Nearly one year after approved use of the first cervical cancer vaccine, lawmakers still struggle with difficult public health questions. How far should state governments go in promoting abstinence, Pap tests and vaccines? Scientific trends show these questions will be more common as other cancer vaccines are developed in coming decades. At stake are thousands of lives and a potential savings of millions of public dollars in long-term and end-of-life care.

By Julia Nienaber Hurst
Gardasil, the first cervical cancer vaccine, has been on the market since June 8, 2006. A second cervical cancer vaccine, Cervarix, begins its approval process this month.

Combined, these vaccines protect against at least four types of human papillomavirus (HPV), two of which are known to cause 70 percent of cervical cancer cases. According to the American Cancer Society, 3,700 American women are likely to die this year from cervical cancer, underscoring the vaccine’s potential to significantly reduce the economic burden to states and save lives.

States may experience savings in other ways as well. The U.S. National Cancer Institute reported in December 2006 that approximately 3.5 million women per year—6 percent of those receiving Pap tests—require follow-up tests for an abnormal Pap result. The second test may range from a repeat Pap test or HPV test to biopsy.

This vaccine could make significant changes.

“You would expect to see a huge decrease in the number of abnormal Pap tests,” Dr. Kevin Ault of the Emory University School of Medicine told the health Web site Healthology in November 2005.

By reducing HPV infection rates, the number of abnormal Pap tests goes down, saving the states money. Ault added, though, the vaccines only eliminate the biggest cause of cervical cancer—not all causes.

Public Health Campaign

In August 2006, the National Lieutenant Governors Association (NLGA) launched “Ending Cervical Cancer in our Lifetime,” a public health education campaign designed to share with constituents the medical facts related to cervical cancer, without advocating specific action. The campaign is funded by two separate independent public policy grants from Merck & Co. Inc., which makes Gardasil, a corporate contribution from GlaxoSmithKline and the National Lieutenant Governors Association.

“Cervical cancer is a scary disease because it’s hidden, mysterious and deadly,” said Minnesota Lt. Gov. Carol Molnau. “It thrives on ignorance, and we (are going) to make people aware of it. No one should die because of cervical cancer.”

The first statement in NLGA materials reads, “The surest prevention of HPV infection, and possibly cervical cancer, is abstinence.” HPV is the most common sexually transmitted virus, according to the Centers for Disease Control and Prevention (CDC).

HPV can be spread through skin to skin contact in the genital area, and most sexually active adults will be infected with HPV at some point in their lives. HPV causes no symptoms and usually goes away on its own, according to the Association of Reproductive Health Professionals. However, high-risk HPV, which stays in the body for years, can cause cervical cancer. Abnormal cells caused by HPV in a woman’s cervix can be detected by a Pap test. Cervical cancer can be prevented or cured by removing these abnormal cells early, so Pap tests are recommended regularly.

The vaccines are shown to prevent 70 percent of the cases of this cancer and, correspondingly, to reduce both death and HPV infection rates. However, only abstinence is wholly effective for prevention of the infection. These facts were laid out in the NLGA public education campaign.

The campaign also promoted the free- and reduced-cost Pap tests available in states and encouraged constituents to pass
on the cervical cancer information to others. Lieutenant governors were joined by abstinence advocates, cancer survivors, university presidents, heads of health departments and Olympian Jackie Joyner-Kersee.

“In Illinois, my home state, more than 640 women will be diagnosed with cervical cancer this year and 190 will die from it,” said Joyner-Kersee. “Cervical cancer affects women of all ages, races, and backgrounds—and it’s time we join together and work toward ending this disease.”

“Cervical cancer is detectable, treatable and curable if found at an early stage,” said Illinois Lt. Gov. Patrick Quinn. “I urge every woman in our state to visit her health care provider and be screened for cervical cancer.”

Public Policy Questions
With the first cancer vaccine now available, state officials grapple with difficult public policy questions. Should states:

- Mandate vaccination? If so, at what age, for which gender, and what provision should be made for parents to opt out of the vaccination?
- Help finance availability of the vaccine?
- Establish or increase Pap test funding and education?
- Establish or increase abstinence education?

Women in Government (WIG), a bipartisan group of female state legislators, reported 45 states considered some type of cervical cancer action already this year. Since September 2006, WIG supported mandatory school-age vaccination and funding for low-income individuals to receive the vaccine.

Mandatory Vaccines
Texas Gov. Rick Perry is engaged in legal debate following his Feb. 2 executive order mandating cervical cancer vaccination of age-appropriate females. With the order, Texas became the first state to mandate vaccination. Virginia Gov. Tim Kaine said in March that he would sign legislation passed by that General Assembly to mandate the vaccine, with an opt-out, for girls entering the sixth grade, beginning in 2008.

The Food and Drug Administration (FDA) approved Gardasil for females ages 9 to 26. The Advisory Committee on Immunization Practices (ACIP) for the CDC later voted unanimously to recommend that girls ages 11 and 12 receive the vaccine. However, Dr. Jon Abramson, ACIP chair, told The Washington Times on Feb. 27 that he personally opposes mandatory vaccination for school attendance. To date, mandatory vaccinations have been for childhood diseases easily transmitted in a classroom setting, such as mumps, polio and whooping cough.

