

# HPV Q & A #4

## December 14 , 2009

***Disclaimer:** This issue of the HPV Q&A is a follow-up to Q&A #3 and includes topics discussed during two teleconferences in September 2009 with Gina Ogilvie, Karen Pielak, and Cheryl McIntyre. New questions and answers are presented, as well as additional information on topics from Q&A #3, with corresponding topic numbers noted.*

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## **NEW TOPICS**

### **1. Will Gardasil™ protect against oral cancers?**

There are many causes of cancers in the mouth and throat, including smoking and alcohol consumption, in addition to HPV transmitted through oral sex. Although HPV infections are associated with oral cancers, unlike with cervical cancer, there is no etiological link that attributes HPV as the **sole** causative agent for oropharyngeal cancers. Therefore, while Gardasil™ protects against HPV infections, currently there is not enough data showing its effect on oral cancers. However, there may be an overall reduction of oropharyngeal cancers as a side benefit of the HPV vaccine program, since some of these cancers do show evidence of HPV infection. Prevention of oralpharyngeal cancers is not a primary intention of the current school-based program.

### **2. Why isn't HPV a reportable disease like other STIs?**

Currently the testing done for cervical cancer screening uses pap smears, not human papillomavirus. Clinical trials on using HPV testing as opposed to cytology are underway. In addition, due to prevalence of the virus in certain age groups, we would expect a high volume of positive results for HPV infection, many of which as the natural history suggests will clear up on their own. In the future there may be testing done directly for HPV, but reporting will likely not include contact tracing.

### **3. I have heard that pharmaceutical companies often push vaccine use in the public. Is this true?**

Vaccine data are reviewed by independent scientific bodies in Health Canada, where panel members are required to declare any conflict of interest. Many studies on the utility of vaccines are funded independently of the manufacturers. For example, the mathematical modelling for the HPV vaccine is funded by the Michael Smith Foundation at UBC.

In addition, any vaccine being licensed does not mean that it will be funded publicly through a government immunization program without extensive and independent review.

#### **4. What is the alternate schedule for the HPV program this year?**

In some Health Authorities, this year's HPV vaccine program will be an extended three-dose schedule at 0, 6, and 12 months. This is needed to accommodate pandemic H1N1 vaccinations. Grade 6 and 9 girls will receive their first dose in September of the current year, the second dose in the spring of the following calendar year, and the third and last dose in September in the following grade level. The decision to extend the schedule is based on responses from all the regional health authorities. In addition, from results of other vaccine administration and subsequent immune responses, it is evident that extending a vaccine schedule will be easier than collapsing it. Even though the 0 – 6 HPV vaccine two-dose trial has demonstrated a good immune response, the Communicable Disease Policy Committee decided to wait for more long-term data before making a change to a 2 dose program.

#### **5. What is mathematical modeling?**

Mathematical modeling uses computer programs to predict outcomes on a model population based on user-input data and parameters. We begin with a population of a size that is similar to the BC population, then assign the model population the same age and gender distribution as found in our real population. Basic HPV related parameters for this model population include prevalence of HPV in the population, the likelihood of people becoming sexual partners, the likelihood of HPV being transmitted during a sexual act, and the total number of sexual partners in a lifetime. Disease status and the pairing of partners are randomly assigned to individuals in the population, while numerical values such as rate of transmission and number of partners are based on values from research data. Parameters such as how people mix sexually are more difficult to model, therefore assumptions and estimates are used so as to best simulate BC population.

The objective of the model is to predict effects of the HPV vaccine on cervical cancer incidence. We can add a parameter into the model where we vaccinate subsets of the population, then observe the resulting prevalence of the disease and compare this to results from the unvaccinated model. Further simulations using sensitivity analysis can establish upper and lower limits on the result, providing best and worst case scenarios.

## **ADDITIONAL INFORMATION ON PREVIOUS TOPICS**

### **6. Which vaccine is being used in the BC HPV vaccine program? (Q&A #3, 1.1)**

In addition to Gardasil™, another vaccine, Cervarix, is being recommended for approval in the United States. It shows similar efficacy as Gardasil™, but only targets subtypes 16 and 18, and not subtypes that are responsible for other HPV-related infections. It has not yet been approved for use in Canada.

### **7. Is the HPV vaccine safe? (Q&A #3, 1.2)**

Additional side effects related to injection of the vaccine includes minor low-grade fevers which resolve within a few days. There have been no admissions resulting from fainting after receiving the HPV vaccine.

Regarding neurological events, there has been no link shown in post vaccine monitoring between autoimmune disorders and the HPV vaccine .

### **8. Where can I find more information about HPV vaccine safety? (Q&A #3, 1.5)**

Advice for the public on how to evaluate information on vaccines can be found on the websites of the Canadian Coalition for Immunization Awareness & Promotion (CCIAP, <http://www.immunize.cpha.ca>) and the Canadian Paediatric Society (<http://www.cps.ca>).

### **9. What are the studies showing regarding the use of Gardasil™ in males? (Q&A #3, 1.6)**

Gardasil™ has been recommended for approval from the FDA for use in males, but is still not licensed in Canada for this use. However, it has been noted that parents have requested prescriptions for off-label use of Gardasil™ for their sons.

**10. Is there any more information about Gardasil™ vaccine duration of protection? (Q&A #3, 1.8)**

A reasonable estimate from mathematical models of antibody titres shows good clinical protection for between 15 and 25 years.

**11. What promotional efforts are planned for the second year of the HPV program? (Q&A #3, 2.2)**

The focus of promotion will be physician education. The results from the Ogilvie et al. (2009) study identified the need to look for ways to provide educational support to BC physicians about the benefits of HPV vaccine, one reason being that family physician advice is an important factor in parents' decision to vaccinate.

## **REFERENCES**

Pielak, K. (Leader). (2009, September 10). HPV Teleconference #2 [Transcript]. Provided by InterCall®.

McIntyre, C. (Leader). (2009, September 21). HPV Teleconference #3 [Audio recording]. Provided by InterCall®.