

## Use of 9-valent Human Papillomavirus (HPV) Vaccine in the Grade 6 Immunization Program Question and Answer Document August 2016

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### 1. What is the 9-valent HPV vaccine, and when was it authorized for use in Canada?

The 9-valent HPV vaccine (HPV9) provides protection against 9 types of HPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58. The HPV9 vaccine (Gardasil®9, Merck Canada, Inc.) was authorized for use in Canada in February 2015.

### 2. Which HPV vaccine will be used in the school-based immunization program in BC?

The HPV9 vaccine will be replacing the 4-valent HPV vaccine (HPV4; Gardasil®) for females in grade 6 in BC starting in September 2016. For Gardasil® and Gardasil®9 product information, see the [Communicable Disease Control Manual, Chapter 2: Immunization Program, Section VII-Biological Products, Human Papillomavirus Vaccine \[Quadrivalent and Nonavalent\]](#).

### 3. How does HPV9 vaccine differ from HPV4 vaccine?

Both vaccines protect against HPV types 16 and 18 that cause about 70% of cervical cancers and the majority of other HPV-associated cancers in both women and men. Both vaccines

also protect against HPV types 6 and 11 that cause about 90% of anogenital warts. HPV9 protects against five additional cancer causing types (HPV 31, 33, 45, 52, 58) which account for about 15% of cervical cancers. These additional five HPV types also account for about 11% of anal cancers in females and 4% in males.<sup>1</sup>

#### 4. What is the immunization schedule for the HPV9 vaccine in the grade 6 program?

The recommended immunization schedule for HPV9 is as follows:

- Females in grade 6: 2 doses given as 0.5 mL IM, separated by at least 6 months.
- Individuals who are known to have immune system defects associated with solid organ transplant, stem cell transplant or HIV infection should be immunized on a 3 dose schedule at 0, 2 and 6 months.

#### 5. The National Advisory Committee on Immunization (NACI) currently recommends a 3-dose series for Gardasil®9. Why is BC offering a 2-dose series?

NACI currently recommends a 3-dose series for HPV9 given at 0, 2 and 6 months, however Merck Inc. has completed studies evaluating the immunological non-inferiority of a 2-dose series for younger individuals. This data was presented by Merck Inc. to the Advisory Committee on Immunization Practices in February 2016. These data have only been presented as a slide presentation and are not yet published. This slide presentation is available at <http://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2016-02/hpv-03-luxembourg.pdf>. In addition, a 2-dose series of HPV9, for those initiating series at 9-14 years of age, has been approved for use in the European Union.<sup>2</sup>

A NACI statement is anticipated in late 2016 supporting a 2-dose series for HPV9, and the product monograph is expected to be updated to reflect a 2-dose series for younger age groups.

#### 6. What if a girl in Grade 6 has previously received one or more doses of HPV4 vaccine?

If a grade 6 girl has not received a complete series of HPV4, she should be offered a complete series of HPV9.

If a grade 6 girl has completed a series of HPV4, she is considered up-to-date for age for the purpose of vaccine coverage assessment. However, she remains eligible for a complete series of HPV9.

**7. What vaccine should be used for eligible girls and young women who did not receive HPV4 vaccine in the school-based program prior to the 2016/17 school year?**

Unimmunized or incompletely immunized females born in 1994-2004 will continue to be eligible for HPV4 up to 26 years of age (inclusive).

**8. Can HPV9 be given to a person who has started or completed a series with HPV4, to get protection against the 5 additional HPV types?**

Yes, however the following points should be considered:

- At this time, HPV9 is only publicly funded in BC for girls in grade 6 starting in the 2016/17 school year, and females 9-26 years of age who are HIV positive. All other individuals will need to purchase HPV9 from a pharmacy or travel clinic.
- A complete series of HPV9 is recommended to ensure protection against the additional five HPV types.
- Available data show no serious safety concerns in persons who were vaccinated with 9-valent HPV vaccine after having received a 3-dose series of quadrivalent HPV vaccine at least 12 months earlier.<sup>3</sup>

**9. Why is HPV9 vaccine not being used for the HPV program for vulnerable males?**

The benefit of protection against the 5 additional types targeted by HPV9 is mostly limited to females for prevention of cervical cancers and precancers. The incremental benefit for males is much smaller. Therefore at this time, based on burden of illness and cost effectiveness, the HPV9 vaccine is not publicly funded for this population.

**10. How does the efficacy of the HPV9 vaccine compare to that of the HPV4 vaccine?**

In studies evaluating the immunogenicity of HPV9 in girls and boys 9-15 years and women 16-26 years, HPV9 was shown to be immunologically non-inferior to HPV4 for types 6, 11, 16 and 18.<sup>4</sup>

Additional studies in women 16-26 years have shown that the risk reduction for disease related to HPV-31, 33, 45, 52, and 58 was 96.7% (95% confidence interval, 80.9 to 99.8) for high-grade cervical, vulvar, and vaginal disease and 96.3% (95% confidence interval, 79.5 to 99.8) for high-grade cervical epithelial neoplasia, adenocarcinoma in situ and cervical cancer.<sup>5</sup>

## 11. How is Gardasil®9 supplied?

Gardasil®9 is supplied in 2 different formats:

### Vials

- GARDASIL®9 is supplied in vials containing one 0.5 mL dose of liquid vaccine. There are 10 vials per box. No reconstitution is required for this product. Syringes and needles for withdrawal and administration are not included in the product package. The dimensions of the carton are 9 cm x 4.5 cm x 4 cm.

### Syringes

- GARDASIL®9 is supplied in prefilled Luer Lock syringes containing one 0.5 mL dose of liquid vaccine in a carton. No reconstitution is required for this product. Needles for administration are not included in the product package. The dimensions of the carton are 13.5 cm x 3 cm x 5 cm.

The vast majority of Gardasil®9 will be supplied in the vial format.

## 12. How will the HPV9 vaccine appear in the Panorama forecaster?

HPV4 and HPV9 vaccines will continue to be appear as ‘HPV’ as Immunizing Agent, and ‘GARDASIL’ as Brand in the Panorama forecaster. The immunizing nurse will need to determine, based on the vaccine eligibility indications as outlined in the [Communicable Disease Control Manual, Chapter 2: Immunization Program, Section VII-Biological Products, Human Papillomavirus Vaccine \[Quadrivalent and Nonavalent\]](#), whether the client is to receive HPV4 or HPV9. Upon entry of the vaccine lot number, the trade name (i.e. GARDASIL® or GARDASIL®9) will be shown on the Immunization Details screen. For more information, see the Panorama Bulletin #IMMS045.

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**REFERENCES:**

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- <sup>2</sup> European Public Assessment Report: Gardasil 9-Product Information available at [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR -  
Product\\_Information/human/003852/WC500189111.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/003852/WC500189111.pdf)
- <sup>3</sup> Garland SM, Cheung TH, McNeill S, et al. Safety and immunogenicity of a 9-valent HPV vaccine in females 12-26 years of age who previously received the quadrivalent HPV vaccine. Vaccine. 2015; 33(48):6855-64.
- <sup>4</sup> Van Damme P, Olsson SE, Block S, et al. Immunogenicity and Safety of a 9-Valent HPV Vaccine. Pediatrics. 2015; 136(1):e28-39.
- <sup>5</sup> Joura EA, Guliano AR, Iversen OE, et al. A 9-valent HPV vaccine against infection and intraepithelial neoplasia in women. N Engl J Med. 2015; 372(8):711-23.