“A child in school is not at an increased risk for HPV like he is measles,” said Abramson.

“The decision to make this mandatory this early has created significant controversy over things that have nothing to do with the vaccine,” said Dr. Joseph Bocchini, chairman of the committee on infectious diseases of the American Academy of Pediatrics.

Some Christian groups such as Focus on the Family support widespread availability of the vaccine, but question whether mandated use at an early age may force parents to discuss sexuality earlier than they planned, and if use will give children a “false sense of security” leading to promiscuity.

“While most of us have welcomed the HPV vaccine with open arms as a tool to mitigate the effects of a sexually transmitted disease that can lead to cervical cancer, we must also recognize that vaccine mandates hold the potential for undermining civil rights, and parental rights in particular,” the Christian Medical and Dental Associations states in a position paper.

The age at which one gets the vaccination, voluntarily or by mandate, “is a delicate balancing act,” said Debbie Saslow of the American Cancer Society. “If the vaccine is given too young, it may wear off. Yet, if given too late, it won’t work.”

The American Medical Association (AMA) reports Cervarix is effective for more than four years, according to presentations made in February to the CDC. Merck, the maker of Gardisil, reports it is testing longevity but know it is effective for five years. Booster vaccines are in development and boosters vary in longevity. A hepatitis B booster is required every 10 years, while others provide lifelong immunity.

Most debate on the vaccine has focused on women because the vaccine is approved for female use. However, testing is underway for potential future approval for males.

“I think vaccinating all sixth graders—boys and girls—is a good idea. It might save their lives someday,” said Dr. Albert Jenson, a member of the research team that perfected the vaccine. In addition, most states have opt-out provisions for vaccinations, but these vary widely. (See resources box)

Financing Vaccines
Gardisil is administered in a series of three shots given over six months and costs $360. State officials may mandate that insurers
cover the cost of the shots. This is being considered in New Jersey, New Mexico, Nevada, Rhode Island and other states. States may also review state employee health plans to determine if they cover the cost of vaccination. Some point out, though, that these types of mandates ultimately drive up the cost of insurance.

In their budget addresses, Kentucky Gov. Ernie Fletcher asked for $4 million for voluntary vaccinations, and Massachusetts Gov. Deval Patrick asked for $24.8 million to provide universal state coverage for three new immunizations, including optional HPV vaccination. Likewise, South Dakota Gov. Mike Rounds has Senate approval for $9.2 million to fund voluntary HPV vaccinations at no cost to females ages 11 to 18. Other states are debating making funding available for the vaccine to Medicaid populations.

Pap Tests
More than half the women who develop cervical cancer have either rarely or never had a Pap test, according to the CDC. Yet, every state offers low cost or free Pap tests. Nationally, though, these programs are only reaching about 20 percent of the women between the ages of 50 and 64 who are eligible, according to the CDC. The average cervical cancer patient is 47, according to the American Cancer Society.

Missouri Lt. Gov. Peter Kinder stressed the need for Pap tests as part of his campaign. “Women should commit to get a regular Pap test and follow up on results. Informed sexual decisions and regular screenings can rid us of cervical cancer,” he said.

Funding for and promotion of Pap tests are additional questions lawmakers face regarding cervical cancer.

Abstinence Education
Some officials say the issues of abstinence and vaccination are not mutually exclusive.

House Bill 358, passed by Utah lawmakers, directed health officials to educate women about the causes, risks and possible prevention of cervical cancer. The legislation would require the Utah Department of Health to conduct an annual public awareness campaign for health care providers, parents and women of all ages.

The language says the campaign must emphasize “abstinence before and fidelity after marriage” as the most effective way to prevent transmission of HPV. This legislative model shows how cervical cancer health education can include both abstinence and vaccination information, much like the NLGA campaign. In Texas, debate surrounding the governor’s executive order focuses on the fact that that state has abstinence-only sex education policies.

Trends
Even if state officials reach a consensus on the difficult questions surrounding the HPV vaccine and cervical cancer, it is unlikely to end the debate. Scientific trends indicate the opposite. Vaccines for other cancers with viral causes are likely on the way.

Dozens of studies dating from the 1990s indicate approximately 15 percent of the worldwide cancer burden is caused by viruses. “Nasopharyngeal cancer, for instance, certain gastric cancers are viral related, liver cancer is linked with the Hepatitis B virus,” Dr. Elizabeth Garner, a gynecological oncologist, told PBS.

HPV itself is already known to be the cause of other cancers. “Cervical cancer is not the only cancer caused by HPV,” said Garner. “Certain vaginal cancers and vulva cancers are also caused by HPV. In men, certain penile cancers are caused by HPV; there are some oral cancers that seem to be related, so these (existing HPV) vaccines have the potential to prevent all these cancers.”

A 2002 study by KJ Syrjanen published at the National Center for Biotechnology Information reports that HPV DNA was found in more than 20 percent of the lung cancer cases studied.

“With this knowledge that it’s possible to accomplish protection against a cancer that’s caused by a virus, there definitely is going to be much more research going into that area,” said Dr. Garner.

The result will likely be more cancer vaccines to market in the future.

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