

Enhanced Meningococcal Vaccine Program For Grade 7 Students

Questions and Answers for Health Units

The Ministry of Health and Long-Term Care (the “ministry”) is providing broader protection against invasive meningococcal disease (IMD) by replacing the Men-C vaccine with the new quadrivalent meningococcal conjugate (**Men-C-ACWY**) vaccine for the Grade 7 school-based immunization program.

About the disease:

Q: What is invasive meningococcal disease (IMD) or meningococcal disease?

A: IMD is caused by the bacterium *Neisseria meningitidis* (commonly known as meningococcus). A small number of people carry these bacteria in their nose or throat without any ill effects. In certain immunocompromised cases, the presence of this meningococcus results in meningitis and meningococemia. Meningococcal meningitis is a severe form of meningitis (inflammation of the meninges, the tissues that cover the brain and spinal cord). Meningococemia is an infection of the blood with *Neisseria meningitidis*. A person may have either meningococcal meningitis or meningococemia, or both at the same time. Other less common manifestations of the disease may include septic arthritis (presence of the bacteria in joints) or pneumonia (inflammation of the lungs) with bacteremia (presence of *Neisseria meningitidis* bacteria in the blood).

Q: How is the *Neisseria meningitidis* bacteria that causes meningococcal disease spread?

A: The *Neisseria meningitidis* bacteria are spread by direct contact with respiratory and oral secretions (saliva, sputum or nasal mucus) of an infected person. To prevent the spread of meningococcal disease, persons should not share objects that have come in contact with another person’s mouth. In other words “swapping spit” with another person should be avoided. Furthermore, persons should ensure good hand hygiene and use the sleeve, shoulder or a tissue to cover coughs or sneezes.

Q: What are the symptoms of meningococcal disease?

A: The signs and symptoms of meningococcal disease can vary widely. Symptoms may include sudden onset of high fever, severe headache, vomiting, stiff neck and a rash. Initially, the rash may not be noticeable. Sensitivity to light, sleepiness, confusion and, in severe cases, coma may also occur. In children and adolescents, there may be early clinical features of sepsis, which is the body's response to infection — an inflammatory

process marked by an elevated heart rate, rapid breathing and abnormal temperature and may include leg or other limb pain, cold hands and feet, and abnormal skin color.¹

Symptoms may be difficult to detect in infants and the infant may only appear lethargic, be difficult to wake, have high fever, be irritable, have high pitched crying, have pale to blotchy skin, or rash, be vomiting, or be feeding poorly.

Adults and children may experience red to purple, pin-point rash or bruises which may appear anywhere on the body and do not blanch with pressure.

As the disease rapidly progresses, people of any age may lose consciousness and have seizures. Meningococcal disease is fatal in 8-15% of cases.

Q: What is the epidemiology of disease throughout the country and in Ontario?

A: In Canada between 1995 and 2003, Group B strains caused 42% of cases or an average of 81 cases per year. The frequency of group B cases varies little from year to year; whereas, the number of cases caused by group C, Y and W135 does vary from year to year.

While Group C has traditionally been dominant, disease epidemiology has changed in recent years with increasing numbers of Groups Y and W-135. Since 2000, there has been an increase in the incidence of disease caused by groups Y and W135, especially in Ontario. Since the introduction of meningococcal C vaccine in 2004, there has been a decrease in the incidence of serogroup C disease.

Q: What are the vaccines that provide protection against IMD and what are their indications?

A: There are a number of vaccines that provide protection against IMD. A vaccine for a particular strain(s) will not protect against other strains. For their clinical indications, see the respective product monograph. For the most up to date NACI statement on meningococcal vaccine, please go to: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/acs-dcc-3/index-eng.php>

Meningococcal Conjugated Vaccines (Polysaccharide linked to protein)

- **Meningococcal Quadrivalent Conjugate (Men-C-ACWY) Vaccine**
Menactra[®]

- **Meningococcal C Conjugate (MenC-C) Vaccines**
Menjugate[®]
NeisVac C[®]
Meningitec[®]

¹ Thompson MJ, Ninis N, Perera R, et al. Clinical recognition of meningococcal disease in children and adolescents. Lancet 2006; 367:397-403.

Meningococcal Polysaccharide Vaccine

- Menomune[®] (Men-P-ACWY)

No vaccine is available yet for serogroup B protection. Serogroup B is known to cause 30-60% of IMD every year and is most common in infants less than 2 years of age. Research to develop an effective group B vaccine is underway in several countries, including Canada.

About the Men-C-ACWY vaccine (Menactra[®]):

Q: What does Men-C-ACWY vaccine protect against?

A: The quadrivalent conjugate vaccine currently approved for use in Canada is Menactra[®]. This is a quadrivalent, protein-polysaccharide conjugate (*Corynebacterium diphtheriae*) vaccine, intended for the prevention of IMD due to serogroups A, C, Y, W-135.

Q: How effective is Menactra[®] vaccine compared to Menomune[®] vaccine?

