

The HPV vaccine is effective and safe, and it is vital

👉 I say so because the experts have said so—
emphatically and on solid scientific footing

Heightedened controversy over the US Food and Drug Administration-approved vaccine against human papillomavirus (HPV) has made headlines in the medical literature and across the lay press in past weeks. What are we clinicians to make of the discussion, 3 years after FDA approval? What can we know with reasonable certainty about the vaccine and its role in the care and well-being of our patients?

First, here are three conclusions about the HPV vaccine that I accept, and that I urge you to accept, too—for the good of protecting your patients against cervical cancer. Second, here is what I know that leads me to those conclusions.

Concluded: Good science stands behind the HPV vaccine

Dr. Harold zur Hausen was a co-winner of the Nobel Prize in Physiology or Medicine in 2008 for the discovery that oncogenic HPV types cause most cases of cervical cancer and many cases of vaginal and vulvar cancer. This important discovery was followed

by delineation of the natural history and molecular mechanisms of virally induced cervical cancer and by development of vaccines against HPV.

Concluded: The HPV vaccine is effective

The FDA approved a quadrivalent vaccine (Gardasil; Merck) against HPV types 6, 11, 16, and 18 in June 2006. In part, the agency's approval was based on studies of approximately 20,000 girls and women, half of whom received the vaccine and half who received a control injection. These studies demonstrated that, in women who had not been previously infected with these viral types, Gardasil was very effective at preventing **1) precancerous changes linked to cervical, vaginal, and vulvar cancer and 2) genital warts.**

In September of this year, an FDA panel reviewed the efficacy and safety of a bivalent HPV type 16 and 18 vaccine (Cervarix; GlaxoSmith-Kline) and recommended that it be approved by the agency. Cervarix will likely be available next year.

Concluded: The HPV vaccine is as safe as any other vaccine

In August, the Centers for Disease Control and Prevention (CDC) published its analysis of 12,424 reports of adverse events following immunization with Gardasil.¹ In comparing the

frequency of HPV vaccine adverse-event reports with reports across different immunizations, the CDC identified two adverse events that occurred more often with Gardasil: **syncope and venous thromboembolism.**

First, it's unclear what mechanism underlies an association between syncope and vaccination.

Second, an association between venous thromboembolic events and vaccination could be due, in part, to a woman initiating estrogen-progestin contraception in a period that overlaps the span of the three Gardasil injections. Here's an example of how causation for that adverse event can be misassigned.

Illuminating case. In my practice area, there was a report recently of a young woman who consulted a gynecologist after beginning sexual intercourse. She started an estrogen-progestin contraceptive and received three Gardasil shots.

Subsequently, the woman suffered trauma to her calf and, in short order, developed deep venous thrombosis (DVT) and pulmonary embolism. Testing revealed a genetic predisposition to thrombosis: She carries the prothrombin 20210A mutation.

Clearly, Gardasil did not cause this woman's DVT; contributors to DVT and to the pulmonary embolism were a genetic predisposition

Would you give the HPV vaccine to your young daughter?
At what age?

Instant Poll

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to thrombosis, calf trauma, and an estrogen-progestin contraceptive. In the CDC's safety report, most women who suffered DVT were either taking an estrogen-progestin contraceptive or smoked cigarettes—two clear risk factors for DVT.¹

Experts say “Yes.” Most professional associations of expert clinicians and investigators support vaccination against HPV because Gardasil is effective and safe. ACOG, for example, and the American Society of Colposcopy and Cervical Pathology (ASCCP), the Society of Gynecologic Oncologists (SGO), and the American College Health Association all support HPV vaccination in appropriate clinical settings.

Concern over vaccine safety persists in the community

Some parents of autistic children believe that childhood vaccinations may contribute to the development of autism. Thorough investigation of the issue by many scientific panels led all of them to conclude that evidence does not support such a link, but some consumers remain concerned.

It is always possible to raise the concern that “we don't know every possible risk of a vaccine, so we should be cautious using them.” It is also easy, and common, when considering vaccine safety, to misinterpret **associated events** as **causally-linked events**. When, as I noted, a woman initiates sexual activity, it is plausible that she simultaneously begins taking an estrogen-progestin contraceptive and is vaccinated against HPV. Side effects associated with the contraceptive could be misinterpreted as caused by the vaccine.

Allow the community of physicians to lead!

Medicine is a complex undertaking.

Practicing it requires experienced, well-trained clinicians to work with patients and their families so that the risks and benefits of any treatment are balanced against the particular circumstances of an individual. My recommendation is that government and society, first, **let the physicians take the lead**, and, second, **reduce the role of public agencies and their proscriptive policies in determining how HPV vaccination should be used** during its first few years of clinical availability.

Here's an example of what I'm calling for. The Advisory Committee on Immunization Practices (ACIP) recommends the HPV vaccine for girls at 11 and 12 years.² Given the heterogeneity of sexual mores in the United States, this recommendation is likely to alarm, and even anger, some citizens.

But there is an alternative open to the ACIP: It can recommend strongly that clinicians, patients, and parents thoroughly discuss the pros and cons of vaccination and, in concert, weigh giving the vaccination at an age that is appropriate for the individual girl or woman, given her circumstances. ACIP should also strongly communicate, as an important public health message, that the vaccine is most effective when a girl or woman is immunized before she is exposed to HPV.

It was likely a strategic error for HPV vaccine advocates to attempt to make it a prerequisite for 11- and 12-year-old girls to be admitted to public high school. Of course, government mandates that touch on personal and private matters often trigger resistance from citizens who oppose what they perceive as intrusive.

Again, I urge: **Let physicians take the lead to help their patients determine the best approach to how the HPV vaccine is used**, based on

Instant Poll

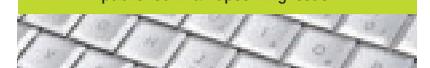


At what age would you agree to have your young daughter vaccinated against HPV?

- 9 or 10 years
- 11 or 12 years
- Between 15 and 17 years
- Just before she starts sexual activity, regardless of age
- I would not recommend that she be vaccinated against HPV at any age

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each woman's personal circumstances.

Any preventive strategy must be broad

The HPV vaccine will continue to be a key means of preventing cervical cancer. But this is a complex disease phenomenon; it's certain that a multimodal approach to prevention will be required to tame it. Individual and societal actions that are likely to reduce the risk of cervical cancer include:

- interventions to reduce poverty and improve education
- delaying sexual debut until maturity
- routinely using a barrier to help prevent transmission of sexually transmitted infection
- limiting the number of one's sexual partners
- large-scale vaccination programs.

It helps us greatly in this effort that we already have a vaccine that works and is safe. ☺



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Dr. Barbieri reports no financial relationships relevant to this Editorial.

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