

# Rotavirus Vaccine

## Questions and Answers for Health Care Providers

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*In April 2014, Manitoba Health, Seniors and Active Living launched a publicly-funded Rotavirus Immunization Program for infants born on or after March 1<sup>st</sup> 2014, using Rotarix™, one of two rotavirus vaccines available for use in Canada and manufactured by GlaxoSmithKline (GSK). In 2018, Manitoba, along with the rest of Canada, switched to RotaTeq®, manufactured by Merck, for use in its publicly-funded Rotavirus Immunization Program for infants born on or after March 1<sup>st</sup> 2018. This document includes an updated list of questions and answers for your reference.*

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### 1. Why is there a Rotavirus Immunization Program offered in Manitoba?

Rotavirus vaccine is offered to protect Manitoba children against a group of gastrointestinal viruses that infect approximately 95% of children worldwide by their fifth birthday.

In Canada, rotavirus infection occurs most often during the winter months, with incidence peaking from March to May.

Symptoms of rotavirus infection include approximately 5 to 7 days of vomiting, profuse watery diarrhea and fever. These symptoms can range from mild-to-severe. Rotavirus gastroenteritis is the most likely type of gastroenteritis to result in hospitalization.

Children less than 2 years of age have the peak incidence with the highest burden of disease and face the most complications (dehydration, electrolyte imbalance and metabolic acidosis). The Canadian Immunization Guide states that approximately 36% of children with rotavirus gastroenteritis will see a physician, 15% will go to an emergency department and 7% will be hospitalized.

Providing rotavirus vaccine protects infants from getting ill and experiencing complications from rotavirus infection that in some cases, can be severe. It will also decrease parental stress and time off work to care for ill children and decrease health care utilization costs.

### 2. Who qualifies for publicly-funded rotavirus vaccine?

The rotavirus vaccine is offered free-of-charge as part of Manitoba's routine childhood immunization schedule. When the publicly-funded rotavirus vaccine was first launched in April 2014, Rotarix™ was used in Manitoba and across Canada at 2 months and 4 months of age for infants born on or after March 1<sup>st</sup> 2014.

Effective April 1<sup>st</sup> 2018, Manitoba and Canada switched to RotaTeq®; all infants born on or after March 1<sup>st</sup> 2018 will receive RotaTeq® at 2, 4 and 6 months of age.

Generally, all infants born on or before February 28<sup>th</sup> 2018 will be on the 2-dose schedule (Rotarix™ at 2 and 4 months). 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 3 doses should be administered.
- If the first dose was unknown, complete the series with 2 doses of RotaTeq®.
- If the first dose was Rotarix™ and Rotarix™ is unavailable, complete the schedule with two doses of RotaTeq®.

For children who are off the routine recommended schedule, the relevant parameters for timing limitations are:

- The minimum age for receipt of the first dose is 6 weeks + 0 days
- The first dose should be given by 15 weeks of age (14 weeks plus 6 days of age)
- The minimum interval between doses is 4 weeks
- The 3-dose series should be completed by 32 weeks or 8 months of age (8 months less 1 day)

### 3. Which rotavirus vaccine does Manitoba use?

As of April 2018, Manitoba, and Canada, uses RotaTeq®, manufactured by Merck. RotaTeq® is an orally administered, live, pentavalent vaccine that is approved by Health Canada. RotaTeq® is indicated for the prevention of rotavirus gastroenteritis caused by serotypes G1, G2, G3, G4 and G-serotypes that contain P1A[8].

### 4. Why does the vaccine series need to be completed before 8 months of age?

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

### 5. How is RotaTeq® packaged?

RotaTeq® is supplied as a sterile solution **for oral use** in a single-dose tube (2mL). It is a pale yellow, clear liquid that may have a pink tint.

New health care providers unfamiliar with this format should be reminded that it is an **ORAL** application and that the vaccine should **NOT BE INJECTED by needle under any circumstances**.

