



CERVICAL CANCER VACCINE - HPV IMMUNIZATION

by Kelly Stapleton

Introduction

On June 8, 2006, the U.S. Food and Drug Administration licensed the first vaccine developed to prevent cervical cancer in females caused by certain types of genital human papillomavirus (HPV). The vaccine, called Gardasil and manufactured by Merck & Co. Inc., protects against four strains of HPV (6, 11, 16, 18), which are responsible for 70 percent of cervical cancers and 90 percent of genital warts. In the same month, the federal agency that evaluates and approves vaccines, the Advisory Committee on Immunization Practices (ACIP), added the vaccine to its recommended schedule of immunizations for females 9 to 26 years of age. As a result, several states introduced legislation mandating the vaccine for girls entering the sixth grade.

Background

HPV and cervical cancer statistics. The U.S. Centers for Disease Control and Prevention (CDC) reports that more than 20 million men and women in the United States are currently infected with HPV, with 6.2 million new infections each year. The CDC estimates that 70 percent of cervical cancer cases are caused by HPV infection. The American Cancer Society estimates that in 2007, over 11,000 women nationally will be diagnosed with cervical cancer, and approximately 3,700 women will die from it. In 2005, approximately 145 new cases of cervical cancer were diagnosed among women in Colorado, a rate of 6.0 per 100,000 women. The Colorado Department of Public Health and Environment (DPHE) estimates that 40 women in Colorado die each year due to cervical cancer.

Advisory Committee on Immunization

Practices. The ACIP, housed within the CDC, is responsible for evaluating the effectiveness and safety of vaccines. Comprised of 15 medical experts, the federal agency is the authority for approving immunizations and vaccines. Based on its approval, a vaccine is established as necessary and essential, and is placed on its list of recommended immunizations. In addition, the ACIP is responsible for establishing guidelines and schedules for age appropriateness, dosage, and interval of dosage of a vaccine. Gardasil was approved by the ACIP in June of 2006 and placed on its list of recommended vaccines.

Coverage of the vaccine. The three-shot immunization is approximately \$120 per shot or \$360 for the total course of three shots. When a vaccine is approved of by the ACIP, Medicaid is mandated to cover the cost of the approved vaccine. In this instance, Medicaid will use funds from the federal Vaccine for Children Program to cover the cost of the vaccine for girls up to the age of 18. Additionally, because the ACIP approved the vaccine, many private insurance companies will also add coverage of the vaccination to their health care plans. While private insurance coverage is not mandatory if an immunization is approved by the ACIP like with Medicaid, Colorado law mandates insurance coverage of all child health supervision services for children up to the age of 13, which includes immunizations placed on the ACIP list of recommended vaccines.¹

Results of Legislative Efforts

During the 2007 legislative session, 41 states

¹Section 10-16-104 (11), C.R.S.

introduced legislation pertaining to the new vaccine with provisions that ranged from mandating the vaccine for girls entering the sixth grade, to promoting educational awareness programs, to allocating state funds to provide the vaccine to uninsured girls.

Colorado. The General Assembly considered legislation to: mandate vaccination of girls entering the sixth grade; require educational awareness promotion; and mandate health insurance coverage. Colorado passed House Bill 07-1301, but it did not pass Senate Bill 07-80, which would have required the vaccination of girls entering the sixth grade.

Specifics of House Bill 07-1301 are as follows.

- It establishes the Cervical Cancer Immunization Awareness Campaign Fund to increase public awareness on the benefits of receiving the vaccine. The act appropriates \$225,000 from gifts, grants, and donations for the educational awareness program and promises \$100,000 from the General Fund for this year and next year if the fund receives \$800,000 in private donations by January 1, 2008. At this time, no donations have been received for the awareness campaign.
- It mandates that private health insurance policies and the Children's Basic Health Care Plan (CBHP) cover the vaccine. According to state estimates, 830 girls are expected to receive the vaccine under CBHP at a cost of \$298,177.
- It encourages federally qualified health centers, which are 'safety net' providers such as community health centers or public housing centers, to contract with local health agencies to administer the vaccine to under-insured girls. The bill allocates \$42,600 to pay local health departments a \$20 administrative fee for each dose given to approximately 710 girls. This funding is in addition to the girls covered by CBHP.

Vaccine mandate. Twenty-four states, including Colorado, introduced legislation mandating vaccination for girls entering the sixth grade. Of the

24 states, Virginia is the only state to pass legislation mandating vaccination of girls entering the sixth grade as a school requirement. Indiana passed legislation that requires parents of sixth-grade girls to sign a statement notifying the school of their decision to vaccinate or not to vaccinate their child.

Initially, Texas was the first state to mandate vaccination for girls entering the sixth grade via Executive Order from Texas Governor Rick Perry. The Executive Order was subsequently overridden by the Texas legislature, who in response to the Executive Order, passed a law that prohibits any school requirement that mandates the HPV vaccine.

Educational awareness campaigns. Nine states — Colorado, Indiana, Iowa, Maryland, North Carolina, North Dakota, Texas, Utah, and Washington — enacted legislation that creates an educational awareness campaign on cervical cancer, the link to HPV, and the vaccine. The laws range from providing funding for an educational awareness campaign to requiring schools to provide educational information to sixth-grade girls and their parents through school literature.

State funding. Eleven states introduced legislation to provide state funding to vaccinate uninsured girls; eight states, including Colorado, approved such measures. South Dakota, providing the largest amount of funding, passed legislation that provides for \$9.2 million in state and federal funding for vaccinating uninsured girls. According to the South Dakota health department, the funding provides for 32,000 doses of the vaccination, which serves approximately 10,666 girls.

Health insurance coverage mandate. Eighteen states introduced legislation to mandate health insurance coverage of the HPV vaccine. Four states, Colorado, Nevada, New Mexico, and Rhode Island, passed such measures.