> BC Centre for Disease Control An agency of the Provincial Health Services Authority

#### Men-C-ACYW-135 Question and Answer Document May 2016

BC is introducing a quadrivalent meningococcal vaccine (Men-C-ACYW-135) program for adolescents to offer protection against meningococcal serotypes A, C, Y and W-135. The following Q & A provides answers to frequently asked questions for health care providers who are responsible for implementing this program.

- 1. When will this program officially start?
- 2. Who is eligible to receive Men-C-ACYW-135 through the school-based program?
- 3. <u>Why has the school-based program changed from a Men-C-C program to a Men-C-ACYW-135 program?</u>
- 4. Why has the school-based meningococcal vaccine program moved from grade 6 to grade 9?
- 5. <u>If a student has received Men-C-ACYW-135 before grade 9, should they be offered a dose in grade 9?</u>
- 6. <u>If a student has previously received a dose of polysaccharide quadrivalent meningococcal</u> vaccine, do they still require the Men-C-ACYW-135 dose in grade 9?
- 7. If a student misses their dose of Men-C-ACYW-135 in grade 9, can they still receive it later, and if so until what age?
- 8. <u>Is a booster dose of Men-C-ACYW-135 required later in adolescence?</u>
- Individuals who are at high risk of meningococcal disease are recommended a booster Men-C-ACYW-135 every 5 years as long as their medical condition exists. Would these students be recommended a routine dose in grade 9?
- 10. Will the infant Men-C-C program remain the same?
- 11. If a child has not received a dose of Men-C-C on or after 12 months of age, what is the recommendation?
- 12. If a student missed their grade 6 dose of Men-C-C, what is the recommendation?
- 13. <u>What is the risk of meningococcal C disease for children between grades 6 and 9, before they are offered Men-C-ACYW-135 in grade 9?</u>
- 14. <u>Are there any timing interval considerations for administration of Men-C-ACYW-135</u> and other meningococcal vaccine products?
- 15. Can a child who received Men-C-C in grade 6 receive Men-C-ACYW-135 in grade 9?
- 16. <u>Can Men-C-ACYW-135 safely be administered to women who are pregnant or breastfeeding?</u>
- 17. <u>Can children receive Men-C-ACYW-135 from another immunization provider if they</u> don't receive it through their school-based program?

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

- 18. Can Men-C-ACYW-135 be administered with other school-based vaccines?
- 19. <u>What Men-C-ACYW-135 vaccines will be supplied to health authorities for the school-based program?</u>
- 20. How is Menactra® supplied?
- 21. <u>How is Menveo® supplied?</u>
- 22. <u>What is the recommended action if Menveo® is inadvertently administered without</u> reconstituting the product first?

#### 1. When will this program officially start?

The official start date for this program is September 1, 2016.

2. Who is eligible to receive Men-C-ACYW-135 through the school-based program?

Students who are in grade 9 will be eligible to receive the publicly funded Men-C-ACYW-135 vaccine.

## 3. Why has the school-based program changed from a Men-C-C program to a Men-C-ACYW-135 program?

BC is replacing the grade 6 Men-C-C program with a grade 9 Men-C-ACYW-135 program to provide broader protection against meningococcal disease, including that caused by serogroup Y. This quadrivalent vaccine will continue to offer protection against serogroup C, which caused outbreaks in school age children and young adults in several provinces including BC prior to introduction of the Men-C-C vaccine. It will also offer protection against serogroup Y, which has resulted in fatal cases in BC in older teens and young adults. From 2001-2015, 23 cases including 4 deaths from serogroup Y meningococcal disease were reported in BC in those aged 15-24 years. While serogroup W-135 has caused only 3 cases and no deaths in this age group in the same period of time, and serogroup A does not occur in North America, these two strains do occur more frequently in other parts of the world and the vaccine will offer this additional protection<sup>1</sup>.

### 4. Why has the school-based meningococcal vaccine program moved from grade 6 to grade 9?

In moving the meningococcal vaccine program from grade 6 to grade 9, direct protection will be provided to students when they are at greatest risk of disease, and prior to the peak age of highest

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

incidence in adolescence (15-19 years of age). The program will also have the potential to result in greater indirect protection as it will not only provide direct immunity to the vaccinated student, but also through reducing carriage of the bacteria in their nose and throat, has the potential to protect both younger and older individuals. A systematic review and meta-analysis showed that carriage prevalence peaked in 19 year olds and subsequently decreased in adulthood. Men-C-ACYW-135 in grade 9 has the potential to result in greater indirect protection across population groups through reduction of carriage in the age group with the highest prevalence<sup>1</sup>.