RotaTeq® must be refrigerated between 2 °C and 8 °C and protected from light.

### 6. How are the oral tube and cap disposed of after use?

Use a biological waste container.

### 7. 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 (as per manufacturer instructions; see question 10 below).

### 8. Are there any precautions that health care providers should take when administering the oral rotavirus vaccine?

There are no case reports in the literature of health care providers contracting rotavirus during the process of administering the vaccine.

There are no additional precautions that should be taken when administering the oral rotavirus vaccine. An immunocompromised immunizer does not need to take special infection control precautions or avoid handling the vaccine.

Gloves are not recommended for any immunizers. As always, if an immunizer comes into contact with the contents of a vaccine or with bodily fluids, they should wash their hands immediately and follow standard precautions and established clinic procedures to clean up any spills on hard surfaces.

### 9. Oral rotavirus vaccine contains sucrose in an amount expected to have an effect on immunization injection pain. When should RotaTeq® be given in relation to other vaccines to elicit a reduction in pain?

Though the impact of RotaTeq® on immunization pain has not been studied directly, it contains sucrose in amounts known to provide analgesic benefits. To obtain this effect, it should be given 1 to 2 minutes prior to the injection of other vaccines. This allows time for the oral vaccine to be absorbed from the mouth, and affect the neurotransmitters in the infant's brain. As breastfeeding combines multiple additional pain management strategies, it should also be encouraged whenever possible during vaccine injections.

### 10. How do I administer RotaTeq®?

Each dose is supplied in a container consisting of a squeezable plastic, latex-free, dosing tube with a twist-off cap, allowing for direct oral administration. The dosing tube is contained in a pouch.

Before giving the vaccine, ensure the vaccine is not expired and has not been damaged or already opened. If you notice anything abnormal (e.g. particles), do NOT use the vaccine and report the issue to the Inventory Management Specialist at Manitoba Health, Seniors and Active Living, as per the Vaccine and Biological Product Complaint Process ([www.gov.mb.ca/health/publichealth/cdc/div/docs/vbpcpf.pdf](http://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbpcpf.pdf)).

Give the vaccine 1 to 2 minutes prior to the injection of other vaccines.

Position the child to give the vaccine while being held by the caregiver; seat the child leaning slightly back. It is okay if a drop remains in the tip of the tube. The sweet taste of the vaccine will likely stimulate the child to swallow the vaccine.



Tear open the pouch and remove the dosing tube.



Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.



Open the dosing tube in 2 easy motions:

1. Puncture the dispensing tip by screwing cap *clockwise* until it becomes tight.



2. Remove cap by turning it *counterclockwise*.



Administer dose by gently squeezing liquid into infant's mouth toward the inner cheek until dosing tube is empty. (a residual drop may remain in the tip of the tube.)

Discard the empty tube and cap in approved biological waste containers according to local regulations.

### 11. 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 or 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)). Given the young age of these clients, it is possible that SCID may be undiagnosed at the time of the appointment. Therefore, to assess for this condition, inquire about a family history of SCID or a history of recurrent, unexplained early deaths in the family. This question is designed to solicit information about infants whose deaths were related to immune compromise rather than deaths in healthy infants ruled to be caused by sudden infant death syndrome (SIDS). Clients who identify a family history of either SCID or recurrent unexplained early deaths should see their family physician for assessment and referral to a pediatric immunologist. If there is a suspected or known immunodeficiency, the child should not be vaccinated until consultation is received.

