Vaccination with RotaTeq

Questions & Answers for Immunization Providers

Office of the Chief Medical Officer of Health
Communicable Disease Control Branch
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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 before they reach 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).

2. **Who qualifies for publicly funded oral rotavirus vaccine?**
   - Infants born in 2017 and later that meet age requirements (i.e., the 1st dose must be given before 15 weeks; the series has to be completed before 8 months of age) are eligible to receive publicly funded oral rotavirus vaccine.

3. **When will New Brunswick be switching from Rotarix™ to RotaTeq®?**
   - Starting May 1 2018, infants who have not received a dose of rotavirus vaccine and meet the age requirements (i.e., the 1st dose must be given before 15 weeks; the series has to be completed before 8 months of age) are eligible to receive the new product RotaTeq®.
   - RotaTeq® (rotavirus vaccine, live, oral, pentavalent) is indicated for the prevention of rotavirus gastroenteritis caused by the serotypes G1, G2, G3, G4, and G-serotypes that contain P1A.
   - Vaccination with RotaTeq® consists of a three-dose series given at 2, 4 and 6 months of age. For children who are off-schedule, the relevant parameters for timing limitations for the three doses of the vaccine are:
     - 1st dose: minimum age for receipt of the first dose is 6 weeks; the maximum age is before 15 weeks;
     - 2nd dose: minimum age for receipt of the second dose is 10 weeks;
     - 3rd dose: minimum age for receipt of the second dose is 14 weeks; the maximum age is before 8 months;
     - the minimum interval between doses is 4 weeks;
     - the three-dose series should be completed by 8 months of age;
     - there is no additional catch-up beyond the timing limitations mentioned above (e.g., infants, in whom the first dose of rotavirus vaccine is inadvertently administered at age 15 weeks or older infants, are not eligible for additional publicly funded rotavirus vaccine to complete series).

4. **If all doses cannot be provided before 8 months, should just one or two doses be given?**
   - If a child is eligible for the first dose (under 15 weeks of age), and it is known that they will be unable to receive all doses before 8 months of age for series completion, one or two doses 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?**
   - RotaTeq® is supplied as an oral suspension (2.0 mL pale yellow clear liquid) in a squeezable tube format.
   - It should be kept refrigerated between 2-8º C and protected from light.

7. **How do you administer RotaTeq® vaccine?**

   Preparation:
   - Tear open the pouch and remove the dosing tube.
   - Clear the fluid from the dispensing tip by holding tube vertically and tapping cap.
   - Puncture the dispensing tip by screwing cap clockwise until it becomes tight.

   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 before 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.

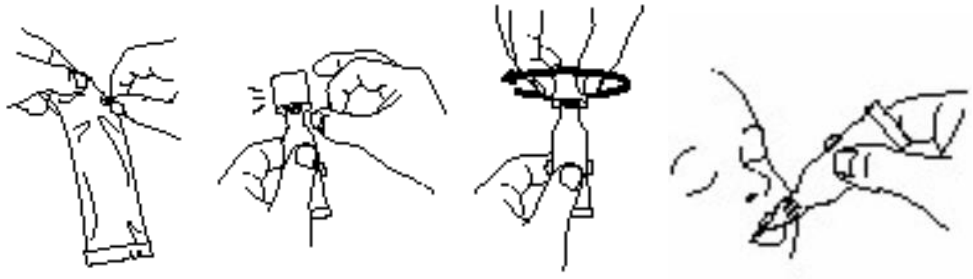

Image courtesy of Merck Inc.

8. **How should I dispose of the squeezable tube after use?**
   - Discard the empty tube and cap in approved biological waste containers.

9. **Should we repeat a "spit-up" dose of vaccine?**
   - 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.

10. **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.

11. **When should RotaTeq® 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 relieve acute injection pain, as would any oral sucrose solution uniquely designed for this purpose. Although the impact of RotaTeq® on injection pain has not been studied, the vaccine contains sucrose in amounts known to provide analgesic benefits. RotaTeq® should be given 1-2 minutes before the administration of other vaccines.

12. **Is additional screening for potential contraindications required before the administration of a rotavirus vaccine?**
    - A routine pre-immunization health assessment should be conducted and include additional screening questions:
      - 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., severely 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.
- Immunocompromised patients such as individuals with malignancies or who are otherwise immunocompromised, and individuals receiving immunosuppressive therapy.
- Individuals infected with HIV.
- Individuals who have received a blood transfusion or blood products, including immunoglobulins within 42 days.

13. What are the expected side effects and adverse events?

- Common side effects include irritability and diarrhea. Uncommon side effects include dermatitis, abdominal pain and/ or flatulence.
- Intussusception occurs at a background rate of about 34 per 100,000 per year in the first year of life. The current rotavirus (RV) vaccines, Rotarix™ (GlaxoSmithKline [GSK] Inc.) and RotaTeq® (Merck & Co, Inc.), have demonstrated a small increased risk of intussusception, of between 1 and 7 cases per 100,000 doses.
- As post-licensure studies of Rotarix™ and RotaTeq® suggest a low but excess risk of intussusception, parents should be informed of this low risk of intussusception following RV vaccine, 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 Rotavirus. As to the magnitude, the differences between the vaccines are marginal, and overall amount to between 1 to 7 cases per 100,000 doses for the current vaccines.
- There is no evidence that children who have a history of intussusception are at a higher risk of another intussusception after receiving RV vaccine. Nevertheless, as a precaution, infants with a history of intussusception should not be given RV vaccines.

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

- 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 except oral polio virus vaccine. Infants who have received oral polio vaccine should have a 2-week interval before receipt of oral rotavirus vaccine.

15. Can RotaTeq® begiven 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 are no data on safety, immunogenicity, or efficacy when Rot-1 vaccine (Rotarix™) is administered as the first dose and Rot-5 vaccine (RotaTeq®) is used as the second dose or vice versa.
- Given that the two 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®.

17. What is the efficacy of rotavirus vaccines?

- Rotavirus vaccine efficacy against rotavirus diarrhea of any severity in developed world settings is 74% to 87 %, and efficacy against severe diarrhea due to rotavirus is 85% to 98%.

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

- Rotavirus vaccine should not be administered to infants with acute moderate or severe gastroenteritis until their diarrhea and vomiting cease. 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 result in the infant not being eligible to receive the vaccine because of age.

19. Are there particular 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.

20. Are there particular considerations for breastfed infants?

- 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.
- Mothers should be encouraged to breastfeed their infants before, during, and after the immunization. The sweet taste of breast milk and other substances in the milk reduces pain and distress (e.g., tryptophan [a precursor of melatonin] which has been reported to increase the concentration of ß-endorphins, thereby producing analgesia and relaxation).

21. 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.

22. 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 a lab-confirmed diagnosis of rotavirus infection. However, those who had a confirmed rotavirus infection in the past should be vaccinated according to the routine schedule because initial infection with rotavirus provides only partial immunity.

23. 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 in infants. Consultation with physician or Medical Office of Health is necessary to assess vaccine eligibility.

References

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