

STAFF REPORT ACTION REQUIRED

Human Papillomavirus (HPV) Vaccination Program Update

Date:	September 4, 2008		
To:	Board of Health		
From:	Medical Officer of Health		
Wards:	All		
Reference Number:			

SUMMARY

The Human Papillomavirus (HPV) vaccine, Gardasil®, has the potential to prevent up to 70% of cervical cancers and 90% of genital warts in Canada. Three doses of vaccine given over a six-month period are needed for full protection.

The Ministry of Health and Long-Term Care (MOHLTC) announced funding for a HPV vaccination program in August 2007, after the Federal Government provided \$300 million on a per capita basis over a three year period in March 2007. The Ontario HPV vaccination program offered free HPV vaccine to all grade eight females through school-based clinics administered by local public health units, starting in the 2007-08 school year. The program aims for immunization coverage of 85% to reduce cervical cancers and associated precancerous lesions caused by HPV.

In the 2007-08 school year Toronto Public Health (TPH) offered vaccine to more than 13,000 grade eight females in 432 Toronto schools. The program is voluntary and requires parental consent. By July 1, 2008, TPH vaccinated over 8,000 grade eight females and achieved an uptake of approximately 60% for the first dose. While Toronto's coverage rate is higher than the 53% achieved for the first dose province-wide, it is lower than in other provinces and lower than the provincial goal.

This report provides information on the HPV vaccination program in Toronto. It recommends that the Government of Ontario provide Long-Term funding for the HPV immunization program (beyond three years) and implement a short-term "catch up" for

females in grades nine to twelve. It also calls on the MOHLTC to identify ways to improve HPV vaccination coverage among grade eight females, to ensure an evaluation of the program and to compensate public health units for the full administrative costs.

RECOMMENDATIONS

The Medical Officer of Health recommends that the Board of Health:

- 1. request that the Government of Ontario provide Long-Term funding beyond three years for HPV vaccination programs for grade eight females;
- 2. request that the Minister of Health and Long-Term Care provide a short-term HPV catch-up program for females in grades nine to twelve;
- 3. request that the Minister of Health and Long-Term Care establish a "once eligible always eligible" policy allowing females currently in grade eight to remain eligible to receive vaccine until they turn 18 years of age;
- 4. request that the Minister of Health and Long-Term Care compensate local public health units for the full administrative costs of the program;
- 5. request that the Minister of Health and Long-Term Care implement strategies to improve HPV immunization coverage among grade eight females;
- 6. reiterate its request that the Minister of Health and Long-Term Care evaluate the HPV vaccination program, including surveillance on the rates of precancerous lesions and cervical cancers;
- 7. forward this report to the Minister of Health and Long-Term Care, the Minister of Health Promotion, the Chief Medical Officer of Health for Ontario, the Provincial Infectious Diseases Advisory Committee, the Association of Local Public Health Agencies, the Council of Medical Officers of Health in Ontario, Cancer Care Ontario, the Ontario Public Health Association and the Public Health Agency of Canada.

Financial Impact

This report will have no financial impact beyond what has already been approved in the Toronto Public Health 2008 Operating Budget.

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

Decision History

At its meeting on July 9, 2007 the Board of Health (BOH) 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 13 years of age, and that public health units be funded to provide HPV vaccine to eligible females¹.

On August 2, 2007, the MOHLTC announced funding for the vaccine for all grade eight females in Ontario.

The BOH further requested at its September 4, 2007 meeting, that the Medical Officer of Health host four community meetings on the HPV vaccination program in the four quadrants of the City and that these meetings be held in collaboration with the various community stakeholders including the school boards and community health centres².

ISSUE BACKGROUND

In March 2007, the federal government announced \$300 million over three years to fund the HPV vaccine, of which \$117 million is allocated to Ontario. In September 2007, Ontario, Nova Scotia, Newfoundland and Labrador and Prince Edward Island implemented a HPV vaccination program, each targeting one age group of pre-adolescent females. In Ontario, coverage rates for the first dose were 53% compared to approximately 80% in the Atlantic Provinces^{3 4}. The remaining six provinces have announced HPV programs beginning the 2008-09 school year (see Table 1). The Territories are currently examining how to implement HPV vaccination programs.

Toronto Public Health completed implementation of the first year of the provincially funded HPV vaccination program in the 2007-08 school year. Uptake of the HPV vaccine in the first year was relatively low, with considerable variation in immunization coverage across participating schools. Overall, 60% of approximately 13,000 grade eight females were vaccinated in 432 schools.

Overall, TPH coverage rates were higher than the provincial average of 53% for the first dose, yet lower than the provincial program goal of 85%. Reasons for low uptake in Toronto and across Ontario include implementing the program within short time-lines amid media controversy and without the benefit of a provincial education campaign.

