

How to Meet the Challenges of HPV Vaccination

BY CHRISTINE KILGORE

Discussing the risks of the human papillomavirus and vaccinating teenage and young adult patients is no easy feat, but many gynecologic practices will find they can do it – and be “in the black” financially – if they just appoint an office “vaccine advocate” to take charge of instituting national vaccination recommendations.

So says Dr. Stanley A. Gall, professor of obstetrics and gynecology at the University of Louisville (Ky.) and the American College of Obstetricians and Gynecologists’ liaison to the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention.

Uptake of the vaccine has been slower and lower than it has been for other vaccines, he and other experts say, and both surveys and interviews with physicians around the country indicate that physicians face a host of moral, ethical, and safety concerns from parents, even though almost 5 years have passed since Gardasil (the first of two HPV vaccines) was licensed.

Pediatricians are vaccine experts and are used to low fees for vaccine administration, but in the case of HPV vaccine,



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they’re challenged by their key age group: the 11- to 12-year-olds for whom the vaccine is recommended as part of the regular immunization schedule.

A recent survey of more than 1,500 parents showed that the HPV vaccine was the most commonly refused pediatric vaccine. Almost 80% of the parents who refused said they believed there had not been enough research on it, 51% said it challenged their belief systems, 59% said they believed their children were at low risk for contracting the sexually transmitted disease, and 37% said they did “not believe the vaccine is effective in preventing the disease” (*Pediatrics* 2010;125:654-9).

Ob.gyns., on the other hand, are better positioned to discuss HPV infection as a sexually transmitted disease, but for many, vaccination requires a true “paradigm shift” in terms of practice values and resources.

HPV vaccination is recommended by ACIP on a “catch-up” basis for young women aged 13-26 years. Most private insurers cover vaccination, sources said, although coverage through some insurers diminishes in the 19- to 26-year age bracket. The public sector, Dr. Gall said, is now “catching up” with the private sector in covering HPV vaccination.

“Practices need to look at the reimbursement they’re getting [or would get]

from a handful of their insurers, and find out if they’re in the black or the red,” said Dr. Gall, a member of ACIP’s working group on HPV. “A lot of times, offices find that even though the amounts are small, they can make money.”

Success with HPV vaccine administration – as well as the administration of other vaccines – often comes with the appointment of a nurse or other practice member who “feels passionate” about the value of vaccination and can take charge of ordering and properly storing vaccines as well as teaching staff about proper vaccination indications, schedules, and techniques, said Dr. Gall.

“The physician shouldn’t even have to think about it,” he said, noting that practices must institute standing orders for vaccines to be delivered in the physician’s absence. “Take it out of their hands and make it a routine in the office.”

Even though the ob.gyn. practice staff may be more likely than pediatricians to find patients and parents more appreciative of HPV risks, it is still important to understand and anticipate the common reasons for refusal of the vaccine, Dr. Gall and other experts told this news organization.

For one, “there isn’t as immediate a preventive effect” to appreciate compared with other vaccines,” said Dr. Gary L. Freed, immediate past chairman of the National Vaccine Advisory Committee and director of the division of general pediatrics and the child health evaluation and research unit at the University of Michigan in Ann Arbor.

“We can do better at being straightforward in addressing the issues of HPV, with both [teens] and their parents,” he said.

The following are some of the suggestions offered and experiences shared by these physicians and others:

► **The “Why Now” Factor.** HPV infection is the most commonly occurring STD. About 20% of adolescents are infected with HPV within 2 years of the onset of sexual activity, said Dr. Joseph Bocchini, immediate past chairman of the American Academy of Pediatrics’ committee on infectious diseases and chairman of the department of pediatrics at the Louisiana State University Health Sciences Center in Shreveport.

It is important to emphasize, however, that vaccination is not about sexual readiness or sexual activity but about preventing cervical cancer – and, sources said, it’s important to give numbers.

Dr. Stan Block, who practices in a six-pediatrician group in Bardstown, Ky., with a large adolescent population, explains that “the lifetime risk of getting cervical, anal, vaginal, or vulvar precancer or cancer goes from about 1 in 20 without vac-

ination to 1 in 50 with vaccination,” and that the risk of venereal warts similarly drops from 1 in 10 without vaccination with Gardasil to about 1 in 100 with vaccination.

