



HPV VACCINE ONE-TIME PROGRAM FOR YOUNG WOMEN QUESTIONS AND ANSWERS FOR IMMUNIZATION SERVICE PROVIDERS

July 16, 2013 – HPV Vaccine One-Time Vaccine Program for Young Women

British Columbia (BC) is expanding the time limited program of free HPV vaccination for young women. The CERVARIX® vaccine program has now expanded to include women ≤ 26 years of age and born before 1994 at the time of series commencement. This one-time program started in April 2012 for young women born in 1991-1993 and has now been expanded as outlined above. The program will continue until available vaccine supply is depleted or the vaccine has expired (August 2015). This program for the prevention of cervical cancer is in addition to the school-based program that has offered HPV vaccine since September 2008. Women born in 1994 or later remain eligible for the GARDASIL® vaccine program.

This document will assist public health and community vaccine providers in answering questions about the program.

1. Why is this one-time program being offered?

This program is being offered because the BC Communicable Disease Policy Advisory Committee chaired by Dr. Perry Kendall, the Provincial Health Officer recommended that BC offer a one-time catch up program for young women. The HPV vaccine is cost-effective in preventing precancerous changes and cancer of the cervix caused by HPV types 16 & 18 in women until about 26 years of age. With this program we are able to protect more women, while targeting our available resources where they can have maximum impact.

The vaccine is preventive, and does not clear already established HPV infection. Because HPV is sexually transmitted and is a common infection, the vaccine is most beneficial to use prior to onset of sexual activity. However, young women, even those who are sexually active, are unlikely to have been infected with both of the strains of HPV associated with cervical cancer, types 16 and 18, and will benefit from vaccination.

2. Why is the program being offered on a time limited basis?

The vaccine program was launched with available one-time funding. The vaccine was purchased by BCCDC and distributed in March 2012. All vaccine for this program has a long shelf life with an expiry date in August 2015. The quantity of vaccine purchased was for the anticipated uptake in young women born in 1991-1993 with a complete 3-dose series of vaccine. It was expected that most or all of the vaccine would be used within a year of its distribution. However, as of June 2013 over half of the original inventory is still available and as a result the CERVARIX® vaccine program eligibility has expanded.

3. How much vaccine will be made available?

Vaccine uptake is closely monitored. As of June 12th, 2013 a total of **44,000 doses** of this vaccine are still available in all public health stocks in BC, which is just over half of the originally purchased **80,000 doses**.

In the future to ensure that providers are informed about the status of this vaccine's supply given its time limited availability, monthly updates about the CERVARIX® supply and the program's progress will be posted on the ImmunizeBC website, in the health professional channel, HPV page: <http://immunizebc.ca/healthcare-professionals/hpv>

4. Which vaccine will be used for the program, and how was this decided?

CERVARIX® (GlaxoSmithKline Inc.) will be used for the one-time program. Vaccine for the one time program was purchased through a competitive tender issued in January 2012. This tender process has allowed us to provide additional protection against cancer to more women.

In its updated statement on HPV vaccines published in January 2012, the National Advisory Committee on Immunization (NACI) concluded that the bivalent vaccine CERVARIX® and the quadrivalent vaccine GARDASIL® (Merck Canada Inc.) provide comparable and very high levels of protection against cancer of the cervix due to HPV types 16 and 18 as well as precancerous changes to the cervix. HPV types 16 and 18 account for about 70% of cancer of the cervix. GARDASIL® also provides protection against HPV types 6 and 11, which cause about 90% of genital warts.

5. Should the vaccine be offered to any young woman of this age group?

Yes, any young woman ≤ 26 years of age at the time of series commencement, born before 1994, without contraindication to receipt of the vaccine should be offered CERVARIX® unless she has had 3 doses (a complete series) of either HPV vaccine in the past.

Clinical guidelines for the use of the vaccine are in the CD Manual, Chapter II, Immunization Program, Section VII, Biological Products, pages 25a/b posted at: <http://www.bccdc.ca/dis-cond/comm-manual/CDManualChap2.htm>

6. Which providers will offer immunization services, and when will the vaccine be available to them?

The vaccine was distributed to health authorities in March 2012 and was available for eligible women since April 2012. As of July 2013 the vaccine will now be offered to those who meet the expanded age-eligibility criteria.

Health authorities will continue to distribute the vaccine to physicians, pharmacists (see below), sexual health and youth clinics, college/ university student health services, and other appropriate immunization service provider settings.

Since April 9 2012, pharmacists authorized to immunize can order the vaccine. All pharmacies located in Vancouver Coastal Health Authority including Sunshine Coast and Howe Sound order from their local health unit. In other areas, the following pharmacies order from McKesson Canada (Coquitlam): Costco, Loblaws, London Drugs, Medicine Shoppe, Overwaitea, Paragon, Pharmasave, Rexall, Safeway, Shoppers, Target and Wal-Mart. All other pharmacies will order from their local health unit.

