Quadrivalent meningococcal ACYW-135 vaccine (Menactra®): Q&A for health care providers

This questions and answers sheet for health care professionals provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment

Updates:

Effective December 2014, Ontario has expanded its publicly funded high risk meningococcal immunization program to include additional high risk conditions, an extended age range for eligibility, and additional primary and booster doses.

What is invasive meningococcal disease (IMD)?

IMD is caused by *Neisserria meningitis* (commonly known as meningococcus) caused mainly by serogroups A, C, Y and W-135. IMD is a very serious infection which can result in meningitis or meningococcemia or both. It occurs in people who either have come into contact with a symptomatic carrier or an individual with meningococcal disease. In rare instances, the bacteria overcome the body's natural defenses and cause serious diseases, including meningitis (infection of the lining of the brain and spinal cord) and septicemia (widespread infection involving the blood and multiple organs). IMD causes death in 8-15% of cases and 11 to 19% of survivors will suffer some form of permanent disability, such as hearing loss, neurological damage or limb loss.

The symptoms of IMD can vary widely, and can include sudden onset of high fever, severe headache, vomiting, stiff neck and a rash. Sensitivity to light, sleepiness, confusion, and in severe cases, coma may also occur. The consequences of meningococcal meningitis can be severe.

What is the epidemiology of IMD in Ontario?

According to Ontario's integrated Public Health Information System (iPHIS) and the Public Health Ontario Laboratories (PHOL) records, there were 793 IMD cases reported in Ontario between 2000 and 2012. The annual incidence rate ranged from 0.94 cases per 100,000 population in 2001 to 0.26 cases per 100,000 population in 2012. The incidence of IMD attributable to serogroup C declined significantly over these years, from 0.30 cases per 100,000 population in 2001 to 0.01 cases per 100,000 population in 2012. A decrease in incidence of serogroup Y and W-135 have also been observed. Conversely, no evident decline in serogroup B incidence has been seen in Ontario. Serogroup B was the most frequently reported IMD serogroup in 2012, accounting for approximately 77% of IMD cases reported in Ontario that year.

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Ontario

In 2012, 35 cases (32 confirmed and three probable) of IMD were reported in Ontario. Disease incidence was highest among children less than one year of age, with a smaller peak among adolescents in the 15-19 year age group. Overall, 63% of cases reported in 2012 were female.

About the publicly funded Men-C-ACYW-135 vaccine, Menactra®

Menactra® is indicated for the active immunization for the prevention of IMD caused by *N. meningitis* serogroups A, C, Y and W-135 vaccine for individuals 9 months of age to 55 years of age. For more information about the vaccine, refer to the vaccine product monograph available at: www.vaccineshoppecanada.com/document.cfm?file=menactra_e.pdf

Who is eligible to receive the publicly funded Men-C-ACYW-135 vaccine and when should they receive it?

The Men-C-ACYW-135 vaccine is publicly funded routinely at school-based immunization clinics for grade 7 students in Ontario, to high risk individuals, as well as for case and contact management.

Effective December 2014, the high risk program will be expanded to include individuals between **9 months to 55 years of age** with the following conditions:

a. Individuals with functional or anatomic asplenia
b. Individuals with complement, properdin, factor D Deficiency or primary antibody deficiencies
c. Cochlear implant recipients (pre/post implants)
d. Individuals with acquired complement deficiency **(NEW)**
e. Individuals with HIV **(NEW)**

In addition, age appropriate primary series and boosters will be provided for all high risk individuals:

Men-C-ACYW (Menactra®) immunization series for high risk individuals 9 months to 55 years of age		
Age at first dose	Recommended Intervals	Minimum Intervals
9 to 11 months	1st dose 2nd dose, 2 months after 1st dose 3rd dose, 2 months after 2nd dose Booster doses every 3 to 5 years	1st dose 2nd dose, 4 weeks after 1st dose 3rd dose, 4 weeks after 2nd dose 4th dose, 4 weeks after 3rd dose and at age ≥12 months *(Note: 4th dose is not required if 3rd dose is given at age ≥12 months and ≥4 weeks after 3rd dose)* Booster doses every 3 to 5 years
12 months to 6 years	1st dose 2nd dose, 2 months after 1st dose Booster doses every 3 to 5 years	1st dose 2nd dose, 4 weeks after 1st dose Booster doses every 3 to 5 years
7 to 55 years	1st dose 2nd dose, 2 months after 1st dose Booster doses every 5 years	1st dose 2nd dose, 4 weeks after 1st dose Booster doses every 5 years

Why has the ministry expanded the publicly funded Men-C-ACYW-135 vaccine program to include additional high risk conditions?

