose 1 (refer to 4.17.11 Adverse events below).56,57

Vaccine viruses replicate in the intestinal mucosa and can be shed in the stool of vaccine recipients, particularly after the 1st dose. Vaccine virus shedding is more common with Rotarix and is detected in the stool a week after vaccination in up to 80% of 1st dose recipients, and in up to 30% of 2nd dose recipients.58,59 RotaTeq is only shed after the 1st dose (in up to 13% of recipients).51 In one study of 80 sets of twins, transmission of Rotarix was observed to occur from 15 vaccinated infants to their unvaccinated twin,60 indicating that transmission of vaccine virus to unvaccinated contacts is likely to occur, but the clinical implication of this has not been studied (refer to 4.17.10 Precautions below).

Adventitious DNA fragments of porcine circoviruses have been detected in both Rotarix and RotaTeq vaccines. However, porcine circoviruses have never been shown to cause illness in humans and are considered non-pathogenic.

- **Rotarix** – GlaxoSmithKline (live attenuated RIX4414 human rotavirus strain, type G1P1A[8]). Each 1.5 mL monodose pre-filled oral applicator or squeezable tube contains ≥10⁶⁰ cell culture infectious dose 50% (CCID₅₀) of the RIX4414 strain; di-sodium adiurate; Dulbecco’s Modified Eagle Medium; sterile water. Manufacture involves exposure to bovine-derived material.

- **RotaTeq** – CSL Limited/Merck & Co Inc (live attenuated human-bovine reassortant rotavirus strains, types G1, G2, G3, G4 and P1A[8]). Each 2.0 mL monodose pre-filled dosing tube contains a minimum dose level of at least 2.0 x 10⁷ infectious units of each of the rotavirus reassortants G1, G2, G3, G4 and P1A[8]; sodium citrate; sodium phosphate monobasic monohydrate; sodium hydroxide; polysorbate 80; cell culture medium. Manufacture involves exposure to bovine-derived material.

### 4.17.5 Transport, storage and handling
Transport according to National vaccine storage guidelines: Strive for 5.61 Store at +2°C to +8°C. Do not freeze. Protect from light.

### 4.17.6 Dosage and administration
Rotavirus vaccines are for oral administration only. Under no circumstances should rotavirus vaccines be injected.

**Rotarix** is recommended for use in a 2-dose course in infants and upper age limits apply; refer to Table 4.17.1. The liquid formulation is presented as a clear, colourless liquid contained within an oral applicator (syringe-type applicator with a plunger stopper or a squeezable tube). The 1.5 mL dose of vaccine should be administered orally from the oral applicator onto the inside of the infant’s cheek. Rotarix does not require reconstitution or dilution.

**RotaTeq** is recommended for use in a 3-dose course in infants and upper age limits apply; refer to Table 4.17.1. It is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration of the 2 mL dose onto the inside of the infant’s cheek. RotaTeq does not require reconstitution or dilution. RotaTeq is a pale yellow, clear liquid that may have a pink tint.

There are limited data available on the safety of administering higher than the recommended dose of rotavirus vaccines or the efficacy of a partially administered dose(s). If most of an oral rotavirus vaccine dose has been spat out or vomited within minutes of administration, a single repeat dose can be administered during the same visit. If an infant regurgitates or vomits only a small part of a vaccine dose, it is not necessary to repeat the dose. Therefore, the regurgitated (and incomplete volume) dose is still considered as the valid dose.

**Co-administration with other vaccines**
Rotavirus vaccines can be co-administered with other vaccines included on the NIP schedule at 2 and 4 months of age (Rotarix) or 2, 4 and 6 months of age (RotaTeq). The available evidence from clinical trials suggests co-administration of oral rotavirus vaccines is safe and effective and does not interfere with the immune response to other vaccine antigens (DTPa, Hib, IPV, hepB, and pneumococcal conjugate vaccines).58,59,62
There are no restrictions on the timing of administration of any other live vaccines in relation to rotavirus vaccines, including BCG or oral poliomyelitis vaccine (OPV), for example, in infants who have received OPV overseas. Delay of rotavirus vaccination for 4 weeks following vaccination with BCG or vice versa is not necessary.

Interchangeability of rotavirus vaccines

Completion of a course of rotavirus vaccine should be with vaccine from the same manufacturer whenever possible. There are very few studies that address the interchangeability of the two available rotavirus vaccines. However, if either dose 1 or 2 of vaccine is given as RotaTeq, a 3rd dose of either rotavirus vaccine may be given, provided that the upper age limit and inter-vaccine interval, as defined in Table 4.17.1, are met.