A: Menactra[®] vaccine is a vaccine that protects against nasopharyngeal (NP) carriage of the meningococcal bacteria, and induces T-cell memory which has the potential to induce long term immunogenic protection. Menomune[®] (Men-P-ACWY) is a polysaccharide vaccine that does not reduce NP carriage and elicits short-term protection lasting only 3 to 5 years. Studies have indicated immunogenic hyporesponsiveness with successive doses of Menomune[®].

Q: What is the Men-C-ACWY vaccine format, dosage and route of administration?

A: Men-C-ACWY is supplied in a 0.5 mL single dose vial. It is a sterile, clear to slightly turbid liquid that should be checked for discoloration and particulate matter before use. Men-C-ACWY should be administered as a single dose intramuscularly in the deltoid region.

Q: What is the age indication for the Men-C-ACWY vaccine?

A: Men-C-ACWY is approved for administration by Health Canada to persons 2 to 55 years of age. However, it is publicly funded for Grade 7 students, persons eligible under the high risk criteria, and close contacts of persons with IMD.

Q: Who is high risk and eligible to receive the publicly funded Men-C-ACWY vaccine?

A: Individuals between 2 and 55 years of age with high risk conditions who are eligible to receive publicly funded vaccine include the following:

- Persons with anatomic or functional asplenia;
- Persons with terminal complement component deficiencies such as properdin or factor D deficiency;
- Cochlear implant recipients (pre-post implant).

Note: For close contacts of a vaccine preventable case of IMD, consult with the ministry.

Q: How long does it take to develop protective antibodies after receipt of Men-C-ACWY vaccine?
A: Following immunization with Men-C-ACWY vaccine, protective antibodies are usually achieved within 7 to 10 days.

Q: Can Men-C-ACWY vaccine be given at the same time as other vaccines?

A: Other essential inactivated or live attenuated vaccines may be given at the same time as the Men C-ACWY vaccine, using a separate site and a separate needle, and documented appropriately.

Q: Who should **not** get the Men-C-ACWY vaccine?

A: Men-C-ACWY is contraindicated in individuals with known hypersensitivity to any component of the vaccine or to latex, which is used in the vial stopper (there is no latex in the pre-filled syringe), nor should it be given to persons who have had a history of Guillain-Barré syndrome (GBS).

Q: What are the possible adverse events following immunization (AEFI) with Men-C-ACWY vaccine?

A: Most people who get the vaccine have no side effects. If AEFIs are experienced they are generally mild and may include: injection site pain, erythema (redness), swelling, headache, malaise, and irritability. These adverse events generally resolve within a few days. Severe reactions to the vaccine are rare.

GBS has been reported, however correlation has not been established. The Centers for Disease Control and Prevention (CDC) in the United States estimated that 1.25 excess cases of GBS may occur for every 1 million doses of Menactra vaccine distributed to persons 11-19 years of age.²

Q: What is Guillain-Barré syndrome (GBS)?

A: GBS is an uncommon disease that causes muscle paralysis and has been associated with certain infectious diseases. It is recommended that persons previously diagnosed with GBS should **not** receive Men-C-ACWY vaccine.

Q: How should the Men-C-ACWY vaccine be stored?

A: In order to ensure that students receive optimal protection, Men-C-ACWY vaccine (like other vaccines) must be maintained at a temperature between +2°C to +8°C from the time of manufacture until the vaccines are administered to individuals. This temperature must be monitored and maintained at all times. Please refer to the Vaccine Storage and Handling Guidelines, 2006 for additional information.

² CDC. Update: Guillain-Barré Syndrome among recipients of Menactra® Meningococcal conjugate vaccine – United States, June 2005-September 2006. MMWR 55(41):1120-1124.

About the Program:

Q: Why is a quadrivalent conjugate meningococcal vaccine now being offered by the ministry and why is the program targeting grade 7 students?

A: In September 2004, Ontario introduced a publicly funded conjugate meningococcal C immunization program for one year olds. This program was expanded in January 2005 to include a catch up program for unimmunized grade 7 students through a school-based program, adolescents 15 to 19 years of age, and high risk individuals.

While meningococcal C vaccine, introduced in 2004, was having an impact on reducing the incidence of disease in children under 5, there were still cases in people over the age of 16. To address this potentially waning immunity, and to enhance the immune memory response, the National Advisory Committee on Immunization (NACI) now recommends that adolescents be immunized with a meningococcal vaccine.

Based on this advisement, Ontario is implementing routine meningococcal immunization for adolescents. The current monovalent meningococcal C vaccine delivered by public health units in the grade 7 program will be replaced with a quadrivalent conjugate meningococcal vaccine. The change to a quadrivalent conjugate meningococcal vaccine (Menactra[®]) will meet NACI's recommendation for a booster dose of meningococcal vaccine, and also provide broader protection against 3 additional types of IMD to include serogroups A, Y, W-135. The vaccine will provide protection to address the changing epidemiology of IMD in Ontario.

Q: Is the quadrivalent conjugate meningococcal vaccine required for a student to attend school in Ontario?

