

Rotavirus vaccines for Australian children

This fact sheet provides information on rotavirus disease and the available vaccines to assist immunisation providers in the delivery of rotavirus vaccinations to children.

Disease and epidemiology

- Rotavirus is the most common cause of acute severe gastroenteritis in children aged <5 years.
- Before the introduction of rotavirus vaccination, there were around 500,000 deaths due to rotavirus each year, predominantly in developing countries.
- Before the introduction of rotavirus vaccine to the National Immunisation Program (NIP), there were around 10,000 hospitalisations (about half of all acute gastroenteritis hospitalisations) and 22,000 emergency department visits due to rotavirus in children aged <5 years in Australia each year.
- Since the introduction of rotavirus vaccines in Australia, there has been a 60–70% decline in rotavirus hospitalisations (around 7,000) in children aged <5 years.

Who should be vaccinated

- Rotavirus vaccines are recommended and funded under the NIP for routine immunisation of Australian infants in the first year of life, in either a 2- or 3-dose course starting from around 2 months of age.
- Immunisation of older infants, children and adults with rotavirus vaccine is not recommended.

Vaccines

- Two oral live attenuated rotavirus vaccines are available in Australia: Rotarix, a human monovalent vaccine (given in a 2-dose schedule at 2 and 4 months of age), and RotaTeq, a pentavalent human bovine reassortant vaccine (given in a 3-dose schedule at 2, 4 and 6 months of age).
- Rotavirus vaccines first became available in early 2006 and were added to the NIP from 1 July 2007.
- There are upper limits on the recommended age of administration of rotavirus vaccines; be sure to check the infant's age before immunisation.

The disease

Rotavirus is an RNA virus that has a characteristic wheel-like appearance when viewed by electron microscopy. It was identified as a cause of infant gastroenteritis in 1973.¹ There are a number of different strains of rotavirus, classified by the 'G' and 'P' outer proteins on the virus. Five strains (G1, G2, G3, G4 and G9) have accounted for around 90% of the serotypes seen worldwide and in Australia.²

Rotaviruses are transmitted by the faecal–oral route. Large numbers of viral particles are shed in faecal matter and the virus is quite stable in the environment, so contamination of hands and objects (fomites) is relatively easy. These routes of transmission are common in daycare centres, family homes and aged care facilities. Virus excretion can occur in individuals without symptoms.²

Children can be infected with rotavirus several times during their lives. The spectrum of illness ranges from mild, watery diarrhoea of limited duration to severe dehydrating diarrhoea with vomiting and fever, which can result in death.

The clinical features of rotavirus gastroenteritis are non-specific, so diagnosis can only be confirmed by laboratory testing of faecal specimens. Infections occurring in the first few months of life are generally asymptomatic.³

Epidemiology

Rotavirus is the leading cause of severe acute gastroenteritis in infants and young children, causing nearly 2 million hospitalisations and 453,000 deaths each year before the introduction of rotavirus vaccines worldwide.^{4,5} Rotavirus is found in all countries, and almost every child in the world will suffer at least one infection by the time they are 3 years old.⁶

In Australia, deaths due to rotavirus are rare due to better access to health services.⁷ However, before the vaccine was introduced, hospitalisations were common, with around 10,000 children aged <5 years hospitalised due to rotavirus each year, which accounted for about half the hospitalisations for any acute gastroenteritis in this age group.^{8,9} This translated to about 4% of children (1 in 27) being hospitalised with rotavirus gastroenteritis by the age of 5 years. In addition, an estimated 115,000 children aged <5 years visited a GP, and 22,000 children required an emergency department visit for rotavirus.^{7,8} Aboriginal and Torres Strait Islander infants and children were hospitalised with rotavirus gastroenteritis about 3–5 times more commonly than their non-Indigenous peers.¹⁰⁻¹² The peak incidence of severe rotavirus disease in Australia was between 6 and 24 months of age,² but disease peaked at an earlier age in Aboriginal and Torres Strait Islander children, particularly those in the Northern Territory.¹²

Rotavirus infections follow a seasonal pattern in temperate Australia with peak incidence in mid to late winter. However, in the northern tropical and arid regions of Australia, there is no consistent seasonal pattern and disease peaks are unpredictable.¹¹

Following the introduction of rotavirus vaccine on the National Immunisation Program (NIP) in 2007, there has been a marked decline in hospitalisations for rotavirus and laboratory-confirmed rotavirus gastroenteritis (refer to '[Vaccine efficacy/effectiveness](#)' below).^{13,14}

Who should be vaccinated

National Immunisation Program (NIP)

Rotavirus vaccination for all infants commenced nationally from 1 July 2007 under the NIP. Two rotavirus vaccines are funded under the NIP: Rotarix and RotaTeq. As of July 2017, all states and territories use Rotarix, which is given in a 2-dose schedule at 2 and 4 months of age (refer also to '[Vaccines, Administration](#)').

Others

Use of rotavirus vaccine in older children and adults is not recommended (refer to '[Other considerations](#)' below).

