

Health **FAX**

New Immunization Schedule & Vaccine Programs: Rotavirus Vaccine, 2 Dose Varicella Schedule, MMRV Vaccine and Tdap for Adults

Attention: **Physicians, Nurse Practitioners & Walk-in Clinics**

Date: July 21, 2011

The Ministry of Health and Long-Term Care (MOHLTC) recently announced that **effective August 8th 2011**, there will be a revised Publicly Funded Immunization Schedule for Ontario launched which will include some enhancements and new vaccine programs. You will be receiving a package of support materials and detailed information in the mail from the MOHLTC about the revised Publicly Funded Immunization Schedules for Ontario and the new vaccine programs. The changes and new vaccine program highlights can be found below:

Rotavirus Vaccine

Infants will now be offered Rotavirus vaccine at their 2 & 4 month visits. There are currently two different products available in Canada; Rotateq® (3 dose schedule) and Rotarix™ (2 dose schedule). The vaccine that is publicly funded in Ontario is Rotarix™ (GSK). The information below pertains only to the Rotarix™ vaccine. Rotarix™ is an **oral vaccine** and should *not* be injected. It can be administered at the same visit as other vaccines as per the Publicly Funded Immunization Schedules for Ontario. Like all other vaccines, it is to be stored between 2-8 °C.

While the recommended schedule is 2 & 4 months, the 1st dose can be given as early as 6 weeks but the 2nd dose must be given by 24 weeks. There must be at least 4 weeks between doses. If an incomplete dose of Rotarix™ is administered to an infant (e.g. spits up, regurgitation of most of the vaccine), a single replacement dose may be given at the same visit. The infant should continue to receive their 2nd dose as per the schedule above.

This vaccine should not be given to infants with the following:

- An allergic reaction to a previous dose of the vaccine or an allergy to any of its components (refer to the product monograph). This product may contain latex.
- Suspected or known to be immunocompromised.
- A history of intussusception.
- Have uncorrected congenital abdominal disorders (such as Meckel's diverticulum).
- "Severe Combined Immunodeficiency Disorder" (SCID).
- Received blood products, including immunoglobulin within 42 days.

Infants who have previously had lab-confirmed Rotavirus may still receive the vaccine, as they can be re-infected with other strains. Premature infants can receive this vaccine using their chronological age (actual date of birth) to calculate their schedule. There are no feeding restrictions required before or after receiving the vaccination.

Side effects of the vaccine include diarrhea and irritability (1-10% of doses given) and abdominal pain, dermatitis and flatulence (0.1-1% of doses given). Excretion of the vaccine virus in the stools of vaccinated infants is known

to occur after vaccination for an average of 10 days, with a peak at 7 days. To minimize the risk of transmission of vaccine virus, careful hand washing should be used after contact with the feces of the vaccinated infant. Rotarix™ has been studied for risk of developing intussusception, because of an association that was found with a previous vaccine Rotashield™ that was used in the United States in 1998. While there have been large studies done that showed no association between Rotarix™ and intussusception, there has been a recent study from Brazil and Mexico (as they introduced Rotarix into their routine childhood immunization schedules in March 2006 and May 2007 respectively) that did show a short-term risk of intussusception (1-7 days following immunization). While the risk of intussusception was found to be 1 in 51, 000 in Mexico and 1 in 68, 000 in Brazil, this same Rotavirus immunization program prevented ~80, 000 hospitalizations and 1,300 deaths annually in these two countries. Thus the risk of intussusception after rotavirus vaccination is much lower than the risk of severe rotavirus disease in unvaccinated children.

On May 7th, 2010, Health Canada issued an advisory indicating ongoing review of information regarding the presence of porcine circovirus in Rotarix™ vaccine. While it is considered a contaminant, it is not known to cause illness in humans. Health Canada concluded there was no evidence that it's presence in rotavirus vaccine poses a safety risk to those who receive the vaccine. It was re-iterated that there is strong safety data both in clinical trials and in clinical practice with millions of patients and this product.

Two Dose Varicella Program and Change to MMRV Vaccine at 4-6 years of age

Ontario is adding a 2nd dose of varicella vaccine to the Publicly Funded Immunization Schedule. A combined vaccine for Measles, Mumps, Rubella and Varicella (MMRV) will now be offered at 4-6 years of age, which will replace the 18 month dose of MMR and provide the 2nd dose of Varicella vaccine. MMR and Varicella vaccines will now be offered in the following routine schedule:

| Age | Vaccine |
|--|----------------------|
| 12 months (after the child's 1 st birthday) | MMR |
| 15 months | Varicella monovalent |
| 4-6 years of age | MMRV |

Detailed catch-up schedules for MMR, Var and MMRV are found on page 6-7 of this HealthFax.