Cost benefit analyses to date indicate that HPV vaccination of preadolescent girls, with and without catch-up of older age groups, is cost-effective in preventing cervical cancer and the burden of HPV diseases ^{5 6 7 8 9}. In December 2007, the Canadian Immunization Committee (CIC) identified school-based vaccination of one female cohort (in grades four to eight) and short-term immunization of one or two additional cohorts as a cost effective health measure for provinces ¹⁰. Five provinces are offering short-term catch-up programs in addition to the routine immunization of a specific grade (see Table 1). Despite evidence of cost-effectiveness, Ontario's program does not have a catch-up program for females in grades nine to twelve.

COMMENTS

Human Papillomavirus (HPV) Burden of Disease

Human Papillomavirus causes cervical cancer, genital warts and other genital cancers. In 2008, it is estimated that 500 women in Ontario will be diagnosed with cervical cancer and 140 will die ¹¹. Cervical cancer screening with Pap smears detects about 55,000 abnormal tests annually in Ontario, with follow-up that may include additional Pap tests, biopsy or removal of precancerous cells ¹². Approximately 5,000 women in Ontario are treated annually for high grade precancerous lesions, which are associated with anxiety and increased health care costs ¹³.

While cervical cancer screening programs are important for the early detection of cancer and are necessary to maintain even with an HPV vaccination program, they have had limited success in reaching vulnerable and under-screened populations, including Aboriginal communities, women living in poverty and new Canadians¹⁴. Approximately half of the women who are diagnosed with cervical cancer were never screened¹⁵.

The HPV Vaccine

Gardasil® is licensed in over 80 countries and is the first HPV vaccine to be approved for use in Canada. It is safe and over 90% effective in preventing HPV types 6 and 11 (which account for 90% of genital warts) and types 16 and 18 (which cause 70% of cervical cancer in Canada). This protection is known to last for at least five years, though immune response patterns are consistent with other vaccine antibody responses that are life long. A booster dose at a later date may be required. A second HPV vaccine called Cervarix® is currently under Health Canada review.

The Toronto Public Health HPV Vaccination Program

Toronto Public Health held three clinics at participating schools through the 2007-08 school year to provide three doses of HPV vaccine, following Toronto District School Board approval on August 29, 2007 and Toronto Catholic School Board approval on September 19, 2007. Additional catch-up clinics were held in the evenings and during the summer months. Signed parental consent was required to receive the vaccine. TPH gave each grade eight female an information package to take home to parents, including a letter outlining the program, a fact sheet on the HPV vaccine, a consent form and a pamphlet. The HPV fact sheet was translated into twelve languages and all materials, including the clinic schedule, were available to parents at www.toronto.ca/health. TPH also provided grade eight teachers an introductory letter and a teaching package including a presentation for students. Upon request, TPH sexual health educators provided HPV-related education to 43 classrooms, and 51 teachers had teacher training on HPV.

TPH issued a press release announcing the program at the beginning of the school year and held four community stakeholder meetings in each of the four quadrants of the City. In March 2008, TPH participated in a debate on the differing perspectives on HPV vaccination sponsored by the University of Toronto Faculty of Law.

In June 2008, the MOHLTC extended the eligibility for grade eight girls in the 2007-08 school year to receive vaccine into grade nine, if a first dose is given before September 1, 2008. Parents were informed of their daughter's on-going eligibility and the community clinics being held during the summer months to provide vaccination to those who missed the opportunity earlier in the year.

HPV Vaccine Uptake in the City of Toronto

Toronto Public Health offered HPV vaccine to over 13,000 females enrolled in 432 public and private schools with grade eight classrooms. Of the 452 schools with grade eight students, 10 did not have female students and 10 private schools declined to participate in the program. Schools that declined the program were provided with a letter and fact sheet to distribute to parents about the HPV vaccine and community clinics where parents could get their daughters vaccinated. By July 1, 2008, TPH achieved an uptake of 61% for the first dose, 59% for the second dose and 52% for the third. Approximately five to10% of vaccinated grade eight females in Toronto received a dose of HPV later than scheduled or at an evening clinic.

Uptake of HPV vaccine in Toronto was not equal for all schools: 9% of participating schools had very poor uptake (zero to 24% of eligible females immunized), 19% had low uptake (25 to 49% immunized), 51% had moderate uptake (50 to 74% immunized) and 22% had good uptake (75 to 100% of eligible females vaccinated). There is no evidence of a geographic or socio-demographic pattern in the distribution of schools with the lowest coverage rates.

Toronto Public Health is currently conducting a study to identify parents' reasons for refusal of HPV vaccination and to determine how coverage rates can be improved. About 17% of parents signed the consent form refusing to have their child vaccinated and an additional 20% did not return the consent form.

