

Human Papillomavirus (HPV) Vaccine Update – Recommendations for Males and Females

Date:	May 22, 2013
To:	Board of Health
From:	Medical Officer of Health
Wards:	All
Reference Number:	

SUMMARY

Human Papillomaviruses (HPV) are the cause of almost all cervical cancers, are a leading cause of other genital cancers and warts, and contribute to cancers of the head and neck. Three out of every four Canadians will have at least one HPV infection in their lifetime. Each year the diagnosis and treatment of HPV-related infections cost the Canadian health care system more than \$300 million.

In 2007, the National Advisory Committee on Immunization (NACI) issued a statement recommending the use of the HPV vaccine for females between nine and 26 years of age to prevent cervical cancer, as well as other infections such as genital warts. That year, the Ontario Ministry of Health and Long-Term Care (MOHLTC) made the HPV vaccine publicly available, free of charge, to all grade 8 girls (13-14 years of age). In September 2012 the MOHLTC also funded a “catch-up” program to vaccinate females born between 1993 and 1998 who had not received all three HPV shots while in grade 8.

Toronto Public Health (TPH) provides HPV vaccine to over 13,000 grade 8 females each year and since September 2012 has also provided over 9,000 vaccinations to females born between 1993 and 1998 in over 60 catch-up community vaccination clinics. As TPH already provides school-based vaccines to grade 7 students (hepatitis B and meningitis vaccines), providing the HPV vaccine to grade 7 females instead of grade 8 females would create efficiencies in the program. Girls could receive any catch-up doses at school-based clinics in grade 8 instead of having to attend a TPH community clinic while in secondary school.

In January 2012, NACI added a recommendation for all males aged nine to 26 to receive HPV vaccine to prevent anal and genital cancers and genital warts. It also recommended

HPV vaccine for all males who have sex with males since they have a disproportionately higher burden of HPV infections. Vaccinating males with HPV vaccine will also reduce the spread of HPV infection to females. Ontario's MOHLTC has not to date acted on this recommendation, and the HPV publicly funded vaccination program remains available only to females in grades 8-12.

In April 2013, Prince Edward Island announced it will be the first province to publicly fund an HPV vaccination program for boys, though other provinces are considering the decision. In February 2013 Australia became the first country to provide publicly funded HPV vaccine to males aged 12-13 years as part of a school-based vaccination program.

Currently males in Ontario can be vaccinated through their health care provider at a cost of approximately \$400 to \$500 for all three shots. This is a significant cost to access a potentially lifesaving vaccine.

Providing the HPV vaccine free of charge to males through TPH's vaccination program supports the principles of health equity. In addition, expanding the HPV vaccination program to males will provide important health benefits not only to the male population, but to society as a whole by: limiting/reducing the spread of infection (genital warts), and reducing morbidity and mortality (due to cancer) and costs to the health care system related to the diagnosis and treatment of genital warts and HPV-associated cancers.

This report outlines the importance of maintaining the publicly funded HPV vaccination program for females (including the catch up program), and recommends the expansion of the school-based publicly funded program to adolescent males and males who have sex with males.

RECOMMENDATIONS

The Medical Officer of Health recommends that:

1. The Board of Health urge the Minister of Health and Long-Term Care to:
 - a) Increase efficiency of the current publicly funded HPV school-based vaccination program for females by administering it in grade 7 rather than grade 8;
 - b) Expand the HPV catch-up program for females in grades 9-12 to include females up to age 26;
 - c) Expand the publicly funded HPV vaccination program to include males in grade 7;
 - d) Consider a catch-up HPV vaccination program for males in grades 9-12;
 - e) Publicly fund the HPV vaccine for men who have sex with men, especially those with HIV;
 - f) Develop a comprehensive educational campaign to improve HPV immunization coverage, including for males; and

- g) Work with Public Health Ontario to continue to monitor adverse events following immunization for the HPV vaccine and report publicly to ensure the ongoing safety of the vaccine.
2. This report be forwarded to the Chief Medical Officer of Health and the Ontario Provincial Immunization Review Task Group and its sub-committees for consideration in the Task Group's final report expected in September 2013.
3. Forward this report to the Provincial Infectious Diseases Advisory Committee on Immunization, the Association of Local Public Health Agencies, the Council of Medical Officers of Health in Ontario, Cancer Care Ontario, the Ontario Public Health Association, the Canadian Paediatric Society, the Society for Obstetrics and Gynecologists of Canada and the Public Health Agency of Canada.