7. How is the vaccine administered, and what is the recommended schedule?

The vaccine is given intramuscularly in the deltoid (upper arm). The recommended schedule is 3 doses, with the second dose given 1 month after the first, and the 3rd dose given 6 months after the first dose. If a series is interrupted and the time between doses is longer than recommended, it does not need to be restarted, and the next dose should be given at the intervals outlined above. The minimum interval between the 1st and 2nd dose is 4 weeks, the minimum interval between the 2nd and 3rd dose is 12 weeks with a minimum interval of 20 weeks between the 1st and 3rd dose. Minimum interval guidance is provided for use in specific circumstances where the client cannot be immunized on the recommended schedule, and is not the preferred schedule. There are no recommendations for booster doses at this time.

8. Do young women need to return to the same immunization service provider for all three doses?

Young women should be encouraged to return to the same provider for series completion. This will allow providers to better forecast their vaccine requirements. However, this will not be possible in all circumstances and the series may be completed with another immunization service provider. To help young women find out where they can get the vaccine, an HPV vaccine locator is available at:

<http://www.dontgetcancer.ca/find-clinic>

9. What if the free vaccine is no longer available when the young woman presents for her 1st or subsequent doses?

As of July 2013, the remaining inventory is sufficient to complete all vaccination of young women who started their 3 dose series in this program, and we recommend that providers should feel confident in initiating a series for young women who have not yet begun their series. At this point in time, it's unlikely that such women will need to purchase a 2nd or 3rd dose themselves, as the publicly funded supply is still substantial and **the expiry date for most of this inventory is August 2015.**

If necessary, CERVARIX® is commercially available for purchase and costs about \$110/ dose. Patients should check with their extended health plans to determine if the cost of this vaccine is covered.

10. What if a young woman has already started on a series of HPV vaccine but has not completed it when she presents for CERVARIX®?

A completed 3 dose series is expected to provide protection against HPV types 16 and 18, regardless of the HPV vaccine(s) used. The National Advisory Committee on Immunization (NACI) recommends that the all 3 doses in an HPV vaccine series be completed with the same vaccine. Young women who started on GARDASIL® but wish to complete the series with CERVARIX® under this program may do so as long as they are aware that a series of fewer than 3 doses of the type 6 and 11 containing vaccine (GARDASIL®) may not provide complete protection against these two strains which cause about 90% of genital warts. If they wish such protection, they should complete the series with GARDASIL®.

The 2-dose series of GARDASIL® being offered in BC to girls in the grade 6 program is not recommended for use at older ages for either vaccine. As well, these girls will be receiving their 3rd dose starting in the fall of 2013 while in grade 9.

11. Will providers have a resource to obtain informed consent and provide a record of immunization to young women?

Yes, the BCCDC created a form for health care providers to obtain informed consent and record HPV immunizations. Further, this form authorizes the BCCDC to enter HPV vaccine records into the provincial immunization registry. This form has been revised as of July 11 2013 and is available at <http://immunizebc.ca/healthcare-professionals/hpv>. The completed form is to be faxed to the BCCDC Immunization Program at (604) 707-2515.

The completed forms sent to the BCCDC will be maintained electronically long term and can potentially be linked to clinical service provision in the future. Pap smear recommendations have not yet changed in relation to HPV vaccine receipt, but it is expected that the receipt of vaccine will have implications for interpretation and management of Pap smear results in future years. Therefore, entry of the record into the immunization registry is important for clinical management. As well, if a vaccine recipient loses their paper record and that record has been entered into the immunization registry, it can be retrieved by contacting their local health unit.

All providers must maintain a clinical record of the immunization service, as required by their professional practice standards. A personal record of immunization should also be provided to the recipient and include the vaccine, product name and date of each dose received.

12. What else is being done to promote the use of this vaccine for this program?

An immunization promotion campaign to support the roll out of vaccine launched in March 2013. This campaign included a series of posters, a text reminder service, online advertising, an HPV vaccine clinic locator and the creation a new microsite: www.dontgetcancer.ca. Young women are encouraged to sign up for the text reminder system at 604-227-4474 after their 1st dose to automatically receive reminders for the 2nd and 3rd doses of their HPV vaccine series. For further details go to: <http://www.dontgetcancer.ca/save-the-date>

13. Why is this program not being offered to boys?

At this time recommendation for publicly funded HPV vaccine for boys has not been made in BC. Only one of the two HPV vaccines is approved for use in males, and that is GARDASIL®.

14. Where else can I find reliable information about this vaccine and about HPV vaccination in general?

Further information is available through the following web sites:

- ImmunizeBC health care professional materials:
<http://immunizebc.ca/healthcare-professionals/hpv>
- January 2012 NACI statement on HPV vaccine:
<http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/12vol38/acs-dcc-1/index-eng.php>
- Public Health Agency of Canada HPV vaccine information:
<http://www.phac-aspc.gc.ca/std-mts/hpv-vph/fact-faits-eng.php>
- GlaxoSmithKline Inc. CERVARIX® Product Monograph:
<http://www.pscervarix.ca/en/product-monograph.aspx>