Moving the 2nd dose of MMR vaccine to 4-6 years of age and including a 2nd dose of Varicella vaccine will help protect children against waning immunity, particularly against Varicella and Mumps. It will also hopefully increase coverage for Varicella.

The MMRV vaccine (Priorix-Tetra™) is publicly funded (free) for children from 4 to 11 years of age. This vaccine can be administered simultaneously, but at different injection sites as any other vaccine on the Publicly Funded Immunization Schedule. Priorix-Tetra™ can be administered IM or SC.

There was an MMRV vaccine product, ProQuad®, used in the US which was found during post-licensure studies to increase the incidence of febrile seizures in children 12-23 months. While this association has not been noted for Priorix-Tetra™, as a precaution, this vaccine is not being used in Ontario in children under 4 years of age. It is also not recommended for persons with a personal or family history of febrile seizures as a precaution.

This vaccine should not be given to children with:

- A severe acute febrile illness.
- Allergies to the vaccine or any component of the vaccine.
- Known allergies to neomycin or who have ever had a severe allergic reaction to eggs.
- A history of a previous allergic reaction to any vaccine against measles, mumps, rubella and varicella diseases.
- Illnesses or who are taking medication that causes them to be immunocompromised.

- A personal or family (sibling or parent) history of febrile seizures of any etiology. These children should continue to receive MMR + Var monovalent vaccine separately. They can be given at the same visit in separate injection sites.
- A history of having recently received immune globulin or blood products (vaccination should be delayed for 3-11 months – refer to Canadian Immunization Guide for recommended interval).

MMR vaccine will be available for those who require their 2nd dose of MMR vaccine prior to 4-6 years (i.e. travel related). Varicella monovalent vaccine will also be available for children who have received both MMR's.

Catch Up Varicella Program – All children born on or after January 1, 2000 are now eligible to receive Varicella vaccine. If a child has already received one dose of vaccine, they are eligible to receive a 2nd dose to complete their two dose series. Children who have not previously received varicella vaccine are eligible to receive 2 doses if they have not had laboratory confirmation of immunity or infection, or been previously diagnosed with varicella disease by a health care provider. Children infected with chickenpox before one year of age may not develop long term immunity and should continue to be immunized with two doses of varicella containing vaccine. The varicella vaccine can be given if it is unknown or uncertain whether the child has had chickenpox before.

If the child has already received 2 MMR's, then Varicella monovalent vaccine should be used to complete their series for Varicella. It is recommended that the same Varicella monovalent product be used for both doses. For minimum intervals between varicella containing products refer to the bottom of page 7 of this HealthFax, as the recommendations for Varicella containing products differ from the usual 1 month interval between live vaccines.

Adult dose of tetanus-diphtheria-pertussis (Tdap) vaccine

It is recommended that all adolescents and adults receive a one-time dose of Tdap vaccine (Adacel® or Boostrix®) to provide increased protection against pertussis. Adolescents in Ontario currently receive pertussis vaccine in their Tdap 14-16 year booster. Ontario is now offering a publicly funded (free) dose of Tdap vaccine for anyone 19-64 years of age who did not receive acellular pertussis containing vaccine as a teen. Tdap vaccine should replace one Td booster, which is due every 10 years.

Boostrix® is a Tdap vaccine that is starting to be distributed in Ontario as a publicly funded (free) vaccine. When you order Tdap vaccine, you may get either Boostrix® or Adacel®. While these products are similar, it is important to refer to the product monograph for each of the specific products.

By increasing vaccine coverage among adults against pertussis, we reduce the risk of transmission to those at risk or who have not been immunized, particularly to young babies who are not completely immunized.

Ordering the Vaccine

Please see the attached revised Vaccine Order Form, which includes Rotarix™, Priorix-Tetra™ and Boostrix®. We have also updated the Health Care Provider section of the website to include the revised form. You can also phone your order in to the Vaccine Order Desk at 877-721-7520 ext 8808.

These new vaccine programs are to officially launch in Ontario the week of August 8th, 2011. Please print off the new form and use it to order these new products with your next order.

