HALDIMAND-NORFOLK HEALTH UNIT

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Communiqué

Rotavirus

Rotavirus (RV) is the most common cause of severe gastroenteritis in infants and children between six and 35 months of age. Rotavirus infection usually starts with fever, abdominal pain and vomiting, followed by diarrhea. These symptoms can be mild to severe and generally last for three to nine days with up to 20 episodes of diarrhea in a day, in some cases. Severe diarrhea and vomiting caused by rotavirus can lead to rapid dehydration, which can be life threatening if untreated. Almost all children experience at least one episode of RV gastroenteritis by five years of age.

In Canada, rotavirus is estimated to lead to hospitalization in one in 62 to one in 312 children under the age of five. Those that don't require hospitalization account for 17,000 ER visits and 41,000 physician visits per year. Parents miss an average of 1.6 days of work to care for a child for each rotavirus episode, adding to the economic burden. Rotavirus infection is seasonal from November to June and peaks in April/May. Equally prevalent in the developed and developing world, rotavirus is highly contagious and does not discriminate. Neither social class, hygienic measures or good nutrition appear to affect its prevention. Rotavirus infection has an incubation period of 18 hours to three days. The disease is transmitted by the fecal-oral route through both close person to person contact and through fomites such as toys and hard surfaces.

In August 2006 a live, **oral**, pentavalent human-bovine reassortant rotavirus vaccine, RotaTeq®, manufactured by Merck Frosst Canada Inc., was approved for use in Canada for the prevention of rotavirus infection in infants **six to 32 weeks of age**. It had also been licensed in the United States several months earlier. A previously licensed rotavirus vaccine was associated with an increased risk of intussusception and subsequently removed from the market. Due to that, the clinical trial program for RotaTeq was one of the largest ever for a vaccine. More than 70,000 infants aged six to 12 weeks were studied in 11 countries. The clinical trial was designed to be large enough to provide a meaningful evaluation not only of its efficacy but also the vaccine's safety with respect to intussusception. RotaTeq® was not associated with intussusception when compared with placebo. In addition it was not associated with an increased risk of other serious diseases when compared with placebo.

Immunogenicity:

In phase three clinical studies, 92.9% to 100% of recipients of RotaTeq® achieved a significant rise in serum anti-rotavirus IgA after a three-dose regimen.

Composition and packaging:

Each 2 ml dose of RotaTeq® contains the following human-bovine reassortants: G1, G2, G3, G4 and P1[8]. The reassortants are propagated in Vero cells using standard tissue culture techniques in the absence of antifungal agents. Each vaccine

dose also contains sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide polysorbate 80 and also cell culture media and trace amounts of foetal bovine serum. There are no preservatives or thimerosal and the packaging container and delivery system are latex free.

Contraindications:

RotaTeq® vaccine should not be given to individuals with a known sensitivity to any component of the vaccine or who have experienced an adverse reaction following a dose of the vaccine.

Administration should be delayed during acute febrile illness unless assessment determines withholding vaccine creates a greater risk for the patient.

Because it is a live vaccine, RotaTeq® should be administered with caution to individuals with immunodeficient close contacts. Such contacts would include people with malignancies, those who are otherwise immunocompromised or individuals who are receiving immunosuppressive therapy. However, because nearly all children are infected with natural occurring rotavirus by the age of five years, vaccination may reduce the risk of exposure of immunodeficient household contacts to naturally occurring rotavirus. A risk/benefit assessment is recommended before administering RotaTeq® to infants known to have immunodeficient close contacts.

Dosage and administration:

RotaTeq® is given in three separate 2 ml oral doses beginning at six to 12 weeks of age. The first dose should not be given if the infant is older than 13 weeks minus a day. Subsequent doses should be administered with an interval of four to 10 weeks between each dose, which includes a two-, four- and six-month immunization schedule.

If for any reason an incomplete dose is administered (the infant spits or regurgitates the vaccine), a replacement dose is **not** recommended. The remaining doses should be administered by 32 weeks of age at the recommended intervals. RotaTeq® can be given to pre-term infants according to their chronological age. RotaTeq® can be given concomitantly with other routinely recommended childhood vaccines with the exception of oral polio vaccine (irrelevant in Canada due to unavailability of oral polio vaccine).

Storage and handling:

RotaTeq® vaccine must be maintained within the cold chain storage and handling guidelines between 2° to 8°.

Availability:

Each dose of RotaTeq® is available in a single dose (2 ml) squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct administration.

RotaTeq® is currently **not publicly funded** but can be purchased at a pharmacy with a physician's prescription.

References:

- *Merck Frosst Canada Ltd, RotaTeq® Product Monograph, Revised October 19, 2007.*
- *Communicable Disease Report Volume 34. ACS-1, January 2008; Statement on the recommended use of pentavalent human-bovine reassortant rotavirus vaccine.*
- *Medical Frontiers International; A report from the 7th Canadian Immunization Conference Winnipeg, Manitoba/December 3-6, 2006.*

Tuberculosis (TB)
Did you know?

Globally there are eight million new cases of TB annually and 1.87 million TB-related deaths. The highest incidence is in the developing countries of Southeast Asia, sub-Saharan Africa and Eastern Europe.

