

## Human papillomavirus vaccine for children and adolescents



Canadian  
Paediatric  
Society

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In 2006, the first vaccine for the prevention of human papillomavirus (HPV) infection was approved for use in Canada in females nine to 26 years of age.

The purpose of the present statement is to review the Canadian Paediatric Society (CPS) recommendations on the use of HPV vaccine for children and youth in Canada. The epidemiology of HPV-6, -11, -16 and -18 infection and its associated diseases in Canada, as well as information on the currently approved vaccine is summarized. For an extensive review of HPV vaccine in Canada, readers are referred to the National Advisory Committee on Immunization statement (1) that was released in February 2007, and the Canadian consensus guidelines on HPV (2).

In 2007, the federal government announced specific funding for the provinces and territories to implement HPV immunization programs. Since that time, several issues of potential controversy have been identified in both the medical literature and public media. These largely question the appropriateness of prioritizing public funds for this vaccine over other potential public health interventions, the long-term safety and efficacy of the vaccine, and the role of the pharmaceutical industry in communicating directly to the public regarding the vaccine. An indepth analysis of these issues is not appropriate in the context of the present statement. The CPS recommendations outlined below are based on the currently available evidence regarding the safety and efficacy of the vaccine. The CPS believes that prioritization of health issues for resource allocation falls under provincial and territorial jurisdiction, and that these decisions should be based on local epidemiology and resources.

### HPV INFECTION, NATURAL HISTORY AND ASSOCIATED DISEASE

HPV, a double-stranded DNA virus, has more than 100 distinct genotypes, of which approximately 40 can infect the genital tract (3). HPV infections are transmitted sexually by direct epithelial-to-epithelial contact. Infection has been documented during sexual touching and other sexual activities, even in the absence of penetrative sexual intercourse (4,5). HPV may also be transmitted vertically to an infant exposed to the virus in the maternal genital tract. Transmission from oral mucosal contact in head and neck infections is also likely. Clinical manifestations from HPV

infection range from benign skin lesions to malignant anogenital or head and neck cancers. HPV genotypes designated as high risk are associated with anogenital cancers, and low-risk genotypes are associated with the development of dysplasia and anogenital warts.

The presence of HPV is necessary for the development of cervical cancer but infection must persist for years before lesions become malignant. HPV-16 and HPV-18 are associated with 70% of squamous cell carcinomas and 86% of adenocarcinomas of the cervix. These same genotypes are also implicated in cancers of the penis, anus, vulva and vagina, as well as in squamous cell cancers of the conjunctiva, mouth, oropharynx, tonsils and larynx. Six HPV genotypes (HPV-31, -33, -35, -45, -52 and -58) are responsible for an additional 20% of cervical cancers worldwide (6).

Infections with HPV-6 and HPV-11 are responsible for 90% of genital warts and for recurrent respiratory papillomatosis, a relatively rare manifestation that is characterized by recurrent warts or papillomas in the upper respiratory tract, with occasional cases of spread to the lungs.

### HPV EPIDEMIOLOGY

HPV is described as the most common sexually transmitted infection (STI). The overall prevalence of HPV infection in Canada ranges between 11% and 29%, with peak prevalence in adolescents and young adults (younger than 25 years of age) (1). The highest rates of HPV acquisition occur in the first five years following onset of sexual activity, with most cases being unrecognized and self-limited (5,7,8).

Recent Canadian data (9) demonstrated that the greatest prevalence of any high-risk HPV is in women younger than 20 years of age, with rates of 20.6%. The overall prevalence of HPV-16 and HPV-18 was 11.6%, while in women younger than 20 years of age it was 16.7% (9). A study (10) in Inuit women, 13 to 20 years of age, found a higher prevalence of HPV infection of 31.7%, although another study (11) did not find increased risk in Aboriginal women in Winnipeg, Manitoba, when compared with their non-Aboriginal counterparts.