Please note: Rotarix® vaccine is only going to be available in very limited supply for the month of August. Our Health Unit will only be allocated a predetermined number of doses of this vaccine, and we will make every effort to distribute this vaccine as equitably as possible. Health Care Providers are encouraged to use their initial supply to immunize those babies who are approaching the upper age indication to receive the vaccine first. It is anticipated that regular supply will be available in September. Thank you for your patience during this time.

Please see the following pages for tables to assist in determining the vaccine schedule(s) based on the child's age, medical history and vaccination history.



TEL: 705-721-7520 1-877-721-7520

Fax: 705-721-1495

Facility/Physician: _____

Phone #: _____

Office Fax #: _____

Office Contact: _____

Date: _____

ATTENTION: Vaccine Order Desk

Vaccine Order Desk: Ext: 8808

General Vaccine/Immunization Inquiries: Ext. 8806

Please order in **Boxes** unless specified. Orders placed by **Wednesday** will be available for pick up the following **Tuesday**.

****All orders must be accompanied by the temperature log for the previous four weeks****

*****Coolers must be between 2-8 Degrees Celsius for vaccine to be released*****

| Antigen | # of Boxes |
|---|------------|
| Pediacel (5 doses/box) Diphtheria, Pertussis, Tetanus, Polio and Act HIB | |
| Quadracel (5 doses/box) Diphtheria, Pertussis, Tetanus, Polio | |
| Tdap (Adacel or Boostrix) (order in doses) Diphtheria, Tetanus, Pertussis | |
| Td Adsorbed (5 doses/box) Tetanus, Diphtheria | |
| Td Polio (5 doses/box) Tetanus, Diphtheria, Polio | |
| IPV (order in doses) Polio | |
| Act HIB (order in doses) Haemophilus influenzae b | |
| MMR (10 doses/box) Measles, Mumps, Rubella | |
| MMRV (order in doses) Measles, Mumps, Rubella, Varicella | |
| Varicella (order in doses) Varicella only | |
| Hepatitis A – Adult - must meet criteria for publicly funded vaccine (order in doses) | |
| Hepatitis A - Pediatric - must meet criteria for publicly funded vaccine (order in doses) | |
| Hepatitis B - Adult - must meet criteria for publicly funded vaccine (order in doses) | |
| Hepatitis B - Pediatric - must meet criteria for publicly funded vaccine (order in doses) | |
| Hepatitis B – for dialysis patients (order in doses) | |
| Pneumo 23 (order in doses) Pneumococcal Polysaccharide | |
| Influenza (10 doses/box) | |
| Prevnar 13 (10 doses/box) Pneumococcal Conjugate 13-Valent | |
| Menjugate (5 doses/box) Meningococcal C Conjugate | |
| TB Mantoux Test (10 doses/box) | |
| Rotavirus (order in doses) | |

Location to be picked up from (please check):

- Barrie Office Huntsville Office Collingwood Office Cookstown Office
- Midland Office Orillia Office Gravenhurst Office South Muskoka Memorial Hospital

BIOS Order # (for office use only): _____

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Rotarix™ Eligibility and Schedules

This chart is intended for information purposes only. It is meant to assist health care providers with the eligibility criteria and timing of routine and alternative vaccine administration schedules for Rotarix™. For the complete childhood immunization schedule, please refer to the *Publicly Funded Immunization Schedules for Ontario*.

Table 1: ROUTINE rotavirus (Rotarix™) immunization

| Recommended routine schedule for rotavirus oral immunization | |
|--|-------------------------|
| Age of vaccination | Recommended dose number |
| 2 months old | Dose 1 |
| 4 months old | Dose 2 |

Table 2: RECOMMENDED vaccines and doses required to complete the rotavirus (Rotarix™) immunization series

| Recommended alternative schedule for rotavirus oral immunization at 6 to 24 weeks of age | |
|--|--|
| Vaccine and dose number | Timing |
| Rotavirus - 1 st dose | First visit* |
| Rotavirus - 2 nd dose | Second visit: 4 weeks after first visit and ≤24 weeks of age |

* Although the vaccine manufacturer has indicated that the first dose may be administered as early as 6 weeks and as late as 20 weeks of age, NACI recommends that the first dose be administered between 6 weeks, and before 15 weeks of age as the safety of providing the first dose of rotavirus vaccine in older infants is not known.

