

Report of the Human Papilloma Virus

Vaccines Subcommittee

*This report is dedicated to the memory of
Senator Gwendolyn Britt.*



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
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Family Health Administration

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October 2009

The Honorable Martin O'Malley
Governor
State House
Annapolis, MD 21401

Dear Governor O'Malley:

On behalf of the members of the Human Papilloma Virus Vaccines Subcommittee, I am pleased to submit the subcommittees report and recommendations to you.

In 2008, the Human Papilloma Virus Vaccine Subcommittee meet five times and heard from a multitude of experts on the issue of HPV, HPV Vaccines, Cervical Cancer, and a host of other issues. Following their November meeting the HPV Vaccines Subcommittee started formulating recommendations and developing a final report with recommendations across a host of issues related to HPV Vaccines in Maryland. This report is a summary of the work of the committees and its recommendations.

The Human Papilloma Virus Vaccines Subcommittee looks forward monitoring the issues and developments surrounding the vaccine and keeping both you and the citizens of Maryland informed as to recommendations for future action.

Sincerely,

Gloria Jetter .
Chair – Human Papilloma Virus Vaccines Subcommittee

Acknowledgements

The Human Papillomavirus (HPV) Vaccine Subcommittee (the Subcommittee) would like to acknowledge the work of Delegate Joseline Pena-Melnyk and Senator Gwendolyn Britt in forging a compromise during the 2007 Legislative Session of the Maryland General Assembly and creating the Subcommittee. Senator Britt passed away in 2008, but her dedication to the issue of cervical cancer will live on for many years to come.

The Subcommittee would also like to thank Secretary John Colmers and his staff at the Maryland Department of Health and Mental Hygiene for their assistance and support over the course of the Subcommittee's deliberations. Additionally, Donna Gugel, Director of the Center for Cancer Surveillance and Control, and her staff aided the work of the Subcommittee and provided access to materials and information quickly and efficiently.

Thanks must also go to the various experts and organizations who presented information to the Subcommittee on various aspects of HPV, HPV vaccines, and cervical cancer. The input of these experts in the Subcommittee's deliberations and development of recommendations was invaluable. That so many individuals agreed to speak to the Subcommittee and assist in their work is a testament to the care and concern about the issue of HPV vaccines in Maryland.

Finally, Elizabeth Eugene deserves special thanks for assistance in the creation of this report as a component of her cornerstone experience at the University of Maryland's School of Public Health. Without Ms. Eugene's help, this report would not possess the quality and depth that it does.

Report of the Human Papillomavirus Vaccine Subcommittee

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Human Papillomavirus Vaccine Subcommittee Membership

Subcommittee Chair	Gloria Jetter American Cancer Society
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Executive Summary

During the 2004 Legislative Session of the Maryland General Assembly, Senate Bill 499 established a Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan. The bill required the Department of Health and Mental Hygiene (DHMH) to staff the Committee, and required the Committee to present findings and recommendations about developments in cervical cancer to the Governor and the General Assembly beginning on October 1, 2004.

Due to the emergence of HPV vaccines in the healthcare market in 2006, the 2007 Maryland General Assembly passed HB 1049, a measure establishing the Human Papillomavirus Vaccine Subcommittee. The bill was signed into law by Governor O'Malley in April 2007 paving the way for the HPV Vaccine Subcommittee. The Subcommittee operates within the Maryland Comprehensive Cancer Control Plan's existing Cervical Cancer Committee.

During 2008, the HPV Vaccine Subcommittee met on five occasions and heard from a number of experts on the issue of cervical cancer, HPV, HPV vaccines, and the implementation of an HPV vaccine in Maryland.

This report is a summary of the Subcommittee's findings and recommendations.

Background

I. Overview

A. Human Papillomavirus

The human papillomavirus (HPV) is the most common of all sexually transmitted infections and persistent HPV infection can cause cervical cancer and genital warts.¹ HPV is accepted as the virus responsible for virtually all cases of cervical cancer,² but recent research indicates that the HPV is also responsible for approximately 90% of anal cancers, 40% of penile, vaginal, and vulvar cancers, 25% of oral cavity cancers, and 35% of oropharyngeal cancers.³ There are over 100 different types of HPV and 15 of these are considered oncogenic, or high-risk types for cancer.⁴ HPV16 and HPV18 are the two most oncogenic HPV types and together account for approximately 70% of cervical cancers.⁵ Among the non-oncogenic types, HPV6 and HPV11 are responsible for about 90% of genital warts.⁶

HPV infections are sexually transmitted through direct contact with skin or mucous membranes.⁵ While condoms offer substantial protection against other sexually transmitted infections, they have not consistently demonstrated a protective effect against HPV, as the virus can be transmitted through contact with areas of unprotected genital skin.^{7,8} Because most infections are not accompanied by overt symptoms, it is easy for individuals to unknowingly spread the virus to others.⁶

Most HPV infections are transient and resolve on their own within 1-2 years,⁹ but cervical cancer can occur through a series of four steps: HPV transmission, viral persistence, progression to precancer, and progression to invasive cancer.⁵ Ten percent to 20% of infected individuals develop persistent HPV infections, and this group is at high risk for progression to high-grade cervical intraepithelial neoplasia (CIN), or precancerous abnormal cell growth on the cervix.¹⁰ Cervical intraepithelial neoplasia (CIN) I may also clear without treatment, but higher grade cervical lesions (CIN II and III) have an elevated probability of progression to invasive cervical cancer.⁶ Further, some research suggests that the risk of progression to CIN II and CIN III is higher among women infected with HPV16, HPV18, and HPV 45.^{2,11} Additional risk factors for CIN progression include cigarette smoking, long-term hormonal contraceptive use, and immunosuppression.¹² The pathway from HPV infection to cervical cancer is roughly 15 years which provides an ample window for early intervention. Most HPV infections are acquired within the first years of sexual activity, and both early age at sexual debut and sexual relations with multiple partners increase the risk of precancerous abnormal cell growth or progression to invasive cancer.⁷ Monogamy can serve as a protective factor, but may not notably reduce the risk of infection as awareness of a sexual partner's other partners is usually poor.¹³ Moreover, divorce and remarriage are common both domestically and globally and provide new opportunities for infection.¹⁴