Financial Impact

There are no direct financial impacts flowing from this report.

DECISION HISTORY

At the January 20, 2012 meeting, the Board of Health (BOH) received the report on Inequalities and Immunization Rates in Toronto School Children. The BOH requested the Medical Officer of Health to report on the advisability of including voluntary HPV immunization for males.

<http://app.toronto.ca/tmmis/viewAgendaItemHistory.do?item=2012.HL10.4>

In addition, three other Board of Health reports have detailed the HPV vaccination program for female students in Toronto:

1. September 4, 2008, Human Papillomavirus (HPV) Vaccination Program - Staff Report
<http://www.toronto.ca/legdocs/mmis/2008/hl/bgrd/backgroundfile-15460.pdf>
2. September 4, 2007, Human Papillomavirus (HPV) Vaccination Program for Grade Eight Females - 2007/08
<http://www.toronto.ca/legdocs/mmis/2007/hl/bgrd/backgroundfile-6598.pdf>
3. June 21, 2007, Public Funding of Human Papillomavirus (HPV) Vaccine
<http://www.toronto.ca/legdocs/mmis/2007/hl/bgrd/backgroundfile-5394.pdf>

ISSUE BACKGROUND

Human Papillomavirus (HPV) Infection

Human Papillomavirus is the most prevalent sexually transmitted infection (STI) in Canada. Three out of every four Canadians will have at least one HPV infection in their lifetime. While 90% of HPV infections resolve on their own without treatment, in some individuals it can lead to cancer of the cervix, genitals and anus, and can cause genital warts. HPV infection can also cause cancers of the throat, mouth and respiratory tract.

HPV is most commonly spread during sexual activity by skin to skin contact with an infected partner. A condom may not always protect against the spread of HPV. The total burden of HPV-associated cancers among males and females is estimated at 5.2% of all cancers worldwide. HPV infections cause over 90% of genital warts in males and females. In females, HPV infection causes almost all cervical cancer, and contributes to other genital cancers. In men, HPV infection is associated with 80-90% of anal cancers, 40-50% of penile cancers, 35% of throat cancers and 25% of mouth cancers. The rates for HPV infections are higher in males who have sex with males (MSM). While pap tests detect cervical cancer in women, no comparable screening test for penile or anal cancer exists for men.

The rates of genital warts are higher in males than in females and contribute negatively to quality of life. The rates peak in women between 20 to 24 years of age and 25 to 29 years of age in men. There is no cure for genital warts so once infected, lifetime treatment may be required.

Each year the diagnosis and treatment of cervical dysplasia (abnormal cells on the surface of the cervix), cervical cancer and genital warts are estimated to cost the Canadian health care system more than \$300 million.

HPV Vaccines

Two HPV vaccines are licensed for use in Canada: Gardasil[®] and Cervarix[®]. Gardasil[®], prevents infection from cancer-causing HPV types 16 and 18 and types 6, 11 which cause 90% of genital warts. It was approved by Health Canada for use in females in 2006 and for males in 2010. Cervarix[®] was approved for females in 2010; it protects against the cancer-causing HPV types (16, 18). Among HPV-associated cancers, HPV types 16 and 18 cause approximately 70% of cervical cancers, 92% of anal cancers, 63% of penile cancers and 89% of mouth and throat cancers.

All HPV vaccines should be given before the start of sexual activity to be most effective. NACI has recommended it can be given to individuals who are sexually active as they likely would not have been infected with all of the types of HPV found in the vaccine and can thus still be protected. Scientific studies confirm that HPV vaccines are very effective. When given before becoming infected, both HPV vaccines are over 95% effective to prevent the HPV types included in the vaccine.

HPV Vaccine Recommendations

In January 2012, the National Advisory Committee on Immunization (NACI) updated its 2007 recommendations for HPV vaccine. NACI maintained the recommendation for all females aged nine to 26 years of age, and added females up to 45 years of age. NACI also recommended the HPV vaccine for all males aged nine to 26 years of age to prevent anal and genital cancers as well as genital warts. Males who have sex with males are particularly at high risk, especially if they are HIV positive, and are also recommended to receive the vaccine.

HPV Vaccine Safety

Over 111 millions of doses of HPV vaccines have been provided around the world, demonstrating an excellent safety record. In Canada, the safety of HPV vaccines is constantly monitored by the Public Health Agency of Canada. Toronto Public Health tracks adverse events following immunization and reports these to the Public Health Agency of Canada.