Other known risk factors for HPV infection include behavioural factors that increase the probability of exposure to the virus including number of sexual partners, early age of first intercourse, never being married and never being

pregnant; endogenous factors such as immunosuppression; and factors that relate to the cervical microenvironment such as other STIs.

### CERVICAL CANCER EPIDEMIOLOGY

Cervical cancer is the second most common malignancy affecting women. In 2005, approximately one million women were estimated to have cervical cancer, with more than 250,000 deaths worldwide (12). The incidence of cervical cancer varies across the age span, with bimodal peaks among women in their 40s and those 70 years of age or older.

With the introduction of Pap screening programs, the overall rates of cervical cancer in Canada have declined since the 1970s. However, a recent Canadian study (13) in provinces with complete epidemiological data demonstrated that incidence rates of adenocarcinoma and adenosquamous carcinoma increased between 1970 and 1972, and between 1994 and 1996. These increases were mainly observed in women 20 to 49 years of age. Similar increases have been reported in other developed countries (13,14). In 2002, 1350 new cases of cervical cancer were identified within Canada, with 390 cervical cancer-related deaths (15).

### AGE OF FIRST SEXUAL RELATIONSHIPS

To be optimally effective at preventing long-term complications of HPV infection, the vaccine must be given before acquisition of infection. Infection can occur before sexual intercourse with the onset of any sexual touching or other activities (4,5). Therefore, it is important to understand the age at which Canadian adolescents have their first sexual relationships. While studies of onset of sexual touching are not available, it has been demonstrated (16-18) that between 1% to 4% of children have had their first sexual intercourse by grade 6, 3% to 4% by grade 7, 17% to 23% by grade 9 and 40% to 46% by grade 11 or by 16 years of age. Sexual touching estimates are likely higher given that sexual touching and exploration often precedes intercourse by some time.

### HPV VACCINE

The currently approved HPV vaccine in Canada (Gardasil, Merck Frosst Canada Ltd) is a quadrivalent vaccine against HPV-6, -11, -16 and -18 genotypes. The vaccine is manufactured using recombinant technology resulting in noninfectious virus-like particles containing protein antigens for each genotype. It targets the two high-risk oncogenic HPV genotypes responsible for the majority of cervical cancers, as well as two low-risk genotypes that are associated with over 90% of genital warts. The aim of the vaccine is to prevent infections and, thus, the diseases subsequently associated with HPV-6, -11, -16 and -18. It is not a therapeutic vaccine and, therefore, must be given before the acquisition of infection with the virus to be optimally effective.

Immunogenicity and efficacy data are available for females 16 to 26 years of age and immunogenicity data are also available for boys and girls nine to 15 years of age (19-22). The vaccine has been shown to induce a robust immunological

response to the component genotypes with greater than 99.5% mounting antibody levels at or above those induced by natural infection, one month after completing the vaccine series. These antibodies have been sustained over at least five years. Postvaccination, neutralizing antibodies have also been demonstrated in cervical secretions. Antibody titres across all vaccine genotypes were significantly higher in adolescent boys and girls (nine to 15 years of age) than in adults (21,22).

Clinical efficacy trials have been conducted in over 20,000 individuals. In a population of women who have not previously been infected with HPV-16 and HPV-18, the vaccine is highly effective with a 95.6% (CI 38% to 98%) reduction in persistent HPV infection from the genotypes present in the vaccine. It is 98% effective against the prevention of dysplastic lesions that are precursors to cervical carcinoma in situ, 100% effective against high-grade vaginal and vulvar lesions (vulval intraepithelial neoplasia 2-3 and vaginal intraepithelial neoplasia 2-3), and 99% effective in preventing genital warts (23-27). Not unexpectedly, three-year data from phase III studies indicate that for a general population of women 16 to 26 years of age who might have encountered HPV-16 and HPV-18 before vaccination and who might not completed the full vaccination schedule, the vaccine efficacy is reduced to 44% to 55% against HPV-16- and HPV-18-induced predysplastic cervical lesions, and is even lower against cervical intraepithelial neoplasia 2-3 disease from all HPV genotypes (26).