B. Burden of HPV and HPV-Related Cancer

1. Nationally

The Centers for Disease Control and Prevention (CDC) estimates that there are 6.2 million new HPV infections each year, and that over 20 million Americans are currently infected.¹ Moreover, approximately 75% of sexually active women will have had an HPV infection by age 50. HPV prevalence is highest among young women. A recent National Health and Nutrition Examination Survey study estimates that 26.8% of women ages 14-59¹⁵ are infected with HPV. Furthermore, 74% of incident cases occur among women 15-24 years of age.¹⁶

It is estimated that 11,070 American women were diagnosed with cervical cancer and 3,870 died in 2008.¹⁷ The international impact of the disease is even more pronounced. Cervical cancer is the second leading cancer among women worldwide with 493,243 incident cases and 273,505 deaths annually.¹⁸ Unlike in the U.S., cervical cancer in developing countries tends to develop earlier than other cancers, and consequently many deaths occur among women who are still raising families.⁵ Domestically, the burden of cervical cancer is disproportionately borne by women of color. The incidence of cervical cancer among White women is 8.2 per 100,000, while the incidence among African-American women is 10.8 per 100,000, and among Hispanic women is 13.2 per 100,000.¹⁹ White women are more likely to be diagnosed at an earlier diagnostic stage than African-American women or Hispanic women, and mortality rates among Hispanic women and African-American women are 1.5 and 2 times that of White women, respectively.²⁰

While HPV's relationship with cervical cancer has been established for quite some time, more recent studies attribute HPV infection to a variety of other cancers among both men and women.²¹⁻²⁴ A recent CDC report estimates that each year HPV also causes 7,360 cancers of the oral cavity and oropharynx, 3,018 anal cancers, 2,260 vulvar cancers, 828 penile cancers, and 601 Vaginal cancers.³ Racial disparities are also evident among these cancer cases, with higher rates of anal cancer among African-American men, higher rates of penile cancer among Hispanic men, and higher rates of vaginal cancer among African-American women.²⁵

Finally, HPV is also responsible for approximately 1 million new cases of anogenital condyloma or genital warts each year.^{6, 26} Although the condition is not life-threatening, genital warts have been associated with psychosocial distress, embarrassment, and relational discord.^{26, 27} Moreover, treatment and follow-up for these cases is considerable, as 70% of cases of warts persist beyond four months and recurrence rates are high.^{28, 29}

2. Maryland

The incidence of cervical cancer in Maryland is 9.3 per 100,000, with 275 new cases diagnosed in 2003.³⁰ This rate is slightly higher than the national average of 8.1 cases per 100,000 women, and reflects an increasing trend, as Maryland cervical cancer incidence rose by 3.3% between 1999 and 2003. Racial disparities in cervical cancer incidence are also present at the State level. The incidence of cervical cancer is 8.4 per 100,000 among White Maryland women and 10.7 per 100,000 among African-American Maryland women.

There were 76 cervical cancer deaths in Maryland in 2007, 46% of which occurred among African-American women although African-American women represent just 28% of Maryland's female population.³¹ The cervical cancer mortality rate among African-American women in Maryland is 3.6 per 100,000 which is more than twice the rate among White women in Maryland (1.5 per 100,000).³⁰ Furthermore, between 1999 and 2003, the average annual cervical cancer mortality rate in Maryland decreased by 10.9% per year among White women, but increased by 2.7% per year among African-American women.

3. Cost Upon the Healthcare System

Nationwide, the direct annual cost of HPV-related disease prevention and treatment was \$4.6 billion in 2005³² with infections among young women accounting for a majority of the economic burden.¹⁶ Although treatment for late stage cervical cancer is expensive, it is actually the treatment of abnormal cytology that accounts for the majority of HPV-related treatment spending because millions of women are affected.³³ There are also substantial direct costs associated with non-cervical disease in the United States including the treatment of genital warts and other anogenital cancers.^{34, 35} In 2003, non-cervical HPV treatment costs associated with HPV types 6, 11, 16, and 18 were approximately \$418 million.³⁶

Furthermore, HPV is responsible for considerable indirect costs associated with premature death and loss of productivity. In 2003, HPV-associated cancers accounted for 181,026 years of potential life lost (YPLL), and were the largest contributor to YPLL in women ages 30 to 34 years.³⁷ The average number of YPLL was 21.8 per HPV-associated cancer death and 16.3 per malignant cancer death, and this discrepancy reflects the tendency for younger individuals to develop and die prematurely from HPV-related cancers. Moreover, HPV-related cancer mortality in 2003 was associated with \$3.7 billion in lost productivity.³⁷

C. Screening for Cervical Cancer

1. Significance of Screening for Cervical Cancer

Sixty years ago, cervical cancer was one of the most deadly cancers among American women, but mortality rates have improved notably due to the widespread use of the Papanicolaou (Pap) screening test.³⁸ Regular Pap test screening decreases a woman's risk of developing cervical cancer as the test enables healthcare providers to detect abnormal cell growth on the cervix prior to the development of invasive cervical cancer. Treatment of these precancerous lesions is far less invasive and costly than treatment of late stage cervical cancer. Moreover, early detection has a significant impact on mortality, as five year survival is nearly 100% among women with pre-invasive cervical lesions, and 92% among women with the earliest stage of invasive cervical cancer.³⁹ However, cervical cancer mortality increases sharply among women with advanced stage cancers. Screening rates for cervical cancer are lowest among low-income women, uninsured women and women of racial or ethnic minority backgrounds,⁴⁰ and the CDC estimates that one-half of women diagnosed with cervical cancer were never screened while an additional 10% were infrequently screened.⁴¹ Mortality rates are also highest among women of lower socioeconomic status, women without regular access to health care, women who are uninsured, and women who are recent immigrants.^{42, 43}

