Rotavirus Vaccination Program

Questions & Answers for Immunization Providers

Office of the Chief Medical Officer of Health
Communicable Disease Control Branch
June 5, 2017

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Program background, rationale and eligibility:

1. **Why is a rotavirus vaccine program being offered in New Brunswick?**
   This vaccine is being offered to protect New Brunswick children against a group of gastrointestinal viruses that infect approximately 95% of children worldwide by time they are 5 years of age. In Canada, rotavirus occurs most often during the winter months, with incidence peaking from March to May. Symptoms of rotavirus include approximately 4-8 days of vomiting, profuse watery diarrhea, and fever. These symptoms can range from mild to very severe, with rotavirus gastroenteritis being the most likely gastroenteritis to result in hospitalization. Children less than 2 years of age have the highest burden of disease and face the most complications (dehydration, electrolyte imbalance and metabolic acidosis). Most other Canadian provinces are already offering rotavirus vaccine. Furthermore, experience in other countries has shown this program to be very effective at reducing disease and healthcare burden from this illness.

2. **Who qualifies for publicly-funded oral rotavirus vaccine?**
   Infants born in 2017 and later that meet age requirements (i.e. 1st dose must be given before 15 weeks; the series has to be completed before 8 months of age).The series consists of only two doses. The routine recommended schedule consists of a two dose series, given at 2 and 4 months.
   For children who are off the routine recommended schedule, the relevant parameters for timing limitations for the two doses of the vaccine are:
   - **1st dose**: minimum age for receipt of the first dose is 6 weeks; the maximum age is 14 weeks and 6 days;
   - **2nd dose**: minimum age for receipt of the second dose is 10 weeks; the maximum age before 8 months;
   - the minimum interval between doses is 4 weeks;
   - the two-dose series should be completed by 8 months of age;
   - there is no additional catch-up beyond the timing limitations mentioned above (e.g. for infants in whom the first dose of rotavirus vaccine is inadvertently administered at age 15 weeks or older, they are not eligible for additional publicly funded rotavirus vaccine to complete series).

3. **Which vaccine will New Brunswick be using?**
   New Brunswick will be using Rotarix™ manufactured by GlaxoSmithKline (GSK). Rotarix™ is an ORAL live attenuated human rotavirus vaccine. It protects against gastroenteritis caused by rotavirus types G1P [8], G2P [4], G3P [8], G4P [8] and G9P [8].

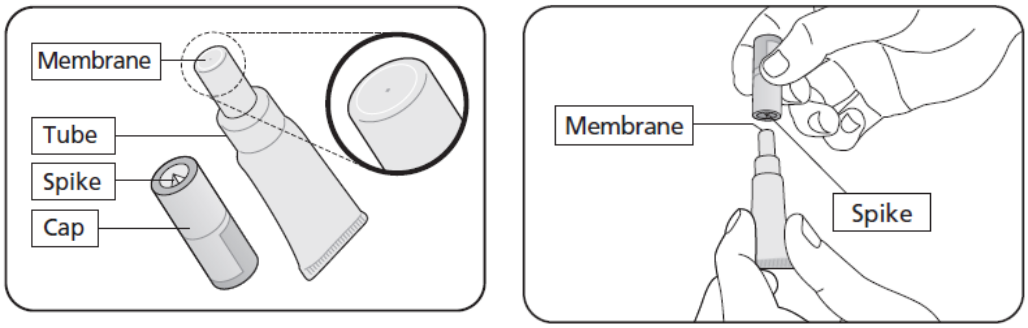
Vaccine preparation and administration:

4. **If both doses cannot be provided before 8 months, should just one dose be given?**
   If a child is age eligible for the first dose (under 15 weeks of age), and it is known that they will be unable to receive the second dose before 8 months of age for series completion, a single dose should be given. Vaccination should not be initiated in infants aged 15 weeks or

older, as the safety of providing the first dose of rotavirus vaccine in older infants is not known.

5. **Why does the series need to be completed before 8 months?**
   The age limit on vaccine series completion is related to a lack of safety data on the administration of this vaccine to older infants.

6. **How is the vaccine packaged?**
   The oral suspension in a squeezable tube format (shown in the image below) contains 1.5 mL of the vaccine which is a clear fluid. It should be kept refrigerated between 2-8º C and protected from light.