A: No, the Men-C-ACWY vaccine is not required for a student to attend school in Ontario. Students not immunized will not be suspended from school, however the ministry strongly recommends that students receive this vaccine to prevent IMD caused by serogroups A, C, W-135, and Y.

Q: What other jurisdictions provide publicly funded Men-C-ACWY for routine immunization?

A: This vaccine is also available as part of the routine childhood schedule in Prince Edward Island and New Brunswick (grade 9), and in the Northwest Territories (for postsecondary students attending school outside NT). In other provinces/territories, it must be purchased privately.

Q: Will the recommendation and eligibility for meningococcal immunization change for infants?

A: The recommendation and eligibility for routine infant immunization remains the same for meningococcal vaccine; one dose of meningococcal C conjugate vaccine (Menjugate[®] or NeisVac-C[®] vaccine) given at 12 months of age.

Q: When will the switch from the monovalent to the quadrivalent meningococcal vaccine start?

A: Grade 7 students can receive the Men-C-ACWY vaccine starting the 2009-10 school year.

Q: Who will administer the Men-C-ACWY vaccine?

A: The vaccine will continue to be offered through the grade 7 Ontario school-based program. The vaccine will be administered by public health nurses in school clinics.

Q: Will students be able to receive the vaccine through their health care practitioner?

A: In special circumstances the vaccine may be released by health units to family physicians or other health care providers for administration to eligible grade 7 students.

Q: Is the vaccine free of charge?

A: The Men-C-ACWY vaccine is provincially funded for all grade 7 students and eligible high risk people.

Q: Will a student remain eligible to receive the quadrivalent meningococcal vaccine after grade 7?

A: Yes. An unimmunized student will remain eligible to receive the quadrivalent meningococcal vaccine if they miss their opportunity while in grade 7. The vaccine can be obtained through their local health unit.

Q: Can a student who was previously eligible or previously vaccinated with the school-based Men-C-C vaccine now receive the Men-C-ACWY vaccine if requested?

A: No. The Men-C-ACWY vaccine is only publicly funded for grade 7 students beginning in the 2009-2010 school year and forward. Unimmunized students who were previously eligible to receive the monovalent meningococcal vaccine (students who were in grade 7 from 2005 to 2008) remain eligible to receive the Men-C-C vaccine from their health care provider or local health unit.

The ministry will continuously monitor the cases of IMD to determine whether there is a need to further expand the program.

Q: Can a grade 7 student receive the Men-C-C vaccine (NeisVac-C[®] or Menjugate[®]) instead of the quadrivalent vaccine?

A: A student (or their parent) may request immunization with the monovalent vaccine instead of the quadrivalent conjugate vaccine. A grade 7 student may be immunized with the monovalent vaccine at their health care provider or local health unit free of charge.

Q: What is the vaccine ordering process for health units?

A: Health units are required to complete a vaccine order form. This form is included in your package and also available on the public health portal www.publichealthontario.ca.

Q: As a health unit, what reimbursement is available for administering the vaccine?

A: Reimbursement for administering the vaccine will remain the same as the Men-C-C program. Health units will continue to use the on-line reimbursement invoicing system for all meningococcal doses administered through the school based program. You will be able to enter the name of the agent administered i.e., Men-C-ACWY or Men-C-C.

Immunizing the student:

Q: What assessment and/or teaching should be done prior to administering the vaccine?

A: Prior to vaccination:

- Be aware of the vaccine being administered. Be familiar with the vaccine product monograph/leaflet included in the vaccine packaging.
- Ensure that the individual (and their parent) is appropriately informed and proper consent is obtained prior to administering the vaccine.
- Ask about all relevant contraindications and precautions to receiving the vaccine
- Provide information regarding the risks and benefits of both receiving and not receiving the vaccine with the opportunity to ask questions
- Discuss common minor side effects and any possible adverse events that may occur

Q: What teaching should be provided after administering the vaccine?

A: After vaccination:

- Provide counselling on common side effects from immunization
- Keep the individual in the clinic for 15 minutes after vaccination and observe for any adverse events, including anaphylaxis. Note: All vaccine providers should have the necessary training and equipment to manage anaphylactic events
- Provide a written record of vaccine administration according to appropriate documentation standards.

Q: What should be done for adverse events following immunization?

A: 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 physician or registered nurse in the extended class any reaction that may be a reportable event. Contact your local public health unit to report any adverse events following immunization. A list of health units can be found at:

http://www.health.gov.on.ca/english/public/contact/phu/phuloc_mn.html.

References

1. Vaccine Product Monographs; Menactra[®], Sanofi Pasteur Ltd., September 2008.
2. Public Health Agency of Canada. Canadian Immunization Guide, 7th edition, 2006. Available at: <http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-pneu-eng.php#sched>.
3. National Advisory Committee on Immunization. *Update on the Invasive Meningococcal Disease and Meningococcal Vaccine Conjugate Recommendations, April 2009*. Available at: <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/acs-dcc-3/index-eng.php>