2. National Breast and Cervical Cancer Early Detection Program

The Breast and Cervical Cancer Mortality Prevention Act of 1990 authorized the CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) to assist low-income, uninsured and underserved women in obtaining screening tests for both breast and cervical cancers.⁴¹ The program seeks to reduce the incidence and mortality rates of breast and cervical cancers by increasing the availability of screening assessments such as breast exams, mammograms, and Pap tests to low-income and uninsured women. The goals of the NBCCEDP support the Healthy People 2010 cancer objectives to increase to the proportion of women age 18 and older who have ever received a Pap test to 97% and to increase to the proportion of women who received a Pap test in the past three years to 90%.⁴⁴

The NBCCEDP specifically seeks to serve women in high-priority groups who have increased risk for breast and cervical cancer. These groups include older women, racial and ethnic minorities, foreign-born women, women with disabilities, homosexual women and women living in rural areas.³⁸ By targeting these populations the program aims to reduce health disparities in breast and cervical cancer outcomes.⁴⁰

Eligible women for cervical screening must be between the ages of 18 and 64 and be at or below 250% of the poverty level.⁴¹ The program is intended to be a payer of last resort, so women must be unable to obtain services through another public or private

health insurance policy. The NBCCEDP's primary services include clinical breast examinations, mammograms, and Pap tests.⁴⁰ In 2000, Congress passed the Breast and Cervical Cancer Prevention and Treatment Act which enables states to offer treatment to women screened under the NBCCEDP through a special Medicaid option program.⁴¹ The CDC estimates that 7-10% of all American women of screening age are eligible to receive NBCCEDP benefits.⁴¹ However, with current funding levels most states can only fund services for a small proportion of eligible women, and just 7.1% of eligible women receive cervical cancer screening through the program.

Since its inception, the NBCCEDP has screened over 3.2 million women and has diagnosed 114,390 precancerous cervical lesions and 2,161 cervical cancers.⁴¹ Furthermore, the Medicaid partnership authorized in 2000 has further strengthened the reach of the program as women identified with cancers or precancerous lesions can be referred for treatment.

3. Maryland Breast and Cervical Cancer Screening Program

One of the NBCCEDP grantees is the Maryland Breast and Cervical Cancer Program (BCCP) administered by DHMH. The BCCP uses a decentralized model to award funds to 24 local jurisdictions to carry out screening activities. Funds are dispersed to 22 health departments and 2 hospitals to coordinate breast and cervical cancer outreach, education, screening and follow-up services. Local jurisdictions subcontract with private physicians, radiologists and laboratories to perform the screenings through a network that includes over 950 providers Statewide, and a local program coordinator arranges screenings for eligible women.⁴⁵ Funds are also used to hire lay health workers to educate and recruit women in target populations to enroll in the BCCP. BCCP screening is also promoted through the Maryland affiliate of Susan G. Komen for the Cure, and the state and local offices of the American Cancer Society.

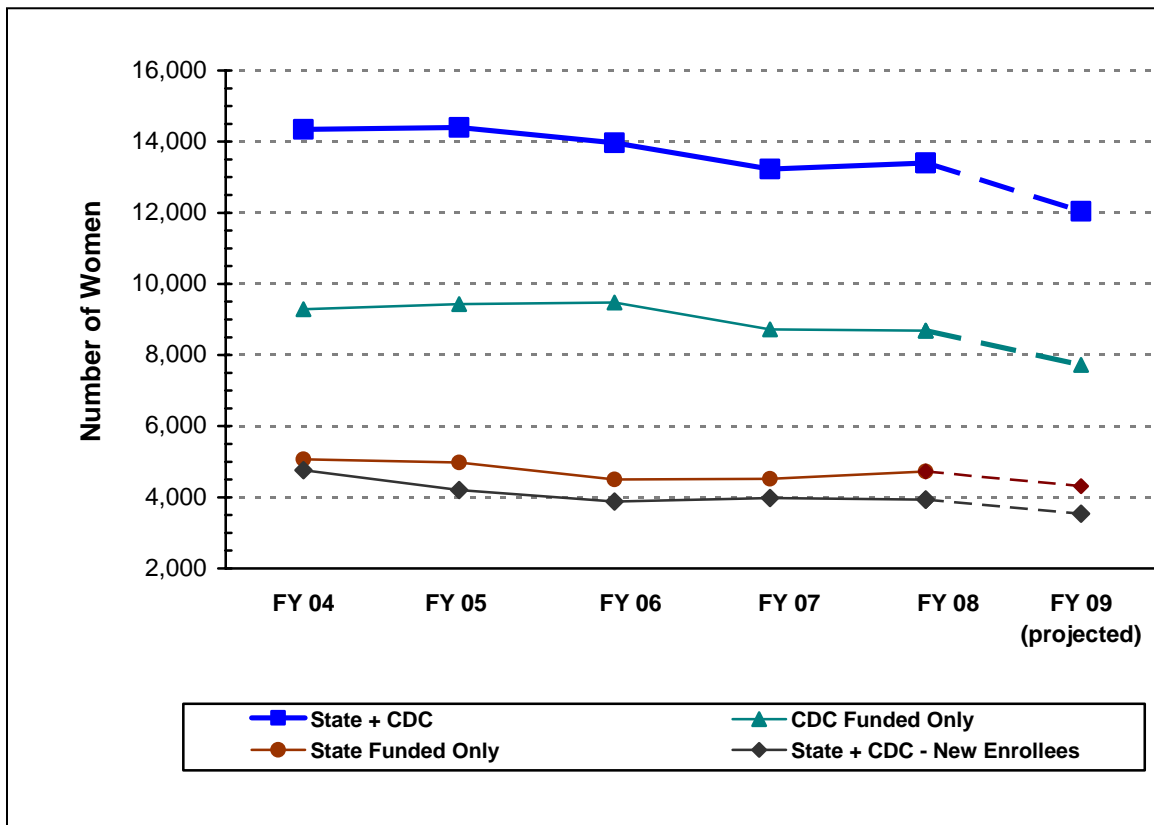
The BCCP program strives to increase breast and cervical cancer screening levels among uninsured, low-income women Statewide. Eligible women must be Maryland residents between ages 40-64 and must be at or below 250% of the federal poverty level.⁴⁵ Further, they must be uninsured, or have a health insurance policy that fails to cover screening services. It is estimated that approximately 78,000 of Maryland women are eligible for the program and the BCCP served approximately 17% of eligible women in fiscal year 2007.