Vaccines

The two oral rotavirus vaccines available are Rotarix (GlaxoSmithKline) and RotaTeq (bioCSL/Merck & Co Inc). There are differences in the composition and number of doses required of each vaccine. Rotarix vaccine contains a single, attenuated human rotavirus of serotype G1P1A[8]. RotaTeq is a human–bovine reassortant vaccine containing five vaccine viruses (types G1, G2, G3, G4 and P1A[8]).

Administration

Rotavirus vaccines are administered orally at the same time as the other vaccines on the childhood immunisation schedule. The interval separating the doses should be no less than 4 weeks.¹⁵ The ages of administration for which the rotavirus vaccines are registered for use in Australia are shown in the [table](#) below.¹⁵

It is important for immunisation providers and parents to note that, unlike other NIP vaccines, there are *upper* limits for the administration of both the first and final doses of rotavirus vaccines. If the first dose of rotavirus vaccine is not provided by the specified age, the vaccine course should not be started.

Recommended upper age limits for administration of oral rotavirus vaccines*

	Doses	Age of routine oral administration	Recommended age limits for dosing			Minimum interval between doses
			1st dose	2nd dose	3rd dose	
Rotarix (GlaxoSmithKline)	2 oral doses (1.5 mL/dose)	2 and 4 months	6–14* weeks	10–24* weeks	N/A (3rd dose not required)	4 weeks
RotaTeq (bioCSL /Merck & Co Inc)	3 oral doses (2 mL/dose)	2, 4 and 6 months	6–12† weeks	10–32† weeks	14–32† weeks	4 weeks

* The upper age limit for receipt of the 1st dose of Rotarix is immediately before 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.

Vaccine efficacy/effectiveness

Both rotavirus vaccines have been shown to have similar efficacy against rotavirus gastroenteritis (of any severity) of around 70%, with high efficacy of 85% to 100% observed against severe rotavirus gastroenteritis.¹⁶⁻¹⁸

Studies in Australia following the introduction of rotavirus vaccines showed that vaccination is between 73% and 88% effective in preventing rotavirus infection.¹⁹⁻²¹ A 64% decline in rotavirus-coded hospitalisations and 39% decline in non-rotavirus-coded gastroenteritis hospitalisations in children aged <3 years was observed following introduction of rotavirus vaccination in Australia.²² Overall, in children aged <5 years, an estimated 7,000 hospitalisations from rotavirus gastroenteritis have been prevented each year, compared to what would have been expected without vaccination.²²

Vaccine safety

The rotavirus vaccines currently registered in Australia were evaluated in some of the largest and most stringent testing in clinical trials ever undertaken for any vaccine. This was, in part, because a previous rotavirus vaccine called RotaShield, which was licensed in the United States in 1998, was withdrawn from the US market within 9 months because it was shown to be associated with an increased risk of intussusception (a rare form of bowel blockage that is most common in infants aged 4–10 months). Intussusception is a rare condition (approximately 200 cases occur annually in infants each year in Australia) and the cause is usually unknown. Prompt medical attention is needed if intussusception is suspected.

The current rotavirus vaccines (Rotarix and RotaTeq) differ in composition to RotaShield. The clinical trials of Rotarix and RotaTeq limited the administration of the first and final doses of vaccine to infants.^{16,17} As these trials did not test the vaccines in older infants, these vaccines are not recommended for use in infants older than the age limits stated in the [table](#) above.

Post-marketing safety monitoring of the two currently used rotavirus vaccines has been conducted in Australia, the United States and other countries. Pooled analysis of data from multiple studies including data from >450,000 vaccine recipients has shown a small increase in the risk of intussusception in the first week after the first dose and, to a lesser extent, the second dose of both rotavirus vaccines.²³ The increased risk of intussusception after rotavirus vaccination is estimated at approximately 6 additional cases of intussusception among every 100,000 infants vaccinated, or 14 additional cases per year in Australia.²⁴

The overall benefits of preventing gastroenteritis from rotavirus are much greater than the small risk of intussusception. On the basis of the established benefits of rotavirus vaccination and the rare occurrence of intussusception, both the World Health Organization and the Australian Technical Advisory Group on Immunisation (ATAGI) have recommended the continued use of rotavirus vaccine for infants under the NIP.^{15,21,25}

Immunisation providers and parents/carers should be aware of the signs and symptoms of intussusception. More information about intussusception is available on both the [Therapeutic Goods Administration](#) (TGA) and [Immunise Australia](#) websites.^{26,27}

Vomiting and diarrhoea have not been noted as important adverse events in post-marketing surveillance of rotavirus vaccines. Vaccine recipients may have a 1–3% higher risk of developing diarrhoea or vomiting in the week after vaccine administration. The incidence of fever, irritability and other adverse events was similar in both vaccine and placebo recipients in clinical trials.^{16,17,28-30}

Contraindications/precautions

Contraindications

Rotavirus vaccine should not be given to any infant who has hypersensitivity to any component of the vaccine or who has had an anaphylactic reaction to a previous dose of either rotavirus vaccine.

