



**STAFF REPORT
ACTION REQUIRED**

**Human Papillomavirus (HPV) Vaccination Program
for Grade Eight Females – 2007/08**

Date:	September 4, 2007
To:	Board of Health
From:	Medical Officer of Health
Wards:	All
Reference Number:	

SUMMARY

Human Papillomavirus (HPV) infection causes genital warts and cervical cancer. Three out of every four Canadians will have at least one HPV infection in their lifetime. In 2006, there were an estimated 510 cases of cervical cancer and 150 deaths in Ontario.

A new HPV vaccine, Gardasil[®], has been licensed to prevent the four most common HPV strains. The strains included in the vaccine are responsible for 70% of cervical cancer and 90% of genital warts in Canada. The vaccine has been reviewed and recommended by the independent National Advisory Committee on Immunization for females between nine and 26 years of age. The cost of the vaccine is approximately \$150.00 per dose and three doses over six months are required to complete the series. The vaccine works best if given before the onset of sexual activity.

On August 2, 2007, the Ministry of Health and Long-Term Care (MOHLTC) announced funding for the HPV vaccine for all grade eight females in Ontario. The vaccine will be administered by public health units across the province in school based clinics beginning in fall 2007.

This report provides information on Toronto Public Health's Human Papillomavirus (HPV) Vaccination Program for grade eight female students in the 2007-08 school year. It recommends that the 2007 Toronto Public Health Operating Budget be increased by \$120,000 gross and \$0 net to reflect funding from the MOHLTC for the administration of HPV vaccine in school clinics.

RECOMMENDATIONS

The Medical Officer of Health recommends that:

1. the Toronto Public Health 2007 Approved Operating Budget be increased by \$120,000 gross and \$0 net to reflect funding from Ministry of Health and Long Term Care (MOHLTC) for the administration of Human Papillomavirus (HPV) Vaccine in school clinics; and
2. the Board of Health forward this report to the Budget Committee for consideration.

Financial Impact

Source of Funds	2007			2008 Gross Incremental
	Gross	Revenue	Net	
One-time funding from the Ministry of Health & Long-Term Care for the HPV Vaccination Program - 2007/2008	\$ 120,000	\$ 120,000	\$ -	\$ (60,000)

One-time funding of \$180,000 is allocated as follows: \$120,000 in 2007 & \$60,000 in 2008

The Ministry of Health and Long-Term Care is funding \$8.50 per dose administered for the HPV Vaccination Program to grade eight females. There are an estimated 14,000 eligible females who attend Toronto schools. It is estimated that a 50% coverage rate will be achieved in the first year of the HPV vaccination program. Two doses will be administered in fall 2007 and the third dose in 2008. One-time funding from the MOHTLC to cover the cost of the third dose from January to June 2008 will be approximately \$60,000.

The Deputy City Manager and Chief Financial Officer has reviewed this report and agrees with the financial impact information.

ISSUE BACKGROUND

At its meeting of July 9, 2007 the Board of Health requested that the Government of Ontario include HPV vaccine as a publicly funded immunization for females between the ages of nine and 26 years, with priority given to females between nine and thirteen years of age, and that public health units receive funding to administer the vaccination program.

On August 2, 2007, the MOHLTC announced funding for the Human Papillomavirus (HPV) vaccine for all grade eight females in Ontario. The funding for this program is being provided through the March 2007 federal budget initiative and represents an investment of \$117 million for the province over three years.

Public health units across the province are expected to initiate a school-based HPV vaccination program for the 2007-08 school year. Three doses of HPV vaccine are required (given at 0, 1-2 and 6 months). Health units will be reimbursed \$8.50 per dose of vaccine administered. An estimated 14,000 females are enrolled in grade eight in 440 schools in Toronto. The vaccination will be voluntary and will require parental consent. Students will not be suspended if they are not vaccinated.

HPV is a viral infection that can lead to cervical cancer and genital warts. The vaccine Gardasil® was approved by Health Canada on July 11, 2006. The vaccine can prevent infection against four strains of HPV– strains 6, 11, 16, 18. In Canada, strains 16 and 18 cause 70% of cervical cancer and strains 6 and 11 cause 90% of genital warts. On February 15, 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. Vaccination for HPV is most beneficial if given to females before sexual activity begins.

All public health units in Ontario will implement the HPV vaccination program as part of the school-based vaccination programs which include Hepatitis B and Meningitis C vaccination for grade seven students.

