WOMEN IN GOVERNMENT

Empowering all women state legislators to effect sound policy

Prevention Connection

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HPV & CERVICAL CANCER SCREENING LEGISLATIVE ACTIVITY

On June 26, 2009, Governor Kulongoski of Oregon signed into law a bill requiring health benefit plans to provide coverage of a human papillomavirus (HPV) vaccine for female beneficiaries at least 11 years of age but no older than 26 years of age. Sponsored by Representative Carolyn Tomei, H.B. 2794 is an example of legislation aimed at making the HPV vaccine readily available without mandating vaccination. Similar laws already exist in Colorado, Iowa, New Mexico, Nevada, and Rhode Island. Legislators in California, Missouri, New York, and Pennsylvania also introduced compulsory HPV vaccine insurance reimbursement bills in 2009.

Legislators in several states, including Alabama, Georgia, Kentucky, Minnesota, and Missouri, introduced bills requiring the creation and distribution of information about HPV and cervical cancer prevention to parents or guardians of girls eligible for HPV vaccination. Unfortunately, none of these bills were enacted; however, similar bills were previously enacted in Indiana, Louisiana, New Jersey, North Carolina, North Dakota, Texas, and Washington.

In Colorado, Representative Tom Massey sponsored H.B. 1204, which was signed into law in June. The bill expands the required coverage for preventive health care to include, among other services, cervical cancer screening.

Hawaii legislators passed a concurrent resolution in May requesting that the Department of Health increase educational efforts to prevent and eradicate cervical cancer. Representative Barbara Marumoto-Coons, Women In Government's Western Regional Director, sponsored H.C.R. 51.

For sample legislation addressing HPV vaccination and cervical cancer screenings, please visit www.womeningovernment.org/prevention/legislative_toolkit/sample-legislation.

CERVICAL CANCER CONFERENCE CALL

On July 7, 2009, Women In Government coordinated a conference call for state legislators featuring three presenters: Mona Saraiya, MD, MPH and Kris Khan, MS, RN, both from the Centers for Disease Control and Prevention (CDC), and Representative Barbara Marumoto-Coons (HI).

Dr. Saraiya's presentation, *Reducing Cervical Cancer Burden through Cervical Cancer Screening*, discussed the epidemiology of cervical cancer and HPV; national disparities in cervical cancer incidence and mortality; cervical cancer screening methods and guidelines; and the future of cervical cancer prevention.

Kris Khan, who works with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), presented on the creation and purpose of the program, program services, and updated legislation to improve the program's impact. She also shared two success stories of women who were diagnosed and then treated for cervical cancer through the program. (See page 4 of this newsletter for more information on NBCCEDP)

Representative Marumoto-Coons spoke about 1) her work to promote HPV and cervical cancer awareness, 2) the Hawaii Department of Health's Cervical and Breast Cancer Office and its work with a variety of outreach groups, and 3) her vision for cervical cancer prevention through strong educational programs.

Following the presentations, the phone line was opened to listeners for questions. Representative Jacqueline Sly (SD) inquired about more recent data on incidence and mortality. (In her presentation, Dr. Saraiya provided 2005 data, the most recent from the CDC). Dr. Saraiya responded that although rates have declined over time, disparities still exist and cervical cancer remains a disease of the poor.

Representative Suzi Wizowaty (VT) asked about the HPV test and the cost-effectiveness of the test in conjunction with a Pap test. Dr. Saraiya gave costs, based on CDC modeling studies, for the traditional and liquid Pap tests and the HPV test. She continued by stating that incorporating the HPV test is only cost-effective if screening patterns are changed in conjunction with the new test.

Representative Kelly Skidmore (FL) asked about barriers to physicians adopting the changing guidelines for cervical cancer screening. Dr. Saraiya agreed that physicians are often hesitant to change practices and mentioned reimbursement programs as a way to limit over-testing for cervical cancer. Dr. Saraiya also mentioned that listeners should be on the lookout for future changes in guidelines and reimbursement practices.