As of March 31, 2013, TPH has administered over 159,000 doses of HPV vaccine. A total of 29 (0.02%) adverse reactions have been reported - most were mild and self-limiting, such as a rash or feeling faint. There were three anaphylactic reactions which resolved immediately with treatment and there were no lasting effects.

HPV Vaccination Programs in Canada

To date, HPV vaccination programs in Canada have focused vaccination on pre-adolescent and adolescent females to primarily prevent cervical cancer. HPV vaccine is provided in every province and territory in Canada to females from grades 4 to 8 and older. Some provinces have provided catch-up programs for older females. Despite the availability of publicly-funded programs, coverage rates have varied across regions, with rates close to 85% in Maritime provinces and Quebec but as low as 50% in other provinces such as Alberta, and between 50-60% in Ontario.

Ontario's HPV Vaccination Program

HPV vaccination programs began in 2007 after federal start up funding was allocated to provinces and territories. In September 2007, grade eight females in Ontario became eligible to receive publicly funded HPV vaccine through school-based clinics. Recently, in June 2012, the MOHLTC announced that all females who were once eligible for HPV vaccine in grade 8, and who did not participate or receive all three doses, were eligible to complete the program for free (known as the catch-up program).

Toronto Public Health's HPV Vaccination Program

Since 2007, TPH has offered vaccine to more than 12,000 grade eight girls in over 400 Toronto schools each year. Three clinics are held at each school throughout the year to provide the three doses within four to six months. Additional catch-up clinics are now held in the evenings and during the summer for girls who missed one of their doses.

The grade 8 program is voluntary and requires parental consent. Each girl receives an information package from TPH to take home to her parents at the start of the school year, including a letter outlining the program, a fact sheet on the HPV vaccine, and a consent form. The HPV fact sheet is translated into 12 languages. TPH also provides a teaching package for grade 8 teachers to provide to students.

For the 2011/12 school year, the HPV vaccination rate for grade 8 females in Toronto schools was 65% for all three doses, higher than the provincial average. As of April 30, 2012, TPH has vaccinated almost 50,000 grade 8 girls with a full 3-dose vaccine series since the program began in 2007. Since September 2012, the TPH catch-up clinics

available to females born between 1993 and 1998 have provided over 9,000 doses at over 60 community clinics.

COMMENTS

A key reason for vaccinating boys with the HPV vaccine is that it will not only protect males against HPV-related diseases, it will also provide indirect protection of women by reducing the transmission of HPV. If HPV vaccination rates in females were high (>80-90%), immunizing girls would be the most cost-effective method of preventing HPV disease in women. Unfortunately the acceptance of the HPV vaccine has been varied in many jurisdictions. Australia and the United Kingdom are among the few countries that have high HPV vaccination rates at about 85% or more. In the United States rates have been quite low, hovering around 50%. In Canada, vaccination rates range from province to province from 50 to 85%. Poor vaccine up-take in North America has been influenced by false information about the HPV vaccine, which has increased parents' concerns regarding safety.

As awareness grows of the role HPV plays in other diseases, arguments can be made for a publicly funded vaccination program for both genders. HPV is widespread among men, with recent studies showing that half of all adult males may be infected with the virus. Heterosexual males may be afforded indirect protection if all females are immunized. However men who have sex with men receive no protection from a female-only vaccination program.

Publicly Funded HPV Vaccination Programs for Males

In February 2013, Australia became the first country to provide publicly funded HPV vaccine to males aged 12-13 years as part of a school-based vaccination program. Males aged 14-15 years will also receive the vaccine as part of a catch-up program until the end of the 2014 school year. Australia has offered free HPV vaccinations to girls between the ages of 12 to 13 years old since 2007. Catch-up programs for females 13 to 18 year olds and 18 to 26 year olds were implemented from 2007 through 2009. Vaccination rates among females in Australia are high, at over 80% in the eligible cohorts. Australia has already been able to see a reduction in pre-cancerous lesions in young women and a reduction in genital warts in young women and men.

In the US, males aged nine to 18 who meet eligibility criteria for the Vaccines for Children Program, such as Medicaid-eligible or the uninsured, can receive free HPV vaccine, though this is not a universal program for all males.