### 12. Can infants born to mothers on immunosuppressive medication be immunized?

As per the Canadian Immunization Guide, special consideration should be given to immunizing infants who have been exposed to monoclonal antibodies in utero. Some monoclonal antibodies taken during pregnancy can, similar to maternal antibodies, pass through the placental barrier, potentially resulting in various forms of temporary immunosuppression in infants. For example, rituximab taken during pregnancy is associated with B-cell depletion in both mother and fetus, while infliximab can be detected in infants up to 6 months after birth. Due to the potential risk of disseminated disease, administration of BCG and oral polio vaccine (which continues to be used elsewhere in the world) is therefore contraindicated in such infants who are less than 6 months of age. One exception to this is palivizumab which is specific for the prevention of respiratory syncytial virus (RSV) infection; it will not interfere with the response to a live vaccine. A longer interval of 6-12 months should be observed following rituximab therapy. There are no data at this time regarding the potential risk associated with rotavirus (RV) vaccine in these infants. Prior to RV immunization, laboratory tests may be useful in assessing humoral and cellular immune status. When considering immunization in the absence of laboratory test results, the decision to immunize should be based on an individual risk-benefit assessment. For example, in jurisdictions with ongoing RV immunization programs, indirect protection through herd immunity is likely to be high and withholding immunization may be considered until more information about the effects of monoclonal antibodies in utero becomes available. Alternatively, when travelling to jurisdictions that do not have RV immunization programs and where exposure to wild-type virus may be high, immunization with RV vaccine may be prudent in order to reduce the risk of potential complications from RV infection. Immune responses to live vaccines that are administered after one year of age (e.g. MMR or MMRV vaccine) are not considered to be affected by in utero exposure to monoclonal antibodies. Infants exposed to monoclonal antibodies in utero should receive all inactivated vaccines according to routine schedule.

Monoclonal antibodies administered to the mother during breastfeeding are thought to have very little or no impact on the infant. Transfer of monoclonal antibodies through breast milk is limited, and the minimal quantities that are ingested are likely to be broken down in the infant's gastrointestinal tract. Infants of breastfeeding women receiving monoclonal antibody treatment should therefore be immunized with both live and inactivated vaccines according to routine schedules.

### 13. 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.

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

Generally, all infants born on or before February 28<sup>th</sup> 2018 will be on the 2-dose schedule (Rotarix™ at 2 and 4 months). 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 3 doses should be administered.
- If the first dose was unknown, complete the series with 2 doses of RotaTeq®.
- If the first dose was Rotarix™ and Rotarix™ is unavailable, complete the schedule with two doses of RotaTeq®.

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 1 month after vaccination ranged from 77% to 96%, 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).

### 15. Can RotaTeq® be given at the same time as other vaccines?

Yes. When other vaccines routinely recommended as part of Manitoba's routine childhood immunization schedule are given at the same time as rotavirus vaccine, the immune responses and safety are unaffected.

Rotavirus vaccine can be administered simultaneously or at any interval before or after other live injectable or intranasal vaccines (including BCG vaccine), if indicated with the exception of oral polio virus vaccine. Infants who have received oral polio vaccine should have a 2 week interval before receipt of oral rotavirus vaccine to ensure the immune response to the rotavirus vaccine is unaffected.

Due to the difference in ages between routinely scheduled doses of rotavirus vaccines in early infancy and MMR/varicella vaccines routinely given at 12 months of age, it is unlikely that health care providers will need to co-administer another live attenuated vaccine at the

same time as rotavirus vaccine. However, this may occur if an infant is travelling and requires early vaccination.

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

Efficacy was documented for two rotavirus seasons following immunization. Among a subset of 4,451 infants who were evaluated, efficacy against any severity of rotavirus gastroenteritis caused by the composite of the vaccine G-serotypes through two seasons after vaccination was 71.3%. The efficacy of RotaTeq® in preventing cases occurring only during the second rotavirus season post-vaccination was 62.6% (RotaTeq® Product Monograph, Merck).

Vaccine effectiveness data from a US case-control study also showed that RotaTeq® provided strain specific effectiveness against G12P[8] (78%) and sustained protection against rotavirus-related hospitalizations and emergency department visits in children up to the 7<sup>th</sup> year of life (6<sup>th</sup> to 7<sup>th</sup> year of life: 69%) (RotaTeq® Product Monograph, Merck).

### 17. What is the efficacy/ effectiveness of rotavirus vaccines?

The rotavirus vaccine is 74% to 85% effective in preventing severe disease in developed countries, with efficacy against any rotavirus gastroenteritis at 85% to 98%.

