

**HUMAN PAPILLOMAVIRUS  
VACCINATION PROGRAM**

**GARDASIL™**

Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18)  
Recombinant Vaccine  
Active Immunizing Agent  
Merck Frosst

# **HUMAN PAPILOMAVIRUS (HPV)**

## **WHAT IS HPV?**

HPV is a common virus.

There are many different types of HPV. Some do not cause harm, while others can cause diseases of the genital area. For most people, the virus goes away on its own within 1 or 2 years. If the virus does not go away, it can develop into cervical cancer, precancerous lesions, or genital warts, depending on the HPV type. HPV Types 6, 11, 16, and 18 account for the majority of HPV-related clinical diseases.<sup>1</sup>

In North America, HPV is estimated to infect half of all sexually active women between the ages of 18 and 22.<sup>2</sup> In addition, approximately 75% of sexually active Canadians will have at least one HPV infection during their lifetime. HPV infection is most common in women aged 20-24 years.<sup>3</sup>

## **HOW DO PEOPLE GET HPV?**

Both women and men can get HPV. Anyone who has any kind of sexual activity involving genital contact with an infected person can get HPV—INTERCOURSE IS NOT NECESSARY! Many people who have HPV may not show any signs or symptoms, so they can pass the virus on without even knowing it. HPV is easily transmitted.<sup>1</sup>

## **WHAT DISEASES ARE ASSOCIATED WITH HPV?**

-  Cervical cancer
-  Vulvar cancer
-  Vaginal cancer
-  Precancerous lesions
-  Genital warts

## **WHAT IS CERVICAL CANCER?**

Cervical cancer is cancer of the cervix (the lower part of the uterus that connects to the vagina). Cervical cancer may be caused by certain types of HPV. When a female becomes infected with certain types of HPV and the virus does not go away on its own, abnormal cells can develop in the lining of the cervix. If they

are not discovered early and treated, these abnormal cells can turn pre-cancerous and then cancerous.<sup>1</sup>

Cervical cancer is the second most common type of cancer in Canadian women ages 20 to 44 (breast cancer is the most common). Over 1350 Canadian women were diagnosed with cervical cancer in 2001, and 400 women died from it.<sup>3</sup>

## **WHAT IS VULVAR CANCER?**

The vulva is the outside part of the vagina. There are two prominent skin folds, known as the *labia majora*, and two small, hairless skin folds called the *labia minora*. The clitoris is found below the spot where the two labia minora meet.

Cancer of the vulva most often affects the inner edges of the *labia majora* or the *labia minora*, but it can also occur on the clitoris.<sup>4</sup>

## **WHAT ARE GENITAL WARTS?**

Genital warts are flesh-colored growths that appear in or around the genital area. They can occur on the penis, in and around the vagina, or in and around the anus/rectum. The types of HPV that cause genital warts are different from the types that can cause cervical cancer. About 2 out of 3 people who have sexual contact with a person who has genital warts will get them. It can take weeks, months or years after contact with an infected partner for warts to occur. The lifetime risk of getting genital warts has been estimated to be over 10%.<sup>3</sup> Genital warts can be treated, but if the HPV is still in the body, 25% of warts will come back within 3 months.

## **PROTECTION AND PREVENTION**



The only way to totally protect against HPV is to avoid any sexual activity that involves genital contact. Condoms may help to protect against HPV infection, but are not 100% effective. There is also a new vaccine called GARDASIL that will help prevent certain types of HPV infections.

### **WHAT IS GARDASIL?**

GARDASIL is a new vaccine that protects against the Human Papillomavirus. It is the only vaccine that may help guard against diseases caused by HPV types 16 and 18, which cause 70% of cervical cancer cases, and HPV Types 6 and 11, which cause 90% of genital warts cases.<sup>1</sup>

The goal of vaccination is to protect young women against HPV and its associated diseases, before they are ever exposed to the virus. This means before they are sexually active!

### **CAN THE GARDASIL VACCINE CAUSE HPV?**

NO! The vaccine contains virus-like particles prepared from HPV Types 6, 11, 16, and 18. These particles do not contain viral DNA and they cannot infect cells or reproduce. Therefore you cannot get HPV from the vaccine.

### **WHO SHOULD BE VACCINATED WITH GARDASIL?**

Girls and women ages 9 to 26 years should be vaccinated to prevent infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, and 18. GARDASIL works when given before a person has any contact with HPV Types 6, 11, 16, and 18. It is best to be vaccinated at a young age, before a woman becomes sexually active.

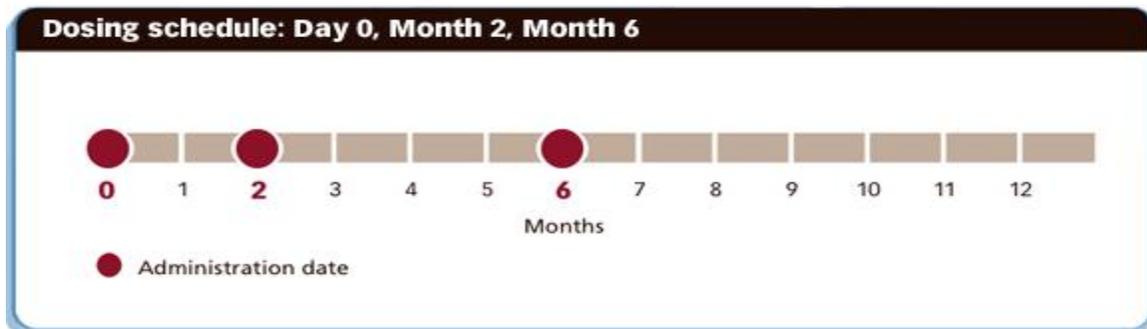
## HOW IS GARDASIL GIVEN?

