TORONTO

STAFF REPORT
ACTION REQUIRED

Public Funding of Human Papillomavirus (HPV) Vaccine

Date:	June 21, 2007
To:	Board of Health
From:	Medical Officer of Health
Wards:	All
Reference Number:	

SUMMARY

This report provides information on the Human Papillomavirus (HPV) and the new HPV vaccine. It recommends that the Ministry of Health and Long-Term Care include HPV vaccine as a publicly funded immunization for females between the ages of nine and 26 years and fund public health units to provide the vaccine to eligible females. It also calls on the Ministry of Health and Long-Term Care to evaluate the effectiveness of the vaccine in preventing cervical cancer.

HPV is one of the most common sexually transmitted infections and can lead to cervical cancer, and anal and genital warts. 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 an estimated 150 deaths from cervical cancer in Ontario.

A new HPV vaccine has been licensed to prevent the four most common HPV types – 6, 11, 16 and 18. It is recommended for females between nine and 26 years of age. The cost of the vaccine is approximately $135.00 per dose; three doses are required to complete the series.

On March 19, 2007, the Federal government announced that the provinces would receive funding to implement vaccination programs against HPV. At present, the Ontario government has not announced if and/or how the HPV vaccination program will be implemented.

RECOMMENDATIONS

The Medical Officer of Health recommends that:

1. the Board of Health request 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;

2. the Board of Health request the Minister of Health and Long-Term Care to fund public health units to provide HPV vaccine to eligible females;

3. the Board of Health request the Minister of Health and Long-Term Care to work with public health units to monitor and evaluate the effectiveness of the HPV vaccine in preventing cervical cancer;

4. the Board of Health forward this report to the Minister of Health and Long-Term Care, the Minister of Health Promotion, the Provincial Infectious Diseases Advisory Committee, the Association of Local Public Health Agencies, and the Ontario Public Health Association; and

5. the Board of Health advocate to the President and Chief Executive Officer of Merck Frosst Canada Ltd. to provide the HPV vaccine at low cost to developing countries to reduce the global burden of HPV-related illness.

Financial Impact

There are no direct financial implications arising from this report.

ISSUE BACKGROUND

Human Papillomavirus (HPV) is a sexually transmitted infection that can cause benign and cancerous ano-genital disease. A vaccine that protects against the most common types of HPV was approved by Health Canada on July 11, 2006. 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. NACI has recommended that females between nine and thirteen years, before onset of sexual intercourse, would experience the greatest efficacy.[1]

On March 19, 2007, the Federal government announced that the provinces would receive $300 million on a per-capita basis over the next three years to implement vaccination programs against HPV. A joint NACI and Canadian Immunization Committee HPV Work Group is developing recommendations to guide the implementation of HPV vaccination programs. Since the Federal funding announcement, Prince Edward Island, Nova Scotia and Manitoba, have announced school-based HPV vaccination programs to begin this year.

Ontario is conducting a review of the HPV vaccine to guide a response to the federal funding announcement. On June 12, 2007, the Association of Local Public Health Agencies (alPHa) adopted a resolution (A07-7) requesting that the Government of Ontario include HPV vaccine as a publicly funded immunization for females between the ages of nine and 26 years. At present, the Ontario Government has not announced if and/or how the HPV vaccination program will be implemented.

COMMENTS

The Human Papillomavirus (HPV)

Human Papillomavirus can infect both skin and mucus membranes and is considered one of the most prevalent sexually transmitted infections (STIs).[2] HPV infection usually goes away on its own, but in some individuals it can lead to cancer of the cervix, vagina, vulva (area around the vagina), penis or anus. It can also cause anal and genital warts.[3]

HPV is most commonly spread during sexual activity by skin to skin contact with an infected partner. Rarely, it is passed through oral sex or from mother to infant during childbirth. Some people do not have symptoms, but they still carry the virus and can infect their sexual partner(s). A condom may not always protect against the spread of HPV.[4]

In Canada, physicians are not required to report HPV infections. HPV infection and related disease burden estimates are based on Canadian prevalence and incidence studies in limited populations, such as patients in routine cervical screening clinics, family planning clinics, STI/HIV clinics and university health clinics.[5] Three out of every four Canadians will have at least one HPV infection in their lifetime.[6] In Canada, prevalence varies greatly between different age groups, ranging from 3.4% to 42.0%. The peak prevalence usually occurs in females around 25 years of age or younger and then decreases with age.[7]

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.[8] In 2006, there were approximately 1,350 new cervical cancer cases and 390 deaths in Canada.[9] In Ontario, there were an estimated 510 cases and an estimated 150 deaths from cervical cancer.[10]

HPV types 6 and 11 cause over 90% of genital warts in Canada.[11] There are no published population-based studies on the disease burden of genital warts in Canada. Canadian prevalence estimates are based on surveillance activities in other developed countries that have similar trends in other reportable STIs.[12] It is estimated that 65% of people that have sexual contact with a partner infected with genital warts will also develop warts. 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.