4.17.7 Recommendations

Infants

Administration of a course of oral rotavirus vaccination is recommended for all infants in the first half of the 1st year of life. Vaccination of older infants and children is not recommended as there are theoretical concerns regarding use in older age groups (refer to 4.17.4 Vaccines above). Vaccination should occur at either 2 and 4 months of age (Rotarix), or 2, 4 and 6 months of age (RotaTeq), according to the following schedules and upper age limits (refer to Table 4.17.1). The 1st dose of either rotavirus vaccine can be given as early as 6 weeks of age, where necessary (refer to Table 4.17.1). If the 1st dose is given at 6 weeks of age, the next scheduled rotavirus vaccine dose(s) should still be given according to the age limits specified for dosing in Table 4.17.1 below.

Rotarix (human monovalent rotavirus vaccine)

The vaccination course of Rotarix consists of 2 doses, at 2 and 4 months of age. The 1st dose should be given between 6 and 14 weeks of age (i.e. prior to turning 15 weeks old), and the 2nd dose should be given by 24 weeks of age (i.e. prior to turning 25 weeks old). The interval between the 2 doses should not be less than 4 weeks.

RotaTeq (pentavalent human–bovine reassortant rotavirus vaccine)

The vaccination course of RotaTeq consists of 3 doses, at 2, 4, and 6 months of age. The 1st dose should be given between 6 and 12 weeks of age (i.e. prior to turning 13 weeks old), and all doses should be given by 32 weeks of age (i.e. prior to turning 33 weeks old). The interval between doses should be at least 4 weeks.

Table 4.17.1: Upper age limits for dosing of oral rotavirus vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>Age of routine oral administration</th>
<th>Recommended age limits for dosing</th>
<th>Minimum interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotarix (GlaxoSmithKline)</td>
<td>2 oral doses (1.5 mL/dose)</td>
<td>2 and 4 months</td>
<td>1st dose: 6–14* weeks</td>
<td>2nd dose: 10–24* weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3rd dose: N/A</td>
</tr>
<tr>
<td>RotaTeq (CSL Limited/Merck &amp; Co Inc)</td>
<td>3 oral doses (2 mL/dose)</td>
<td>2, 4 and 6 months</td>
<td>1st dose: 6–12‡ weeks</td>
<td>2nd dose: 10–32† weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3rd dose: 14–32† weeks</td>
</tr>
</tbody>
</table>

* The upper age limit for receipt of the 1st dose of Rotarix is immediately prior to turning 15 weeks old, and the upper age limit for receipt of the 2nd dose is immediately prior to turning 25 weeks old.

† The upper age limit for receipt of the 1st dose of RotaTeq is immediately prior to turning 13 weeks old. The 2nd dose of vaccine should preferably be given by 28 weeks of age to allow for a minimum interval of 4 weeks before receipt of the 3rd dose. The upper age limit for the 3rd dose is immediately prior to turning 33 weeks old. For infants presenting for their 2nd dose after reaching 29 weeks of age, a 2nd and final dose can be given, provided the upper age limit of 32 weeks (immediately prior to turning 33 weeks old) has not been reached.

For infants in whom the 1st dose of rotavirus vaccine is inadvertently administered at an age greater than the suggested cut-off (i.e. after the 14th week of age for Rotarix or the 12th week of age for RotaTeq), the remaining vaccine doses should be administered as per the schedule, providing the minimum interval between doses can be maintained within the recommended age limits for subsequent doses. The timing of the 1st dose should not affect the safety and efficacy of the 2nd and 3rd doses. Infants who develop rotavirus gastroenteritis before receiving the full course of rotavirus vaccination should still complete the full 2- or 3-dose schedule (dependent on the brand of vaccine), because one rotavirus infection only provides partial immunity.

Older infants

Vaccination of older infants, children or adults is not recommended. Infants should commence the course of rotavirus vaccination within the recommended age limits for the 1st dose and doses should not be given beyond the upper age limits for the final dose of the vaccine course (refer to ‘Infants’ above). The incidence of severe rotavirus infection...
decreases with increasing age and the benefit and safety profile of rotavirus vaccination in older infants and children has not been established.

**Preterm infants**

Vaccination of preterm infants using either rotavirus vaccine is indicated at a chronologic age (without correction for prematurity) of at least 6 weeks, if the infant is clinically stable. Preterm infants (born at <37 weeks gestation) appear to be at increased risk of hospitalisation from viral gastroenteritis. In clinical trials, RotaTeq or placebo was administered to 2070 preterm infants (25–36 weeks gestational age; median 34 weeks) who experienced rates of adverse events after vaccination similar to matched placebo recipients. Efficacy against rotavirus gastroenteritis of any severity appeared comparable to efficacy in full-term infants (73%; 95% CI: −2 to 95%). These conclusions would also be expected to apply to Rotarix vaccine, which appears safe and immunogenic in preterm infants. If standard infection control precautions are maintained, administration of rotavirus vaccine to hospitalised infants, including hospitalised preterm infants, would be expected to carry a low risk for transmission of vaccine viruses.