COMMENTS

The Human Papillomavirus (HPV)

Human Papillomavirus is the most prevalent sexually transmitted infection (STIs). Three out of every four Canadians will have at least one HPV infection in their lifetime. HPV infection usually resolves without treatment, but in some individuals it can lead to cancer of the cervix and genitals, and can cause warts. HPV infection is not legally reportable to the Medical Officer of Health.

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.

HPV causes almost all cases of cervical cancer in Canada. It is estimated that HPV types 16 and 18 cause over 70% of cervical cancers. Cervical cancer is the third most common type of cancer affecting Canadian women between 20 and 49 years of age. In 2006, there were approximately 1,350 new cervical cancer cases and 390 deaths in Canada. In Ontario, there were an estimated 510 cases and an estimated 150 deaths from cervical cancer. HPV types 6 and 11 cause over 90% of genital warts in Canada. There are treatments and medication to remove warts, but even if treated successfully, there is no cure for HPV infection and genital warts can recur. Each year the diagnosis and treatment of cervical dysplasia (abnormal cells on the surface of the cervix), cervical cancer and genital warts is estimated to cost the Canadian health care system more than \$300 million. With the introduction of HPV vaccination, regular Pap screening programs still need to continue.

The HPV Vaccine

Gardasil[®] is the only HPV vaccine currently licensed in Canada to prevent the four most common strains of HPV – 6, 11, 16 and 18. It is manufactured by Merck Frosst Canada Ltd. It is recommended for females between 9 and 26 years of age. The HPV vaccine is safe and well tolerated. The cost of the vaccine is approximately \$150.00 per dose; three doses are required to complete the series. There is currently no licensed HPV vaccine for males but studies are on-going. Another vaccine against HPV, Cervarix[™] is under Health Canada review.

Scientific studies confirm that the Gardasil[®] vaccine is very efficacious against the four HPV strains in the vaccine. It is most effective if given before the onset of sexual activity since it is not as effective once HPV infection has occurred. As has been the case for other new vaccines at the time of licensing, the long-term efficacy and need for booster doses, and the long-term safety of Gardasil[®] are unknown at this time. Gardasil[®] has been studied in nearly 30,000 women in 33 countries at 130 investigation sites. The longest follow up to date is five years. The vaccine has been safe and well tolerated in studies carried out to date. The most common side effect from vaccination is inflammation at the site of injection. Serious side effects appear to be rare but will be monitored as the vaccine is used in larger populations. The vaccine is licensed for use in other countries including the entire European Union, the United States, Australia, New Zealand, Mexico, Brazil and others.

The use of Gardasil[®] to prevent cervical cancer should be accompanied by education and regular Pap test screening, since the vaccine does not protect against all strains of HPV or other sexually transmitted infections.

Implementation of HPV Vaccination Program for Grade Eight Females

The goals of the HPV Vaccination Program include offering the HPV vaccine to grade eight females in all 440 Toronto schools with grade eight classrooms and to achieve initial immunization coverage rates of 50% (7000 females) or more.

Currently Toronto Public Health does not provide school-based vaccination clinics to grade eight students. The HPV immunization program will be implemented along with the Hepatitis B (HBV) and Meningitis C (MenC) immunization programs for grade seven students. TPH nurses currently visit over 400 schools with grade seven classrooms twice each year to offer HBV and MenC vaccine. A third visit to schools will be added to the schedule to accommodate the three-dose schedule of the HPV vaccine. The following is the schedule for vaccine administration:

- First shot from September 17 to November 9, 2007 (HPV, HBV, MenC)
- Second shot from November 12 to January 25, 2008 (HPV only) and
- Third shot from February 11 to June 13, 2008 (HPV, HBV, MenC)

TPH is working closely with the Toronto District School Board and the Toronto Catholic District School Board to ensure the schools are aware of the new program and that clinics are scheduled with the least disruption to the schools.

Efforts will be made to ensure that all eligible females are informed about this program. A media campaign consisting of a press release will announce the program to parents and the community at the beginning of the school year. The MOHLTC will also be launching a multimedia campaign in the beginning of September. Each grade eight female will be given a letter for parents outlining the program, a fact sheet on the HPV vaccine and a consent form. Parent letters, fact sheets and consent forms will be translated into twelve languages. Grade eight teachers have also been given an introductory letter and a teaching package. All of the materials including the clinic schedule will be available on the TPH web site.

Conclusion

The federal government and the MOHLTC have taken a substantial step to prevent cervical cancer in Ontario by implementing a publicly funded HPV immunization program. TPH will ensure the new vaccine against HPV is promoted and offered to all grade eight females in Toronto beginning in the fall of 2007. HPV immunization will reduce the risk of HPV infection in Toronto and eventually lead to a reduction in the incidence of cervical cancer.

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