Proposed HPV Vaccine Mandates Rile Health Experts Across the Country

By Liz Savage

While the HPV vaccine is being touted by many as one of the greatest breakthroughs in cancer prevention, some public-health experts are concerned that the rush to mandate the vaccine could backfire.

About 20 states have proposed legislation to require adolescent girls to be vaccinated against HPV (human papillomavirus) since Merck’s vaccine was approved by the U.S. Food and Drug Administration in June 2006 to prevent cervical cancer. But many state legislators have backed down after parents, advocacy groups, and public-health officials protested the proposed mandates. Many blame Merck’s lobbying efforts for the unprecedented push to vaccinate against HPV, while others point to overeager provaccine advocacy groups. Whatever the cause for this political hubbub, the debate has brought HPV vaccination into the national limelight.

The problem, some say, is that the controversy is focused on the wrong issues. “This is a marvelous vaccine. And instead of talking about that and how we can try to bring this to everyone who should get it, the discussion has shifted to be about the controversy of mandating vaccines,” said Alan Hinman, M.D., a senior public-health scientist at the Taskforce for Child Survival and Development in Decatur, Ga.

Misguided Mandates?

Hinman is one of many public-health experts who think efforts to mandate the HPV vaccine are premature. Jon Abramson, M.D., chairman of the Advisory Committee on Immunization Practices— the Centers for Disease Control and Prevention committee that recommended the vaccine last summer—said that while he recommends the vaccine for girls, a mandate poses serious logistical and financial problems.

But the criticism of the proposed mandates is more wide reaching. “I think the advocates have been well meaning [in their efforts] to reduce cervical cancer by 70%, but I think it’s misguided. And all the people that have been advocating don’t understand the complexities that go into a mandate,” said Walt Orenstein, M.D., former director of the CDC’s national immunization program and currently associate director of the Emory Vaccine Center. For one, he said, it’s important to have consensus among parents, physicians, and public-health experts for a vaccine program to be successful—something that is hard to achieve before everyone has all the facts. Some parents oppose a mandate because of concerns over parental autonomy or that it might encourage sexual behavior among vaccinated girls.

Orenstein and other public-health experts say it’s just too early to consider a mandate that would require the vaccine before kids could go to school because there are still too many unknowns. “Here people were considering mandates before the official recommendations were even published,” Orenstein said. (In September 2006, Michigan was the first state to propose legislation to require sixth-grade girls to be vaccinated against HPV.) For example, researchers don’t know for sure how long the vaccine will provide protection. Studies indicate that it lasts at least 5 years, though some evidence indicates that it might last longer. “We just don’t know what to tell these girls,” said Diane Harper, M.D., a professor at Dartmouth Medical School.

Another reason to wait before mandating is to see how many parents voluntarily get their daughters vaccinated. It may turn out that we don’t need to mandate it, if enough girls willingly get the vaccine, said Claire Hannan, executive director of the Association of Immunization Managers. Even if only a small percentage of girls are getting it, Hannan isn’t sure that a mandate is the way to solve the problem, she said. “We feel like [vaccine mandates] should be used to protect children in school and achieve high coverage rates and to get that last group that, for whatever reason, hasn’t
gotten the vaccine—not to implement a new vaccine and not to get really high coverage of the vaccine in the first year. We think that school laws are really important and they should not be thrown around every time a vaccine comes on the market.”

Without long-term data on the vaccine, she said, the entire vaccination program is at risk if the HPV vaccine has unforeseen consequences, such as encouraging parents to opt out of other vaccinations, or has rare side effects.

Other potential consequences of the vaccine include sending girls the wrong message, Harper said. “I’m concerned that people believe that they are impervious to cervical cancer [after being vaccinated] because that’s what the ads and TV and media have been saying.” The vaccine protects against two types of HPV that cause 70% of cervical cancers, but vaccinated girls will still be susceptible to 13 other cancer-causing strains. “So by mandating the vaccine, the message that is sent is that we think this is such a great vaccine that everybody has to have it and it will protect you from cancer. And the truth is if these girls don’t continue in a Pap screening program, we’re going to be in worse shape than we were prior to the vaccine,” she said.

Financial barriers could also prevent many girls from receiving the vaccine. At $360 for the three required doses, Merck’s HPV vaccine (Gardasil) is one of the most expensive vaccines recommended for children. Already, many doctors are not providing it to patients because they can’t afford the upfront price tag or they are worried that insurance companies will not fully reimburse them. Requiring the vaccine would add to the mounting vaccination costs for state health departments, private physicians, and parents. In 1995, it cost $155 to give a child all the CDC-recommended vaccines; today, the cost has risen to $834, not including the HPV vaccine, according to CDC statistics.

Mopping up the Mess
But not everyone thinks it’s wise to move so cautiously. According to Bradley Monk, M.D., professor of gynecologic oncology at the University of California–Irvine Medical Center, every day 10 women die of cervical cancer in the United States, and to delay mandating this vaccine because of some uncertainty is like not using penicillin because you’re waiting for a better antibiotic.

“We just want responsibility, and responsibility comes from education. And that’s what mandatory vaccination is all about. It’s not forcing people to get vaccinated. It’s forcing them to refuse vaccination in writing,” Monk said.

Efforts to address concerns over vaccine mandates are already under way. To ease financial burdens, some states, including New Hampshire and South Dakota, have established programs to provide free HPV vaccinations to any girl in the state who wants it. In New Hampshire, this solution may take the place of a mandate. “We feel we have adequate access for uninsured and patients on Medicare that we don’t feel it’s necessary at this early stage in the vaccine [to mandate it],” said Michael Dumond, program manager of the New Hampshire Immunization Program. Also, Merck’s HPV vaccine has been added to the federal Vaccines for Children program, which provides free vaccinations to children who are uninsured or eligible for Medicaid.

Several studies are under way to try to address the uncertainties about the vaccine’s lasting effects. Merck and GlaxoSmithKline—which announced last month that it submitted a licensing application to the FDA for its own HPV vaccine—are continuing their trials to determine how long the vaccine protects against the virus. The CDC also has a safety monitoring system in place to look for rare side effects in new vaccines.

Of course, those studies will take time, and in the interim, experts agree that better public education on this issue is critical. Several recent studies have shown that accurate knowledge of HPV and the vaccine is low, despite that, by age 50, at least 80% of women will have had an HPV infection. (Most infections clear up on their own.) A study in the February 1 Cancer Epidemiology Biomarkers and Prevention showed that most American women were uninformed about HPV and its link to cervical cancer. Only 40% of the women had ever heard of HPV, and less than 50% of those women knew that it causes cervical cancer.

Several states are now considering legislation to provide information on HPV vaccination to parents, a move that might lead to mandates in the future. To be successful, education campaigns will have to overcome concerns of vaccinating against a sexually transmitted disease. That stigma could hinder the vaccine’s acceptance among parents, but a recent study found that even among women with only one sexual partner, more than 14% had HPV.

Education might be the key to helping parents understand why the vaccine is considered such a breakthrough. “It is very important that girls get vaccinated before they start having sex, since studies have shown that most girls will develop HPV shortly after first having sex,” said Curtis Allen, a CDC spokesperson. “Many parents say, ‘My daughter isn’t having sex. She’s too young for that.’ That’s the point.”