



Communiqué

Vaccine Safety Surveillance and Assessment in Canada

The Public Health Agency of Canada collects case reports on adverse events following immunization from provincial and territorial health departments, health care professionals and the pharmaceutical industry. These forms of surveillance are both active and passive.

Passive surveillance encompasses all spontaneous adverse event reporting. When a patient experiences an adverse event following immunization, physicians and other designated health care providers are required by the Health Protection and Promotion Act to complete both sides of the Adverse Events Following Immunization (AEFI) form and send/fax it to the local health unit. A blank AEFI form is included with this issue of the Communiqué and can also be obtained from the Haldimand-Norfolk Health Unit. The data on the completed form is reviewed at the local health unit by the Medical Officer of Health (MOH), again at the provincial level health department and then by the Public Health Agency of Canada. The information is stored in the Canadian Adverse Events Following Immunization (CAEFI) database and is used to signal adverse events that may require more in-depth investigation. The main function of the CAEFI Surveillance System (CAEFISS) is to ensure the continued safety of vaccines on the Canadian market by monitoring adverse events following immunization with vaccines.

Active surveillance is done following severe adverse events in children by the Immunization Monitoring Program ACTIVE (IMPACT). This is a hospital-based network funded by the Public Health Agency of Canada (PHAC) and administered by the Canadian Paediatric Society. The 12 IMPACT hospitals encompass approximately 90% of tertiary care paediatric beds in Canada. All serious adverse events detected by IMPACT are reported to the patient's home province as well as to PHAC.

Ad hoc studies, epidemiologic or clinical, may be undertaken by public health or academic investigators to further characterize events of concern, assess whether there is an actual causal link between the vaccine and a given adverse event or learn about risk factors that increase the likelihood that an adverse event will occur.

Revised Recommendations for Mumps Vaccine

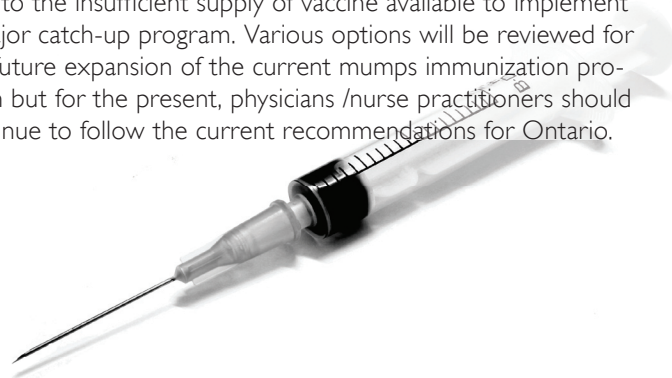
Recent outbreaks of mumps, together with waning immunity in certain age groups, has prompted the National Advisory Committee on Immunization (NACI) to revise recommendations for mumps vaccination here in Canada. The largest and most recent outbreak started in April 2007 and by early September, 711 cases had been confirmed in Nova Scotia and New Brunswick along with some 30 cases in other provinces. Most reported cases occurred in university-aged students.

The recent NACI recommendations are as follows:

- **Infants and children:** two doses of mumps-containing vaccine given as measles, mumps rubella (MMR); the first dose given on or shortly after the first birthday and second dose after 15 months of age or before school entry.
- **Students at educational institutions:** secondary and post-secondary students should have documented receipt of mumps-containing vaccine or have laboratory evidence of immunity or a history of laboratory-confirmed mumps disease or have been born before 1970 (immunity assumed).
- **Health care workers (HCW):** HCWs should have documented receipt of two doses of mumps-containing vaccine or have laboratory evidence of immunity or a history of laboratory-confirmed mumps disease or have been born before 1970 (immunity assumed).

Following the publication of any NACI recommendations, each province/territory reviews these recommendations and determines to what extent, and how, they will be implemented in that jurisdiction based on the local epidemiology as well as logistical issues.

These recommendations need to be phased in over time due in part to the insufficient supply of vaccine available to implement a major catch-up program. Various options will be reviewed for the future expansion of the current mumps immunization program but for the present, physicians /nurse practitioners should continue to follow the current recommendations for Ontario.



Current Ontario Recommendations and Requirements for Mumps Immunization are as follows:

- **Children:** Ontario recommends two doses of MMR for the routine immunization of children. The first dose should be given after the first birthday at 12 months of age and the second dose at 18 months (consistent with NACI recommendations). Only one dose of mumps vaccine is required under the Immunization of School Pupils Act for pupils up to 18 years of age (two doses of measles vaccine are required).
- **Students attending post-secondary institutions:** Ontario is recommending that all students returning to or starting university/college in Nova Scotia or New Brunswick who have not had two documented doses of MMR, and who have not had confirmed mumps infection or laboratory documented immunity against mumps, should be offered a second dose (publicly funded).

Resources: Ontario Ministry of Health and Long-Term Care
Canada Communicable Disease Report (CDDR) | August 2007; 33(DCC-9):
1-10

PENTACEL® changing to PEDIACEL®

PENTACEL® is changing to a more convenient format called PEDIACEL®.

What's different?

- PEDIACEL® is a ready-to-use, fully liquid version of PENTACEL®. No reconstitution is required for PEDIACEL®.
- Slightly smaller packaging (38% smaller) will contain five single dose vials with latex-free stoppers.
- The polio portion of the vaccine is grown on a vero cell line (African monkey kidney cells) rather than a human diploid cell line.
- PEDIACEL may contain trace amounts of the antibiotics neomycin, streptomycin and polymyxin B whereas PENTACEL may contain only trace amounts of neomycin and polymyxin B.

What's the same?

- Sanofi Pasteur is the manufacturer of both vaccines
- The PEDIACEL® antigens (Diphtheria, pertussis, tetanus, polio and Haemophilus Influenzae type b) and their concentrations are identical to those in Pentacel®.
- The dose is the same (0.5ml), and the paediatric dosing remains unchanged (2, 4, 6 and 18 months).
- The safety and immunogenicity of PEDIACEL® were shown to be comparable to PENTACEL® in a Canadian clinical trial.

Resources: Sanofi Pasteur Limited
Ontario Ministry of Health and Long-Term Care

Coming Soon!



A form to evaluate the **Communiqué** will be mailed out to each facility in late February. A return envelope with postage will be included and your response will be anonymous.

The purpose of this evaluation is to gather information from you in the hope of providing you with the timely information that you need. **Watch for it and please complete and return it by the requested return date.**

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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