A recent study (28) has demonstrated long-term HPV type-specific immune memory with excellent boosting of antibodies following a fourth dose of HPV vaccine five years after the initial series. In the absence of clinical efficacy studies beyond five years, this robust immune memory demonstrates that there will likely be sustained long-term efficacy.

### VACCINE ADMINISTRATION AND STORAGE

The vaccine is supplied in single-dose vials or prefilled single-use syringes containing 0.5 mL of the vaccine product. It must be stored at temperatures between 2°C and 8°C. Gardasil, the quadrivalent vaccine, is administered intramuscularly at zero, two and six months, and can be given at the same time as the hepatitis B vaccine. The vaccine is not recommended for use in pregnant women.

### VACCINE SAFETY

The quadrivalent HPV vaccine is safe and well tolerated. Local injection site reactions, including pain, redness or swelling, have been common in both vaccine and placebo recipients with a slightly higher frequency (6% to 8%) in the vaccine recipients than among the placebo group. The majority (94%) of these reactions were mild to moderate in intensity. Among 1184 adolescent boys and girls, nine to 15 years of age, 75% of vaccine recipients and 50% of placebo recipients reported local injection site reactions across the vaccination series (19). There were no significant differences in systemic reactions between

vaccine and placebo recipients. The product monograph (25) for the vaccine reports that there have been five serious events among 11,640 recipients including bronchospasm (possibly related), gastroenteritis (possibly related), headache and hypertension (definitely related), vaginal hemorrhage (probably related) and injection site pain and movement impairment (probably related). The vaccine has not resulted in allergic reactions or other immune-mediated diseases.

Vaccinated cohorts were studied for up to five years before vaccine approval, which is longer than most other recently licensed vaccines. No additional adverse events were identified during this time. A recent report (29) from the Global Advisory Committee on vaccine safety stated that “the current evidence on the safety of HPV vaccine is reassuring” and that there were no concerns with the safety profile of the vaccine (29).

During vaccination campaigns of adolescents with other vaccines, episodes of postvaccination dizziness and syncope have been identified. These are reduced in frequency with postvaccination observation for 15 min and encouragement of good hydration. Although not reported as an issue with the HPV vaccine specifically, these strategies may be of benefit given the age of potential vaccine recipients (29,30).

As with all new vaccines, it is important to conduct postmarketing surveillance to identify any unexpected, rare adverse events that may arise.

### HPV VACCINE COST AND COST-EFFECTIVENESS

The purchase cost for a three-dose series of the vaccine is \$404.85. There have been several cost analysis studies (31-37) of HPV universal vaccine programs, published or presented, based on natural history or dynamic modelling. All of these studies have identified weaknesses and none are considered definitive. However, their overall conclusions predict that compared with current screening practice, vaccinating girls before 12 years of age appears to be cost-effective. Sensitivity analyses conclude that vaccination programs are most cost-effective when performed at younger ages. The predicted costs per quality-adjusted life year are between US\$14,583 and US\$32,028, depending on what parameters were included in the models.

In the Canadian context, modelling has predicted that eight girls would need to be vaccinated to avoid one case of genital warts, 324 to avoid one case of cervical cancer and 729 to avoid one death from cervical cancer (37). The Canadian costs per quality-adjusted life year are between \$21,000 and \$31,000 (38). These studies conclude that HPV vaccination of adolescent girls, in addition to current cytology-based screening in Canada, is likely to be a cost-effective use of health care resources. However, they emphasize that unless screening practices are able to be modified somehow (eg, wider screening intervals), the cost of HPV immunization will strongly outweigh the direct costs saved through reduced health care resource use.

