Ontario

Ministry of Health

Updates to the Ontario Rotavirus Immunization Program: Product change to Rotarix® vaccine

Questions and Answers for Health Care Providers

Starting August 1, 2021, the Ontario publicly funded rotavirus immunization program will transition to the Rotarix® vaccine from the RotaTeq® vaccine.

This questions and answers sheet for health care providers provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment. For more information about the Rotarix® vaccine, please refer to the product monograph authorized by Health Canada.

What is rotavirus disease?

Rotavirus (RV) disease is a common cause of gastroenteritis in infants and young children, characterized by an acute onset of vomiting, fever, abdominal pain and watery diarrhea which may last three to eight days. In infants and young children, rotavirus infection can lead to severe dehydration.

Before the introduction of the publicly funded rotavirus immunization program, almost all children were infected by 5 years of age.

What RV vaccine products are available for use in Canada?

RV vaccine is indicated for active immunization against rotavirus gastroenteritis in infants. Two rotavirus vaccines are authorized for use in Canada:

Rot-1, Rotarix®, live, oral, monovalent, attenuated, human rotavirus vaccine manufactured by GlaxoSmithKline (GSK) Inc.

Rot-5, RotaTeq®, a live, oral, pentavalent rotavirus vaccine manufactured by Merck Canada Inc.

Are the two RV vaccine products considered equal?

Although prevalence of RV serotypes varies across regions, both RV vaccines provide protection against the predominant strains in North America. The National Advisory Committee on Immunization (NACI) recommends either vaccine, without a preferential recommendation for one over the other.

Why is Ontario changing the RV vaccine product used in the publicly funded program?

Ontario participates in the federal vaccine purchasing program. During the most recent vaccine contracting process, a split contract with GSK Inc. and Merck Canada Inc. was awarded. Based on the contracts awarded Ontario will be receiving the Rotarix® manufactured by GSK Inc.

Who is eligible to receive the publicly funded RV vaccine in Ontario? When should the first dose of RV vaccine be administered?

All infants in Ontario are eligible to receive the RV vaccine, with the first dose typically given at 2 months of age according to the Publicly Funded Immunization Schedules for Ontario. The RV vaccine can be given as early as six weeks of age according to the product monographs.

Infants born on or after June 1, 2021 should start their rotavirus vaccine series with the Rotarix® vaccine. This infant cohort will receive their first dose of Rotarix® in August 2021 at 2 months of age.

How is RV vaccine administered? What is the recommended immunization schedule for both RotaTeq® and Rotarix®?

Rotarix® is given orally as a 2-dose series, routinely at 2 and 4 months of age. The minimum interval between the first dose and second dose is 4 weeks.

RotaTeq® given orally as a 3-dose series, routinely at 2, 4 and 6 months of age. The minimum interval between doses is 4 to 10 weeks.

Both Rotarix® and RotaTeq® products can be given together with other routine infant vaccines administered at the ages these products are given. Infants should receive **all** doses in the vaccine series (i.e., 2 doses for Rotarix® and 3 doses for RotaTeq®) to achieve optimal protection against rotavirus.

Recommended RV vaccine schedules			
Vaccines	**Dose 1**	**Dose 2**	**Dose 3**
Rot-1 - Rotarix® (1.5 mL/dose) 2-dose series	2 months of age	4 months of age	----------
Rot-5 - RotaTeq® (2.0 mL/dose) 3-dose series	2 months of age	4 months of age	6 months of age

NOTE:

Rot-1: first dose should be administered < 15 weeks of age and all doses administered <25 weeks of age.

Rot-5: first dose should be administered < 15 weeks of age and all doses administered <32 weeks of age.

Can the two RV vaccine products be used interchangeably to complete a series?

According to NACI, the two vaccines differ in composition and schedule, the vaccine series should be completed with the same product whenever possible.

If RotaTeq® was the vaccine used to start the immunization series and is not available, complete the series with Rotarix®. In this scenario, a total of 3 doses of vaccine should be administered.

Note: If any dose in the series is RotaTeq®, a total of 3 doses of rotavirus vaccine should be administered.

