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HPV VACCINE AND STATE MANDATES

In June 2006, the Food and Drug Administration (FDA) announced its approval of a vaccine known commercially as Gardasil for prevention of the common and potentially deadly human papillomavirus (HPV), which can cause cervical cancer in women. At the same time, the Advisory Committee on Immunization Practices (ACIP), an advisory body to the federal Department of Health and Human Services and the Centers for Disease Control and Prevention (CDC), adopted a recommendation that females 11 to 12 years old should receive the HPV vaccine. The CDC endorsed that recommendation in March 2007.

In the wake of these events, several states moved to encourage, study, or mandate the use of the vaccine for school-age girls. This flurry of legislation led to a national discussion about the authority of the state to mandate use of a drug that some parents and others feel should be a matter of personal choice.

A RUSH OF STATE LEGISLATION

As of August 2007, the National Conference of State Legislatures reports that bills relating to the HPV vaccine have been introduced in 41 states and the District of Columbia. Of those states, at least 25 proposed legislation to mandate the vaccine for girls in middle school. Currently, Virginia and the District of Columbia have approved mandates. In Texas, the governor issued an executive order to such effect, but was overridden by the state legislature.

The Texas override signaled a backlash against the push for a vaccine mandate. Even

Virginia's and the District of Columbia's laws have delayed implementation dates of fall 2008 and 2009, respectively, and both have liberal exemption provisions. In total, 17 states have enacted legislation related to the HPV vaccine.

WISCONSIN ACTION

On August 16, Senators Lena Taylor and Robert Wirch introduced legislation aimed at preventing cervical cancer. 2007 Senate Bill 252 would direct the Department of Public Instruction, in conjunction with the Department of Health and Family Services (DHFS), to collect information on HPV and to share that information with school districts, private schools, and charter schools. The schools in turn would be required to make this information available to parents of students enrolled in grades 6 through 12 at the beginning of each school year, starting with the 2008-09 school year. The information compiled would have to include the recommendations by ACIP.

According to the drafting file, an early version of the bill would have repealed these statutory changes after DHFS had promulgated a rule requiring vaccinations against HPV, and after a statement to that effect had been published in the Wisconsin Administrative Register. This provision was not included in SB-252.

Senate Amendment 1, introduced on August 16, amends the bill's language to make DHFS responsible for the collection of the information. The bill has been referred to the Senate Committee on Health and Human

Services. A similar bill, 2007 Assembly Bill 492, was introduced on August 28. It is currently in the Assembly Committee on Public Health.

HPV AND CERVICAL CANCER

According to the FDA, HPV is the most common sexually transmitted disease in the United States, with an estimated 6.2 million Americans infected each year. While most strains of HPV are cleared by the body's immune system, certain types can cause abnormal cells on the lining of the cervix, which may in turn lead to cervical cancer.

Gardasil, manufactured by Merck, is effective against the two types of HPV that cause 70 percent of cervical cancer. It is also effective against the two types of HPV that cause 90 percent of genital warts. A vaccine developed by GlaxoSmithKline call Cervarix targets two strains of HPV and is awaiting FDA approval.

Higher incidence in minorities

Cervical cancer appears to occur more frequently in African-American and Hispanic women. According to statistics from the National Cancer Institute, the incidence rate of cancer of the cervix uteri for African-American women was 11.4 percent per 100,000 women per year from 2000 to 2004. The rate for Hispanic women was higher, at 13.8 percent. The rate for White women was 8.5 percent, while the rate for all races was 8.7 percent.

Although Hispanic women have a higher incidence of cervical cancer, African-American women have a higher death rate from the disease. The mortality rate for African-American women from 2000 to 2004 was 4.9 percent per 100,000 women per year. For Hispanic women the rate was 3.3 percent; for American Indian/Alaska Native women, 4.0 percent; for Asian/Pacific Islander women, 2.4 percent; and for White women, 2.3 percent.

Wisconsin and cervical cancer

According to the State Cancer Registries, administered by the CDC, between 2001 and 2003 Wisconsin had an annual incidence rate of 6.8 percent for cervical cancer. The average annual count for that period was 191 cases. Milwaukee County had the highest average annual count of 39 cases, with an incidence rate of 8 percent. According to the American Cancer Society, there will be an estimated 170 new cases of cervical cancer in Wisconsin during 2007.