Women in the BCCP may receive a variety of clinical services including mammograms, Pap tests, pelvic exams, and clinical breast exams. Between 2003 and 2007, 22,090 Maryland women received Pap tests, and 664 Pap tests had an abnormal result. Of those, 149 had a result of CIN II, CIN III, or carcinoma-in-situ, and 17 had invasive cervical cancer.⁴⁶ If a Pap test is abnormal, local program staff arrange for women to obtain diagnostic procedures which can be paid for with BCCP funds, such as a cervical biopsy or colposcopy.⁴⁵ The BCCP is unable to cover the cost of advanced diagnostic procedures or treatment, but local staff work with women who need these services to apply to either the Women's Breast and Cervical Cancer Health Program

(under the Maryland Medicaid Treatment Act) or the Breast and Cervical Cancer Diagnosis and Treatment Program, a separate State program, which covers diagnostic work-up and treatment, if needed.⁴⁷

BCCP fund reductions in fiscal year 2009 led some local programs to layoff staff, and many programs capped enrollment. Simultaneously, local programs have reported increases in applications as women who have lost jobs and/or insurance have turned to the BCCP for services. The graph below depicts the trends in women screened in the Maryland BCCP between FY04-FY09.

Number of Unique Women Screened by the Maryland Breast & Cervical Cancer Program by Fiscal Year



II. HPV Vaccine Background and Development

A. Vaccine Introduction

In June of 2006, Gardasil was introduced by Merck pharmaceutical company as the first vaccine against HPV infection to enter the market.⁴⁸ In 2006, GlaxoSmithKline's HPV vaccine Cervarix was approved for use in the European Union and is expected to gain approval in the United States at some point in the future, though an exact date is not known. Gardasil protects against four strains of HPV known to cause 90% of genital warts and 70% of cervical cancer.⁴⁹ The vaccine is indicated for girls ages 9-26, and routine HPV vaccination is recommended by the Advisory Committee on Immunization Practices (ACIP).⁵⁰ The vaccine can prevent the development of HPV infections, but cannot treat existing infections.^{51, 52} Consequently, the vaccine should ideally be administered to girls prior to the onset of puberty or sexual activity.⁵³ The CDC reports that the vaccine has been tested on thousands of females aged 9-26 in the United States and around the world, and the most common reported side effect has been soreness at the injection site. Six percent of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS) were considered serious, which is about one-half of the average percentage of serious reports for other vaccines; by comparison, the overall average in VAERS for any serious adverse event following vaccination ranges from 10% to 15%.⁴⁹ Additionally, routine HPV vaccination has been shown to be cost-effective when administered to pre-teens with respect to HPV incidence, disease progression and quality-adjusted life year (QALY) measures.^{35, 54, 55, 56, 57, 58}

B. Significance of a Vaccine for Cervical Cancer Prevention

The introduction of the HPV vaccine broke new ground in public health as it is the first vaccine that can prevent certain cancers.^{59, 60} Thus, the HPV vaccine has provided an opportunity to augment current screening programs,^{61, 62} and could potentially offer extra protection to low-income and minority women who are least likely to receive frequent cytology screening.⁶³ Due to the long time frame between HPV infection and cancer development, there is not yet evidence to demonstrate that the vaccine reduces cancer rates, but it is expected that vaccination will lead to reduced rates of cervical cancer and other cancers caused by HPV 16 and HPV 18.^{59, 64} While the HPV vaccine has been publicly promoted as a method to prevent cancer, the vaccine's most powerful economic impact may be its ability to prevent pre-cancerous lesions,^{64, 35} as fewer infections could also reduce the number of abnormal Pap tests and costs associated with follow-up treatment.⁵⁶ Finally, widespread vaccination has been associated with significant reductions in health disparities for other vaccine-preventable diseases,^{65, 66} and HPV vaccination could significantly reduce health disparities associated with HPV infection.⁶⁷

C. Access and Availability

In Maryland, the Vaccines for Children Program (VFC) covers the cost of HPV vaccination for females aged 11-18, but private insurance coverage is variable. Vaccines

for Children is a federally-funded program that provides free vaccines to children who might not otherwise be vaccinated because of inability to pay.⁶⁸ The program covers all vaccines recommended by the Advisory Committee on Immunization Practices and funds are distributed through the CDC to state health departments. The Maryland VFC then distributes the vaccines at no charge to the 800 private physicians' offices and public health clinics registered as VFC providers.⁶⁹ The Maryland VFC covers children enrolled in Medicaid, uninsured children, and American Indian or Alaska Natives, and covers approximately 29% of females aged 11-18 Statewide.

The three-dose HPV vaccine typically costs between \$300 and \$390 per person, and this expense discourages uptake among those without public or private coverage.^{59, 70} Vaccine coverage is variable among girls with private insurance policies and coverage is extremely limited for women between the ages of 19-26, as most public and private policies only cover the vaccine for females through age 18.⁷¹ Moreover, some individuals have had difficulty getting vaccinated because only a subset of providers routinely stock and administer the HPV vaccine.⁷²

III. Other State Policy Approaches to the HPV Vaccine

Other State Approaches

Following the introduction of the HPV vaccine in 2006, state legislators nationwide began to consider if and how states should respond, and submitted a variety of bills ranging from exploratory research to mandatory vaccination as a requirement for school-entry.

A chart summarizing the various approaches taken in state legislatures around the country since 2006 can be found in Appendix A on page 24.

