

TALKING POINTS

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Cervical Cancer and the HPV Vaccine

Is there a new vaccine to prevent cervical cancer?

No. Gardasil, a new vaccine being marketed by Merck Co. Inc., is a vaccine to prevent four types of HPV (Types 6, 11, 16, 18)¹, the most common sexually transmitted disease in the United States. Each year approximately 6.2 million people are newly infected by one of over 40 different types of HPV.² Two of these types (16 and 18) account for approximately 70 percent of cervical cancer cases in the United States. These four types of HPV cause approximately 90 percent of genital wart cases.³ HPV is spread through sexual contact.

How widespread is cervical cancer in Michigan?

In 2005, there were 305 new cervical cancer cases in Michigan. Each year, just over 100 women die from cervical cancer. Cervical cancer represents approximately 1% of all cancer cases among females.⁴ Deaths from cervical cancer have decreased 74% since the introduction of Pap tests nearly 60 years ago.⁵

Is cervical cancer curable and preventable?

“The primary cause of cervical cancer is the human papillomavirus (HPV), the most common sexually transmitted virus in the United States. A Pap test can detect cervical cancer when it is nearly 100 percent curable.”⁶ “Cervical cancer is one of the few cancers that can be prevented by using the same precautions as with other sexually transmitted diseases...Experts believe that virtually all cervical cancer deaths could be prevented by a combination of safe sex practices, routine Pap smears, and appropriate follow-up of abnormal screening results.”⁷

Are Pap tests still needed?

“Yes. Since no vaccine is 100% effective and Gardasil won’t provide protection against the HPV types *not* in the vaccine, or against existing HPV infections, routine Pap screening remains critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.”⁸

Is the vaccine administered in one injection?

No. The manufacturer recommends that the vaccine be administered in 3 injections over a 6 month period.⁹ The CDC says, “It is not yet known how much protection girls/women would get from receiving only one or two doses. For this reason, it is very important that girls/women get all three doses of the vaccine.”¹⁰

How much will the vaccine cost?

The vaccine is \$120 per dose (about \$360 for a full series).¹¹ According to the Michigan Department of Education, in 2002, there were 68,550 sixth grade girls enrolled in the public schools of Michigan.¹² Full immunization of all sixth grade girls would cost \$24.7 million dollars. An accurate count of sixth grade girls in non-public schools is not available.

How long will the vaccine work and is a booster needed?

According to Merck, the manufacturer of the vaccine, “The duration of immunity following a complete schedule of immunization with GARDASIL has not been established.”¹³ The CDC says that “Current studies (with five-year followup) indicate that the vaccine is effective for at least five years.”¹⁴ “More research is being done to find out how long the vaccine will last, and if a booster vaccine is needed years later.”¹⁵

What about males?

Males are infected with HPV at roughly the same rate as females. “Over half of sexually active men in the United States will have HPV at some time in their lives.”¹⁶ “Certain types of HPV have been linked to cancer... The American Cancer Society estimates that about 1,530 men will be diagnosed with penile cancer in the U.S. in 2006” and “1,910 men will be diagnosed with anal cancer. The risk for anal cancer is 17 times higher among gay and bisexual men than among heterosexual men.”¹⁷ However, there is no HPV vaccination available to men because, “There are currently no efficacy data available to support use of HPV vaccines in males. Efficacy studies in males are ongoing.”¹⁸

Was this tested on children?

The vaccine’s efficacy was tested on 20,541 women 16 to 26 years of age in four international studies. The manufacturer then administered the vaccine to 1,121 girls 9-15 years old and determined that their immunity levels were “non-inferior to anti-HPV responses in 16 to 26-year-old adolescent and young adult women... On the basis of this immunogenicity bridging, the efficacy of GARDASIL in 9 to 15-year-old girls is inferred.”¹⁹

When should a woman get vaccinated?

Public health officials say women should get vaccinated before they initiate sexual activity because they have not been exposed to HPV. If a woman is already infected with a type of HPV, the vaccine will not prevent disease from that type.²⁰

Notes:

1. Merck & Co., Inc., Whitehouse Station, NJ. Prescribing Information (PI) Circular, June 2006. Download at: http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf
2. HPV Vaccine Questions & Answers, Center for Disease Control and Prevention, August, 2006. Download at: <http://www.cdc.gov/std/hpv/hpv-vaccine.pdf>
3. Merck PI Circular
4. The Cancer Burden in Michigan: Selected Statistics, Michigan Public Health Institute and Michigan Cancer Consortium, December 2005. Download at: http://www.michigan.gov/documents/CancerBurdenInMichigan-AllSections_114310_7.pdf
5. http://www.michigan.gov/documents/CervicalCancerAwarenessArticle_145389_7.pdf
6. *Cervical Cancer is Preventable*, Michigan Department of Community Health, Revised November 30, 2005. Downloaded at http://www.michigan.gov/documents/CervicalCancerAwarenessArticle_145389_7.pdf
7. Facts About Cervical Cancer, Michigan Department of Community Health, December 2005. Downloaded at http://www.michigan.gov/documents/CervicalFacts_6648_7.pdf
8. Product Approval Information – Licensing Action, GARDASIL, Food and Drug Administration, Center for Biologics and Evaluation Research, September, 2006. Download at: <http://www.fda.gov/cber/products/hpvmer060806qa.htm>
9. Merck PI Circular
10. HPV Vaccine Questions & Answers, CDC
11. *ibid.*
12. Pupil Student Counts, Michigan Department of Education, Download at: http://www.michigan.gov/cepi/0,1607,7-113-21423_30451_30460—,00.html
13. Merck PI Circular
14. HPV and HPV Vaccine: Information for Healthcare Providers, Center for Disease Control and Prevention, August, 2006. Download at: <http://www.cdc.gov/std/HPV/hpv-vacc-hcp-3-pages.pdf>
15. HPV Vaccine Questions & Answers, CDC
16. HPV and Men, Center for Disease Control Fact Sheet, Division of STD Prevention Download at: http://www.cdc.gov/std/hpv/hpv_and_men.pdf
17. *ibid.*
18. HPV and HPV Vaccine: Information for Healthcare Providers
19. Merck PI Circular
20. HPV Vaccine: What You Need To Know, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Sept, 5, 2006 Download at <http://www.cdc.gov/nip/publications/VIS/vis-hpv.pdf>