



IN EVERY ISSUE

First Approved HPV Vaccine Could Slash Number of Cervical Cancers

BY EMMA JOHNSON

It was a landmark medical breakthrough when, 23 years ago, human papillomavirus, or HPV, was found to cause almost all cervical cancers.

The fight against the disease just won another battle, as Gardasil®, the first vaccine proven to prevent the most dangerous strains of HPV, was approved in June by the Food and Drug Administration—promising to drastically reduce cervical cancer death rates worldwide. Some say the sexually transmitted HPV could be eradicated completely.

Doing so could save millions of lives. Each year about 10,000 U.S. women are diagnosed with cervical cancer, and about 40 percent will die from it. Cervical cancer also affects 500,000 women worldwide each year—killing more than half. Though millions carry the virus in the United States alone, the vast majority never get cancer.

Douglas Lowy, MD, the National Institutes of Health researcher who helped develop the vaccine, called Gardasil a monumental achievement. “Women will have fewer serious HPV infections that may lead to abnormal Pap smears requiring treatment,” Dr. Lowy says. “The likelihood of cervical cancer will be lower, and they’ll have fewer genital warts.”

Studies involving more than 20,000 women showed that Gardasil is 100 percent effective in preventing HPV types 16 and 18, which cause 70 percent of cervical cancer cases, and types 6 and 11, which cause 90 percent of genital warts, when administered before a woman becomes sexually active. The vaccine, approved for women ages 9 to 26, is given in a series of three injections over a six-month period, each priced at \$120. It has shown no serious side effects.

Enthusiasm for the future of a cervical cancer cure is boosted by a second vaccine, Cervarix™, in development by GlaxoSmithKline, which expects to file the vaccine for approval later this year. While Merck’s Gardasil has proven effective in guarding against HPV strains associated with both cervical cancer and genital warts, Cervarix has thus far only been proven to stave off the cancer-causing types 16 and 18. “There is presumably room for two manufacturers,” says Dr. Lowy, who is involved in studies of both vaccines. “There will be a lot of demand on a worldwide basis because cervical cancer is the second most common cancer among women worldwide” after breast cancer, he says.

The impact of this discovery is heightened by Merck’s continued research into whether Gardasil protects against other strains of the virus (HPV is a group of

more than 100 viruses), potentially increasing the understanding of the vaccine's power to prevent cervical cancer.

But the task of reducing HPV is faced with social and economic hurdles in addition to the scientific. Convincing parents to vaccinate their children may be one obstacle. A recent survey of 200 women ages 23 to 53 found that 77 percent would be willing to accept an HPV vaccine for themselves, while 67 percent of those who had a daughter and 66 percent who had a son were willing to have their child vaccinated. (The reason to vaccinate boys is because they can serve as asymptomatic carriers and pass the virus to female sexual partners.)

There was initial concern that conservative groups would oppose HPV vaccination, but the Family Research Council, a leading Christian lobby group, came out in support of the product.

The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommended in late June that HPV vaccination be made available to all FDA-approved age groups, which means health insurance plans will now be likely to cover the \$360 price tag and availability should be widespread by August. The committee also wants the vaccine included in the federal Vaccines for Children Program, which provides free immunization to uninsured and underinsured children. Merck has rolled out an aggressive disease education program connecting HPV with cervical cancer, and the company is also pitching the vaccine to pediatricians, primary care doctors and gynecologists through a shared sales team of 1,000 representatives.

However, public health experts worry that administering the product in the developing world, where the majority of HPV cases exist, is problematic. In an effort to bridge the economic gap, the Bill and Melinda Gates Foundation recently donated \$27.8 million to the Seattle-based Program for Appropriate Technology in Health to work with drug makers and public health organizations to facilitate HPV vaccination in developing countries.

Bradley Monk, MD, a gynecologist and associate professor at the University of California Irvine Medical Center, where he conducts research on HPV and cervical cancer, says that despite obstacles, he hopes Gardasil will be the beginning of the end of cervical cancer worldwide. "It's like smallpox—we vaccinated the world. It killed hundreds of thousands of people and now it's completely gone."