Images courtesy of GSK Inc.

7. **How do you administer the vaccine from a tube format?**

   Preparation:
   - Pull off the cap. Keep the cap – you need this to pierce the membrane.
   - Hold the tube upright.
   - Repeatedly flick the top of the tube until it is clear of any liquid.
   - Clear any liquid from the thinnest section of the tube by flicking just below the membrane.
   - Use small spike inside the top of the cap – press the cap down to pierce the membrane.

   Administration:
   - To minimize the chance of a spit up dose, administer the oral rotavirus vaccine at the beginning of the appointment while the child is happy. Give the vaccine 1-2 minutes prior to the injection of other vaccines.
   - The child should be held by the caregiver in a relaxed but firm seated or semi-recumbent position, depending on the child's preference.
   - Squeeze the liquid gently into the side of the child's mouth-towards the inside of their cheek.

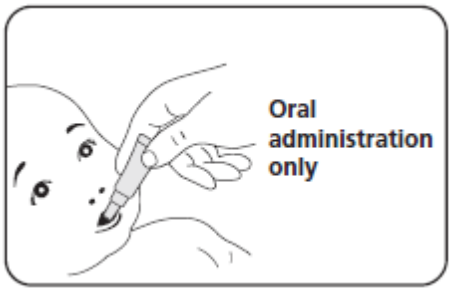


Image courtesy of GSK Inc.

8. **What if the spike breaks off into the tube during preparation?**
   Discard the tube and get another.

9. **How should I dispose of the squeezable tube after use?**
   Use a biological waste container.

10. **Should we repeat a "spit up" dose of vaccine?**
    No. The National Advisory Committee on Immunization, NACI, states that spit up doses should not be re-administered as the safety of administering a repeat dose of rotavirus vaccine is not known. In clinical trials spitting up was rarely seen. To minimize the chance of a spit up dose, administer the oral rotavirus vaccine first while the child is happy.

11. **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 immune compromised immunizer does not need to take special infection control precautions or avoid handling the vaccine. Glove use during immunization is not routinely recommended. If gloves are worn, they should be changed between patients. Perform hand hygiene after removing gloves. 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 procedure to clean up any spills on hard surfaces.

12. **When should Rotarix™ be given in relation to the injection of other vaccines to elicit a reduction in pain?**
    Oral rotavirus vaccine contains sucrose in an amount expected to have an effect on immunization injection pain, as would any oral sucrose solution especially designed for this purpose. Though the impact of Rotarix™ 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 1-2 minutes prior to the injection of other vaccines. This allows for 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 be also encouraged, whenever possible, during vaccine injections.

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

Yes. A routine pre-immunization health assessment should be conducted. With the introduction of rotavirus vaccine, this health assessment should include questions screening for contraindications specific to rotavirus vaccine including:

- A history of intussusception.
- An uncorrected congenital gastrointestinal disorder (e.g., Meckel's diverticulum). Uncorrected or corrected inguinal hernia is not identified in the literature as a contraindication to immunization. Neither gastro-esophageal reflux disease (GERD), nor taking medications for GERD have been identified as a contraindication to vaccination with 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 be referred to a pediatric immunologist. If a client identifies a suspected or known immunodeficiency, the child should not be vaccinated until consultation is received.

14. Can Rotarix™ be given at the same time as other vaccines?

Yes. When other vaccines routinely recommended in the New Brunswick infant 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 vaccines (injectable or intranasal) 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. Due to the difference in ages between routinely scheduled doses of rotavirus vaccines in early infancy and MMR and varicella vaccines routinely given at 12 months, it is unlikely that providers will need to co-administer another live attenuated vaccine at the same time as rotavirus vaccine, except in the circumstance of infants being vaccinated with MMR vaccine for travel, which may be done as early as 6 months of age.

15. Can Rotarix™ be given after receiving a blood transfusion or blood products, including immunoglobulins?

No safety or efficacy data are available for the administration of rotavirus vaccine to infants who have recently received immune globulins or other blood products. In theory, there is minimal or no interaction between blood products or Ig preparations, and rotavirus vaccine. Rotavirus vaccine may be given concomitantly with, or at any time before or after, an immune globulin preparation or other blood product has been administered.