Maryland HPV Vaccine Subcommittee

I. Formation of the HPV Vaccine Subcommittee in Maryland

Senator Delores Kelley of Baltimore County initially sponsored Senate Bill 54 (2007) entitled *Health - General - Vaccine for Prevention of Cervical Cancer*, the first Maryland bill to address the HPV vaccine. Senate Bill 54 was supported by a number of co-sponsors including Gwendolyn Britt of Prince George's County. The bill called for mandatory vaccination of all sixth grade girls as a requirement for entry into Maryland public schools by September of 2008. Although similar legislation had been introduced in other states including neighboring Virginia, criticism about mandating the vaccine elsewhere led the senators to withdraw the bill, and Senator Britt replaced it with Senate Bill 774 entitled *Cervical Cancer Committee - HPV Vaccine Subcommittee*. Senate Bill 774 had 14 additional co-sponsors and Delegate Joseline Pena-Melnyk sponsored its crossfiled bill, House Bill 1049 (2007), *Cervical Cancer Committee - HPV Vaccine Subcommittee*, with 44 co-sponsors.

Senate Bill 774/House Bill 1049 used a more cautious approach than Senate Bill 54 as the bills called for the creation of a Subcommittee comprised of representatives from a variety of educational, medical, and political groups to study the implications of the new vaccine such as vaccine cost, distribution, age guidelines, public education programs and parental rights, and present its findings in a written report to the Maryland General Assembly. Representatives from the American Cancer Society, the Children's National Medical Center, the Maryland State Teachers Association, the Center for Cancer Surveillance & Control within DHMH, and the University of Maryland School of Medicine testified in support of the bills at hearings and no one testified in opposition. The bills ultimately passed and were signed into law by Governor O'Malley in April 2007 paving the way for the Subcommittee. The Subcommittee was established in the existing Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan, and it aims to study barriers to HPV vaccination and mechanisms to improve access in order to ensure vaccine administration to all recommended females.

II. Mission of the HPV Vaccines Subcommittee in Maryland

Legislative Mandates (SB 774/HB 1049 (2007))

1. Examine federal and state programs relating to the HPV vaccine;
2. Develop a public awareness and education campaign about the HPV vaccine with an emphasis on parental education;
3. Evaluate the availability and affordability of the HPV vaccine, including coverage by health insurers and public health programs;
4. Identify barriers to the administration of the HPV vaccine to all recommended individuals;
5. Identify and evaluate appropriate mechanisms the State may use to increase access to

- the HPV vaccine, including mandating the HPV vaccine for enrollment in school on or before September 1 of each year; and
6. Submit a report on its findings and recommendations to the Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan.

III. HPV Vaccine Subcommittee Meeting Schedule and Agenda

In 2008, the Human Papilloma Virus Vaccine Subcommittee met five times and heard from a multitude of experts on the issue of HPV, HPV vaccines, cervical cancer, and a host of other related issues.

January 22, 2008 – White Marsh, MD

Greetings and Introductions

- Introduction of members and Chair
- Background of HPV Vaccine Subcommittee Development
- Goals and Objectives of HPV Vaccine Subcommittee

Meeting Summary

In January 2008 the HPV Vaccine Subcommittee met at the American Cancer Society's (ACS) office in White Marsh, Maryland to get acquainted and set their meeting agenda for 2008. It was during this meeting that the group was given the background of the HPV Vaccine Subcommittee development and covered the mandated goals and objectives of the group.

March 5, 2008 – White Marsh, MD

Burden of Cervical Cancer and HPV Vaccines Primer

- Introduction to Cervical Cancer and HPV
- Burden of Cervical Cancer in MD
- Current Cervical Cancer Programs in MD
- HPV Vaccines: An Introduction

Meeting Summary

In March 2008 the HPV Vaccine Subcommittee met again at the ACS office in White Marsh. At this meeting the group received an overview of the burden of cervical cancer and HPV in Maryland and nationally, as well as an update on the current cervical cancer programs in Maryland. The highlight of this meeting was a talk given by Dr. Douglas Lowy from the National Cancer Institute. Dr. Lowy was responsible for the development of the biological underpinnings of the HPV vaccines and provided the Subcommittee with an overview of their development and function.

May 7, 2008 – Gambrills, MD

Current Guidance on Available HPV Vaccines

- Organizational Guidelines on Vaccination with HPV Vaccines
- Federal Guidelines on the Vaccination of Females with HPV Vaccine
- HPV Vaccine Mandates Passed/Implemented Across the Country
- HPV Vaccine Presentations by Pharmaceutical Companies

Meeting Summary

In May 2008 the HPV Vaccine Subcommittee convened at the ACS offices in Gambrills, MD. At this meeting the Subcommittee received information on the guidelines or positions of various organizations on the issue of HPV vaccine implementation. The Subcommittee also reviewed an extensive list of HPV vaccine mandates which have been passed or implemented across the country. The final part of the meeting was spent on presentations from both Merck and Glaxo-Smith-Kline about their specific HPV Vaccines.

June 24, 2008 – Baltimore, MD

HPV vaccines: Availability, Affordability, and Access

- Current Maryland Vaccine Programs
- Bioethics and Health Economics Information (JHSPH)
- Impact of an HPV Vaccine Mandate on Organizations (e.g. Maryland Schools)

Meeting Summary

In June 2008 the HPV Vaccine Subcommittee gathered at the Johns Hopkins University Bloomberg School of Public Health. The focus of this meeting was to assess the availability, affordability, and access to HPV vaccines. At the meeting, the Maryland Vaccines for Children (VFC) Program presented an overview of the program and presented data on the uptake of the HPV vaccine in its patient population. The Maryland Department of Education also spoke about the impact of vaccine mandates on the schools and the potential the HPV vaccine could have in the future. The meeting closed with Dr. Andrea Sutherland speaking to the Subcommittee about the bioethical implications of HPV vaccines and how those considerations should be considered moving forward.

November 13, 2008 – White Marsh, MD

- Discussion of Recommendations

Meeting Summary

In November 2008 the HPV Vaccine Subcommittee met for the last time at the ACS office in White Marsh to begin discussing the information presented at the previous four meetings and how that information would shape their final recommendations. The focus of this meeting was a roundtable discussion whereby a consensus was reached on a variety of issues. Following their November meeting, the HPV Vaccine Subcommittee began formulating recommendations and developing a final report with recommendations across a host of issues related to HPV vaccines in Maryland.

