

The cancer-preventing HPV vaccine a dozen years on: Progress, fear and loathing

November 9 2018, by Marie Mccullough, The Philadelphia Inquirer

A dozen years after the debut of the HPV vaccine, its track record of warding off infections that cause cervical cancer and other malignancies keeps getting better.

That's why the U.S. Food and Drug Administration in October expanded the age range for Merck's Gardasil. Previously approved for adolescents and those up to age 26, the shots can now be given to men and women up to age 45, bringing the United States in line with markets including Europe and Canada.

But, ironically, this powerful cancer-prevention tool also faces growing fear and rejection, stoked by anti-vaccine activism.

So-called vaccine hesitancy—concerns and doubts about vaccines in general—has become a global public health problem. Even in that context, the HPV vaccine stands out. In Japan, Denmark, Ireland and some other countries, bogus claims of HPV vaccine harms have derailed immunization campaigns that were initially highly successful.

"There has been a uniquely hostile reaction to the HPV vaccine," said Patti Gravitt, an HPV researcher at George Washington University's Milken Institute School of Public Health.

A Merck scientist disagreed.

"I don't think it's more hated or less hated," said Alain Luxembourg, the

company's director of clinical research. "It's a recent vaccine, an innovation, a medical advance. It attracts attention."

Genital strains of HPV, the human papillomavirus, are so ubiquitous that almost all sexually active people—not just promiscuous ones—will be infected at some point. While most HPV infections are wiped out by the immune system, high-risk strains can persist and initiate cancer of the cervix, vagina, anus, vulva, penis, mouth and throat.

Worldwide, that translates to more than 600,000 cancers a year—nearly 5 percent of all cancers.

The original version of Gardasil, approved in 2006, protected against two high-risk HPV types, plus two types that cause genital warts. The current version, Gardasil 9, approved in 2014, protects against seven high-risk types that cause 90 percent of cervical cancers, as well as the two wart types. (Revaccination with the newer product is not recommended.)

Giving the vaccine to boys and girls at age 11 or 12 is recommended. At that point, their immune response is optimal, and they likely haven't been exposed to the virus through sexual activity. People who miss out can still get "catch-up" shots up to age 26.

"After 10 years of use and over 270 million doses administered globally, HPV vaccines have proved safe and effective," the World Health Organization declared last year. "Transmission of the most common and dangerous HPV types is declining in countries with high coverage rates."

Although it will take more time to see the impact on cancer rates, many studies show vaccination has reduced genital warts, precancerous lesions that can progress to cancer and oral infections—the kind that have fueled an explosion in head and neck cancers in recent decades,

particularly in men.

Nonetheless, parents and doctors have been cool to Gardasil, put off by its novelty, the link to sex, the need for two or three shots, and misperceptions. Just under half of adolescents ages 13 to 17 were immunized last year, far fewer than for other childhood vaccines.

"Patients are always asking me, 'Do you really think this is important for my daughter?'" said Mark S. Shahin, chief of gynecologic oncology at Sidney Kimmel Cancer Center of Thomas Jefferson University. "They aren't even thinking of boys, which is crazy. To have the maximum benefit, you have to vaccinate both males and females."

Vaccination rates could be boosted by requiring the shots for school, or by giving them to infants, said Judith Wolf, an infectious-disease specialist at Drexel University College of Medicine. Neither scenario is likely.

"Hypothetically, infants would respond to the vaccine, but we'd have to prove that in clinical trials," she said. "I'm unaware that anyone is interested in doing that."

Given lagging uptake among the targeted "tween" age group, why expand to middle age? Because, even if adults have been exposed to a few HPV types, they can still be protected from other types.

"The odds that any individual will have been exposed to all nine vaccine types are vanishingly rare," Wolf said.

Merck's latest data, from an international study of 3,200 women ages 27 to 45 who got the vaccine or a placebo, show the value. Over an average of 3 { years, the vaccine was 88 percent effective in preventing persistent HPV infection, [genital warts](#), and precancerous genital lesions.

The FDA said the effectiveness in men is extrapolated from those results, and from a small study that found the vaccine stimulated immunity in males ages 27 to 45.

But here's the caveat: Even among women who got the placebo, harmful infections were uncommon; only about 1 percent developed warts or precancerous cervical lesions.

Gravitt, at George Washington University, said, "There is data for efficacy, but the expanded population is at low risk. We need to focus on (adolescent) uptake and not be distracted by people who aren't likely to benefit."

While FDA approval frees Merck to market to the older group, the federal panel that decides vaccine policy is not expected to weigh in until next year. The Advisory Committee on Immunization Practices (ACIP) could recommend Gardasil use up to age 45—which would encourage insurance coverage—or leave the choice to doctors and patients.

Scientific groups and global health authorities—including the European Medicines Agency and the U.S. Centers for Disease Control and Prevention—keep monitoring the safety of the vaccine. They have concluded that it does not cause chronic pain, heart arrhythmias, autoimmune diseases, life-threatening allergic reactions, stroke, neurological disorders or premature ovarian failure.

But parents, anti-vaccine groups, even academics can still claim it does. (A New York University law school faculty member co-authored the just-published book, "The HPV Vaccine on Trial: Seeking Justice for a Generation Betrayed.") And the media can still sensationalize the unsubstantiated claims, fueling a panic.

Japan is the most extreme illustration. Vaccination rates among

adolescent girls plunged from more than 70 percent in 2013 to less than 1 percent today. The collapse began when Japanese media carried unverified reports of vaccine harms, even showing parents' videos of girls in wheelchairs or having apparent seizures. Then the Japanese government suspended the recommendation for HPV vaccination, even though its own health ministry found no evidence to support the allegations. The suspension remains in effect.

The World Health Organization's advisory committee on [vaccine safety](#) lamented, "Despite the extensive safety data available for this vaccine, attention has continued to focus on spurious case reports and unsubstantiated allegations."

In Denmark and Ireland, government and private health authorities responded to plunging [vaccination rates](#) with strong campaigns that have been rebuilding public confidence in the vaccine.

It's interesting that one of the poorest countries on Earth—where cervical cancer is a major killer because of the lack of screening programs—now boasts 93 percent vaccine coverage of sixth-grade girls. Rwanda's program, launched in 2011, received free and then discounted [vaccine](#) from Merck. But the government also invested in a nationwide community-education campaign that reached religious, educational, political, and tribal leaders.

"It was important first to explain the link with cancer," Agnes Binagwaho, a Rwandan pediatrician who served as health minister during the campaign, wrote in the Conversation.

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Citation: The cancer-preventing HPV vaccine a dozen years on: Progress, fear and loathing

(2018, November 9) retrieved 26 June 2024 from

<https://medicalxpress.com/news/2018-11-cancer-preventing-hpv-vaccine-dozen-years.html>

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