# Rotavirus Vaccine

## Questions and Answers for Health Care Providers

*Manitoba's publicly funded rotavirus immunization program began in 2014 for infants born on or after March 1, 2014. Over time, Manitoba has used different rotavirus vaccines based on the product allocated to Manitoba as part of the national procurement process. This document provides updated questions and answers for your reference.*



### 1. Who is eligible for publicly funded rotavirus vaccine?

The rotavirus vaccine is offered free-of-charge as part of Manitoba's routine childhood immunization schedule. The most current criteria are available on Manitoba's Vaccine Eligibility site at https://www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html.

### 2. Why does the vaccine series need to be completed before eight months of age?

The age limit for vaccine series completion is related to a lack of safety data on the administration of the rotavirus vaccine to older infants.

### 3. Should a spit-up dose of vaccine be repeated?

No. The Canadian Immunization Guide states that spit up doses should not be re-administered, as the safety of administering a repeat dose of rotavirus vaccine is unknown. In clinical trials, spitting up the vaccine dose was rarely seen.
To minimize the chance of a spit up dose, administer the oral rotavirus vaccine first before the child becomes distressed by injections or other procedures.

### 4. Is additional screening for potential contraindications required prior to administration of rotavirus vaccine?

Yes. A routine pre-immunization health assessment should be conducted, including questions screening for contraindications specific to rotavirus vaccine, such as:

- A severe allergic reaction to a previous dose of rotavirus vaccine, any contents of the vaccine or its container.
- A history of intussusception.
- An uncorrected congenital malformation of the gastrointestinal tract, such as Meckel's diverticulum, that would predispose the child to intussusception. However, infants with chronic gastrointestinal disease who are not considered immunocompromised are likely to benefit from rotavirus vaccine.
- Any suspected or known immunodeficiency conditions (e.g. severe combined immunodeficiency disorder (SCID)). If there is a suspected or known immunodeficiency, the child should not be vaccinated until consultation is received.

### 5. Can infants with known or suspected immunodeficiency – such as those born to mothers on immunosuppressive medication be immunized?

Infants exposed in utero to maternal immunosuppressive medications may have known or suspected immunodeficiency, because some medications can cross the placental barrier and result in variable levels and duration of immune suppression in the infant. Decisions about rotavirus vaccination for infants with known or suspected immunodeficiency—other than severe combined immunodeficiency (SCID), which is a contraindication to rotavirus vaccine —should be made on a case-by-case basis. Because recommendations continue to evolve, providers should review current national guidelines or consult a paediatric infectious diseases specialist to assess risks and benefits for the specific infant.

### 6. Should the rotavirus vaccine be administered if an infant has immunocompromised caregivers?

Yes. The theoretical risk of vaccine virus transmission should be balanced against the protection the vaccine provides against wild type rotavirus gastroenteritis, which results in attack rates of 47% among susceptible household contacts.
The vaccine virus is excreted in stool after vaccination. The virus is detected in approximately 50 per cent of stools after the first dose, and seven to 18 per cent of stools after the second dose.
All household contacts, regardless of their immune status, should be advised to wash their hands thoroughly after changing diapers. Since the risk of vaccine virus transmission and subsequent vaccine virus-derived disease is reported to be less than the risk of wild type rotavirus transmission, infant vaccination should be encouraged in households where immunocompromised persons reside (Anderson, 2008).
Transmission of the vaccine virus from immunized infants has been found to occur between infants and children. The frequency is not widely quantified but is thought to be much less frequent than with wild type virus. One author reported approximately 18.8 per

cent (95 per cent confidence interval: 10.9 per cent to 29.2 per cent) transmission rate between twins (one vaccinated, one unvaccinated) (Payne et al. 2010 cited in Han, 2009). Current guidelines continue to recommend rotavirus vaccination even when infants have immunocompromised household contacts, because the risk of wild-type rotavirus infection is greater than the theoretical risk of vaccine-strain transmission.
There is no evidence that rotavirus is a teratogen. Pregnant women are unlikely to become infected with the vaccine virus if hand washing precautions are taken, and because most adults have some pre-existing immunity to rotavirus. Attention to hand hygiene after vaccination is recommended, including after changing diapers of babies who have been vaccinated, or preparing food in settings where vaccinated infants are present, such as day nurseries. These are routine recommendations for these practices because of the risk of fecal-oral transmission of human stool pathogens.