V. Recommendations of the HPV Vaccine Subcommittee

1. Examine federal and state programs relating to the HPV vaccine.

During the course of meeting, the HPV Vaccine Subcommittee examined all federal programs and state programs related to the HPV vaccine and have detailed those programs on pages 17 and 18 of this report.

2. Develop a public awareness and education campaign about the HPV vaccine with an emphasis on parental education.

Given the lack of available State funds for public health education programs, the HPV Vaccine Subcommittee determined that there would be no coordinated publicly-funded awareness campaign to inform parents and providers alike about the HPV vaccine. Rather than developing a new campaign, various entities (i.e., pharmaceutical companies and non-profit organizations) have developed campaigns and messages about the vaccine, which can and should be utilized in a coordinated effort.

Recommendation:

The HPV Vaccine Subcommittee recommends the development of a public/private partnership between private, non-profit, and governmental healthcare groups with the mission to educate Maryland residents about the HPV vaccine. The campaign can utilize existing materials and messages to educate the public and healthcare providers on the HPV vaccines. By utilizing existing educational materials, the cost for such a program will be minimized, the education of parents and providers can occur, and many of the misunderstandings about the HPV vaccine can be dispelled.

3. Evaluate the availability and affordability of the HPV vaccine, including coverage by health insurers and public health programs.

In June 2008 the HPV Vaccine Subcommittee gathered at the Johns Hopkins University Bloomberg School of Public Health. The focus of this meeting was to assess the availability, affordability, and access to HPV vaccines.

According to information provided by Merck, the only company currently with a marketable HPV vaccine, the suggested price of the three-shot HPV vaccine regimen is \$360. Private insurance coverage of the HPV vaccine depends upon the given formulary of an insurance plan. The cost of vaccinating a child, even at \$360, could be a hindrance to a parent wanting to get their child vaccinated.

At the meeting the Maryland Vaccines for Children (VFC) Program presented an overview of the program and presented data on the uptake of the HPV vaccine in its patient population. VFC was followed by the Maryland State Department of Education speaking generally about the impact of vaccine mandates on the schools and the potential the HPV vaccine may have in the future, should it be mandated.

Additionally, the HPV Vaccine Subcommittee determined that accurately assessing vaccine coverage by health insurers was a difficult and time-consuming task given the multitude of policy and formulary variations within the self-insured and non-self-insured plans. Work has begun with the Maryland Insurance Administration to determine coverage to the extent possible, but in advance of that, the Subcommittee made the vaccination coverage recommendation below.

Recommendation:

The HPV Vaccine Subcommittee strongly recommends that policy measures around mandating insurance coverage of the HPV vaccine be pursued at the federal and State level to assure that all females who wish to partake of the vaccine have affordable access to the vaccine via insurance coverage. Children within the Vaccine for Children Program have unfettered access to the HPV vaccine, but those children covered by private insurance are not always afforded such a benefit, thus creating a disparity in access to the vaccine.

To eliminate the access disparity, the Subcommittee recommends that private insurance plans regulated by federal and state governments be required to pay for the vaccine without parents or guardians incurring any costs beyond the normal co-pay for vaccine administration. Parents with private insurance wishing to have their children vaccinated should not be required to pay for the vaccine out-of-pocket and then apply for reimbursement.

4. Identify barriers to the administration of the HPV vaccine to all recommended individuals.

Dr. Andrea Sutherland, a bioethicist at the Johns Hopkins University Bloomberg School of Public Health addressed the HPV Vaccine Subcommittee about some of the pertinent ethical and practical barriers to the administration of the HPV vaccine. Dr. Sutherland identified the following barriers to the administration of the HPV vaccine:

- Goals for the Vaccine – What is the goal for the vaccine and how does it fit with societal norms?
- Balancing Benefits and Burdens of a Vaccine – Are there other alternatives to a vaccine if implementation places too much of a burden?
- Effectiveness – Is there sufficient data to indicate that the vaccine is safe and effective?

- Fair Implementation and Equal Access – Do all those required to be vaccinated have equal and unfettered access to the vaccine?
- Educating Stakeholders – Has there been sufficient education of the population?

Recommendation:

The HPV Vaccine Subcommittee again recommends the development of a public/private partnership between private, non-profit, and governmental healthcare groups with the mission to educate Maryland parents and providers alike about the various aspects of the HPV vaccine. By undertaking such a partnership, the above-identified barriers mentioned can be addressed, hopefully minimized, and vaccine use in the appropriate population will increase.

5. Identify and evaluate appropriate mechanisms the State may use to increase access to the HPV vaccine, including mandating the HPV vaccine for enrollment in school on or before September 1 of each year.

The Maryland State Department of Education (MSDE) addressed the HPV Vaccines Subcommittee regarding the implications of mandating the HPV vaccine for school entry. MSDE presented information and data on the impact of other vaccine mandates on the school system.

Recommendation:

The HPV Vaccine Subcommittee recommends that the Maryland General Assembly or another policy-making body refrain from mandating the HPV vaccine as a school entry requirement. To require vaccination without appropriate education of providers and parents alike, as well as not having insurance coverage for the vaccine, may place an undue burden on parents and schools and may cause disruptions in the education of children.

The HPV Vaccine Subcommittee further recommends that the HPV vaccine mandate issue continue to be monitored over the next three years, or until such time as the vaccine has been readily available to consumers for at least five years. Given the above recommendations concerning a comprehensive provider, parent, and public education campaign, the vaccine may take root within Maryland as a matter of normal healthcare practice without the requirement of mandatory vaccination.

During Fall 2011, the five year anniversary of the vaccine's introduction, the HPV Vaccine Subcommittee will collect all relevant data on the uptake of the vaccine in the target population and determine whether a school entry mandate should be considered more seriously at that time. Further, should the federal government permit the vaccination of school age boys with the HPV vaccine, the

Subcommittee recommends a waiting period to determine the safety and efficacy of such a change in vaccine policy.

