

Questions about the HPV Vaccine

I am getting a lot of questions on whether or not patients should get the new vaccine against Human Papilloma Virus (HPV). My short answer is probably not yet. This vaccine is being advertised as a major advance in cancer prevention, but I feel important warnings are being left out.

The HPV Vaccine

Gardasil is the current vaccine approved for use in girls ages 9-26 years old. It is given in 3 doses. The 2nd dose is given 2 months after the first, and the 3rd dose 6 months later. It has been in testing since only 2001. **Long term trials are still pending.** It is marketed as being able to prevent 70% of HPV infections of the cervix and 90% of genital warts. It works much better if given **BEFORE** you become sexually active. After you become sexually active, the vaccine is **much less** effective.

The company that makes the HPV vaccine is **Merck**, the same company that manufactured the anti-inflammatory Vioxx and the vaccine Rotavax. After widespread use, Vioxx was found to cause an increased risk of heart attacks and stroke in previously healthy people. Rotavax was a vaccine for infant diarrhea, and was removed from the market after it was found to cause an increased risk of a rare type of bowel blockage that can kill infants. Neither problem was found in the FDA review process. Both products have now been removed from the market.

HPV and Cervical Cancer

Cervical cancer used to be the number one cause of cancer in women worldwide. However, in the United States, because of routine pap testing over the last 40 years, it is now listed as a rare cancer. This is a tremendous success story for medicine. This is why physicians recommend regular PAP smears to their female patients. If you are an American woman and you get cancer, there is only a 1% chance it will be cervical cancer.

HPV infection is very common, affecting up to half of sexually active adults. Certain strains of HPV can increase your risk of cervical cancer and other strains can cause genital warts. Most people who are infected with the virus have no symptoms and the infection clears up without intervention. Some people just develop genital warts. Other people can develop pre-cancerous changes, which if untreated, can become cancer. There are other factors that play a role in the risk for cervical cancer such as smoking, Chlamydia, diets low in fruits and vegetables, infection with AIDS, or after an organ transplant. And equal numbers of men are infected with HPV, yet penile cancer in men is very, very rare.

The HPV Vaccine Prevents Some Types of HPV Infection

The first thing to emphasize is that the vaccine **has NOT been proven to prevent cervical cancer.** It only helps prevent infection with 4 types out of the 100 known types of HPV virus. Cervical cancer usually takes many years or even decades to develop. The trials show that the vaccines are very effective in reducing some HPV type 16 and 18 pre-cancer changes. Though these two types of the virus account for around 70% of cervical cancer, this still leaves women at risk from other causes. **Cervical screening with pap smears will be just as**

important after vaccination. The vaccine is therefore going to be an additional expense to PAP smears rather than a substitute.

The HPV Vaccine Does Not Prevent Other Sexually Transmitted Infections

Secondly, though HPV is the most common sexually transmitted infection (STI), it is only one of well over 20 STIs. Those who have sex with multiple partners are still at considerable risk of acquiring an STI even if using condoms and even if they are vaccinated. The need for the 'safe sex' message will not diminish. Condoms offer little or no protection against HPV, so abstinence outside of marriage and faithfulness within it will remain an important sexual health promotion message.

The HPV Vaccine Carries Some Unknown Risks

Thirdly, many unknowns will remain for a long time to come. It has been approved by the Federal Drug Agency (FDA) but for a new vaccine, there is still too little known about its long term safety.

- There have been a few cases of arthritis, including forms of rheumatoid arthritis, attributed to the vaccinated group in research studies. Whether this is a significant problem is not known, as the vaccine has only been studied for 5 years.
- The vaccine is most effective if given before you start having sex. It has not been tested in women who have had more than 4 sexual partners or who are older than 26.

We don't know that if by preventing infection to HPV types 16 and 18, you become more susceptible to other types of HPV infection. I feel that these other types of HPV virus might be more likely to cause cervical cancer. The answer is we just don't know yet, and need to wait on a vaccine against all types of HPV or further research data.

The HPV Vaccine is Very Expensive

Fourthly, the vaccine is very expensive. The recommendation is to spend \$360 on every adolescent female child. Your insurance may not cover the cost of the vaccine. For those in Medicaid, it is creating a major financial crisis by draining state tax dollars that could be used on vaccine to prevent diseases that we know kill and injure children, such as polio, influenza, and meningitis. HPV is not a public health threat in the same way that influenza is. HPV does not lurk in the air, in swimming pools, or on playground equipment.

Why You Should Wait on the HPV Vaccine

So if large numbers of people are infected with HPV, and it rarely causes cancer, why spend so much money on a new and yet unproven treatment? The current vaccine is good at preventing infection, but that does not mean it will prevent cancer. My advice is to be patient and wait another year or two for results of further testing.

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<http://www.medilexicon.com/medicalnews.php?newsid=62176>

excerpt from above article:

"GARDASIL safety appears to have been studied in fewer than 2,000 girls aged 9 to 15 years pre-licensure clinical trials and it is unclear how long they were followed up. VAERS is now receiving reports of loss of consciousness, seizures, arthritis and other neurological problems in young girls who have received the shot," said NVIC President Barbara Loe Fisher. "At the same time, parents who take their daughters to private pediatricians are going to be shocked to find that they will be paying two to three times the widely publicized \$360 cost for the three-dose series. The cost is going to break the pocketbooks of parents and break the banks of both insurance companies and taxpayers, when the reality is that almost all cases of HPV- associated cervical cancer can be prevented with annual pap screening of girls who are sexually active."

Fine print- Merck's cost analysis (to society) is based on the vaccine preventing infection for 4 types of HR HPV with 90% of population vaccinated and 100% vaccine efficacy for the 4 types of vaccine. The vaccine they market is for 2 types of HPV.

The other cost analyses include more realistic assumptions about the vaccines success, even so they assume that boosters will be needed only every 10 years. (11 years old 21 years old 31 years old and 41 years old). The first people to get the vaccine are now 5 years from the primary series. If some cost assumptions change slightly the vaccine strategy becomes the same price as or more expensive than a PAP driven prevention strategy (in part because all researchers assume that PAPs will always be needed).

So in summary: Gardasil may be safe. It may prevent cancer the same or better than PAPs alone. It may cost less or the same as PAPs alone. It may cause nuisance side effects or a significant number of serious side effects such as guillan barre or arthritis.