HPV infection also has financial, social and emotional consequences. 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.[13] People diagnosed with genital warts or with abnormal Pap tests can experience feelings of depression, shame and guilt, fear of partner rejection, loss of sexuality, anxiety, and fear.[14]

The HPV Vaccine

Gardasil™, a quadrivalent vaccine manufactured by Merck Frosst Canada Ltd., has been licensed to prevent the four most common HPV types – 6, 11, 16 and 18. It is recommended for females between 9 and 26 years of age. Studies found that the HPV vaccine was safe and caused no serious side effects.[15] The cost of the vaccine is approximately $135.00 per dose; three doses are required to complete the series. There is currently no licensed HPV vaccine for males but studies are on-going.

Scientific studies confirm that the Gardasil™ vaccine has high efficacy against the four most common HPV types.[16,17] However, the efficacy of the vaccine is limited by several factors.

One key factor is that not all cervical cancer is caused by HPV types 16 and 18. At least 15 other types have been identified as causing cervical cancer.[18] Therefore, sexually active women would still require regular Pap tests whether or not they receive the vaccine.

A second key factor is that a person can still develop cervical cancer if they are infected with HPV before receiving the vaccine. This is why immunization before becoming sexually active is preferable. A Canadian survey found that the average age of first sexual intercourse among females is 15.7 years.[19] Whether vaccinating young girls against HPV can prevent cancer is difficult to demonstrate and will require long-term observation of a large number of treated women.[20,21] This highlights the importance of population-based research and the need for ongoing monitoring and surveillance.

A third key factor is that the HPV vaccine offers protection for at least five years based on effectiveness data[22]. Duration of immune protection and the need for a booster dose is unknown at this time and will require long-term observation. Careful monitoring of the vaccine for unintended adverse consequences will also be critical.[23,24]

The federal and provincial governments are examining these and other scientific, medical, economic, and sociological questions raised by the HPV vaccine. Currently, the Ontario government is considering if or how it will implement a publicly funded HPV immunization program. Considerations include the optimal delivery method, and how best to promote the HPV vaccine to health care providers, parents and recipients. The NACI and Canadian Immunization Committee recommendations are anticipated by the end of this year and will provide further direction to provincial governments on how to implement a HPV vaccination program.

HPV in Developing Countries

In most developing countries, cervical cancer is the number one cause of cancer-related deaths among women. It is estimated that women in developing countries account for 85 percent of the annual cases of cervical cancer (estimated at 493,000 cases worldwide) and the annual deaths from cervical cancer (estimated at 273,500 deaths worldwide).[25] For example, in India, 75,000 women die from the disease each year.[26]

Cervical cancer rates are highest among the poor largely because these women do not have access to effective screening and treatment programs. Most women with cervical cancer only arrive at health centers when their disease is advanced and incurable.[27] Reducing the risk of cervical cancer globally would, in the long term, produce benefits for Toronto's multicultural population. Immigrant women experience greater barriers to Pap test screening. Vaccination with HPV vaccine prior to immigration could protect this vulnerable group and avert health-care costs as well.

The availability of an HPV vaccine has the potential to reduce the global burden of cervical cancer. Yet one of the greatest barriers to the introduction of the new HPV vaccine in developing countries will be the price. At an estimated $400 dollars for a three-dose series, it will be out of reach for many developing countries unless they receive significant donor support. For countries with a gross domestic product of less than $1,000 per capita, the per-dose cost may need to be as low as $1 to $2 to make vaccination both cost-effective and affordable. For countries with a gross domestic product of less than $1,000 per capita, the per-dose cost may need to be as low as $1 to $2 to make vaccination both cost-effective and affordable.[28]

Currently, the World Health Organization (WHO), the Alliance for Cervical Cancer Prevention, the International Agency for Research on Cancer (IARC), the Bill & Melinda Gates Foundation, Harvard University, and PATH (a global health group) are among a number of organizations seeking to help developing countries understand HPV disease burden and determine how best to introduce the new vaccine.

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