Table 3: RECOMMENDED and minimum ages and intervals for rotavirus (Rotarix™) oral immunization

| Recommended and minimum ages and intervals for rotavirus oral immunization | | | | |
|--|-------------------------------|---------------------------|-----------------------------------|-------------------------------|
| Vaccine and dose number | Recommended age for this dose | Minimum age for this dose | Recommended interval to next dose | Minimum interval to next dose |
| Rotavirus – 1 st dose | 2 months | 6 weeks | 2 months | 4 weeks |
| Rotavirus- 2 nd dose | 4 months | 10 weeks | — | — |

NOTE: According to the Rotarix™ product monograph, all doses should be administered by 24 weeks of age. The product monograph is available at: http://www.gsk.ca/english/docs-pdf/Rotarix_2011.pdf

MMR, Varicella and MMRV Eligibility and Schedules

Tables 1 and 2 are intended for information purposes only. They are meant to assist health care providers with the eligibility criteria and timing of routine, alternative and catch-up vaccine administration schedules for MMR, varicella and MMRV vaccines. For the complete childhood immunization schedules, please refer to the *Publicly Funded Immunization Schedules for Ontario*.

Table 1: ROUTINE MMR, Varicella and MMRV Immunizations

| Eligible age cohort | Recommended doses and schedule | | |
|------------------------------|--------------------------------|------------------------------|--------------------------------|
| | MMR | Var | MMRV |
| Starting at 12 months of age | 1 dose (12 months of age) | 1 dose (15 months of age) | 1 dose (4 - 6 years of age) |

Table 2: CATCH-UP Two-Dose Varicella Immunization

| Eligible age cohort | Recommended doses and schedule | | |
|--|--------------------------------|---|------|
| | MMR | Var | MMRV |
| Children born on or after Jan. 1, 2000 who are at least 12 months of age and have already received two doses of MMR vaccine | No | 1 dose or 2 doses Depending on immunization status with appropriate interval between doses: MMR and Varicella: 4 week interval Varicella and Varicella: 3 month interval | No |

Table 3 is a reference for the administration and timing of the MMR, varicella and MMRV vaccines. Reference to the number of visits pertains to visits required to complete the immunization series for the specific scenario and is not intended to illustrate the number of visits to complete the primary series for all childhood immunizations.

Table 3: RECOMMENDED vaccines and doses required to complete measles, mumps, rubella and varicella vaccine immunization series

| Child's current age | Vaccine history of | | Recommended vaccines and doses required to complete measles, mumps, rubella and varicella vaccine immunization series (See table below regarding minimum intervals between doses) |
|---------------------|--------------------|---------|---|
| | MMR | Var | |
| 12 months | 0 doses | 0 doses | <i>First visit:</i> MMR <i>Second visit:</i> Varicella at 15 months <i>Third visit:</i> MMRV at 4-6 years |
| 13 to 47 months | 0 doses | 0 doses | <i>If child is ≤ 14 months of age</i> <i>First visit:</i> MMR <i>Second visit:</i> Varicella <i>Third visit:</i> MMRV at 4-6 yrs <i>If child is ≥ 15 months of age</i> <i>First visit:</i> MMR and Varicella <i>Second visit:</i> MMRV at 4-6 years |
| | 0 doses | 1 dose | <i>First visit:</i> MMR <i>Second visit:</i> MMRV at 4-6 years |
| | 1 dose | 0 doses | <i>First visit:</i> Varicella <i>Second visit:</i> MMRV at 4-6 years |
| | 1 dose | 1 dose | <i>First visit:</i> MMRV at 4-6 years |
| | 2 doses | 0 doses | <i>If child is ≥ 14 months of age</i> <i>First visit:</i> Varicella <i>Second visit:</i> Varicella |
| | 2 doses | 1 dose | <i>If child is ≥ 14 months of age</i> <i>First visit:</i> Varicella |
| 4 to 11 years | 0 doses | 0 doses | <i>First visit:</i> MMRV <i>Second visit:</i> MMRV |
| | 0 doses | 1 dose | <i>First visit:</i> MMRV <i>Second visit:</i> MMR |
| | 1 dose | 0 doses | <i>First visit:</i> MMRV <i>Second visit:</i> Varicella |
| | 1 dose | 1 dose | <i>First visit:</i> MMRV |
| | 2 doses | 0 doses | <i>First visit:</i> Varicella <i>Second visit:</i> Varicella |
| | 2 doses | 1 dose | <i>First visit:</i> Varicella |

| Vaccines | Recommended minimum interval between doses |
|--|--|
| MMR and MMR / MMR and Varicella | 4 weeks |
| MMR and MMRV / MMRV and MMRV | 6 weeks |
| Varicella and Varicella / Varicella and MMRV | 3 months |

Rotarix™ Oral Vaccine Administration For Health Care Providers

This fact sheet provides basic information. It is not intended to provide or take the place of medical advice, diagnosis or treatment.

