

COMBINING GARDASIL WITH OTHER VACCINES

Testing involving Gardasil with other childhood vaccines has only been conducted with the Hepatitis B vaccine. The National Vaccine Information Center called on the FDA and CDC to issue warnings that Gardasil should not be combined with other vaccines, and that girls be monitored for fainting, seizures, tingling, numbness and loss of sensation in the fingers and limbs for 24 hours after vaccination.¹⁸

LONG-TERM CONSEQUENCE OF THE HPV VACCINE

The long-term effects of the vaccine on young girls are completely unknown. Merck states in its product insert that Gardasil has not been tested to see if it causes cancer¹⁹ or if a young woman's reproductive health will be affected.²⁰ Additionally, Merck acknowledges that the vaccine has not been tested for genotoxicity (testing to see if the vaccine is toxic to human DNA).²¹

“A careful review of the literature, including that submitted by the manufacturer with its application for approval of Gardasil reveals a sufficient number of unanswered questions to lead us to conclude that a universal immunization program aimed at girls and women in Canada is, at this time, premature and could possibly have unintended consequences for individuals and for society as a whole.”²²

Dr. Abby Lippma,
Canadian epidemiologist, McGill University

USURPING PARENTAL CONSENT

Most parents are unaware that their child, regardless of age, could be considered capable of making her own healthcare decisions in Ontario.²³ This means that your daughter can choose to accept or refuse immunization, even if you have indicated otherwise in a consent form.

Public health nurses are required to ask every student if they understand, have any questions, and consent to be immunized. If the parent wishes the student to be immunized and the student refuses, the immunization will **not** be given. Likewise, a student who is judged capable of giving informed consent may be immunized even if the parents have **not** consented.²⁴

“This vaccine should not be mandated for 11-year-old girls.... It's not been tested in little girls for efficacy. At 11, these girls don't get cervical cancer — they won't know for 25 years if they will get cervical cancer. Giving it to 11-year-olds is a great big public health experiment.”²⁵

Dr. Diane Harper,
Lead researcher, HPV vaccine development

CONCLUSION

Gardasil is being hailed as one of the major health advances of the early 21st century and yet many parents have refused to accept this vaccine as a just another regimen in their child's immunization schedule. Given all the questions concerning Gardasil's safety, and the fact that the vaccine is still in the testing stages, we recommend that concerned parents inform themselves of the facts and request that the government and public health officials **suspend** their distribution to minor girls until its safety can be adequately proven.