Refer also to 4.17.10 *Precautions* below for other special risk groups and hospitalised infants.

**4.17.8 Pregnancy and breastfeeding**

There are no restrictions on the infant’s consumption of food or liquid, including breast milk, either before or after vaccination with either rotavirus vaccine.

Infants living in households of pregnant women can receive rotavirus vaccines. Most pregnant women will have pre-existing immunity to rotavirus, but protection from transmission of wild-type infection through the vaccination of infant contacts may benefit adults, including pregnant women, and outweighs any theoretical concern regarding exposure to vaccine viruses.

**4.17.9 Contraindications**

The contraindications to rotavirus vaccines are:

- anaphylaxis following a previous dose of either rotavirus vaccine
- anaphylaxis following any vaccine component
- previous history of intussusception or a congenital abnormality that may predispose to IS

The risk of recurrence of IS unrelated to rotavirus vaccination is in the order of 10%. In addition, certain congenital malformations affecting the gut (e.g. Meckel’s diverticulum) increase the risk of IS. Because of the possible association of rotavirus vaccination with an increased risk of IS (refer to 4.17.11 *Adverse events* below), it is considered prudent to withhold administration of rotavirus vaccines to an infant with a previous history of IS or with a known uncorrected congenital malformation associated with increased risk of IS.

- severe combined immunodeficiency (SCID) in infants

Case reports from the United States indicate prolonged vaccine virus-associated gastrointestinal disease following receipt of rotavirus vaccines among infants with SCID. Because these infants are unlikely to generate a protective immune response to vaccination and because of potential harm, rotavirus vaccines are contraindicated for infants with SCID. For infants with less severe forms of immunocompromise, the risk of vaccine-associated disease is likely to be less than the risk of natural infection (refer to 4.17.10 *Precautions* below).

**4.17.10 Precautions**

**Infants with acute gastroenteritis**

Infants with moderate to severe acute gastroenteritis should not be vaccinated until after recovery from their acute illness. Infants with mild gastroenteritis (including mild diarrhoea) can be vaccinated. The use of rotavirus vaccines has not been studied in infants with acute gastroenteritis.

**Infants with moderate to severe illness**

As with other vaccines, infants with a moderate to severe illness should be vaccinated after recovery. In addition to the factors mentioned above, this avoids superimposing potential adverse events related to vaccination with the concurrent illness.

**Infants with underlying conditions predisposing to severe rotavirus gastroenteritis**

Conditions predisposing to severe or complicated rotavirus gastroenteritis include metabolic disorders and chronic gastrointestinal disease, such as Hirschsprung’s disease, malabsorption syndromes or short gut syndrome. Data on the safety of live rotavirus vaccines among such infants is limited. In one report, RotaTeq was reported to be tolerated in 8 of 9 infants with high-output ileostomies, while 1 infant experienced an increase in ileostomy losses. However,
because of the greater risk of serious rotavirus disease, the benefits from vaccination are expected to outweigh the risk in these infants.

**Infants who are immunocompromised**

There are theoretical concerns that vaccine-associated gastrointestinal disease could occur in immunocompromised infants who receive rotavirus vaccines, and infants with the most severe forms of immunocompromise (SCID) should not receive rotavirus vaccine (refer to 4.17.9 Contraindications above). However, the risk for those infants with less severe immunocompromise may be less than the risk from natural infection. The risks and benefits of vaccination should be considered in the context of the infant’s specific immunocompromise with appropriate specialist advice (refer to 3.3.3 Vaccination of immunocompromised persons).

Rotavirus vaccines have been administered to HIV-infected infants in clinical trial settings. Specific data on the safety and efficacy of rotavirus vaccines in these infants are limited, but suggest that the vaccines are safe and immunogenic in HIV-infected, but clinically stable, children. (Refer also to 3.3.3 Vaccination of immunocompromised persons and Table 3.3.4 Categories of immunocompromise in HIV-infected persons, based on age-specific CD4+ counts and percentage of total lymphocytes.) There are no data on the use of rotavirus vaccines in infants born to women who have received immunosuppressive therapy in pregnancy (refer to ‘Use of immunosuppressive therapy during pregnancy’ in 3.3.2 Vaccination of women who are planning pregnancy, pregnant or breastfeeding, and preterm infants).

**Infants living in households with people who are immunocompromised**

Infants living in households with immunocompromised persons should be vaccinated. In general, immunocompromised household members are afforded protection by vaccination of young children in the household and this is considered to outweigh the risk of transmitting vaccine virus shed in stools to the immunocompromised household member. However, there have been no studies to specifically address this question. Hand washing and the careful disposal of soiled nappies are likely to minimise any risk of vaccine transmission to other household members. (Refer also to 3.3.3 Vaccination of immunocompromised persons.)