Rotavirus vaccine should not be given to any infant with a previous history of intussusception or a congenital abnormality that may predispose them to intussusception.²⁸

Rotavirus vaccine should not be given to infants with severe combined immunodeficiency (SCID). Case reports indicate prolonged vaccine virus-associated gastrointestinal disease after rotavirus vaccination in infants with SCID.^{31,32} As these infants are unlikely to generate a protective immune response to the vaccine, and because of the potential harm, rotavirus vaccines are contraindicated for infants with SCID.

As recommended for all vaccines, rotavirus vaccine should not be given during any moderate to severe febrile illness (refer to ['Precautions'](#) below).^{33,34}

Precautions

Infants with an acute moderate to severe illness, including acute gastroenteritis, should not be vaccinated until their condition has improved. However, infants with mild gastroenteritis can be vaccinated.^{29,30}

Infants with pre-existing chronic gastrointestinal conditions (such as congenital malabsorption syndrome, Hirschsprung's disease, short-gut syndrome) are at risk of more severe disease from rotavirus and so stand to benefit more from vaccination. Data on the safety of rotavirus vaccines

in these groups are limited. However, given their greater risk of serious rotavirus disease, the benefits of vaccination in these infants are expected to outweigh the risk.¹⁵

While rotavirus vaccination is not recommended for infants who are severely immunocompromised, the risk for infants with less severe immunocompromising conditions may be less than the risk of infection. This should be considered in the context of the infant's specific condition and with appropriate specialist advice. Infants with HIV who are clinically stable can usually safely receive rotavirus vaccines.

Infants born to mothers who received immunosuppressive therapy (biological disease-modifying anti-rheumatic drugs [bDMARDs]), particularly in the third trimester, are not recommended to receive rotavirus vaccine.

Infants living in households with persons who have or are suspected of having an immunodeficiency disorder or impaired immune status can be vaccinated.^{29,30} Vaccine rotaviruses can be shed in the stool of vaccine recipients, particularly after the first dose. However, the protection of the immunocompromised household member afforded by vaccination of young children in the household outweighs the small risk for transmitting vaccine virus to the immunocompromised person and any subsequent theoretical risk for vaccine virus-associated disease.²⁸⁻³⁰

Hospitalised infants, including premature infants, who are otherwise clinically stable and at the appropriate chronological age, can be given rotavirus vaccines in the hospital setting, particularly if delaying the dose would preclude completing the immunisation schedule on time.²⁸⁻³⁰ Limited data on the use of rotavirus vaccine in premature infants and other infants with medical risk conditions suggested that vaccination was well tolerated when given without other vaccines.^{35,36}

Concomitant administration

Rotavirus vaccines can be co-administered with other vaccines on the NIP, including other live vaccines. Evidence from clinical trials suggests that co-administration of oral rotavirus vaccines is safe and does not interfere with the immune response to the other vaccine antigens.

Although co-administration of rotavirus vaccines with BCG vaccine has not been assessed in clinical trials, there is unlikely to be any interference between the two vaccines and they can be co-administered at any time in relation to one another.

Interchangeability

Few studies address the interchangeability of the two available rotavirus vaccines. Completion of a vaccination course should preferably be with the same brand of rotavirus vaccine. If an infant has received one or two doses of RotaTeq, a third dose of either rotavirus vaccine can be given. The upper age limits and minimum intervals between doses must still be met.

Other considerations

Why is catch-up immunisation or primary immunisation of older infants and children not suggested?

The three main reasons why catch-up immunisation or immunisation of older children is not considered appropriate are: (1) the concerns regarding intussusception (discussed in '[Vaccine safety](#)' above); (2) lack of data about the efficacy and safety of the vaccines in older infants or children; and (3) the main burden of rotavirus disease is in children <3 years of age. Older children are usually protected from developing severe disease due to rotavirus because they have acquired partial immunity from being infected earlier in life.^{2,37} Unlike other childhood diseases, such as measles and chickenpox, natural rotavirus infection doesn't offer lifetime protection, but provides protection from severe disease when subsequently exposed to the virus.

Similarly, vaccination of adults is not recommended because it is likely that they may have partial pre-existing immunity and are unlikely to experience severe rotavirus disease.

Advice to parents

Rotavirus causes about half of all episodes of hospitalised gastroenteritis in infants and young children. Rotavirus vaccination is the best way to protect children against rotavirus disease. Rotavirus vaccination provides similar protection to natural infection, but without causing disease along the way.² The vaccine will not prevent diarrhoea and vomiting caused by other infectious agents but is very good at preventing severe diarrhoea and vomiting caused by rotavirus. The vaccines are highly effective especially in young children, and are between 73% and 88% protective against rotavirus gastroenteritis.^{19,20} Children who receive the rotavirus vaccine are less likely to be hospitalised, visit the emergency department or see a doctor for gastroenteritis.^{16,17,29,30}

The overall benefits of preventing gastroenteritis from rotavirus are much greater than the small risk of intussusception, a risk that is further reduced by giving the vaccine within the required age limits. On the basis of the established benefits of rotavirus vaccination and the rare occurrence of intussusception, both the World Health Organization and the Australian Technical Advisory Group on Immunisation have recommended the continued use of rotavirus vaccine for infants.^{15,25}

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