Adverse reactions are tracked by TPH and reported to the Public Health Agency of Canada. By July 1, 2008, TPH provided over 22,000 doses of HPV vaccine. A total of 19 (0.1%) adverse reactions were reported - most were mild and self-limiting, and none were severe. As of January 8, 2008, the Public Health Agency of Canada had received a total of 145 reports of adverse reactions following vaccination with Gardasil®. None were severe, and most were local injection site reactions.

Planned HPV Vaccination Program for 2008-09 School Year

In June 2008, TPH provided parents of grade seven females with a HPV information package for the 2008-09 school year. HPV resources were also disseminated to Toronto physicians during the summer months through the TPH Communique newsletter and as part of the Cold Chain inspection program.

Additional resources consisting of a poster, fact sheets and consent forms will be provided to students in the fall of 2008, including translated materials. A provincial mass media campaign is already underway targeting parents and grade eight females through

radio, print, cinema and internet advertisements. TPH will continue to collaborate with school boards and provide teacher training and classroom instruction on HPV when requested.

Cost-Analysis of HPV Vaccination Programs

The MOHLTC has \$117 million federal dollars over three years to fund the program. Health units receive \$8.50 per dose administered to grade eight females. This fee is based on a school-based vaccination clinic model and is lower than the \$10 - \$13 per dose recommended by the Canadian Immunization Committee²⁰ if the vaccine is administered by a nurse through a school-based program. The Alberta Public Health Association²¹ has recommended \$20 per dose.

The administrative costs for community-based clinics were not originally part of the MOHLTC cost reimbursement. Approximately five to 10% of vaccinated females in Toronto received vaccine in TPH clinics held in the evening and during the summer, indicating the need for a flexible clinic schedule.

Toronto Public Health calculates the full administrative cost (excluding vaccine) for implementing the HPV vaccination program at \$15 per dose. TPH requests that the MOHLTC re-evaluate the cost to administer the HPV vaccination program and compensate local health units for the full cost.

CONCLUSION

The HPV vaccination program is a promising cervical cancer prevention strategy. It requires a coordinated and sustained communications plan and strong public health leadership. With high vaccine uptake, a reduction in HPV-related disease would be expected to occur after 10 years or more. The provincial government should provide Long-Term funding for the program, and address reasons for poor vaccine uptake and improve the overall impact of the program by offering short-term catch-up vaccinations for females in grades nine to twelve, and a public education program.

Toronto Public Health continues to work to ensure that HPV vaccine is available for all grade eight female students. There is on-going collaboration with Toronto school boards and private schools to improve vaccine uptake for the 2008-09 school year. However, to improve vaccination coverage rates, the province must sustain a strong and consistent multi-media campaign, one that especially meets the needs of multi-ethnic communities.

Finally, the province is urged to re-evaluate the costs of administering the HPV vaccination program and to compensate local public health units for the full administrative costs of providing the vaccine.

CONTACT

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SIGNATURE

Dr. David McKeown Medical Officer of Health

Attachments

Table 1 – Provincial and International HPV Vaccination Programs References

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Program	Year	On-going Female Cohort	Short-term Catch-up		
	Implemented	Immunized*	of Female Cohorts*		
Provincial HPV Vaccination Programs					
Ontario	2007-08	Grade 8			
Newfoundland and Labrador	2007-08	Grade 6			
Nova Scotia	2007-08	Grade 7			
Prince Edward Island	2007-08	Grade 6			
Alberta	2008-09	Grade 5	Grade 9 starting in Sept 2009 until 2012		
British Columbia***	2008-09	Grade 6	Grade 9		
Manitoba	2008-09	Grade 6			
Saskatchewan	2008-09	Grade 6	Grade 7		
New Brunswick	2008-09	Grade 7	Grade 8 2008-09 year only		
Quebec	2008-09	Grade 4 (receive 2 doses and a third dose in grade 9)	 Grade 9 catch-up (receive all three doses) under 18 years may also receive free vaccine** 		
Linited Kinadone***		al HPV Vaccination programs			
United Kingdom***	2008-09	12 to 13 years of age in school year 8	 17 and 18 years of age in school years 12 and 13 (starting in 2009) 15 and 16 years of age in school years 10 and 11 (starting in 2010) 		
Australia***	From April 2007	12 and 13 years of age	 13 to 18 years until the end of the 2008 school year up to and including 26 years of age through general practice** 		
France***	March 2007	14 years of age	Catch-up recommended for up to 23 years of age who are not sexually active		
Holland	September 2009	12 years of age	Catch-up for 13 to 16 years		
Norway	2007	12 years of age	Catch-up for up to 16 years of age		
* **		through gonoral practice *** jurice	liction has cost honofit data		

^{*} school-based program ** vaccine also administered through general practice *** jurisdiction has cost-benefit data

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