The State of Cervical Cancer Prevention

Currently, HPV testing has unrestricted Medicaid coverage in 46 states and compulsory insurance reimbursement in six. Twenty-eight states have a Statewide Cervical Cancer Elimination Task Force. HPV vaccination is mandatory in only one state, Virginia. Six states require insurance reimbursements of the HPV vaccine and seven have HPV vaccine information programs in place. State legislators continue to advance prevention efforts in their states by reintroducing previously failed bills on cervical cancer prevention and creating new bills for consideration.

To assist in the efforts, Women In Government is holding its 5th Annual HPV and Cervical Cancer Summit, November 5th-7th in Washington, DC. Among the many topics, the Summit's agenda includes guest speakers, an overview of legislative practices, and the future of cervical cancer prevention.

For more information on the Summit or to register for the event, please visit www.womeningovernment.org/fifth-annual-hpv-and-cervical-cancer-summit.

CERVICAL CANCER SCREENING GUIDELINES

Cervical cancer screening has reduced cervical cancer mortality in the U.S. by more than 70 percent since the introduction of the Pap test in the 1950s. The traditional Pap test (also known as Pap smear), in which a swab of cells is taken from the cervix and placed on a slide, is still in use today. A liquid-based Pap test uses the same collection procedure; however, the cells are placed into a liquid before analysis under the microscope. Regardless of the type of Pap test, this screening saves lives, often diagnosing abnormalities in the cervix before cancer can develop.

More recently, physicians began testing for the presence of the HPV DNA. Due to the high infection and self-clearance rates of HPV among adolescent and young women, the Food and Drug Administration (FDA) approved the HPV test for women age 30 and older. In addition, this test is recommended as a follow-up if a Pap test is abnormal. While this test may be used in conjunction with the Pap test, it is not approved as a substitute.

Although guidelines vary slightly for cervical cancer screenings, the experts agree that screenings are essential in the fight against cervical cancer.

CERVICAL CANCER SCREENING GUIDELINES

	American Cancer Society	American College of Obstetrics and Gynecology	US Preventive Services Task Force
Age to Start	Age 21 or after 3 years of sexual activity	Age 21 or after 3 years of sexual activity	Age 21 or within 3 years of sexual activity
Intervals			
Traditional Pap	< 30: Annually ≥30: every 2-3 years for women with 3 negative Paps	< 30: Annually ≥30: every 2-3 years for women with 3 negative Paps	At least every 3 years
Liquid-based Pap	<30: every 2 years ≥30: every 2-3 years for women with 3 negative Paps	<30: Annually ≥30: every 2-3 years for women with 3 negative Paps	Insufficient evidence
Pap with HPV testing	Not more often than every 3 years if negative Pap and HPV	Not more often than every 3 years if negative Pap and HPV	Insufficient evidence
When to Stop			
Hysterectomy	Total hysterectomy for benign disease	Total hysterectomy for benign disease	Total hysterectomy for benign disease
Age	Age 70 - if 3 consecutive normal Pap tests and no abnormal Pap tests within 10-year period	Evidence inconclusive	Age 65 if normal Pap tests

Source: Centers for Disease Control and Prevention, www.cdc.gov/std/hpv/ScreeningTables.pdf.

U.S. HPV VACCINATION COVERAGE INCREASES

On September 17, 2009, the Centers for Disease Control and Prevention (CDC) released the 2008 vaccination coverage rates for American preteen and teens aged 13 to 17 years. The HPV vaccine, which targets the human papillomavirus that can cause cervical cancer, is recommended for girls ages 11 or 12 years (if missed at this age, can be given later) and is a three-dose series. In 2008, 37.2 percent of adolescent females had started the HPV vaccine series compared with 25.1 percent of adolescent females in 2007.

While this data is promising, HPV vaccination coverage varies among states, ethnicities, and poverty levels. Only 15.8 percent of Mississippi's adolescent females versus 54.7 percent of Rhode Island's adolescent females had started the HPV vaccine series. Variations among the states may be attributed to differences in state immunization policies including insurance reimbursement and funding for awareness programs.