The HPV Vaccine Subcommittee believes that if a multifaceted approach consisting of parental and provider education, insurance coverage mandates, and further evaluation of vaccine uptake data is used, a mandated vaccination requirement for school entry is not necessary at this time.

6. Submit a report on its findings and recommendations to the Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan.

This report constitutes the findings and recommendations of the HPV Vaccine Subcommittee. The report will be submitted to the Cervical Cancer Committee.

Appendix A
Other State Approaches to the HPV Vaccine

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
California	10/06/05	11/17/05	S.B. 615, c. 550								Requires the Cervical Cancer Awareness Campaign to educate providers about HPV and its link to cervical cancer, including information regarding prevention, early detection, options for testing, and treatment costs.
Colorado	5/29/07	5/29/2007 (Mandatory coverage required for policies issued on or after 1/1/08)	H.B. 1301, c. 318				X	X	Requires: (1) the Dpt. of Public Health and Environment to reimburse a local public health agency's administrative costs for vaccinating underinsured females entering sixth grade; and (2) specified individual and group insurance policies, including HMOs, to provide coverage for the full cost of vaccination for all females for whom a vaccination is recommended by the Advisory Committee on Immunization Practices of the US DHHServices. Authorizes the medical assistance program to provide as an optional service immunization for females under 20 years of age.		

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
District of Columbia²	5/4/2007	1/1/08 (education) 01/01/09 (vaccination)	L.B. 17-30, Act 17-39, Law 17-10	X ³ (6th grade)	X						Requires the Mayor to initiate a public information campaign, including multiple HPV vaccine education forums in each ward, aimed at educating the public on: (1) the connection between HPV and cervical cancer; (2) the importance of protecting oneself against HPV infection; (3) the value of screening for cervical cancer through regular pap tests; and (4) the effectiveness and risks of the HPV vaccine.
Hawaii	4/15/05	4/15/05	H.R. 123/H.C.R. 164								Requires the Hawaii Cervical Cancer Elimination Task Force to educate and urge medical providers to make educational information available to patients about HPV and prevention of cervical cancer. ⁴
Illinois	8/24/2007	8/24/07 (education) No later than 7/1/11 (vaccination)	S.B. 937, PA 95-422				X	X	Requires: (1) the state Department of Public Health to provide HPV vaccinations as medically indicated at no cost to girls under 18 years of age who are otherwise uninsured; and (2) specified group or individual insurers, including specified public employee health plans and health maintenance organizations, to provide coverage for the HPV vaccine.	Requires the state Department of Public Health to provide all female students who are entering 6th grade and their parents or legal guardians written information about the link between HPV and cervical cancer and the availability of a HPV vaccine.	Requires the state Department of Public Health to provide all female students who are entering 6th grade and their parents or legal guardians written information about the link between HPV and cervical cancer and the availability of a HPV vaccine.

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State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Indiana	4/26/07	7/1/07	S.B. 327, P.L. 80-2007		X ⁵	X					Requires schools to provide the parents of 6th grade female students with information concerning the link between cervical cancer and HPV infection and that immunization against HPV infection is available. Requires the state Department of Health to provide schools with information including: (1) the latest scientific information on immunization against HPV infection and the immunization's effectiveness against cervical cancer; (2) that a Pap smear is still critical for the detection of precancerous changes in the cervix to allow for treatment before cervical cancer develops; (3) information concerning the means in which HPV infection is contracted; and (4) a statement that any questions or concerns concerning immunizing the child against HPV could be answered by contacting a health care provider.
Iowa	4/20/07	4/20/07	H.F. 611, c. 2007-98							Requires that children attending grades 7 through 12 in public and non public schools be taught age-appropriate and research-based information about HPV and the availability of a vaccine to prevent HPV. ⁶	

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Louisiana	6/16/08	6/16/08	HB 359, Act 210								Requires each city, parish, and other local public school board that provides information relative to immunizations to provide to the parent or legal guardian of each student in grades six through twelve information relative to the risks associated with HPV and the availability, effectiveness, and known contraindications of immunization against HPV. Requires the information to describe the link between HPV and cervical cancer, the means by which HPV is spread, and where a person may be immunized against HPV. The information must be updated annually.
Maine ⁷	6/12/07	1/1/08	S.P. 45/L.D. 137, c.73								Requires the Breast and Cervical Health Program to implement statewide public education efforts regarding cervical cancer prevention and early detection, including the availability of the HPV vaccine.
Maryland ⁸	4/24/07	7/1/07	S.B. 774/H.B. 1049, c.191								Requires the Subcommittee on the Human Papillomavirus Vaccine to develop a public awareness and education campaign about the HPV vaccine with an emphasis on parental education.

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Montana	05/08/07	05/08/07	S.B. 505, c. 473								Requires task force to identify and recommend strategies for educating the public about the availability and efficacy of the HPV vaccine, including appropriate methods for educating parents and adolescents about the risks of HPV, modes of transmission and availability of the vaccine.
Nevada	6/14/07	7/1/07	S.B. 409, c. 527				X		Requires specified individual and group insurers, including health maintenance organizations and Medicaid, to provide coverage for expenses incurred for administering the HPV vaccine to females at such ages as recommended for vaccination by a competent authority, including, the Centers for Disease Control and Prevention of the United States Department of Health and Human Services, the Food and Drug Administration, or the manufacturer of the vaccine.		

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
New Jersey	8/6/07	8/6/07	S.B. 2286, c. 134								Requires the state Commissioner of Education to develop an educational fact sheet about HPV for distribution to parents or guardians of students in 7th through 12th grade. Requires the state Commissioner of Health and Senior Services to: (1) establish a public awareness campaign to inform the general public about the clinical significance and public health implications of HPV, including its causes, and the most effective means of prevention and treatment; and (2) prepare a patient information brochure regarding HPV, including its causes and most effective means of prevention and treatment, and distribute it to all pediatricians in the state.
New Mexico	4/2/07	6/15/07	S.B. 407, c. 278				X		Requires individual or group health insurance policies, including health maintenance organizations, to provide coverage for the HPV vaccine to females 9 to 14 years of age.		

