

## Expanded Eligibility for Human Papillomavirus (HPV) Vaccination for Select Male Populations Q&A Document – August 2015

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## **1. Can you tell me more about the expanded eligibility criteria for HPV vaccination?**

On July 7<sup>th</sup> 2015, the BC Ministry of Health announced a publicly funded, targeted HPV vaccine program using quadrivalent HPV vaccine for boys and young men up to the age 26 who are at a higher risk of contracting the virus and unlikely to be protected through indirect protection (female vaccination). This program expansion aims to provide protection to those who are most vulnerable to HPV infection and related disease. The program complements BC's publicly funded HPV vaccine program for Grade 6 girls and a publicly funded time-limited catch up program for young women up to age 26.<sup>1</sup>

This expanded HPV immunization program has an official start date of September 1, 2015.

## **2. Which males are considered to be at higher risk for contracting HPV disease and therefore eligible for publicly funded HPV vaccine?**

Those eligible will include the following males at the time of series commencement:

- Males 9 to 26 years of age (inclusive) who are:
  - Men who have sex with men (MSM) including those who are not yet sexually active and who are questioning their sexual orientation
  - Street involved
  - Living with HIV
- Males 9 to 18 years of age (inclusive) in care of the Ministry of Children and Family Development (MCFD)
- Males 12 to 17 years of age (inclusive) in youth custody services centres
- Boys and young men in any of these groups who have previously started the vaccine series and have outstanding doses

## **3. What if males 27 years of age and older want to receive the HPV vaccine?**

The National Advisory Committee on Immunization (NACI) recommends quadrivalent HPV vaccine for men 27 years of age and older who have sex with men (MSM). However these individuals do not qualify for publicly funded vaccine. Those not eligible for free HPV vaccine, but who would like to receive the vaccine, can purchase it from most pharmacies and travel clinics. The quadrivalent HPV vaccine costs approximately \$150 per dose.

#### 4. Why aren't all males eligible for publicly funded HPV vaccine?

Canadian cost effectiveness analyses of routine male vaccination are not sufficiently favourable to warrant introduction of a universal male program at current vaccine pricing. Modeling suggests that a routine male vaccination program is not cost effective when female vaccination rates are high, as immunization of girls and young women provides indirect protection to heterosexual males.<sup>2</sup> In contrast, this same protection has little to no impact on men who have sex with men (MSM).<sup>1</sup>

There are peer-reviewed publications indicating that vaccination of MSM aged to about 25 years falls within the range of cost-effectiveness considered acceptable for public funding.<sup>3</sup> Those over 26 years of age have a higher likelihood of prior infection and are less likely to benefit from HPV vaccine which prevents new and persistent infections.

#### 5. How are decisions to fund vaccines made in BC?

In BC, decisions to fund vaccine programs are made by the Ministry of Health based on recommendations from the Communicable Disease Policy Advisory Committee chaired by the Provincial Health Officer. This expert committee makes recommendations based on epidemiology, evidence about the vaccine's effectiveness and safety, economic analyses, and a variety of other considerations. It also takes into account recommendations of national and international expert groups. Recommendations for new vaccine programs or expansions are also weighed by the Ministry against other new health initiatives.

#### 6. Which HPV vaccine will be used?

The quadrivalent GARDASIL® vaccine will be used for the male HPV vaccine program. This is the same vaccine provided to girls in the BC Grade 6 program.

There are over 100 types of HPV. GARDASIL® protects against infection from HPV types 16 and 18 which cause about 70% of cervical cancers, 80% of anal cancers and other cancers of the mouth, throat, penis, vagina and vulva. GARDASIL® also protects against infection from HPV types 6 and 11 which cause about 90% of genital warts.<sup>4</sup>

## 7. Is this vaccine safe?

Yes, the GARDASIL® vaccine is very safe. Vaccines are only approved for use in Canada after numerous clinical studies demonstrate safety and effectiveness. GARDASIL® has been authorized for use in Canada since 2006. The National Advisory Committee on Immunization (NACI) recommended the use of this vaccine for girls in 2007. In 2008, BC introduced GARDASIL® for girls in the school-based immunization program. In February 2010, GARDASIL® was authorized to expand its indications to include males 9 to 26 years of age.<sup>5</sup> In 2012, NACI released an updated statement on the use of HPV vaccine in which it recommended the vaccine for males.<sup>5</sup>