Adolescent females below the poverty level have exhibited better initial vaccination coverage than those females at or above the poverty level (46.4 percent versus 35.8 percent). Among ethnic groups, coverage levels for Hispanic females are substantially higher than white females (44.4 percent versus 35.0 percent). It is unclear exactly why Hispanic females' coverage was higher. However, according to the CDC, a greater percentage of the survey participants below the poverty line were Hispanic rather than white. The HPV vaccine is included in the Vaccines for Children Program (VFC), which serves Medicaid-eligible, uninsured and underinsured children. Therefore, VFC has removed the cost barrier for females below the poverty line.

Legislative efforts such as increasing the awareness of HPV through educational programs and reducing cost barriers through insurance reimbursements may decrease the disparity in HPV vaccination coverage among the states, ethnic groups and poverty levels.

For resources and sample legislation on HPV and cervical cancer, please visit www.womeningovernment.org/prevention.

FDA Advisory Committee Recommends Approval for HPV Vaccines

On September 9, 2009, the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee recommended approval of HPV Vaccines Gardasil (Merck) and Cervarix (GlaxoSmithKline).

The Committee voted 7-0, with one abstaining vote, that clinical data on Gardasil supported the vaccine's efficacy in preventing genital warts in males aged nine to 26 years. Merck's data indicated that Gardasil was 89 percent effective in preventing genital warts (HPV types 6 & 11). Gardasil is already FDA-approved for females aged nine to 26 years.

The Committee also voted 12-1 and 11-1 that clinical data on Cervarix supported the vaccine's efficacy and safety, respectively, in preventing cervical cancer. GlaxoSmithKline's Cervarix is for females aged 10 to 25 years and it targets two HPV types (16 & 18).

While the Committee has recommended approval, the FDA will make the final decision whether or not the HPV vaccines will be approved.

CULTURAL BARRIERS TO HPV VACCINATION AND CERVICAL CANCER PREVENTION

Globally, cervical cancer kills more than 270,000 women every year.[1] Approximately 80 percent of these deaths occur among women in developing countries. Cervical cancer is caused by human papillomavirus (HPV), a virus transmitted primarily through sexual contact.[2]

New developments in cervical cancer prevention include an HPV vaccine and the HPV test. The HPV vaccine is routinely recommended for females aged 11 to 12 years but can be administered to girls as young as nine years of age and to women as old as 26 years who have not yet received the vaccine.[3] The HPV test is designed as a long-term screening for persistent HPV infection. Both the vaccine and the HPV test offer the promise of dramatically reduced cervical cancer incidence and mortality. However, these new technologies are not widely available in developing countries because of both cost and limited health system infrastructures.

In developing countries where such technologies are slowly becoming available, cultural barriers may prevent girls and women from receiving these life-saving prevention tools. Some cultural barriers that exist include the limited mobility of women, resistance to pelvic exams, general beliefs about medical care, and stigma attached to sexually transmitted infections. In order to prevent community resistance to these technologies, cervical cancer and possible death must be underscored rather than HPV and sexually transmitted infections.

In many cultures, women are discouraged or even forbidden from leaving their home or village, even to seek medical care. Cultures where modern medicine is used only in emergency situations are less likely to seek preventative medical care. In both scenarios, women are unlikely to obtain the necessary gynecological exam for a Pap test or HPV testing. Girls are also unlikely to receive the HPV vaccination, unless the vaccine is delivered in schools or by community health workers in the home. In Uganda, a demonstration project studied the differences of in-home and in-school vaccinations between two similar districts. The project results showed more success for the girls vaccinated in schools because follow-up and monitoring was easier.[4]

Stigma is an especially difficult barrier to overcome. HIV voluntary counseling and testing (VCT) programs frequently encounter this problem. The stigma of HIV is so great that individuals are reluctant to be seen entering a clinic where testing occurs. The same stigma may occur for HPV testing – women may resist screening for themselves if the notion of sexual promiscuity is tied up in the process. These communities will require especially sensitive information about HPV testing for screening efforts to succeed and for prevention and treatment of cervical cancer to occur.