It is important to note that most of the cost-effectiveness studies conducted thus far have been funded by the two pharmaceutical companies who will be or are marketing the HPV vaccine

### RECOMMENDATIONS

- HPV vaccine should be administered routinely to all girls between nine and 13 years of age. To increase the likelihood that the vaccine will be administered before the onset of any sexual activity (therefore providing optimal protection against initial infection with the HPV vaccine genotypes), the vaccine should be given as early as programmatic issues allow.
  - Given that street-involved children and youth, as well as those taken into care by authorities (ie, foster care, group homes) are at higher risk of early onset of sexual activity, increased numbers of sexual partners and STIs as well as being at greater risk of missing immunization opportunities, specific attention should be paid to immunizing this population of girls (39).
- The vaccine should be administered to all unimmunized females 13 years of age and older, for whom the vaccine is approved, as a ‘catch up program’.
- Females who have had previous Pap abnormalities (including cervical cancer), genital warts or known HPV infection should also be offered HPV vaccination because they may not have had infection with all of the HPV genotypes included in the vaccine and may still benefit from its administration.
- Physicians caring for children and youth must continue to advise that immunized girls take part in the currently recommended cervical cancer screening programs once they are sexually active.
- Education programs explaining behaviours that can reduce the acquisition of nonvaccine HPV genotypes and other STIs must continue for all children and adolescents who are sexually active, regardless of their HPV immunization status. These behaviours include consistent condom use and limiting the number of sexual partners, neither of which are completely effective against acquisition of HPV infection.
- While the efficacy of the HPV vaccine has not yet been demonstrated in males and, therefore, cannot be recommended at this time, immunological data are convincing and efficacy studies should be addressed as an urgent research priority. Some countries have already initiated immunization programs for boys.
- While data regarding the immunogenicity and efficacy of HPV vaccine in immunocompromised individuals are currently lacking, such individuals may be offered the vaccine based on expert opinion. The dose and schedule

should be in accordance with recommendations for the nonimmunocompromised population.

- There are several urgent research priorities that should be addressed regarding HPV vaccine. These include but are not limited to:
  - Enhanced Canadian epidemiological knowledge of HPV infection and disease across the age spectrum in both males and females;
  - Vaccine efficacy in males;
  - Vaccine safety and efficacy in immunocompromised individuals;
  - Long-term outcomes following HPV immunization;
  - Cost-effectiveness studies that are independent of industry; and

- Optimal and alternate vaccine dosing schedules.
- Physicians caring for female children and youth should counsel patients and their parents about the HPV vaccine, making it available even in the absence of a provincially or territorially funded universal program.
- Physicians caring for children and youth should advocate for and support the funding and implementation of universal HPV vaccination programs within all provinces and territories.

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### INFECTIOUS DISEASES AND IMMUNIZATION COMMITTEE

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**Consultant:** Dr Noni E MacDonald, IWK Health Centre, Halifax, Nova Scotia

**Liaisons:** Drs Upton Dilworth Allen, The Hospital for Sick Children, Toronto, Ontario (Canadian Pediatric AIDS Research Group); Scott Alan Halperin, IWK Health Centre, Halifax, Nova Scotia (Immunization Program, ACTive); Charles PS Hui, Children's Hospital of Eastern Ontario, Ottawa, Ontario (Health Canada, Committee to Advise on Tropical Medicine and Travel); Larry Pickering, American Academy of Pediatrics, Red Book Editor and ex-officio member of the Committee on Infectious Diseases, Elk Grove, Illinois, USA; Marina Ines Salvadori, Children's Hospital of Western Ontario, Ottawa, Ontario (CPS representative to the National Advisory Committee on Immunization)

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**Liaison:** Dr. Sheri M Findlay, McMaster Children's Hospital – Hamilton HSC, Hamilton, Ontario (Canadian Paediatric Society, Adolescent Health Section)

**Principal author:** Dr Lindy Michelle Samson, Children's Hospital of Eastern Ontario, Ottawa, Ontario

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The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate. Internet addresses are current at time of publication