The National Advisory Committee on Immunization (NACI) in Canada updated its statement on the use of the Men-C-ACYW-135 in January 2013. The statement provides several recommendations. In order to align with current scientific advice, within the approved age indications approved for use in Canada, Ontario's high risk meningococcal immunization program has been updated to include two newly eligible cohorts, individuals with HIV and persons with acquired complement deficiency (e.g., persons receiving eculizumab) and to offer age appropriate primary series and booster doses.

When is an appropriate schedule to administer the meningococcal polysaccharide ACYW-135 (Men-P-ACYW-135) for high risk individuals 56 years of age and older?

Ontario publicly funds the Men-P-ACYW-135 vaccine for individuals 56 years of age and older with high risk conditions, as the Men-C-ACYW-135 vaccine is not licensed for use in individuals over 55 years of age (although NACI has recommended use for this age group).

High risk individuals are eligible to receive a single dose of the Men-P-ACYW-135 vaccine as the final booster five years after their last booster dose of Men-C-ACYW. For example, if a patient was 54 years of age when they received their single last booster dose of Men-C-ACYW-135, they are eligible to receive a single dose of Men-P-ACYW-135 at 59 years of age.

What is an appropriate interval between the monovalent meningococcal conjugate C vaccine (Men-C-C) and the Men-C-ACYW-135?

For eligible individuals, the Men-C-ACYW-135 vaccine should be given 4 weeks apart from the monovalent Men-C-C vaccine. For more details, please refer to the *Publicly Funded Immunization Schedules for Ontario*, available on the ministry's website.

Who should not receive the Men-C-ACYW-135 vaccine?

Individuals with a history of anaphylaxis after a previous dose of a meningococcal conjugate vaccine as well as individuals with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container should not receive the vaccine.

Precautions should be taken for the following individuals who:

- have high fever or serious illness (immunization should be postponed)
- have allergies to any component of the vaccine
- are pregnant or nursing
- have a weakened immune system
- have bleeding disorder or taking blood-thinning medications
- have previously had Guillian-Barré Syndrome.

What is the vaccine ordering process?

Order the vaccine for high risk individuals through your local public health unit. Information about your public health unit can be found at: www.phdapps.health.gov.on.ca/PHULocator.

How should the Men-C-ACYW-135 vaccine be stored?

In order to ensure that children receive optimal protection, the Men-C-ACYW-135 vaccine (like other publicly funded vaccines) must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the vaccine is administered to individuals. This temperature must be monitored and maintained at all times. For additional information on provincial vaccine storage and handling requirements please consult the Vaccine Storage and Handling Guidelines, available at: www.health.gov.on.ca/en/pro/programs/publichealth/oph_standards/docs/guidance/guide_vaccine_storage.pdf

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

Under section 38 of the ***Health Protection and Promotion Act, R.S.O. 1990***, Ontario physicians, nurses, pharmacists and other health care providers (as listed under the section) are required to inform the person who consents to immunization of the importance of immediately reporting to a physician or a registered nurse in the extended class (nurse practitioner) of 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 Ontario (PHO) website along with a provider questions and answers fact sheet, available at: www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/Pages/Immunization-Resources.aspx. Please send the completed form to your local public health unit.

This information is monitored and reviewed on an ongoing basis by PHO and reported to the Public Health Agency of Canada (PHAC) to support national vaccine safety surveillance. Health care providers are required to report AEFIs to their local public health unit. A list of public health units in Ontario is available at www.health.gov.on.ca/en/common/system/services/phu/locations.aspx

Who can I contact for more information?

- Further information, including Ontario's publicly funded immunization schedule, is available on the Ministry of Health and Long-Term Care's website for health care professionals at: www.health.gov.on.ca/en/pro/programs/immunization.
- If you have further questions, please contact your local public health unit. To find your local public health unit, visit: www.phdapps.health.gov.on.ca/PHULocator.
- Immunization information is available at: www.ontario.ca/vaccines.