The same stigma could prevent girls from receiving the vaccine as well. According to the head of the Indian Council of Medical Research, N.K. Ganguly, "People will say 'my girl is very virtuous, why vaccinate?'"[5] In cultures where the honor of the family is determined by the chastity of its daughters, receiving the vaccine could put the lives of girls in danger. Campaigns for vaccination in these settings can focus on cervical cancer rather than HPV. Using this approach, rather than HPV, in Panama was highly successful. Panama's Ministry of Health partnered with UNICEF to vaccinate girls aged 10 to 11 years at no cost.[6] Promotion of the vaccine contained no mention of the sexual transmission of HPV and used the term "cancer vaccine" exclusively. As a result, opposition to the vaccine was almost non-existent.

Governments and other organizations considering the introduction or expansion of HPV vaccination and HPV testing should take the following steps to ensure success:

- Generate educational materials about testing and vaccination using local terms and language.
- Recruit prominent members of the community to advocate for HPV vaccination of girls and HPV testing.
- Determine cultural barriers to vaccination and testing; problem-solve solutions that allow women and girls to receive these life-saving technologies.
- Consider alternative language that does not threaten cultural norms about women's sexuality; adjust language to meet the needs of the community.
- Develop a delivery plan for vaccination. Vaccinate girls in schools or, if a large proportion of girls are not attending school, develop the means for community health workers to administer the vaccine.
- Diminish HPV testing stigma by incorporating testing into other health services used by women. Options include: prenatal clinics, family planning facilities, and pediatric visits. If appropriate, offer the option of self-collected vaginal swabs to reduce the stigma of gynecological exams.

Too many women in the developing world are dying from a preventable disease. Expanding HPV vaccination and HPV testing to more women will reduce the burden of the disease. Cultural barriers, including stigma, negatively impact efforts to increase access and coverage of these life-saving technologies. Preventing cervical cancer on a global scale is possible. Governments and other organizations must be creative in the promotion of HPV testing and vaccination to ensure success. ■

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NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM

National Breast and Cervical Cancer Early Detection Program

Early detection of breast and cervical cancer correlates to increased survival. Annual screening for breast and cervical cancer can save many lives. Unfortunately, many women in the U.S. are unable to afford this basic lifesaving medical service.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) was created by the Breast and Cervical Cancer Mortality Prevention Act of 1990. The NBCCEDP program assists low-income, uninsured, and underinsured women in accessing screening and diagnostic services for breast and cervical cancer.

Facts about NBCCEDP

- Funds all 50 states, the District of Columbia, 5 U.S. territories, and 12 American Indian/Alaska Native tribes or tribal organizations.
- The Breast and Cervical Cancer Prevention and Treatment Act, which passed in 2000, gave states the option to offer women diagnosed through NBCCEDP access to treatment through Medicaid. As a result, all 50 states and the District of Columbia approved this Medicaid option.
- CDC estimates that 8 to 11 percent of U.S. women are eligible to receive NBCCEDP services.
- Since 1991, more than 3.3 million women have been screened and 8 million screening tests for breast and cervical have been conduced under the program.
- Screenings have led to the diagnosis of 37,117 breast cancers, 2,324 invasive cervical cancers, and 121,500 premalignant cervical lesions.
- In 2008, the program screened 321,296 women for cervical cancer and found 5,201 cervical cancers and high-grade precancerous lesions.
- CDC estimates that only 7.1 percent of eligible women were screened for cervical cancer.
- Some states' programs have wait lists or close before the end of the fiscal year because funding runs out.

NBCCEDP Eligibility Rules for Cervical Cancer Screening

- Women at or below 250 percent of the federal poverty level (In 2009, $27,075 for a single woman, $36,425 for a two person family, and $55,125 for a family of four).
- Uninsured or underinsured.
- Aged 18 to 64 years.

State-level NBCCEDP

- More women can be screened in states that provide funds to supplement those of the CDC.
- Can make decisions about the enrollment of providers.
- Emphasize reaching the underserved populations, including immigrant women and women in rural or very isolated communities.
- Can use funds to provide transportation and/or patient navigation to get the women to providers.

For more information on NBCCEDP, please visit www.cdc.gov/cancer/NBCCEDP/.