### 7. Can rotavirus vaccine be given to hospitalized infants?

Rotavirus vaccine may be considered for hospitalized infants in consultation with the infant's physician specialist and the infection control professionals in the facility.

### 8. Are there issues related to circulating maternal antibodies interfering with the response to the live attenuated vaccine?

Studies have not identified interference with circulating maternal antibodies as an issue in vaccine antibody response. The rotavirus vaccine provides comparable protection against laboratory-confirmed rotavirus infection in both breastfed and formula fed infants.

### 9. Are the two rotavirus vaccines, RotaTeq® and Rotarix® interchangeable?

Given that the two rotavirus vaccines differ in composition and schedule, **the vaccine series should be completed with the same product whenever possible.**

- If any dose in the series was RotaTeq®, a total of three doses should be administered.
- If the first dose was Rotarix®, and there is no more Rotarix® available, complete the series with two doses of RotaTeq®, for a total of three doses.
- If the product used for any previous dose is unknown, use a three-dose series.

A randomized, multicenter, open-label study investigated the non-inferiority of the immune responses to the two licensed rotavirus vaccines when administered as a mixed schedule (i.e. both RotaTeq® and Rotarix® used for one person), compared with administering a single vaccine schedule alone. The study demonstrated that the immune responses to all the sequential mixed vaccine schedules were shown to be non-inferior when compared with the two single vaccine reference groups. The proportion of children seropositive to at least one vaccine antigen at one month after vaccination ranged from 77 per cent to 96 per cent and was not significantly different among all the study groups. All schedules were well tolerated. The study concluded that mixed schedules were safe and induced comparable immune responses when compared with the licensed rotavirus vaccines given alone (Libster et al, 2016).

### 10. What is the duration of protection?

Rotavirus vaccines provide protection for at least two rotavirus seasons, with continued protection against severe disease for several years.

### 11. What is the known risk of intussusception following rotavirus vaccination?

Published data from several countries suggests a small increased risk of intussusception, using current rotavirus vaccines.
Intussusception in the first year of life occurs at a rate of 34 per 100,000 per year. However, the rate varies with age in the first year of life and peaks between five and 10 months of age. Post-marketing surveillance from multiple countries has identified a small increased risk of intussusception following rotavirus vaccination. Epidemiologic studies estimate an excess of approximately 1 to 7 additional cases per 100,000 doses, primarily within the first 7 days after Dose 1 or Dose 2.

The Global Advisory Committee on Vaccine Safety (GACVS) has reviewed these data and concluded that the risk is low, and that the benefits of rotavirus vaccination far outweigh the potential risk of intussusception. The National Advisory Committee on Immunization (NACI) continues to recommend routine infant rotavirus vaccination.

### 12. Are there special considerations for premature infants?

As with all vaccines, this vaccine should be given according to chronological (non-adjusted) age. The same schedule, precautions and contraindications should be applied as is the case with full- term infants.

### 13. Are there special considerations for breastfed infants?

No. There are no restrictions on the infant's consumption of food or liquid, including breast milk, either before or after receiving the oral rotavirus vaccine. The efficacy of the rotavirus vaccine series is similar among breastfed and non-breastfed infants.

### 14. Should the vaccine be given to a client who has already had rotavirus gastroenteritis?

Yes. The majority of rotavirus infections are not laboratory-confirmed, and therefore, whether or not an infant has had rotavirus infection is unknown. However, those who have confirmed rotavirus infection in the past should be vaccinated according to the routine schedule because initial infection with rotavirus provides only partial immunity.

### 15. What is the tariff code for rotavirus vaccines?

Manitoba uses two tariff codes:

- **Tariff 8778 — for RotaTeq® (Rota-5)**
- **Tariff 8897 — for Rotarix® (Rota-1)**

Both tariff codes remain active to ensure that each product is accurately captured on a client's immunization record within Manitoba's Immunization Registry. Correct coding is essential for clinical decision-making, forecasting, and program monitoring.

## References

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