Public Health Division

Attachment D

Measles-Mumps-Rubella-Varicella (MMRV) Vaccine Program

Questions and Answers for Health Care Providers

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

The Ministry of Health and Long-Term Care ("the ministry") is introducing a new measles, mumps, rubella, varicella (MMRV) vaccine to the *Publicly Funded Immunization Schedules for Ontario* to protect children against measles, mumps, rubella and varicella infection.

About the MMRV vaccine (Priorix-Tetra™):

Q1: What does the MMRV vaccine protect against?

A1: The new combination MMRV vaccine, approved for use in Canada in December 2007, is Priorix-Tetra™. The vaccine is indicated for active immunization against measles, mumps, rubella and varicella diseases. These are common childhood illnesses that can lead to serious complications such as bacterial skin infections, encephalitis, mumps meningitis and congenital rubella syndrome.

Q2: What is the age indication for the Priorix-Tetra™ vaccine?

A2: The Priorix-Tetra™ vaccine was approved by Health Canada for children from nine months to six years of age. Efficacy has not been evaluated in children older than six years of age. However, based on previous immunogenic and safety experience with the separate component vaccines (i.e., Priorix® and Varilrix®), this vaccine can be used in children up to 12 years of age.

In Ontario, Priorix-Tetra™ is currently publicly funded for children four through to 11 years of age as per the eligibility criteria outlined in Attachment B - **Table 1: ROUTINE** MMR, Varicella and MMRV Immunization.

Q3: Where do I find more information about the vaccine such as common side effects, contraindications, storage recommendations and where to inject the vaccine?

A3: Refer to the vaccine product monograph for Priorix-Tetra™ available at http://www.gsk.ca/english/docs-pdf/Priorix_tetra_2010.pdf

Q4: How should Priorix-Tetra™ be administered?

A4: Priorix-Tetra™ can be administered with other vaccines but at different injection sites as per the *Publicly Funded Immunization Schedules for Ontario*.

About the publicly funded program:

Q5: Why has the province introduced the MMRV as a second dose for the MMR and varicella vaccines?

A5: Starting August 8, 2011, the second dose of the MMR vaccine will be replaced with the combination MMRV vaccine. However, the MMR vaccine will continue to be used for the first dose at 12 months of age as well as for those individuals who are not eligible to receive MMRV or require the MMR vaccine for medical or travel related reasons. This combined MMRV vaccine will reduce the number of vaccine injections required

Ontario

(versus receiving the MMR and varicella vaccines separately).

There is evidence to suggest that utilizing the MMRV vaccine has the potential to increase the uptake of the varicella vaccine and, thus, have a greater impact on controlling varicella disease.

Two doses of the varicella vaccine are now recommended as part of the routine childhood schedule. Children will be offered this second dose of the varicella vaccine in the form of MMRV vaccine.

Q6: What is the epidemiology of measles, mumps, rubella and varicella in Ontario?

A6: Before measles vaccine was used widely, almost all children got measles. Now, because of the routine use of vaccine, measles is rare in Canada. In fact, there were only 81 confirmed cases of measles reported in Ontario from 2006 to 2010. These cases were either imported or linked to imported cases.

During the period 2006-2010, there were three mumps outbreaks in Ontario, the largest of which occurred in 2008 and resulted in 324 cases in a community with low immunization coverage. During this time there were 564 confirmed cases of mumps reported in Ontario.

Since 2006, Ontario has reported an average of three cases (range two to five cases) of rubella per year with just 14 confirmed cases reported from 2006 through to 2010. These cases were either imported or linked to imported cases.

Varicella is mainly a childhood disease that develops in 50% of unvaccinated Canadian-born children before they reach five years of age and in 90% of unvaccinated children before 12 years of age. Since the introduction of the one-dose varicella vaccine in 2004, Ontario reported 32,135 cases of chickenpox. Eight hundred and fifty-six of these cases were severe, resulting in health complications, hospitalization or death. Since 2008, approximately 7,400 cases of varicella have been reported annually in Ontario, a 23% reduction in annual reported cases.

Q7: Who is eligible to receive the publicly funded MMRV vaccine and when should they receive it?

A7: Refer to the eligibility criteria outlined in Attachment B - **Table 1: ROUTINE** MMR, Varicella and MMRV Immunization.

Q8. Why has the ministry moved the second dose of MMR vaccine from 18 months to the new MMRV vaccine at four to six years of age?

A8. The ministry is continuing to recommend the first dose of the MMR vaccine at 12 months of age and the first dose of the varicella vaccine at 15 months of age as separate injections. For safety reasons, the ministry is not recommending the MMRV vaccine as a first dose nor as a second dose at 18 months of age.

According to post-licensure studies in the United States on the MMRV vaccine, ProQuad™, children who were 12 to 23 months of age were at a greater risk of febrile seizures when the ProQuad™ vaccine was given as the first dose compared with MMR and varicella vaccines given as a first dose separately at the same visit[1].