In April 2013, Prince Edward Island (PEI)'s Department of Health and Wellness announced that they will provide HPV vaccine to males as part of their grade 6 program beginning September 2013. This is the first province in Canada to provide publicly funded HPV vaccine to males. The rationale for providing HPV vaccine to males in PEI was based on declining costs for the HPV vaccine, coupled with stable provincial funds for the HPV vaccination program. In seven years since the program was started, the vaccine costs have declined substantially. PEI's Chief Public Health Officer has advised

that this was one of the major factors in expanding the program to males. The declining cost in the vaccine has made it feasible to expand the program to males without any additional costs or investment to PEI's provincial budget.

Ethical Arguments for an HPV Vaccination Program for Males and Females

From a health equity perspective, the vaccine should be provided to both males and females. Currently females in the right age group can get all three shots (a value of \$400 to \$500) for free, while males who want protection are forced to pay out of pocket.

While the HPV vaccine Gardasil[®] does have the potential to prevent cervical cancer in females, it will also prevent genital warts which are a burden for both males and females. In fact, the burden of genital warts is higher in males, in addition to the burden of other male genital cancers.

Providing the vaccine to males may reduce the stigma associated with a female-only vaccine, such as was seen with the rubella vaccine. In the 1970's the rubella vaccine was provided to females to prevent congenital rubella syndrome, a condition that occurs when a pregnant women contracts rubella infection during pregnancy. The risks to healthy males for rubella were minimal. However, the rates of rubella vaccination among females were not high. When rubella vaccine was provided to both males and females universally, then vaccination rates among women increased.

NACI has recommended the HPV vaccine for all males aged 9-26, but especially for MSM as they are particularly at higher risk. By the time males self-identify as MSM, they have usually begun sexual activity whereas the HPV vaccine is most effective if given before the onset of sexual activity. Having a universal program for all pre-adolescent/adolescent boys will capture this high risk group in time to protect them.

Cost Implications to Add an HPV Vaccination Program for Males

The economic burden of HPV-related disease is significant and there is increasing awareness of the role of HPV in causing other diseases such as head and neck cancers. In 2007 the Society of Obstetricians and Gynecologists of Canada issued the Canadian Consensus Guidelines on Human Papillomavirus, projecting an annual economic burden of \$300 million. The majority of this cost (\$244 million) is due to 9.3 million Pap tests conducted annually; the remaining \$53.7 million was estimated to be due to genital or cervical disease. The impact of HPV infection on other cancers such as head and neck and respiratory papillomatosis was not included in this analysis.

After seven years of the publicly funded program in Ontario, HPV vaccination rates among females have been slow to rise. The price of Gardasil[®] was recently reported as reduced. If the budget allotted for the program has not changed, then the additional cost for governments to provide vaccine to males and females through school-based programs would be partially offset by price savings. Canadian researchers have recently reported that a two dose HPV vaccination schedule may be feasible for pre-adolescent females.

This will further reduce costs as the third dose of vaccine may not be required in this age group, similar to findings from research on the hepatitis B vaccine.

The benefits of providing the vaccine to a cohort of males will be a reduction in genital warts, genital cancers in males as well as increasing the herd protection so that women are further protected.

Move School HPV Vaccination Program to Grade 7

If the HPV vaccine were provided in grade 7, it would create efficiencies and potentially reduce costs. Currently TPH provides hepatitis B and meningitis vaccine to grade 7 students. Adding HPV vaccine to grade 7 when TPH staff are already in the school will improve efficiencies, create an opportunity to provide catch-up vaccinations in grade 8 and is safe. This recommendation has also been put forward by Ontario's Provincial Infectious Diseases Committee on Immunization.

Ontario's Immunization System Review

The MOHLTC is currently undertaking a review of Ontario's publicly funded immunization system. The review will inform the Ministry's development of a five-year immunization plan for the province. The review began in the fall 2012. A final report is expected to go to the Chief Medical Officer of Health in the summer/fall of 2013.

As well, Ontario's Public Health Sector Strategic Plan, launched April 2013, has as its second strategic goal to improve the prevention and control of infectious diseases, with a focus on immunization.

Given the Immunization System Review and Public Health Sector Strategic Plan, the timing is ideal to evaluate and expand Ontario's current HPV vaccination program to males and females, and to offer the program in grade 7 instead of grade 8. Providing the HPV vaccine to both males and females before the onset of sexual activity has the potential to save many lives from HPV-related cancers, reduce health care costs and improve quality of life from a reduction in genital warts.

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