#### 5. If a student has received Men-C-ACYW-135 before grade 9, should they be offered a dose in grade 9?

In BC, if a student has previously received a dose of Men-C-ACYW-135 in grade 7 or later (i.e., at which point a child would be at a minimum age of 11 years and 8 months), this will be considered a valid adolescent dose. While such students will be considered up-to-date for age for Men-C-ACYW-135, they will be eligible for a publicly funded dose of Men-C-ACYW-135 to optimize protection during the peak age in later adolescence. These students should be given the option of receiving the quadrivalent vaccine in grade 9 or later in high school, preferably 5 years after their first dose or prior to leaving high school. If they wish to defer the dose beyond grade 9, it will be up to the student/parent to remember to make an appointment with a health care provider at a later date. Other jurisdictions in Canada offer Men-C-ACYW-135 vaccine programs in earlier school years, such as grade 7 in Ontario. For various reasons, including private purchase or travel, students may present in grade 9 with a record of prior receipt of Men-C-ACYW-135. NACI recommends a single routine conjugate meningococcal vaccination in adolescence, routinely at 12 years of age<sup>2,3</sup>.

# 6. If a student has previously received a dose of polysaccharide quadrivalent meningococcal vaccine, do they still require the Men-C-ACYW-135 dose in grade 9?

Yes. These students are recommended a conjugate quadrivalent meningococcal vaccine. If a student has received a dose of polysaccharide meningococcal vaccine (e.g., Menomune<sup>TM</sup>), they should be immunized with Men-C-ACYW-135. A 6 month interval is recommended<sup>3,4,5</sup>.

### 7. If a student misses their dose of Men-C-ACYW-135 in grade 9, can they still receive it later, and if so until what age?

Yes, if a student misses their dose of Men-C-ACYW-135 in grade 9, they are eligible to receive this dose up to 24 years of age (inclusive). This is based on the intention of providing protection during

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

peak prevalence of incidence in later adolescence and to reduce cases of serogroup Y disease in the age group 15-24 years<sup>1,3,6</sup>.

#### 8. Is a booster dose of Men-C-ACYW-135 required later in adolescence?

NACI has not determined the need for booster doses after the dose given in adolescence at this time. Studies assessing the long term durability of the immune response to Men-C-ACYW-135 given in adolescence are emerging. Booster doses may be recommended for individual students, including those with high risk medical conditions and those traveling to areas with high rates of meningococcal disease based on individual risk assessment<sup>1,3,6</sup>.

## 9. Individuals who are at high risk of meningococcal disease are recommended a booster Men-C-ACYW-135 every 5 years as long as their medical condition exists. Would these students be recommended a routine dose in grade 9?

Students who are at high risk of meningococcal disease are recommended a booster dose of Men-C-ACYW-135 every 5 years for as long as their medical condition persists. Therefore, these students who have received a dose of Men-C-ACYW-135 within the past 5 years do not require a routine dose in grade 9. If a student has not received a dose within the past 5 years, they are recommended to receive a dose as part of the grade 9 program. These students' medical history and schedules should be consulted prior to a dose of Men-C-ACYW-135 being administered through the school-based program<sup>5</sup>.

#### 10. Will the infant Men-C-C program remain the same?

Yes, the routine infant schedule of 2 doses of Men-C-C offered at 2 months and 12 months of age will remain unchanged.

### 11. If a child has not received a dose of Men-C-C on or after 12 months of age, what is the recommendation?

If a child has not received a dose of Men-C-C on or after 12 months of age, they remain eligible for a dose of Men-C-C until grade 9, at which time it is recommended they receive Men-C-ACYW-135 as part of the grade 9 school-based program. An interval of at least 4 weeks is required between any conjugate meningococcal C vaccine and any conjugate quadrivalent meningococcal vaccine.

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

### 12. If a student missed their grade 6 dose of Men-C-C, what is the recommendation?

As of July 1, 2016, students born on or after January 1, 2002 who did not receive a dose of Men-C-C in grade 6 program do not require a catch-up dose of Men-C-C. These students should wait until they are in grade 9 when they will be offered Men-C-ACYW-135 as part of the new program in grade 9.