No data exists regarding the administration of the first dose of MMRV vaccine for children who are older. However, according to expert opinion, it is likely that children who are two to under four years old may experience febrile seizures because that is the biologic window of vulnerability for febrile seizures in children.

There have been subsequent studies that compared the administration of the ProQuad™ vaccine as a second dose to children who were four to six years of age. These studies found that the rate of febrile seizures in children who received the MMRV vaccine, as a second dose between four to six years of age, was similar to that found in children who received the second dose of the MMR and varicella vaccines separately at the same visit.

Based on the available evidence from the ProQuad™ studies and in consideration of expert opinion, the ministry has chosen to offer the MMRV vaccine as a second dose to children who are at least four to six years of age. Furthermore, it is anticipated that this change from administration of the MMR vaccine at 18 months to the new MMRV vaccine at four to six years of age may help alleviate waning immunity to both mumps and varicella in later life.

[1] Centers for Disease Control and Prevention. Use of combination measles, mumps, rubella and varicella vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMRW 2010; 59:1-12.

Q9. Are there any risks associated with the second dose of MMRV being given at four to six years of age rather than at 18 months?

A9. In Ontario, prior to 2005, MMR vaccine was offered at 12 months and four to six years of age. In 2005, the immunization schedule for MMR vaccine was changed to 12 months and 18 months of age due to a number of factors, mainly to enhance protection against measles at an earlier age. Since 2005, Ontario has experienced very few measles cases. The move to giving the second dose of MMR vaccine in the form of MMRV at four to six years of age is not expected to increase the risk of disease. This change to the four to six year old visit for the second dose as MMRV vaccine is based on consideration of the evidence on the risk of febrile seizure in children 15 to 23 months of age as well as waning immunity for mumps (as evidenced by outbreaks in Ontario) and varicella.

In addition, the MMRV vaccine provides protection against four antigens in a single vaccine, reducing the number of injections a child receives and potentially increasing uptake for varicella immunization. It is highly recommended that children receive the full immunization series for measles, mumps, rubella and varicella prior to school entry.

Q10: What are the detailed schedules for children who have not completed or have not started their MMR or varicella vaccine series?

A10: See detailed schedules for MMR, varicella and MMRV immunization series outlined in Attachment B - **Table 3: RECOMMENDED** vaccines and doses required to complete measles, mumps, rubella and varicella vaccine immunization series.

Q11: Who should <u>not</u> receive the MMRV vaccine?

A11: Children should not receive the vaccine if they have:

- allergies to the vaccine or any component of the vaccine;
- known allergies to neomycin; or
- previously experienced an allergic reaction to any vaccine against measles, mumps, rubella and/or varicella diseases.

Special considerations are needed for children who have:

- a weakened immune system or those on medications that suppress their immune system;
- a personal or family history of febrile seizures of any etiology (children should be vaccinated with the MMR and varicella vaccines separately);
- previously experienced a severe allergic reaction to eggs or anything that contained eggs;
- been given Immune Globulin or blood products (vaccination should be delayed for three to 11 months); or
- severe acute febrile illness (administration of MMRV should be postponed; however, vaccination can occur if the individual has a minor infection).

Q12: What is the vaccine ordering process?

A12: Order the vaccine through your regular vaccine supply source (i.e., local public health unit or the Ontario Government Pharmaceutical and Medical Supply Service [OGPMSS]).

Q13. How should the MMRV vaccine be stored?

A13. In order to ensure that children receive optimal protection, the MMRV vaccine (like other vaccines) must be maintained at a temperature between +2°C and +8°C from the time of manufacture until the vaccine is administered to individuals. This temperature <u>must</u> be monitored and maintained at all times.

Q14: What should be done for adverse events following immunization (AEFIs)?

A14: Under section 38 of the ***Health Protection and Promotion Act, R.S.O. 1990***, physicians or other persons authorized to administer an immunizing agent are required to inform the person who consents to immunization of the importance of immediately reporting to a health care provider any reaction that may be a reportable event. Local public health units should subsequently be notified of the adverse event.

The AEFI reporting form can be found on the Public Health Agency of Canada website along with a User Guide at: www.phac-aspc.gc.ca/im/aefi-form-eng.php. Send the completed form to your local public health unit.

A list of health units can be found at: www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

References:

1. Public Health Agency of Canada. (2006). Canadian Immunization Guide (7th ed.).

2. National Advisory Committee on Immunization (NACI). Statement on measles-mumps-rubella-varicella vaccine. Canadian Communicable Disease Report. 2010; 36:1-22. Available from http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/10vol36/acs-9/index-eng.php.

3. Centers for Disease Control and Prevention. Use of combination measles, mumps, rubella and varicella vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMRW 2010; 59:1-12.

4. Vaccine Product Monograph; Priorix-Tetra™, GlaxoSmithKline Inc., May 2010. http://www.gsk.ca/english/docs-pdf/Priorix_tetra_2010.pdf