GARDASIL is given in the muscle of the upper arm or thigh in 3 separate 0.5-mL injections over 6 months:

First dose: At a date you and your doctor or healthcare professional choose

Second dose: 2 months after the first dose

Third dose: 6 months after the first dose



Getting all 3 doses will allow you to get the full benefits of GARDASIL. All 3 doses should be given within 1 year.

## WHY IS IT IMPORTANT TO BE VACCINATED EARLY?

Like other vaccines, GARDASIL works to help prevent illness. GARDASIL works when given before there is any contact with HPV Types 6, 11, 16, and 18. That's why it's important to get vaccinated now—not later. Early vaccination will help to protect against future cervical cancer and genital warts.

## WHAT IF I ALREADY HAVE HPV?

It would still be beneficial to be vaccinated with GARDASIL, because it is unlikely that you have been infected with all 4 types of the virus covered by the vaccine.

## **ARE PAPER TESTS STILL NECESSARY AFTER BEING VACCINATED?**

YES! Vaccination with GARDASIL does not take the place of Pap tests (cervical cancer screenings). GARDASIL may not fully protect everyone and does not prevent all types of cervical cancer, so it is important to continue regular cervical cancer screenings. Pap tests have been proven to help save lives.

A Pap test looks for abnormal cells in the lining of the cervix before they have the chance to become precancerous or cervical cancer. The more severe the abnormality, the more likely it is that cervical cancer could develop in the future. Having an abnormal Pap test is not a reason to panic—it does not always mean that you are at risk for cancer or even have HPV. Your doctor or healthcare professional may repeat the Pap test or do other tests as needed. Pap tests will still be an important part of taking control of your health—and taking care of yourself.<sup>1</sup>

Women who are 21 years or older, and females under 21 years of age who have been sexually active for three years or more, should have a pap test done. There is no age limit. Once a woman become sexually active, she should have a yearly pap. If she has 2 normal pap tests, and is not taking any birth control or hormones, she should have a pap done every 2 to 3 years. However, if she is taking birth control or hormones, she should have a pap every year.<sup>4</sup>

## **IMPORTANT INFORMATION ABOUT GARDASIL**

Anyone who is allergic to the ingredients of GARDASIL should not receive the vaccine. Non-medical ingredients include aluminum, sodium chloride, L-histidine, polysorbate, sodium borate and water. The product does not contain preservatives or antibiotics.

GARDASIL is not for women who are pregnant.

GARDASIL will not treat these diseases and will not protect against diseases caused by other types of HPV.

## **POSSIBLE SIDE EFFECTS OF GARDASIL**

-  Pain, swelling, itching, and redness at the injection site
-  Fever
-  Nausea
-  Dizziness

## WHAT IS THE COST OF GARDASIL?

Currently, GARDASIL is not included on any provincial vaccination programs. However, young females should ask their healthcare providers for more information. A doctor can provide a written prescription for the three required shots.

Each dose (0.5 ml) cost's \$169.52 total from the pharmacy. Total cost / person = \$508.56. Gordon Stueck has chosen to sell GARDASIL from his pharmacy at the wholesaler price plus refrigeration cost, as he considers this to be a strong health issue. This works out \$156.42 / dose x 3 = \$469.26.

In the long run, vaccination with GARDASIL will save the health care system money. The overall yearly cost of invasive disease and death in Canada from cervical cancer has been estimated to be ~ \$270 million.

The cost of the vaccination is minimal, if you take into account what you may be preventing. Consider the cost of travel time for treatments for HPV diseases, and the emotional turmoil and uncertainty associated with further testing and delays. In addition, if a female becomes infected with HPV, she will require more frequent monitoring. For example; women with HPV types 16 and 18 should undergo a colposcopy every 6 months. These tests are not pleasant.

Please consider the HPV vaccination program. If you have any further questions, contact myself or Gordon Stueck at Stueck Pharmacy Ltd. in Leader, Sk.

### References:

- 1) Merck. Gardasil [Online]. [cited 2007Jan 04]; Available from: URL: <http://www.gardasil.com>.
- 2) Cervical cancer vaccine approved in Canada. CBC News [Online]. 2006 Jul 18. [cited 2007 Jan 04]; Available from: URL: <http://www.cbc.ca/health/story/2006/07/18/cervical-cancer.html>.
- 3) Compendium of Pharmaceuticals and Specialties. Gardasil Product Monograph [online version (e-CPS)]. CPhA, 2007. [cited 2007 Jan 04]; Available from: URL: <https://www.e-therapeutics.ca>.
- 4) American Cancer Society. Cancer Reference Information [Online]. [cited 2007 Jan 09]; Available from: URL: <http://www.cancer.org>.