1. Public Health Agency of Canada Recommendation on Human Papillomavirus Immunization Program <http://www.phac-aspc.gc.ca/publicat/2008/papillomavirus-papillome/papillomavirus-papillome-12-eng.php#1131>
2. Canadian Women's Health Network, Gardasil: What you need to know about the HPV vaccine, <http://www.cwhn.ca/resources/cwhn/hpv.html>
3. What you should know about HPV and getting vaccinated, Merck Frosst Canada Ltd., 2007. <http://www.merckfrosst.ca/mfcl/en/corporate/index.html>
4. Cancer system quality index 2008: cervical cancer screening, Toronto, ON: Cancer Care Option, 2008. <http://www.cancercare.on.ca/english/home/pcs/screening/cervscreening/>
5. Public Health Agency of Canada, <http://www.phac-aspc.gc.ca/publicat/updates/cervix-98-eng.php>
6. Canadian Women's Health Network, HPV, Vaccines, and Gender: Policy Considerations, <http://www.cwhn.ca/resources/cwhn/hpv-brief.html>
7. Canadian Women's Health Network, Gardasil: What you need to know about the HPV vaccine, <http://www.cwhn.ca/resources/cwhn/hpv.html>
8. VRAN, HPV (Human Papilloma Virus) & Cervical Cancer Vaccine: Merck's Gardasil, Overview; 4. Excessive Cost: Winlaw, BC Canada). <http://www.vran.org/vaccines/hpv/hpv.htm>
9. www.nmaseminars.com/files/WhatDoWeReallyKnowAbouttheHPVaccine.doc., Gardasil package insert. 2006, page 5, paragraph 6. <http://www.fda.gov/cber/label/hpvmr060806LB.pdf>
10. www.nmaseminars.com/files/WhatDoWeReallyKnowAbouttheHPVaccine.doc., Gardasil package insert. 2006, Page 2, paragraph 2. <http://www.fda.gov/cber/label/hpvmr060806LB.pdf>
11. Public Health Agency of Canada, The Facts on the Safety and Effectiveness of HPV Vaccine; <http://www.phac-aspc.gc.ca/std-mts/hpv-vph/fact-faits-vacc-eng.php#1>
12. A Judicial Watch Special Report, HPV Vaccine Records, June 30, 2008; <http://www.judicialwatch.org/documents/2008/JWReportFDAHPVaccineRecords.pdf> Vaccine Adverse Event Reporting System.
13. Julia Brotherton, M.D., public health physician, National Centre for Immunization Research and Surveillance, Westmead, New South Wales, Australia. Sept. 9, 2008, Canadian Medical Association Journal
14. Barbara Loe Fisher, NVIC President; Vaccine Safety Group Releases GARDASIL Reaction Report, Feb. 22, 2007. <http://www.nvic.org/PressReleases/PR081507HPV.htm>
15. A Judicial Watch Special Report, HPV Vaccine Records, June 30, 2008; pg. 13. <http://www.judicial-watch.org/documents/2008/JWReportFDAHPVaccineRecords.pdf>
16. Canadian Women's Health Network, CWHN HPV, Vaccines and Gender: Policy Considerations, June 25, 2007.
17. Janice Shaw Grouse, A Reality Check for the HPV Vaccine, Sept. 26, 2008; www.beverlyhaysinstitute.org/articleidisplay.asp?id=15822&department=BLI&categoryid=dotcommentary
18. National Vaccine Information Center, <http://www.nvic.org/PressReleases/PR081507HPV.htm>
19. www.nmaseminars.com/files/WhatDoWeReallyKnowAbouttheHPVaccine.doc., Gardasil package insert. 2006, Page 8, paragraph 17. <http://www.fda.gov/cber/label/hpvmr060806LB.pdf>
20. www.nmaseminars.com/files/WhatDoWeReallyKnowAbouttheHPVaccine.doc., Gardasil package insert. 2006, Page 9, paragraph 1. <http://www.fda.gov/cber/label/hpvmr060806LB.pdf>
21. www.nmaseminars.com/files/WhatDoWeReallyKnowAbouttheHPVaccine.doc., Gardasil package insert. 2006, Page 8, paragraph 17. <http://www.fda.gov/cber/label/hpvmr060806LB.pdf>
22. Lippman, A, Melnychuk, R, Shimmin, C, Boscoe, M. "Human papillomavirus, vaccines and women's health: questions and cautions." Canadian Medical Association Journal, 48:177 (5), (2007) and Canadian Women's Health Network, HPV, Vaccines, and Gender: Policy Considerations, <http://www.cwhn.ca/resources/cwhn/hpv-brief.html>
23. Health Care Consent Act, 1996.
24. Information for Parents about the Health Care Consent Act and School Based Immunization Programs. [http://chd.region.waterloo.on.ca/web/health.nsf/DocID/58E567D07B3BAF52852572C90056520E/\\$file/Consent_ParentsInfo.pdf?openement](http://chd.region.waterloo.on.ca/web/health.nsf/DocID/58E567D07B3BAF52852572C90056520E/$file/Consent_ParentsInfo.pdf?openement)
25. Dr. Diane Harper, lead researcher, HPV vaccine development. (VRAN, HPV (Human Papilloma Virus) & Cervical Cancer Vaccine: Merck's Gardasil. <http://www.vran.org/vaccines/hpv/hpv.htm>



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The HPV Vaccine

Is it Safe for My Daughter?



What
Parents
Need To
Know

BACKGROUND

In January 2007, Canada's National Advisory Committee on Immunization (NACI) made the recommendation that girls ages 9 to 13 be vaccinated against the sexually transmitted infection, human papillomavirus (HPV). In addition, the NACI recommended that older girls and women who might already be sexually active but not infected with the virus also be vaccinated.¹

In June 2007, the Ontario government began distributing the HPV vaccine at school-based clinics for girls in grade eight.

One year later, growing concern over the vaccine's safety and efficacy make it increasingly more difficult for parents to decide whether or not to vaccinate their daughters.

WHAT IS HPV?

HPV is an exclusively sexually transmitted disease. Any person who is sexually active can contract the virus (skin-to-skin contact alone can allow transfer of HPV). There are more than 100 types of HPV viral strains but most infections occur without any symptoms and go away without any treatment. Most women who get an HPV infection **do not** develop cervical cancer.²

WHAT DOES THE HPV VACCINE DO?