Scenarios to Complete Rotavirus Series:

Scenario	Response
1 or 2 doses of RotaTeq® was given and RotaTeq® is available	Complete the 3-dose series with RotaTeq® at an interval of 4 to 10 weeks between each dose. All doses should be administered by 32 weeks of age.
1 dose of RotaTeq® was given and RotaTeq® is **not** available	Complete series with 2 doses of Rotarix® at an interval of 4 weeks between doses. Two doses should be completed by 24 weeks of age.
2 doses of RotaTeq® were given and RotaTeq® is **not** available	Complete series with 1 dose of Rotarix® by 24 weeks of age.
If the product is unknown for previous dose(s)	Complete series with 2 doses of Rotarix® vaccine **Note: If any dose in the series was RotaTeq®, a total of 3 doses of RV vaccine should be administered. All doses are required to be administered by 24 weeks of age.**

What happens if an infant spits out or regurgitates most of the RV vaccine?

Please refer to the specific product monograph for details on the rotavirus vaccine product given.

Is it safe to administer RV vaccine to infants who are breastfed?

Yes, breastfed infants can receive rotavirus vaccine.

Can premature infants receive RV vaccine?

As per the general age limits for vaccination, RV vaccines are safe and effective when administered to healthy preterm infants starting at 6 weeks of chronological age, with the first dose administered before 15 weeks of chronological age.

Who should not receive RV vaccine?

Please refer to the product monograph for details on contraindications and precautions for the specific RV vaccine.

What are the potential side effects or adverse events that could be experienced following RV vaccination?

Most infants who receive RV vaccine tolerate the vaccine well and have no side effects. However, as with any vaccine, side effects can occur. Possible common reactions include diarrhea, vomiting, irritability/fussiness, cough/runny nose, fever, loss of appetite and otitis media.

Uncommon reactions include flatulence, abdominal pain, dermatitis, nasopharyngitis and bronchospasm. Based on studies and surveillance of RV vaccines there is a small increased risk of intussusception, particularly within the 7 days after the first dose.

What is the risk of intussusception following RV vaccine administration?

Intussusception in the first year of life occurs at a background rate (i.e., not associated with RV vaccination) of about 34 per 100,000 per year. The rate varies with age in the first year of life and peaks between 5 and 10 months of age.

Post-licensure studies of Rotarix® and RotaTeq® suggest a small increased risk of intussusception, in the range of an additional 1 to 7 cases of intussusception per 100,000 doses in the 7 days following the first and second doses.

Parents should be informed of this small increased risk following RV vaccination, particularly during the 7 days following the first dose. Parents should also be counselled regarding the signs and symptoms of intussusception and the importance of seeking medical care, should symptoms develop. They should also be informed that the risk of intussusception remains small compared to the benefit of RV vaccination in preventing disease, and of the potential for severe diarrhea with RV infection.

What are the symptoms of intussusception?

Intussusception is a rare type of bowel obstruction that occurs when one portion of the bowel slides into an immediately adjacent segment (also known as telescoping or prolapse). Complications of this can lead to intestinal swelling, inflammation and decreased blood flow to the part of the intestines involved.

Symptoms of intussusception include stomach pain with severe crying (which may be brief); several episodes of vomiting; blood in the stool; or a baby may act weak or become very irritable. Intussusception is very rare.

What is the risk of transmission of the vaccine form of RV following vaccine administration?

Following vaccination, viral antigen shedding in the stool may be detected in some vaccinated infants, which can be from a week to several weeks. Please see the product monograph for specific vaccine details.

Transmission of the vaccine virus to household contacts can occur but is uncommon. Infants living in households with persons who have or are suspected to have immunosuppressive conditions or who are receiving immunosuppressive medications can receive rotavirus vaccine. The benefits of protecting immunocompromised household contacts from naturally occurring rotavirus by immunizing infants outweighs the very small risk of acquiring vaccine virus from vaccinated infants.

To minimize the risk of transmission of vaccine virus, caregivers should be advised to practice hand hygiene after contact with the vaccinated infant, especially after changing diapers and before food preparation or direct contact with other unvaccinated infants, pregnant women or an immunocompromised person.

Where do I find more information about the vaccines, such as common side effects, contraindications, storage recommendations and administration?

The product monograph for Rotarix® is available at: http://ca.gsk.com/en-ca/products/rotarix/

The product monograph for RotaTeq® is available at: https://www.merck.ca/static/pdf/ROTATEQ-PM_E.pdf

For general information on rotavirus and vaccination, please visit the Canadian Immunization Guide at: https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html