“We explain that even precancerous lesions can have serious consequences, like surgery and the inability to have children,” said Dr. Block, who estimates that his practice has an 85%-90% HPV vaccination rate in female patients.



Tell patients that at least 10,000 women die each year of cervical cancer, and HPV causes cervical cancer.

Dr. Michael E. Pichichero, director of the Rochester (N.Y.) General Hospital Research Institute, advises telling patients and parents that “studies show without a doubt that when you vaccinate at a younger age, you get much higher immunity levels.”

And Dr. Charles Wibbelsman, a pediatrician who is chief of adolescent medicine at Kaiser Permanente in San Francisco, advises telling patients that at least “10,000 women die each year of cervical cancer



Emphasize vaccination is not about sexual activity, but about preventing cervical cancer.

DR. BOCCHINI

and countless others have cervical cancer, and that HPV causes cervical cancer.”

► **Safety.** At least several studies have shown that the vaccine would receive greater acceptance if it was perceived to be safe by parents.

“I tell parents that the vaccine has now been received by literally hundreds of thousands in this country, and that there are no serious adverse events associated with the vaccine,” said Dr. Freed. “Then I say that in the same time period, there likely have been at least several thousand young women who have been infected with HPV who will develop precancerous cervical lesions and may go on to develop cervical cancer.”

Others said they refer parents who are concerned about safety to the CDC’s Web site for vaccine safety profiles (www.cdc.gov/vaccinesafety/vaccines/hpv). “This way, it’s not me talking, and not the manufacturer, but a body with a lot of credibility,” said Dr. Gall.

According to the CDC Web site,

approximately 32 million doses of Gardasil were distributed in the United States from the time the vaccine was licensed in 2006 until September 2010. All serious adverse event reports made to the Vaccine Adverse Event Reporting System have been fully investigated, with staff finding “no pattern or clustering ... to suggest they were caused by the HPV vaccination,” the Web site says.

Syncope and fainting are common in preteens and teens after injections, the CDC notes, making the recommended 15-minute postvaccination observation period extremely important. Patients should lie down or sit for this period of time.

► **Duration of Efficacy.** Manufacturers have tracked vaccine recipients for up to 8-10 years at this point, with no “breakthrough cases” of HPV infection, sources said.

“We can [say] that, as with any new vaccine, we [don’t know] how long efficacy will last, but that we do know the vaccine is highly immunogenic, that we’re seeing no breakthrough cases in the recipients being followed, and that we know protection will last at least 7 and a half years, and likely significantly longer,” said Dr. Bocchini. If needed in the future, a booster dose will become available.

► **Vaccine Differences.** The most important facts for parents and/or older patients to know, several physicians said, is that both Gardasil and Cervarix protect against the two strains of HPV (types 16 and 18) that are believed to cause 70% of all cervical cancers, and that Gardasil also protects against HPV-6 and -11, the most common cause of genital warts.

Teens should know the value of protecting against genital warts, they said. “There are about a million new cases of genital warts each year in this country, and the amount of money spent treating them is equivalent to the amount of money spent treating cervical cancer,” not to mention the fact that genital warts cause significant anguish, said Dr. Gall.

Dr. Pichichero, however, said that Cervarix contains a novel adjuvant that is believed to be responsible for its ability to generate a greater antibody response to HPV-16 and -18, compared with Gardasil. Higher antibody titers may translate into a longer duration of protection, he said.

Cervarix also has been shown, he said, to afford some level of cross-protection against other HPV strains that are responsible for a small yet significant proportion of cervical cancer cases. Although such differences should be weighed in the long term, right now it seems that parents are more concerned about safety and experience with the vaccines, and physicians should focus on this, he said.

Dr. Block has done research for both manufacturers and is on the speakers bureau for Gardasil (Merck’s HPV vaccine). Dr. Pichichero has served as a consultant for both Merck and GlaxoSmithKline, the manufacturers of Gardasil and Cervarix, respectively. Dr. Gall said he was working on clinical trials and is a speaker for GSK and Merck. The other physicians reported no disclosures. ■