In Ontario, when comparing rotavirus-specific gastroenteritis hospitalization post-rotavirus vaccine period to a pre-rotavirus vaccine program, there was a 75% reduction in hospitalizations.

An evaluation conducted by the National Enteric Surveillance Program in 2017 identified that the rates of rotavirus hospital discharges among infants in Manitoba (<12 months of age) declined from approximately 100 cases/100,000 in 2006 (before Manitoba launched its Rotavirus Immunization Program) to 6 cases/100,000 in 2015 (after Program launch). In addition, the rates of rotavirus infection dropped from 6.9 cases/100,000 in 2006 to 2.0 cases/100,000 in 2015.

### 18. What is the efficacy/ effectiveness of RotaTeq® between doses?

A post-hoc analysis of the Rotavirus Efficacy and Safety Trail (REST) was conducted to determine whether RotaTeq® confers early protection against rotavirus gastroenteritis before completion of the 3-dose regime. The data showed that RotaTeq® reduced the rates of combined hospitalizations and emergency department visits between doses 1 and 2 by 82%, and between doses 2 and 3 by 84%. This data suggests that RotaTeq® provides a high level of protection between doses against hospitalizations and emergency department visits for rotavirus gastroenteritis starting as early as 14 days after the first dose (Dennehy et al, 2011).

### 19. What are the expected side-effects of RotaTeq®?

Common side-effects include diarrhea in the 7 day period after vaccination and vomiting.

Some post-marketing studies have found an association with intussusception which may occur rarely after vaccination.

Vaccine providers are asked to report adverse events following immunization (AEFI) (<http://www.gov.mb.ca/health/publichealth/cdc/dic/aefi.html>), particularly:

- Intussusception in the first 21 days following any dose of rotavirus vaccine.

- Any serious or unexpected adverse event temporally related to vaccination. An unexpected AEFI is an event that is not listed in the product information but may be due to the immunization, or a change in the frequency of a known AEFI.

### 20. What is intussusception?

Intussusception occurs when one portion of the bowel slides into the next, much like pieces of a telescope, creating a blockage in the bowel.

In most infant cases, the cause is unknown, but it has been linked with viral infection. It occurs most frequently in babies between the ages of 5 and 10 months at a rate of 34 cases/100,000 per year.

Symptoms are abdominal pain, usually evident because of bouts of persistent crying and the infant drawing up their legs and vomiting. Sometimes blood is seen in the stools. This condition is managed in hospital, where a barium or air enema is used to reverse the blockage. Most cases recover completely with no further problems. Complications can occur if treatment is delayed, and surgery or antibiotics may be needed.

Intussusception can recur in up to 10% of radiologically reduced cases, sometimes within a few days and usually within the next 6 months. For this reason, a history of intussusception is a contraindication to receipt of rotavirus vaccine.

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

Published data from several countries are suggestive of a small increased risk of intussusception using current rotavirus vaccines (RotaTeq® and Rotarix™).

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 5 and 10 months of age.

Surveillance for intussusception following the introduction of routine infant rotavirus immunization programs in several countries suggested a small increased risk of intussusception following rotavirus vaccination. Subsequent epidemiologic studies using different methods have estimated the risk as between 1 and 7 excess cases of intussusception per 100,000 doses in the 7 days following the first and second dose of rotavirus vaccine. The Global Advisory Committee on Vaccine Safety (GACVS) of the WHO reviewed the findings from these studies and noted that the findings remain reassuring; the risk of intussusception following current rotavirus vaccines is small.

The National Advisory Committee on Immunization (NACI) statement on rotavirus vaccine was updated in 2010 prior to the publication of the recent studies, but NACI has not withdrawn or otherwise modified its recommendation for the routine use of rotavirus vaccines in the infant schedule.