The Ontario Ministry of Health and Long-Term Care reports there are approximately 780 new cases of TB diagnosed in the province each year. Most of these cases are in the greater Toronto area, particularly Peel and York Region. The Ottawa-Carleton area also has a higher than average incidence of TB. Most of these cases are people who have immigrated to Canada within the past five years. In 2007, there were no new cases of active TB reported in Haldimand and Norfolk Counties. However in January 2008, Hamilton Health Department reported three active cases of TB in students at McMaster University.

PLEASE REMEMBER

A positive TB skin test is reportable to public health, whether active TB is suspected or not.

Resource:

- *Ontario Safety Association for Community & Healthcare; Fast Facts, Revised March 2006.*
- *Canadian Network for Public Intelligence Alerts Posting, January 9, 2008.*

Use of Thimerosal-Containing Products

Recommendations

Currently, in Canada, some multi-dose preparations of influenza or hepatitis B vaccines are the only thimerosal-containing products that might be offered to children as part of the routine childhood immunization schedule. Thimerosal-free influenza and hepatitis B vaccines have also become available in recent years. Having reviewed all the available evidence, NACI reaffirms its recommendations:

- There is no legitimate safety reason to avoid the use of thimerosal-containing products for children or older individuals, including pregnant women.
- A previous episode of anaphylaxis attributed to thimerosal is an absolute contraindication to the use of thimerosal-containing vaccines. While at least one such event has been described, the link to thimerosal was not proven. Prior history of erythema multiforme, Stevens-Johnson syndrome (a rare serious disorder of the skin and mucous membrane, also called erythema multiforme major) or toxic epidermal necrolysis from thimerosal exposure would also be an absolute contraindication to future exposure. Thimerosal has never been reported to cause such reactions.
- If there is a documented history of a delayed hypersensitivity reaction to thimerosal (as manifest by a large local reaction or an eczematous rash) or a positive patch test reaction to thimerosal, immunization with thimerosal-containing vaccines can proceed, but individuals should be advised that long-lasting local or systemic cutaneous reactions can occur. They should report any reaction of concern following immunization so that it can be managed appropriately.
- The long-term goal of removing thimerosal from vaccines, provided there are safe alternatives to ensure that multi-dose vials are sterile, still applies, since this is one achievable way to reduce total environmental exposure to mercury.

Conclusion

Public confidence in vaccines and high rates of vaccine uptake are critical to the continued effectiveness of immunization programs. Even when risks are purely theoretical, experience has shown that unaddressed public concerns can drastically decrease immunization coverage, to the detriment of public health. Thus the call to remove thimerosal from vaccines seeks to maintain public confidence by avoiding even theoretical risk. NACI makes recommendations based on the best available scientific evidence. Vaccine safety is an essential consideration in any recommendation made by NACI. Concerns regarding thimerosal, as reviewed in the 2003 statement, were purely theoretical. Nevertheless, NACI identified them as important issues for further consideration and study. The weight of evidence now available, however, refutes any link between thimerosal and autism. Therefore, NACI concludes that there is no reason for vaccine providers or other health care professionals who may counsel individuals regarding immunization to raise any concerns about exposure to thimerosal.

Reference:

- *Communicable Disease Report Volume 33.ACS-6, 1 July 2007; Thimerosal: Updated Statement.*

Thimerosal content of vaccines marketed in Canada as of May 12, 2007*

Preservative Amounts (2 to 50 ug/dose)	Trace Amounts (< 1 ug/dose of vaccine)	None		
Epaxal	Engerix B (multidose)	Actacel	Infanrix-Hib	Prevnar
Fluviral	Infanrix-hexa	Adacel	Infanrix-IPV	Priorix
JE-VAX	Twinrix	Avaxim	Infanrix-IPV/Hib	Quadracel
Menomune A/C/Y/W-135 (multidose vial)	Twinrix Junior	Avaxim = pediatric	Influvac	RabAvert
Recombivax HB (multidose vial)		BCG	Liquid Pedvax	Recombivax HB singledose vial
Tetanus toxoid (adsorbed)		Boostrix	Menactra	RotaTeq
Vaxigrip (multidose vial)		DT Polio Absorbed	Meningitec	Td Adsorbed
		Dukoral	Menjugate	Td Polio Adsorbed
		Engerix B singledose vial	Menomune A/C	Tripacel
		Eolarix	Menomune A/C/Y/W-135 singledose vial	Typherix
		FSME-IMMUN	MMR II	Typhim Vi
		Gardasil	Mutacol	Vaqta
		Havrix	Neisvac-C	Varilrix
		Hiberix	Pediacel	Varivax III
		Imovax Polio	Pediarix	Vaxigrip singledose vial
		Imovax Rabies	Pentacel	ViVaxim
		Inactivated Poliomyelitis Vaccine (IPV)	Pneumo 23	Vivotif
		Infanrix	Pneumovax 23	Vivotif L
				YF-VAX

Reference:

- *Communicable Disease Report Volume 33.Acs-6, Thimerosal: Updated Statement.*

* A more detailed and, as appropriate, updated table of vaccine contents, including preservatives such as thimerosal, can be found at www.naci.gc.ca.

Communique is a newsletter distributed by the Haldimand-Norfolk Health Unit for those who work in the area of Vaccines and Vaccine Preventable Diseases. If you have ideas or suggestions of topics for future Communiqués, please contact

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