For individuals born prior to January 2002 who have not received their dose of Men-C-C in grade 6, they remain eligible for a dose of Men-C-C up to 24 years of age (inclusive).

### 13. What is the risk of meningococcal C disease for children between grades 6 and 9, before they are offered Men-C-ACYW-135 in grade 9?

Introduction of Men-C-C into childhood and adolescent immunization programs in BC has led to dramatic reductions of meningococcal C disease over the last decade. In the past 10 years, there have only been 2 cases of meningococcal C disease in BC among individuals under 20 years of age (both in 15-19 year olds, in 2008). Herd immunity has been associated with reduction of carriage of meningococcal C bacteria, which is thought to be important in adolescent populations and instrumental in reduction of disease. It is anticipated that herd immunity, resulting from immunization of infants and adolescents under ongoing and previous programs, will continue to provide protection and reduction of carriage in a dolescent populations, including for those students who would have been immunized at an earlier age in a previous adolescent program. Given the low incidence of disease and the impact of herd immunity, the anticipated risk of extending the program by three years until grade 9 is low. Invasive meningococcal disease is reportable in BC and is closely monitored for evidence of re-emergence<sup>1</sup>.

#### 14. Are there any timing interval considerations for administration of Men-C-ACYW-135 and other meningococcal vaccine products?

The recommended interval between Men-C-ACYW-135 and the following products is a minimum of at least:

- 4 weeks between doses of any conjugate meningococcal C vaccine,
- 8 weeks between doses of any other conjugate quadrivalent meningococcal vaccine, and
- 6 months following a dose of any polysaccharide meningococcal vaccine<sup>5</sup>.

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

#### 15. Can a child who received Men-C-C in grade 6 receive Men-C-ACYW-135 in grade 9?

Yes, students who received Men-C-C vaccine in grade 6 are recommended to receive Men-C-ACYW-135 in grade 9.

### 16. Can Men-C-ACYW-135 safely be administered to women who are pregnant or breastfeeding?

The Canadian Immunization Guide recommends that routine inactivated vaccines, including Men-C-ACYW-135, may be administered to pregnant women if indicated. The Council of the Society of Obstetricians and Gynaecologists of Canada further indicates that meningococcal vaccines are both safe and efficacious in pregnancy. Given the access and opportunity that school-based programs offer to students for immunization, administration of Men-C-ACYW-135 is considered both safe and beneficial for pregnant students. Inactivated vaccines, such as conjugate or multicomponent meningococcal vaccines, may be administered to women who are breastfeeding<sup>7,8</sup>.

## 17. Can children receive Men-C-ACYW-135 from another immunization provider if they don't receive it through their school-based program?

While students are encouraged to receive their dose of Men-C-ACYW-135 through the school-based program, they may be able to receive the vaccine from family physicians or pharmacists. The vaccine, however, may not be routinely stocked by these other providers and may need to be specially ordered. Students or parents who wish to access this vaccine outside of public health should contact their health care provider to ensure Men-C-ACYW-135 is available.

#### 18. Can Men-C-ACYW-135 be administered with other school-based vaccines?

Men-C-ACYW-135 vaccine may be administered concomitantly with other vaccines recommended in adolescence. Two studies have found that co-administration of Menveo® and Tdap may result in a lower immune response to two of the pertussis antigens compared to Tdap vaccine given alone; however the clinical significance of this is unknown. At this time there is no recommendation indicating that these vaccines cannot be administered at the same time<sup>3,6</sup>.

> BC Centre for Disease Control An agency of the Provincial Health Services Authority

### **19.** What Men-C-ACYW-135 vaccines will be supplied to health authorities for the school-based program?

Two brands of Men-C-ACYW-135 will be available in BC: Menveo® and Menactra®. Product availability and supply may be impacted by the health authority in which you work. Check with your immunization lead regarding the product your health authority will be using. Both vaccines are conjugate quadrivalent meningococcal vaccines and provide protection against serogroups A, C, Y and W-135.

#### 20. How is Menactra® supplied?

Menactra® is supplied in boxes of 5 x 1 dose vials. Each vial contains 0.5 mL of clear to slightly turbid liquid. No reconstitution is required for this product. Syringes and needles for withdrawal and administration are **not** included in the product package. The package dimensions are 3.50° (L) x 0.95° (W) x 1.88° (H)<sup>9</sup>.



