



## Health, Seniors and Active Living

Public Health and Primary Health Care

Communicable Disease Control

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### **RE: NACI STATEMENT UPDATES**

Dear Health Care Provider:

Canada's National Advisory Committee on Immunization (NACI) has recently released the following vaccine safety statement/update:

#### **NACI Update on MMRV and Risk of Febrile Seizure**

This is a recently-released NACI update concerning the increased risk of febrile seizure following the administration of combination measles-mumps-rubella-varicella (MMRV) vaccine products, including Priorix-Tetra™ (GlaxoSmithKline [GSK] Inc.) and ProQuad™ (Merck Canada Inc.). There is evidence that these products are associated with a small but real increased risk of febrile seizures in the 7 to 10 days following immunization with the first dose in infancy, as compared to measles-mumps-rubella (MMR) and varicella vaccines administered in separate injections. This risk is estimated at about one additional febrile seizure for every 2,300 to 2,800 doses of MMRV vaccine.

As per NACI, infants aged 12 to 47 months may receive a first dose of MMR and varicella vaccines separately or the combined MMRV formulation. Manitoba Health, Seniors and Active Living (MHSAL) is encouraging all immunization providers to take into account parental acceptability of the increased risk of febrile seizure, potential impact on the perception of safety and vaccination coverage, as well as the need for an additional injection.

The 2010 NACI Statement on MMRV indicated that the rate of febrile seizures after the administration of GSK's MMRV vaccine Priorix-Tetra™ had not been reported to be higher when compared with MMR+V administered separately. Since then, evidence has accumulated that shows an increased risk of febrile seizures after the first dose of MMRV given up to 47 months of age, as compared to MMR and varicella given separately.

#### *Reported occurrences in Manitoba:*

Analysis of data available through Manitoba's adverse events following immunization (AEFI) passive surveillance system did not reveal an increased occurrence of febrile seizures following immunization with combined MMRV (Priorix-Tetra™) since Manitoba started providing the combined product in 2012, compared with separate MMR+V prior to 2012.

The NACI statement is posted on the Public Health Agency of Canada website at

<http://healthycanadians.gc.ca/publications/healthy-living-vie-saine/vaccine-measles-mumps-rubella-varicella-seizures-2016-vaccin-rougeole-rubeole-oreillons-varicelle-convulsions/index-eng.php>.

## **NACI Statement on Rotavirus Vaccine and Risk of Intussusception**

This is a recently-released NACI statement concerning post-licensure studies of the Rotavirus (RV) vaccines Rotarix™ (GlaxoSmithKline [GSK] Inc.) and RotaTeq™ (Merck Canada Inc.), suggesting a low but excess risk of intussusception. The differences between the vaccines are marginal, and overall, amount to between 1 and 7 cases per 100,000 doses for the current vaccines.

As per NACI, RV vaccines continue to be recommended for infants starting at 6 weeks to less than 15 weeks of age. Manitoba Health, Seniors and Active Living (MHSAL) is encouraging all immunization providers to inform parents of this low risk of intussusception following RV vaccine, particularly during the seven days following the first dose.

Parents should 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 RV.

### *Reported occurrence in Manitoba:*

Since the RV vaccine became publicly funded in Manitoba in April 2014, to date, approximately 71,000 doses had been administered. In that time, MHSAL's adverse events following immunization (AEFI) passive surveillance system received two reports of intussusception following immunization with RV (Rotarix™).

The NACI statement is posted on the Public Health Agency of Canada website at

<http://www.healthycanadians.gc.ca/publications/healthy-living-vie-saine/statement-rotavirus-vaccines-intussusception-2016-declaration-vaccins-antirotavirus-intussusception/index-eng.php>.

Sincerely,

*"Original Signed By"*

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