

# 10 Things To Know About The New HPV Vaccine

The Food and Drug Administration has approved a new version of Gardasil, the vaccine against human papilloma virus (HPV) manufactured by Merck & Co. The updated vaccine shields against nine strains of the virus, a known cause of cervical cancer, while the original vaccine protects against just four types of HPV.

## 1. The new vaccine, Gardasil 9, has the potential to prevent 90 percent of cervical, vulvar, vaginal, and anal cancers.

It shields against HPV types 16 and 18, plus the newly added types 31, 33, 45, 52, and 58, according to the [FDA](#).

“The strains that they’ve added are probably not as common [in people with cancer] as 16 and 18,” says Leah Millheiser, M.D., a clinical professor of gynecology at Stanford University. But they are still worrisome: In a [Journal of Infectious Diseases](#) study, types 16, 18, and 31 alone represented 37 percent of infections among women infected with “high-risk” HPV — that is, one of the types associated with elevated cancer odds. Another study, published in the International [Journal of Cancer](#), found that in North America, the strains most common in women with invasive cervical cancer were 16, 18, 45, 31, 33, and 52, respectively. The earlier version of the vaccine, released in 2006, guarded against the two strains of HPV — 16 and 18 — responsible for 70 percent of cervical cancers in the United States. Both versions of the vaccine protect against two types of HPV — 6 and 11 — known to cause genital warts.

## 2. The FDA based its decision on a clinical trial that included about 14,000 females ages 16 to 26.

They received either Gardasil or Gardasil 9. The researchers found that the updated version of the vaccine was 97 percent effective in preventing cervical, vulvar, and vaginal cancers caused by the additional strains of HPV (31, 33, 45, 52, and 58) that Gardasil 9 shields against. The new vaccine was just as effective as the original at preventing cancer caused by the strains of HPV (6, 11, 16, and 18) shielded against by the first version of Gardasil. According to Diane Harper, M.D., an expert in women’s health and public health, who led early research efforts for the HPV vaccine, these claims should still be considered speculative, since clinical trials are only able to assess cases of pre-cancer in patients (it’s unethical to allow participants to progress to the point of cancer).

## 3. Gardasil 9 is approved for use in females ages 9 to 26 and males ages 9 to 15.

A study conducted on approximately 4,000 females and males ages 9 to 15, confirmed the vaccine’s efficacy for this age group. At the time Merck submitted Gardasil 9 for approval, the data was lacking for older males, but Noel Brewer, an associate professor of health behavior at the University of North Carolina at Chapel Hill — who has conducted research for Merck — anticipates that within a year the FDA will approve the vaccine for males ages 16 and older.

## 4. It’s safe to be re-vaccinated.

For those who have already been vaccinated, it’s most likely safe to get the updated version if you desire the additional protection that Gardasil 9 offers, says Brewer.

## 5. The research is unclear on how long the new vaccine will last.

“We do not know that this is actually going to last long enough to really prevent any cancers,” says Harper. Unpublished data only demonstrates two years of protection against HPV for Gardasil 9, she says. “If HPV vaccines do not last longer than 15 years, there can be no cancer prevention.” Research for the first-generation vaccine suggests it lasts up to six years, according to the CDC. “We don’t have long-term data on the new vaccine,” concedes Mark Einstein, M.D., director of gynecologic oncology research at Montefiore Medical Center. However, he says, data from early clinical trials for the original version of Gardasil suggests the protection lasts at least a decade. Adds Brewer: “We call it a new vaccine, but I don’t think that’s really true. What we have is the current vaccine with some added protection. And for the current vaccine, we have a lot of data that goes out pretty far.” If Gardasil 9 proves to stop working, say, after 10 years, people who were

vaccinated as children may require a booster as adults to maintain their protection. However, if anything, “the evidence suggests that rather than going for more vaccines, we’re going toward less,” says Brewer. In many countries, the HPV vaccine has gone from three doses to two, and the U.S. will most likely follow suit within the next few years, he says.

#### **6. Gardasil is more effective if administered *before* a person becomes sexually active.**

Parents have also expressed concern about vaccinating their young children against a virus that’s contracted through sexual contact. Why not simply wait until age 16 or 17, rather than vaccinating at age 11? “You cannot predict when somebody is going to become sexually active,” says Bonnez. “And being sexually active doesn’t necessarily mean intercourse — there are lots of sexual activities that can perhaps transmit the virus. So the best guarantee is to get vaccinated before you really can be exposed to HPV.” Vaccinating someone who’s already been exposed to HPV “is not going to do much but give them a pain in their arm,” adds Einstein, who is also an assistant professor of gynecology at Albert Einstein College of Medicine.

#### **7. The vaccine is more effective in younger people.**

Even if parents are confident their children won’t become sexually active until they’re 18, the vaccine is still more effective in younger people. “As women get older, above the age of 26, their immune response is not going to be as good,” says Millheiser. Research has even shown that in a cohort of females ages 9 to 26 — the age range for which the vaccine is approved — the older women exhibited a weaker antibody response to the vaccine, she says.

#### **8. As with its predecessor, Gardasil 9 has minimal side effects.**

In a study of 13,000 people, the most common adverse reactions were pain at the injection site, swelling, redness, and headaches, according to the FDA.

#### **9. Gardasil 9 may reduce the rate of abnormal Pap smears among women — and that may translate to fewer invasive tests being performed.**

Why? The updated vaccine covers types of HPV that are less likely to cause cancer than types 16 and 18, but that still account for a large number of pre-cancers detected through screenings, says William Bonnez, M.D., a professor of infectious diseases at the University of Rochester, who helped develop the technology that led to the HPV vaccine. “Most of these pre-cancers don’t go on to be cancer.” Since Gardasil 9 shields against pre-cancer caused by these types, “women will be less likely to have abnormal Pap smears that require expensive, sometimes painful follow-up,” says Brewer. In fact, Brewer expects that eventually, the updated vaccine will prompt changes in cervical cancer screening recommendations for women. “Because the vaccine is more effective in preventing cervical cancer, we’ll be able to screen less often,” he says. “Maybe we can do it every 10 years. Or maybe you get screened once when you’re 30, and if it’s negative, then you don’t get screened again.”

#### **10. But women should not forgo Pap smears just yet.**

“The vaccine is really more of a safety net, not a replacement for screening,” says Einstein. “There are over 100 strains of HPV. [The strains that Gardasil protects against] are the more common forms of HPV that cause cervical cancer and these other types of cancer, but not the only ones,” adds Millheiser. “I certainly have patients who received the full series of HPV vaccines who come back with cervical dysplasia several years later.” So women should not forgo routine screening for cervical cancer until national recommendations change.