The Advisory Committee on Immunization Practices (ACIP) reviewed the available data from the above studies and recommends that the benefits of rotavirus vaccine greatly outweigh the potential risks of intussusception in the US population.

Intussusception rates in rotavirus vaccines have been monitored closely due to previous experiences with RotaShield®, which was withdrawn by Wyeth-Lederle from the US market due to a risk of intussusception estimated at 1 case per 10,000 recipients following the first dose. The estimated risk of intussusception with the two new rotavirus vaccines is much smaller than the risk that was seen with RotaShield®.



In summary, the evidence indicates that intussusception can occur as a result of vaccination with either RotaTeq® or Rotarix™ but that the risk is low, on the order of approximately 1 to 7 cases/100,000 doses.

### **22. Can the vaccine virus be spread to others including susceptible household contacts?**

The vaccine virus is excreted in stool after vaccination. The virus is detected in approximately 50% of stools after the first dose and 7% to 18% of stools after the second dose.

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.

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/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% (95% confidence interval: 10.9% - 29.2%) transmission rate between twins (one vaccinated, one unvaccinated) (Payne et al. 2010 cited in Han, 2009).

No case reports describing the risk of transmission to adults caring for infants were found in a search of the literature (Anderson, 2008).

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 following 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 such practices because of the risk of fecal-oral transmission of human stool pathogens.

### **23. Is there a duty to inform clients (particularly for those who, for religious reasons, do not eat pork) about the presence of porcine circovirus-1 in the vaccine?**

No. While fragments of porcine circovirus (PCV)-1 and -2 DNA have been found in the vaccine, these viruses contain no pig or other animal material. Receiving the vaccine would not contravene religious practices.

Clients who have questions can be made aware that while porcine circovirus fragments are considered to be a contaminant in these vaccines, they are not known to cause illness in humans. Health Canada states that there is no evidence that the presence of PCV-1 or PCV-2 in rotavirus vaccines poses a safety risk to recipients (<http://www.hc-sc.gc.ca/dhp-mps/brgtherap/activit/fs-fi-rotavirus-questions-eng.php#q10>).

### **24. Should the rotavirus vaccine be postponed if the infant is ill?**

As with other vaccines, administration of the rotavirus vaccine should be postponed in infants suffering from acute febrile illness or moderate-to-severe diarrhea and vomiting until their condition improves, unless postponing will result in scheduling of the first dose after 15

weeks of age. However, the presence of a minor infection such as a cold or mild gastroenteritis should not result in the deferral of the vaccine.

### 25. 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.

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

Age-eligible infants should receive the vaccine only at the time of hospital discharge to prevent possible transmission of vaccine strain rotavirus to other hospitalized infants. However, the same timelines for administration must be followed.

### 27. 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 receipt of oral rotavirus vaccine. The efficacy of the rotavirus vaccine series is similar among breastfed and non-breastfed infants.

Breastfeeding mothers should be encouraged to feed babies during immunization injections given at the same visit and following rotavirus vaccine as part of a comprehensive immunization injection pain reduction strategy.

### 28. 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.

### 29. What is the tariff for RotaTeq®?

A new tariff code has been added to delineate between the two rotavirus vaccines: tariff 8778 for rota-5 (RotaTeq®). The old tariff code, 8897, is still active and is to be used for rota-1 (Rotarix™) administration. It is of utmost importance to delineate which vaccine (tariff 8778 or 8897) was used for the vaccine to be accurately captured in the Manitoba Immunization Registry in order to aid in clinical decision-making.

### 30. What if dose 1 and/or 2 are unknown? (i.e. it is unclear if RotaTeq® or Rotarix™ was given).

Generally, all infants born on or before February 28<sup>th</sup> 2018 will be on the 2-dose schedule (Rotarix™ at 2 and 4 months). 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 3 doses should be administered.
- If the first dose was unknown, complete the series with 2 doses of RotaTeq®.
- If the first dose was Rotarix™ and Rotarix™ is unavailable, complete the schedule with two doses of RotaTeq®.

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