GARDASIL STUDIES

According to an FDA press release marking the approval of Gardasil, a number of studies were done to test the efficacy of the vaccination. Four studies, including one in the U.S. and three multinational, tested the vaccine in 21,000 women between age 16 and 26. For those women who were not already infected with HPV, Gardasil was "nearly 100% effective in preventing precancerous cervical lesions". The FDA notes that the study period was not long enough for cervical cancer to develop, but the prevention of the lesions was assumed to be "highly likely" to result in the prevention of cancer.

Two more studies were performed on younger girls aged 9 to 15 to measure their immune response to the vaccine. The study showed the immune response to be as good as that found in the older study group, "indicating that the vaccine should have similar effectiveness" for 9- to 15-year-olds.

The press release also states that Gardasil's safety was evaluated in about 11,000 individuals. Merck agreed to conduct several studies after Gardasil was licensed, to evaluate safety and long-term effects, monitor outcomes for pregnant women, and evaluate the vaccine's effects on men.

WISCONSIN IMMUNIZATION LAW

Wisconsin's immunization program is defined in Section 252.04, Wisconsin Statutes. Subsection (3) states that the immunization requirement is waived if the parent or legal guardian (or the student, if an adult), submits a written statement to the school objecting to the immunization for reasons of health, religion, or personal conviction. The rules implementing the statutes can be found in HFS Chapter 144 of the Administrative Code. Immunizations are required for diseases including diphtheria, tetanus, pertussis, influenza, hepatitis B, measles, mumps, rubella, and varicella (chickenpox).

ISSUES IN THE MANDATE DEBATE

The HPV vaccine debate is different from other discussions on mandated immunizations because it concerns prevention of a virus that is primarily a sexually transmitted disease and because the vaccine is administered to young girls before they are adults and able to legally consent to sexual activity. Another concern is the speed at which the vaccine was approved, recommended, and pushed to be mandated.

Ensuring access v. right to choose

Proponents of the vaccine mandate have made the case that the risks and ramifications of cervical cancer are important enough to require the shot for young girls entering middle school. A mandate, some argue, would ensure access to the vaccine by all girls and women, including those most at risk of developing cervical cancer. Gardasil currently retails for \$120 per dose, or \$360 for the full three-dose regimen, making economic status an important factor in who receives the shot. (Local health departments in Wisconsin offer the shots for a reduced amount, and in some cases it is available for free.) Mandating the vaccine for young girls will ensure that it is

given when it is most effective, before sexual activity begins.

Those opposed to mandating the vaccine have made the argument that such a move takes an important decision out of the hands of parents and infringes on their right to make decisions on their child's medical care. Some also argue that because HPV is not spread by casual contact, there is no public health justification for a vaccine mandate. Still another argument is made that the vaccine encourages promiscuity in young girls, who may eschew other methods of reducing their risk, such as abstinence or monogamy.

Moving too fast?

Others worry about the precedent set by the process of mandating the HPV vaccine. They point out that the first legislation on the vaccine was introduced in September 2006, only three months after the recommendation by ACIP and before it was officially adopted by the CDC. The role and influence of Merck is also questioned. Some argue that because Merck immediately lobbied legislators for the mandate, instead of working with state public health officials, the issue has not been considered carefully enough.

The speed of the vaccine's approval itself is also an issue for some. Those who took part in clinical trials of Gardasil have been monitored for five years at the most. The test sample primarily included older girls and women, even though the vaccine was assumed to be most effective for younger girls. It is not clear whether boosters will be needed to keep the vaccine effective for the long-term.

Both supporters and opponents of HPV prevention legislation believe that because of the debate focusing on mandates, the issue of HPV prevention has been obscured.

CONCLUSION

The HPV prevention legislation has opened a new discussion about women's health care and the role of the state in

providing that care. As advances and innovations are continually made in the field of medicine and medical practice, states will have to determine what their role is in the medical decision-making of their citizens.