Gardasil, the HPV vaccine, produced by Merck Frosst Canada Ltd., was developed to target only four of the 100 different types of human papilloma viral strains. The four strains are comprised of types 6 and 11 that cause genital warts, as well as, types 16 and 18 that can cause pre-cancerous lesions, cervical cancer, anal cancer and other genital cancers.³

WHAT IS THE INCIDENCE OF CERVICAL CANCER?

Every year in Ontario about 500 women are diagnosed with cervical cancer and 150 die from the disease annually.⁴ Even without the availability of the HPV vaccine in Canada, the rates of deaths from cervical cancer have been dropping for years due to the widespread availability of publicly-funded programs for Pap screening which still remains the most effective measure in preventing cervical cancer.⁵

WHY IS THE RISK OF DYING FROM CERVICAL CANCER SO LOW?

In 90 percent of all cases, a woman's immune system is strong enough to clear an HPV infection on its own.⁶ As long as women are getting regular PAP screening, cervical abnormalities can be caught early and treated.⁷

WHAT IS THE COST OF GARDASIL?

The Ontario government is offering the vaccine free to girls in grade eight at school-based clinics only. They will not cover the cost for those who go to their family doctor for the vaccine. Three injections over a six-month period are required for each girl at a cost of approximately \$135.00 per injection. The total cost nationwide for this one vaccine is estimated to be almost \$1 billion dollars.⁸ The federal government has contributed \$300 million, about one third of the vaccine cost, while the other two thirds of the cost comes from the provinces.⁸

HOW LONG IS GARDASIL EFFECTIVE?

Merck states on their package insert that the duration of immunity from the HPV vaccine is **unknown**.⁹ The vaccine is being promoted as being effective for anywhere from three to five years, although the clinical trials followed it for four years. It is too soon to know if girls will require a booster shot even if they have not been sexually active.¹⁰

Is Gardasil Safe?

No vaccine is completely without side effects. As of August 2008, the Public Health Agency of Canada has received a total of 220 adverse event reports following HPV immunizations in Canada.¹¹ The PHAC has indicated that for each report, more than one adverse event could be reported.

Gardasil has been available in the United States since June 2006. Judicial Watch, a public interest group that monitors government programs, obtained documents from the Food and Drug Administration through the Freedom of Information Act. **To date, the documents detail at least 21 deaths and 9,749 adverse events related to the Gardasil vaccine.**

The documents indicate that the reactions range from severe headaches, dizziness, temporary loss of vision, foaming at the mouth, loss of consciousness, coma, paralysis, Guillain-Barre Syndrome, miscarriages and outbreaks of genital warts and death.¹²

Gardasil may also cause more allergic reactions than other vaccines. Australian researchers at the Westmead Children's Hospital reported that young girls who received Gardasil were five to 20 times more likely to suffer a rare and severe allergic reaction (anaphylaxis) compared to other vaccines given in school clinics such as hepatitis B...¹³

*"There are twice as many children collapsing and four times as many children experiencing tingling, numbness and loss of sensation after getting a Gardasil vaccination compared to those getting a Tdap (tetanus-diphtheria-acellular pertussis) vaccination."*¹⁴

Barbara Loe Fisher, NVIC President

Despite all of these reports, Merck continues to promote Gardasil as safe and maintains that there is no scientific evidence proving a causal relationship with Gardasil and any of the deaths or illnesses.

WHAT ARE THE WARNINGS?

Public Health units are working closely with school boards to ensure that the HPV immunization program be implemented. Each eligible female is given a letter for her parents outlining the program, a consent form and a fact sheet. Parents are assured in the letter and fact sheet that Gardasil is safe and that aside from the typical reactions that most people experience during routine vaccinations, there is little to worry about. **But nowhere in the literature are parents given a complete list of the possible side effects.**

Can parents make an informed decision if they are not made aware of all possible adverse reactions?

QUESTIONABLE TESTING

Despite the fact that Gardasil is being marketed as "widely tested" **it is still in the testing stages and will not be fully evaluated until September 2009.**¹⁵

There is limited data on the effects of the vaccine on the primary target population (pre-teen and early teenage girls). Of the more than 25,000 participants in the clinical trials, fewer than 1,200 were preteen girls (ages 9 to 15) and only 100 of them were nine-year-olds. This small group was followed for only 18 months.¹⁶ Of equal concern is the fact that the clinical trials pre-screened all participants for medical conditions and only healthy girls were included in the study. The trials did not evaluate the vaccine's impact on those with undiagnosed medical conditions.¹⁷

Can a school-based vaccination program that does not pre-screen your daughter's medical history determine whether or not she will be at risk?