The following information is provided for all health care providers administering the Rotarix™ oral vaccine for the first time.

Patient care & preparation

Health care providers should:

- Ensure the infant is the appropriate age to receive the Rotarix™ vaccine (i.e., six to 24 weeks of age);
- Establish if the infant is healthy before administering the vaccine (i.e., no fever over 38°C, diarrhea and/or vomiting);
- Screen each infant for contraindications (e.g., intussusception), precautions and allergies to any previous vaccine prior to vaccine administration;
- Assess if the infant:
 - is taking steroids of any sort other than inhaled asthma sprays or steroid creams (e.g., cortisone or prednisone) that may impair their immune response to the vaccine;
 - has received a recent blood transfusion or blood products, including immunoglobulins, in the past 42 days;
 - has a disease or is having treatment which causes low immunity (e.g., leukemia, cancer, HIV/AIDS, radiotherapy or chemotherapy); and
 - has severe allergy to latex.
- Provide education to the parent or caregiver on careful hand hygiene when changing the infant's diaper, especially if the infant lives with someone who has a disease or is having treatment which causes low immunity (e.g., leukemia, cancer, HIV/AIDS, radiotherapy or chemotherapy);
- Take reasonable steps to ensure that informed consent for the immunization is obtained from the appropriate parent/guardian;
- Provide position and comfort measures during vaccine administration;
- Follow standard precautions for infection control to minimize the risks of spreading disease during vaccine administration; and
- Store, handle and prepare vaccine properly to maintain the integrity of the vaccine.

Special handling instructions for Rotarix™ vaccine

Oral vaccines should be administered prior to administering injections or performing other procedures that might cause discomfort.

Rotarix™ is presented as a clear, colorless liquid, free of visible particles, for administration. The vaccine is ready to use; no reconstitution or dilution is required.

Always check the expiry date of the vaccine on the label and packaging. The Rotarix™ vaccine should be stored between +2°C to +8°C, in the original package and protected from light.

The rotavirus vaccine should be administered orally without mixing with any other vaccines or solutions.

Instructions for using the Rotarix™ vaccine oral applicator:

Note: Rotavirus vaccine must not be administered by injection

1. Remove the vaccine from the refrigerator immediately prior to use.
2. Remove the protective tip cap from the oral applicator.
3. Ask the parent or caregiver to hold the infant in the nursing or feeding position (seated in a reclining position).
4. Administer the entire amount of the liquid slowly down one side of the inner mouth cheek (between the cheek and gum) toward the back of the infant's mouth and allow the infant to swallow the vaccine.
 - Do not administer the vaccine too far back into the mouth which may initiate the gag reflex.
 - Do not administer the vaccine directly into the throat.
 - Detailed information on oral delivery of the vaccine is included in the vaccine product monograph.



5. The oral vaccine must be swallowed and retained.
6. To prevent spitting or failed swallowing, stimulate the rooting-and-sucking reflex for the infant to suck the medication from the syringe and swallow. For infants who are five months of age and older, lightly stroke the throat in a downward motion to stimulate the infant to swallow.
7. If the infant spits out, fails to swallow, or regurgitates most of the vaccine dose, a single replacement dose may be given at the same vaccination visit. The infant should continue to receive any remaining doses in the recommended series. Please check the vaccine product monograph for details on regurgitation procedures.
8. Discard the empty applicator and cap in approved biological waste containers.

9. Once the vaccine has been administered, the infant may be breastfed or given something to drink (e.g. formula).

There is no restriction on the infant's consumption of food or liquid, including breast milk, either before or after the vaccination.

Documentation

Document the immunization information in the patient's health records according to the standards of the *Regulated Health Professions Act (RHPA)* and your regulatory college.

Update the patient's personal immunization record "Yellow Card" each time you administer a vaccine.

Adverse Events Following Immunization (AEFIs)

When all vaccines have been administered, the patient should remain in the office for a 15 minute period of observation for any adverse vaccine events.

Similar to all vaccines, rotavirus vaccine needs to be monitored for safety and for any AEFIs. Physicians, nurses and pharmacists should report adverse events associated with the administration of an immunizing agent (vaccine).

Adverse vaccine events should be reported to your local public health unit.

Who should I contact if I have any questions?

For more information please contact your local public health unit.