#### 21. How is Menveo® supplied?

Menveo® is supplied in boxes of 5 dose packages consisting of 5 vials each of lyophilized vaccine containing the meningococcal A antigen and the liquid component containing the meningococcal C, Y, and W-135 antigens that is used for reconstitution. A dose of Menveo® requires reconstitution. To reconstitute Menveo®, use a graduated syringe to withdraw the entire contents of the vial containing the meningococcal C, Y, and W-135 components and inject into the vial containing the lyophilized Men A conjugate component vial. Invert and shake the vial vigorously. Syringes and needles for withdrawal and administration are not included in the product package. The package dimensions are 3.46" (L) x 1.65" (W) x 1.73" (H)<sup>10</sup>.

> BC Centre for Disease Control An agency of the Provincial Health Services Authority



### 22. What is the recommended action if Menveo® is inadvertently administered without reconstituting the product first?

If Menveo® is inadvertently administered without proper reconstitution, and only the vial containing the liquid Men C, Y and W-135 components is administered, re-administration of the product is recommended. In this circumstance, the lyophilized Men A conjugate component will not have been administered, therefore, a second full dose of appropriately reconstituted Menveo® should be administered after an interval of at least 8 weeks from the invalid dose.



> BC Centre for Disease Control An agency of the Provincial Health Services Authority

#### **REFERENCES:**

<sup>3</sup> National Advisory Committee on Immunization. Canada Communicable Disease Report. Update on the use of quadrivalent conjugate meningococcal vaccines [Internet]. Ottawa: 2013; 39(ACS-1):1-40. Available from: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/13vol39/acs-dcc-1/index-eng.php

<sup>4</sup> Centre for Disease Control and Prevention. Meningococcal vaccination for adolescents: Questions and answers information for healthcare professionals [Internet]. Atlanta (GA): 2015. Available from: http://www.cdc.gov/vaccines/vpd-vac/mening/faqs-hcp-adolescent-vaccine.html

<sup>5</sup> British Columbia Centre for Disease Control. Communicable Disease Control Manual, Immunization. Section VIII – principals of immunology. Vancouver (BC): 2009. Available from: <u>http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Epid/CD%20Manual/Chapter%2</u>02%20-%20Imms/SectionVIII PrinciplesofImmunology.pdf

<sup>6</sup> Canadian Immunization Guide. Public Health Agency of Canada. Part 4: Active vaccines [Internet]. Ottawa: 2014. Available from: <u>http://www.phac-aspc.gc.ca/publicat/cig-gci/p04-eng.php</u>

<sup>7</sup> Canadian Immunization Guide. Public Health Agency of Canada. Part 2: Vaccine safety [Internet]. Ottawa: 2014. Available from: <u>http://www.phac-aspc.gc.ca/publicat/cig-gci/p02-02-eng.php#contraindications</u>

<sup>8</sup> Gruslin A, Stebin M, Halperin S, Money D, Yudin M. Immunization in pregnancy. Journal of Obstetrics and Gynaecology Canada [Internet]. 2009 November. Available from: https://docs.google.com/viewerg/viewer?url=http://sogc.org/wp-content/uploads/2013/01/gui236CPG0911.pdf

<sup>9</sup> Sanofi Pasteur Limited. Product Monograph Menactra® [Internet]. Toronto (ON): 2012. Available from: <u>https://www.vaccineshoppecanada.com/document.cfm?file=menactra\_e.pdf</u>

<sup>10</sup> GlaxoSmithKline Inc. Product Monograph Menveo® [Internet]. Mississauga (ON): 2015. Available from: http://ca.gsk.com/media/1213533/menveo.pdf

<sup>&</sup>lt;sup>1</sup> Naus, Monika. Briefing notes for the new vaccines task group. On file at BC Centre for Disease Control. Vancouver (BC): 2016.

<sup>&</sup>lt;sup>2</sup> National Advisory Committee on Immunization. Canada Communicable Disease Report. Update on the invasive meningococcal disease and meningococcal vaccine conjugate recommendations [Internet]. Ottawa: 2009; 35(ACS-3):1-40. Available from: <u>http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/09vol35/acs-dcc-3/index-eng.php</u>