There is a large body of evidence that supports the excellent safety profile of GARDASIL®.<sup>6-8</sup> This information comes from clinical trials and postmarketing safety evaluations including passive and active surveillance and epidemiologic studies.<sup>9</sup> The following have been investigated and found not to be associated with HPV vaccines: death, venous thromboembolic events, Guillain-Barré syndrome, and autoimmune disorders.<sup>8-10</sup> Anaphylaxis occurs with the same frequency observed following other commonly used vaccines, at a rate of 1 to 10 per million recipients.<sup>9</sup> Syncope, which had been noted in early use of the vaccine, occurs at a frequency similar to that which follows other vaccines given to young adolescents.<sup>9</sup>

## 8. How is GARDASIL® administered, and what is the recommended schedule?

The recommended schedule for males is the same as for females and varies by age at the time of vaccine series commencement. The following table illustrates the vaccine schedule for immunocompetent<sup>A</sup> males:

| Age at time of receipt of 1 <sup>st</sup> dose | Doses Required | Schedule (months) |
|--|----------------|-------------------|
| 9-14 years                                     | 2              | 0, 6              |
| 15-26 years                                    | 3              | 0, 2, 6           |

<sup>A</sup> Males who are known to have immune system defects associated with solid organ transplant, stem cell transplant or HIV infection are not considered “immunocompetent” and should receive 3 doses of HPV vaccine given at 0, 2 and 6 months regardless of age.

The vaccine is administered intramuscularly (IM) into the deltoid muscle. For more information on the administration of GARDASIL® vaccine, please refer to Section VII of the [BC Immunization Manual](#).

## **9. Should I administer the vaccine if I can't guarantee my client will complete the series?**

There is currently no evidence to suggest that one dose of GARDASIL® offers adequate long term protection. Health care providers are strongly encouraged to strategize and seek opportunities to provide completion of series to eligible individuals. However, the decision to recommend and start a series should not be based on likelihood of completion of the series.

## **10. What if my client passes the eligible age cohort before completing the vaccine series? Would they no longer qualify for publicly funded vaccine?**

Eligibility is based upon the age of series commencement. Therefore eligible males who initiate the GARDASIL® series between 9 and 26 years of age continue to be eligible for series completion after 26 years of age.

## **11. What if my client informs me they are MSM but I question the veracity of their claim?**

Health care providers do not need to seek proof of eligibility for any indications associated with this new male HPV immunization program. For example, individuals who self-identify as MSM, or parents who present with their son and inform you that their son meets eligibility criteria for the publicly funded male HPV immunization program, should be provided free GARDASIL® vaccine.

## **12. Which provider group(s) will be responsible for rolling out this program?**

Multiple provider groups will be involved in both promoting and providing GARDASIL® to eligible males. Having a number of different access points assists in reaching eligible males. Providers involved include, but are not limited to, the following:

- Public health staff (includes public health nurses, outreach nurses, STI nurses, community advocacy nurses, etc.)
- Physicians (e.g., physicians who conduct medical assessments as youth enter the MCFD system or intake for youth correction programs, family doctors, HIV care providers, etc.)
- Pharmacists
- Student health services staff
- Youth corrections staff

### **13. Will the HPV vaccine be offered to eligible males in school settings?**

No, GARDASIL® will not be offered to eligible males in school settings. Operationally it would be challenging for public health staff and, given the sensitivity of some of the eligibility criteria, eligible males may not want to present in a school setting. Parents with eligible sons that are school-aged should contact their local public health unit to receive the publicly funded GARDASIL® vaccine.

Health authorities are encouraged to consider including information about this new immunization program within established communications to parents of school-age males (e.g., in school newsletters).

### **14. How do I document administration of the vaccine to these boys and young men?**

Health care providers outside of public health should document the administration of GARDASIL® using pre-established protocols. Public health staff working in health authorities will input information about doses administered to individuals into existing immunization registry systems. Providers outside of public health should make concerted efforts to report back to public health on doses provided as applicable.

It is important to provide clients with proof of immunization for their personal records. The following are useful resources that providers should promote to their clients:

#### **1. ImmunizeCA App**

This app helps individuals and families keep track of their immunizations electronically. The benefit of using this app as a personalized electronic documentation record is that it keeps this information at hand, and may serve as a back-up to a missing paper-based immunization record. This app is available for free download at the App Store, Google Play and Blackberry World and can be accessed online at [immunize.ca/app](http://immunize.ca/app) for all smartphones.