FOR MORE INFORMATION

A copy of 2007 SB-252 is available at: <http://www.legis.state.wi.us/2007/data/SB252hst.html>

Section 252.04, Wisconsin Statutes, on immunization: <http://nxt.legis.state.wi.us/link.asp?stats/252.04>

HFS Chapter 144, Administrative Code: <http://nxt.legis.state.wi.us/link.asp?code/ch.hfs144>

ACIP Resolution on HPV vaccine: www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0606hpv.pdf

Press release marking FDA approval of Gardasil: www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html

CDC's *Morbidity and Mortality Weekly Report* on HPV vaccine:

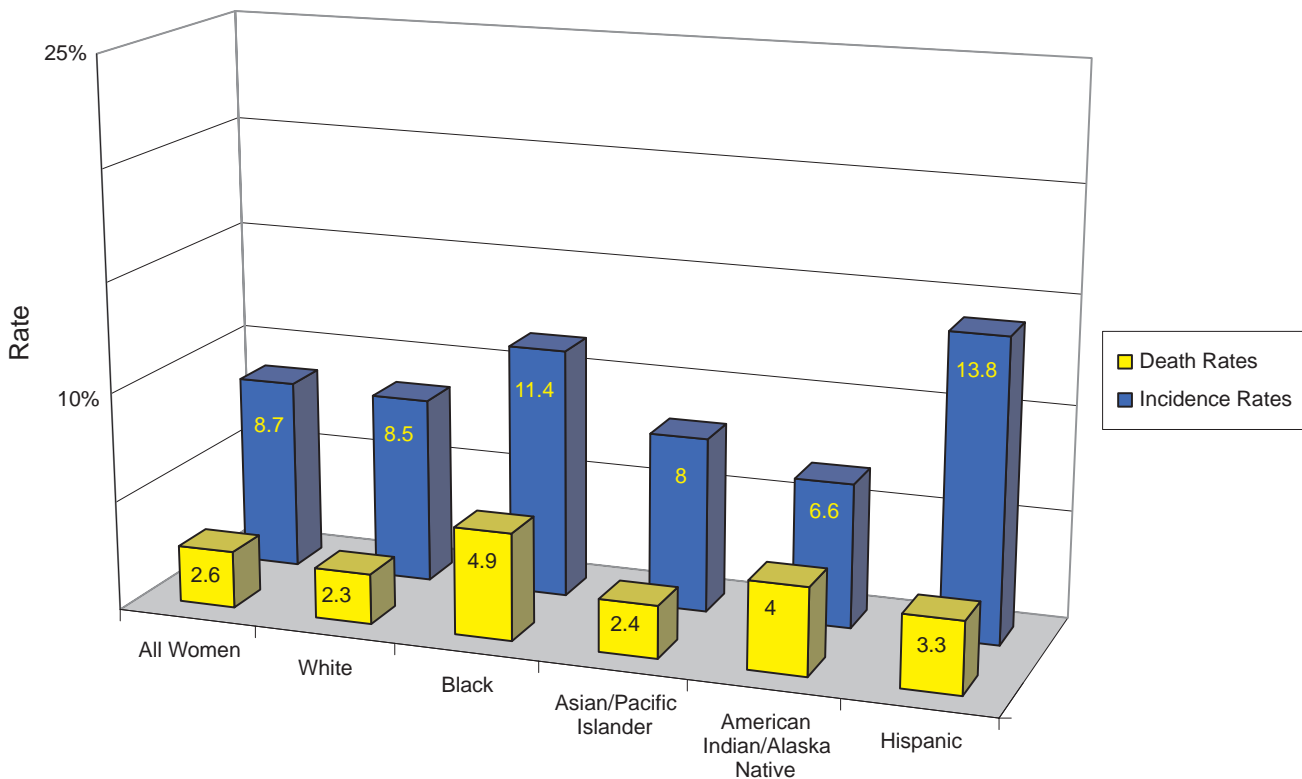
www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm

National Conference of State Legislatures - HPV Vaccine: www.ncsl.org/programs/health/HPVvaccine.htm

Gardasil Web site (Merck): www.gardasil.com

GlaxoSmithKline Web site: www.gsk.com (search "Cervarix")

**CHART: CERVICAL CANCER IN THE UNITED STATES
Comparison of Incidence and Death Rates by Race
(per 100,000 women per year, 2000-2004)**



Source: National Cancer Institute at: <http://seer.cancer.gov/statfacts/html/cervix.html>
Graphic created by Wisconsin Legislative Reference Bureau.