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				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
North Carolina	5/31/07	7/1/07	S.B. 260, SL 2007-59								Requires local boards of education, charter schools, and public and private schools to ensure that parents and guardians of children in 5th through 12th grade are provided with information about cervical cancer, cervical dysplasia, HPV, and the vaccines available to prevent these diseases.
North Dakota	3/28/07	7/1/07	H.B. 1471, c. 232								Requires the state Department of Health to: (1) educate the public about HPV and the availability of a HPV vaccine; (2) promote immunization against HPV; and (3) distribute informational materials regarding HPV and its vaccine.
Pennsylvania	07/07/06	09/05/06	H.V. 801, Act 2006-74								Establishes Cervical Cancer Task force to develop plan to educate women about HPV and cervical cancer.
South Dakota	3/16/07	3/16/07	H.B. 1061, c. 201					X	Authorizes the state Department of Health to offer the HPV vaccine to any woman who is at least 11 years of age and less than 19 years of age.		

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Texas	5/8/07	5/8/07	H.B. 1098, c. 43			X					Requires the state Health and Human Services Commission to provide educational material about the HPV vaccine that is unbiased, medically and scientifically accurate, and peer reviewed, available to parents or legal guardians at the appropriate time in the immunization schedule by the appropriate school.
Texas	5/11/07	9/1/07	H.B. 1379, c. 59							Requires the Department to develop course materials and instruction to include: (1) that both males and females may be infected with HPV and symptoms may not be present; (2) that younger women are at greater risk of HPV infection than older women; (3) information regarding the role of HPV in the development of cervical cancer; and (4) information regarding the continuing need for women to undergo Pap smear testing, even if they have received a vaccination against HPV.	Requires the state Department of Health to: (1) produce and distribute informational materials regarding vaccines against HPV; (2) develop educational programs for parents regarding HPV and promoting awareness of a minor's need for preventive services for cervical cancer and its precursors; and (3) develop and maintain an Internet website that targets the public and health care professionals and provides accurate, comprehensive information on all aspects of cervical cancer prevention, including vaccination against HPV.

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

State	Date Enacted	Date Provisions Effective	Bill Number	School HPV Vaccination			HPV Vaccine Coverage			HPV Health Education	
				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Vermont	6/10/08	6/10/08	HB 887, Act 203							Permits school districts to include a module within the secondary school health class curricula relating to cervical cancer and the human papillomavirus. Requires the state Department of Education to work with relevant medical authorities to update the current model module to reflect up-to-date information and practices for health education in this area. ⁹	
Virginia	4/4/07	10/1/08	S.B. 1230, c. 922/H.B. 2035, c. 858	X ¹⁰ (6th grade)					Requires the appropriate local health departments to administer vaccines required by the Board without charge.		

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

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				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
Washington	5/2/07	7/22/07	H.B. 1802, c. 276								Beginning with sixth grade, requires all public schools in the state to provide parents and guardians with information about HPV and its vaccine at the beginning of every school year. Requires the state Department of Health to prepare the information materials to be distributed and requires private schools to notify parents that information on the HPV disease prepared by the Department is available.
¹ School Health Education includes only laws requiring education for students in a school setting. Requirements for parental education or student education conducted outside of a school setting are included under Health Education.											
² District of Columbia law also requires the Mayor to: (1) ensure that all communications from the Department on the HPV vaccination program prominently features information pertaining to the ability of parents or guardians to opt out of the program; (2) extend, by rulemaking, the HPV vaccination requirements to males, consistent with standards set forth by the CDC; and (3) require the Department to develop reporting requirements for the collection and analysis of the HPV vaccination data.											
³ District of Columbia law exempts students whose parents or legal guardians object to the vaccine for religious, health, or personal reasons.											
⁴ Hawaii law is voluntary in that the resolution <i>requests</i> that the governor to establish the State Cervical Cancer Elimination Task Force. The law also requires the Task Force to raise of public awareness of the causes of cervical cancer, the value of prevention, and new technology. The Task Force must dissolve itself by 6/10/10.											
⁵ Indiana law allows parents to opt out of providing information to the school concerning whether the student was immunized.											
⁶ Iowa school education provision allows an exemption from the requirement, upon a school's request, if it is determined that the request made is an essential part of a planned innovative curriculum project.											
⁷ Maine law requires the state Department of Health and Human Services to establish as a priority for future budget requests the need to provide sufficient resources to provide the HPV vaccination to the population of low-income females in the state that fall into the age cohort identified by the federal Centers for Disease Control and Prevention as needing vaccination against HPV. The law also requires the Department's Office of Minority Health to convene meetings with racial and ethnic minority groups to examine cervical cancer incidence in racial and ethnic minority populations and develop recommendations to improve cervical cancer prevention and early detection in these populations.											
⁸ Maryland law requires the Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan to collaborate with the Department and the State Council on Cancer Control ("Council") to: (1) promote public awareness on the causes and nature of cervical cancer, personal risk factors, the value of prevention, early detection, options for testing, treatment costs, new technology, medical care reimbursement, and physician education; and (2) examine new and emerging medicines, including vaccines, that are being developed in an effort to cure cervical cancer.											

State Laws Addressing HPV Vaccination, HPV Education, and HPV Task Forces (as of March 31, 2009)

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				Mandatory Vaccination	Notification of Vaccination Status Required	Mandatory Vaccination Prohibited	Third-Party Reimbursement	State Required/Authorized to Provide/Reimburse for Vaccine	Coverage Requirements	School HPV Education Requirements ¹	HPV Health Education Requirements
⁹ Vermont law states that <i>if</i> a school district includes a module within the secondary school health class curricula related to cervical cancer and HPV, then the state Dept. of Education is required to work with medical authorities to update the module to reflect up-to-date information and practices for health education in this area.											
¹⁰ Virginia law exempts students whose parents or guardians object to the vaccine for religious, medical, or personal reasons.											

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