**Recent administration of antibody-containing blood products**

Infants who have recently received antibody-containing blood products and are at an eligible age should be vaccinated. The interval between vaccination and receipt of the blood product should be as long as possible, but without delaying administration of vaccine beyond the suggested age limits for dosing (as per Table 4.17.1 above). This recommendation for maximising the interval between receipt of antibody-containing blood products and rotavirus vaccination is based on theoretical concern that passively acquired antibody to rotavirus may interfere with vaccine immunogenicity.

**Hospitalised infants**

Administration of rotavirus vaccine to hospitalised infants, including premature infants, is likely to carry a low risk for transmission of vaccine viruses if standard infection control precautions are maintained. Provided that the infant is medically stable, vaccination should not be delayed, particularly if the delay would result in an infant being beyond the upper age limit for vaccination (refer to 4.17.7 Recommendations above). If a recently vaccinated child is hospitalised for any reason, no precautions other than routine standard precautions need be taken to prevent the spread of vaccine virus in the hospital setting.

4.17.11 Adverse events

**Intussusception**

Although clinical trials of the two available vaccines did not find an association between vaccination and intussusception (IS) (refer to 4.17.4 Vaccines above), one post-marketing study in Australia found evidence of a 4- to 5-fold increase in the risk of IS in the 7 days following the 1st dose of either Rotarix or RotaTeq. However, no overall increase in the risk of IS was detectable over the first 9 months of life. A similar apparent increase in risk for IS following the 1st dose of Rotarix has been observed in Mexico, and a smaller increase after the 2nd dose of Rotarix in Brazil. A study in the United States found no increased risk of IS following RotaTeq; however, the study was limited by small numbers, which reduced power to determine a low range risk increase. A subsequent Australian study estimated the increased risk of IS to be approximately 9-fold in the first 7 days after dose 1, and 2-fold in the first 7 days after dose 2 of either vaccine. The baseline risk of intussusception for Australian infants is around 80 cases per 100 000 infants. The increased risk of IS following rotavirus vaccination, from the most recent Australian study, is estimated as approximately 6 additional cases of intussusception among every 100 000 infants vaccinated, or 14 additional cases per year in Australia. This estimate assumes that infants in which an episode of IS occurs shortly after vaccination would not have otherwise experienced a ‘natural’ episode of intussusception; however, this cannot be determined from current data. Importantly, studies from both Australia and overseas have demonstrated the substantial impact of vaccination in preventing rotavirus morbidity and mortality (refer also to 4.17.3 Epidemiology above). Rotavirus vaccines continue to be recommended for use on the basis of this positive benefit to risk profile.
Immunisation providers should inform parents and carers of the rare risk of intussusception and how to be alert for the signs and symptoms of the condition.

Rotavirus vaccine should not be given to an infant who has had a confirmed intussusception because there may be an increased risk of the condition recurring (refer to 4.17.9 Contraindications above).

Other adverse events

No significant increase in post-vaccination vomiting, diarrhoea or fever has been reported during follow-up of several thousand recipients of Rotarix compared to those who were unvaccinated. Detailed follow-up of 11 700 recipients of RotaTeq or placebo reported no increase in fever or irritability in the week after vaccination among vaccinated infants, but a small increase in the incidence of vomiting (7% versus 5%) and diarrhoea (10% versus 9%). Vomiting and diarrhoea have not emerged as important adverse events following immunisation in post-marketing surveillance of rotavirus vaccines.

Infants who report an episode of diarrhoea or vomiting following vaccination should still receive subsequent rotavirus vaccine doses, as required and age eligible. The potential causes of diarrhoea/vomiting following vaccination include: gastroenteritis unrelated to rotavirus vaccination or infection (e.g. another viral agent); natural rotavirus infection (as vaccination is neither immediately protective nor 100% protective against all disease); or symptoms from vaccine virus replication (less likely). If rotavirus is detected by routine stool testing on a recently vaccinated infant, a positive test result can represent either natural infection or vaccine virus (as vaccine virus shedding occurs commonly after vaccination (refer to 4.17.4 Vaccines above). Specific testing is required to differentiate between vaccine virus and natural infection; however, this is rarely clinically indicated.

4.17.12 Variations from product information

The product information for Rotarix states that the vaccine should not be administered to subjects with any chronic gastrointestinal disease. The ATAGI recommends instead that pre-existing chronic gastrointestinal disease is not a contraindication to rotavirus vaccination, with the exception of those conditions that may predispose to IS (refer to 4.17.9 Contraindications and 4.17.10 Precautions above).

The product information for RotaTeq states that in the event that a dose of vaccine is spat out or vomited post vaccination, a replacement dose should not be given. The ATAGI recommends instead that if most of a dose is spat out or vomited then a single replacement dose may be given (refer to 4.17.6 Dosage and administration above.)

References

A full reference list is available on the electronic Handbook or website www.immunise.health.gov.au.


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