#### **2. BCCDC Immunization Record Card**

This provincial hard copy resource is wallet-sized and practical for those who wish to keep documentation of immunization in their wallet. This resource can be accessed via the following link: <http://www.immunizebc.ca/sites/default/files/graphics/bccdc-record-wallet-card-out.pdf>

## 15. Will Panorama/PARIS immunization registries be updated to reflect the new HPV vaccine eligibility?

MSM is currently an available risk factor for recording in Panorama. If a practitioner enters MSM as a risk factor for a client 9 to 26 years of age, the client will be forecasted to receive the GARDASIL® series of 2 or 3 doses depending on their age at first dose. Other eligibility criteria for the new program (e.g., youth in custody) will not be available for entry into Panorama to avoid labelling. If a first dose of GARDASIL® is recorded for a male aged 9 to 26 years of age without the MSM risk factor, it will be assumed that the client meets one of these other eligibility criteria, and the remaining doses in the 2 or 3 dose series will be forecasted (depending on their age at first dose).

PARIS's immunization planner will not plan for GARDASIL® for this population but doses entered for this cohort will be validated.

## 16. How do I ensure continuity of care if my client uses a pseudonym?

Providers can encourage their clients to use the same pseudonym (even if it is not their real name) and the same birthday each time they book an immunization appointment. Vaccine lot numbers should be recorded in the client chart along with the date and site used. Providers can record administration details on the record of immunization given to clients and indicate when the next dose of the vaccine is due.

## 17. How will this change be communicated to other health care providers and what promotional materials will be available to them?

A "Dear Health Care Provider" letter will be issued. Regional health authorities can use and adapt this resource as needed when communicating to their respective health care providers about the new HPV immunization program.

These new eligibility criteria and administration guidelines will also be updated in Section VII of the [BC Immunization Manual](#) within the product pages for GARDASIL®.

Plans to develop promotional materials for the new program are underway. Posters and wallet-size brochures are being considered for development. These resources will be available online and can be ordered from health authorities on an as-needed basis. Health authorities will circulate promotional materials to providers and community groups as appropriate.

## 18. How will this change be communicated to the public?

The BC Ministry of Health issued a press release on July 7<sup>th</sup> 2015 informing the public of the HPV immunization program expansion. This press release can be accessed via the following link: <https://news.gov.bc.ca/stories/hpv-immunization-program-expanded-to-vulnerable-boys>

An updated HPV Health File will also be available shortly through HealthLinkBC <http://www.healthlinkbc.ca/>.

ImmunizeBC will have information regarding the new HPV program expansion prior to the start of the program this September.

All individuals that work closely with this population should promote this program to eligible males.

## 19. Why is the 9-valent HPV vaccine not going to be used for this program?

The 9-valent HPV vaccine (GARDASIL<sup>®</sup>9) was approved for use in Canada in January 2015. GARDASIL<sup>®</sup>9 covers the same four HPV strains as GARDASIL<sup>®</sup> but also covers HPV types 31, 33, 45, 52 and 58.

|                          | <b>Bivalent HPV Vaccine (CERVARIX<sup>®</sup>)</b> | <b>Quadrivalent HPV Vaccine (GARDASIL<sup>®</sup>)</b> | <b>9-valent HPV Vaccine (GARDASIL<sup>®</sup>9)</b> |
|--------------------------|--|--|---|
| <b>HPV types covered</b> | 16 and 18  | 6, 11, 16 and 18                                       | 6, 11, 16, 18, 31, 33, 45, 52 and 58                |

Approximately 20% of cervical cancers in females are caused by the five additional types in the 9-valent HPV vaccine.<sup>11</sup>

|                        | <b>6, 11, 16, 18 Contribution</b> | <b>31, 33, 45, 52, 58 Contribution</b> | <b>Total 9 Types</b> |
|------------------------|-----------------------------------|--|----------------------|
| <b>Cervical Cancer</b> | 70%                               | 20%                                    | <b>90%</b>           |

In contrast, these 5 additional types account for only 5% of HPV-associated invasive cancers in males. Therefore, the incremental benefit of 9-valent HPV vaccine in males is small.

There are currently no published data available for the 9-valent HPV vaccine in a 2-dose schedule. The National Advisory Committee on Immunization (NACI) has not yet issued a statement on the 9-valent HPV vaccine.



For more information about the 9-valent HPV vaccine, providers can refer to the U.S. Advisory Committee on Immunization Practices (ACIP) resource for health care providers on the 9-valent HPV vaccine:

<http://www.cdc.gov/vaccines/who/teens/downloads/9vHPV-guidance.pdf>

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