16. **Are the different rotavirus vaccines, e.g., RotaTeq® (Merck) and Rotarix™ (GSK) products interchangeable?**
    There is no information on vaccine interchangeability. Whenever possible, the series should be completed with the same product. However, if the product used for a previous dose(s) is not known, complete the series with the available product. If any prior dose is known to be RotaTeq®, a complete series requires a total of 3 doses by 8 months of age (e.g. If a child arrives from another province and has received 2 doses of RotaTeq, he/she is eligible for 1 dose of Rotarix to complete the 3 dose series).

Vaccine efficacy, precautions and safety:

17. **What is the duration of protection?**
    Efficacy is documented for two rotavirus seasons following immunization. There are no robust data on efficacy after this point (Vesikari, 2010).

18. **What is the efficacy of rotavirus vaccines?**
    Vaccine efficacy against severe disease has been shown to be 85-96%, with efficacy against any rotavirus gastroenteritis at 87% in the first season after vaccination. This persisted through the second rotavirus season with vaccine efficacy against severe rotavirus gastroenteritis at 79-86% and any rotavirus gastroenteritis at 71.9%.

19. **What are the expected side effects of Rotarix™?**
    Common side effects include irritability and diarrhea. Uncommon side effects include dermatitis, abdominal pain and/ or flatulence. Some post-marketing studies have found an association with intussusception which may occur rarely after vaccination. Intussusception in the first year of life occurs at a background rate of about 34 per 100,000 per year. Studies have estimated the risk from rotavirus vaccine to be from 1-7 additional cases per 100 000 doses in the 7 days following the first and second doses of vaccine. Parents should be informed of the low risk of intussusception following rotavirus vaccine (1 to 7 cases per 100,000 doses), particularly during the 7 days following the first dose. Parent education should include 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 rotavirus vaccination in preventing disease and of the potential for severe diarrhea from rotavirus .The temporal criteria for rotavirus vaccine associated adverse events are as follows: 0-7 days diarrhea (at least 3 explosive episodes), 0-42 days intussusception.

20. **Can the vaccine virus be spread to others including susceptible household contacts?**
    It is known that the vaccine virus is excreted in stool for at least 10 days after vaccination. This occurs in approximately 50-80% of vaccinees after dose 1 and 7-18% of vaccinees after dose 2. 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. Transmission of the vaccine virus from immunized infants has been found to occur between infants/children, though this is thought to be much less frequent than with wild type virus and has not been widely quantified, however one author reports a ~18.8% (95% confidence interval: 10.9%–29.2%)

transmission rate between twins (one vaccinated, one unvaccinated) (Han, 2009, as reported in Payne et al., 2010). No case reports were found demonstrating a risk of transmission to adults caring for infants in a search of the literature (Anderson, 2008).

There is no evidence that rotavirus is a teratogen. Infants living in households with pregnant women can be vaccinated. The risk of infection and disease from vaccine virus is low because most women of childbearing age have pre-existing immunity to rotavirus through natural exposure and rotavirus infection during pregnancy is not known to pose a risk to the fetus.
(Reference: http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-rot-eng.php#a5)

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 standard recommendations for such practices because of the risk of fecal oral transmission of human stool pathogens.

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 containing immunocompromised persons (Anderson, 2008).

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

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

22. What if a child has a mild to moderate diarrheal illness at the time of vaccination?

Rotavirus vaccine should not be administered to infants with acute moderate or severe gastroenteritis until their diarrhea and vomiting ceases. However, infants with mild acute gastroenteritis can be vaccinated, particularly if there is concern that the infant may not return for their vaccine or that postponing the vaccine will make the infant age ineligible to receive vaccine.

23. 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 and precautions and contraindications should be used as in full term infants.

24. 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.

25. 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.

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

The majority of rotavirus infections are not laboratory confirmed and therefore it is rare to have lab confirmed diagnosis of rotavirus infection. 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.

27. Should the rotavirus vaccine be given to an infant of a mother who received immunosuppressive therapy during pregnancy or lactation?

Immunosuppressive therapy given to a mother during pregnancy or lactation can cause immunosuppression of infants. Consultation with physician or Medical Office of Health is necessary to assess vaccine eligibility.

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