Report of the

Pennsylvania Cervical Cancer Task Force

Presented to the:
Senate Public Health and Welfare Committee and
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Pennsylvania Cervical Cancer Task Force Report

Executive Summary

Overview of the Cervical Cancer Task Force:

The Pennsylvania Cervical Cancer Task Force (Task Force) was established through Act 74 of 2006, which created the Cervical Cancer Education and Prevention Act. The Act authorized the Pennsylvania Department of Health (Department) to establish a Task Force to evaluate the education and prevention of cervical cancer and develop a report that would provide: recommendations to raise public awareness on the prevention, early screening and detection of cervical cancer; and recommendations to reduce the occurrence of cervical cancer in women in this Commonwealth. The Task Force is composed of health care and public health professionals who met five times in 2006 and 2007 to develop the recommendations listed throughout this report.

Scope of the Problem - Cervical Cancer and HPV:

Cervical cancer is an important public health problem that cannot be ignored. Cervical cancer is one of the most preventable cancers, which is why no one should die from this disease. According to the American Cancer Society, about 3,700 women nationwide die each year of cervical cancer. In 2003, 154 Pennsylvania women died of cervical cancer, which represents 154 missed opportunities for screening, early diagnosis and treatment.

Virtually all cases of cervical cancer are caused by the Human Papillomavirus, or HPV; 70 percent of which can be prevented by the HPV vaccine. It is believed that as many as two-thirds of cervical cancer cases worldwide are attributable to HPV, with many studies indicating that between 50 and 80 percent of women have been exposed to some form of the virus by the age of 50. This underscores the importance of women becoming more educated about the Pap test, which is a simple procedure that collects cells from the cervix and is the best tool to detect cervical cancer in its earliest stages. The number of deaths would decrease dramatically if more women had a Pap test on a more regular basis. But even if women develop cervical cancer, the chances of a cure are as high as 90 percent — if discovered early.

If unrecognized and untreated, cervical cancer has many costs. The true burden of cervical cancer is not only measured in human costs, as evident in the number of deaths per year, but also in the financial costs associated with this disease. It is estimated that as a nation we spend $4 billion or more (2004 dollars) annually on prevention and treatment of disease related to HPV. Pap test screening and treatment for precancerous lesions represents an investment in the prevention of cervical cancer. Women from low-income households are at higher risk for developing severe and life threatening cervical disease due to additional risk factors such as smoking and lack of access to preventive care. Since these same women are more likely to be underinsured or uninsured, a greater cost of their care is borne by the state.

Key Findings:

- Cervical cancer can be prevented by raising public awareness and education about behaviors that lessen the risk of an individual for exposure to the HPV. Since HPV is acquired primarily through intimate sexual contact, public education concerning behaviors that lessen the risk of acquiring HPV should target the highest risk age groups (adolescents and young adults).
- Cervical cancer prevention can also be attained through educational campaigns informing women that the Pap test needs to be part of a woman's regular health checkup. This includes becoming educated on how it's done, what it means, when it's abnormal, and why it needs to be part of their regular health checkups. Once the cervix has been exposed to HPV, Pap test screening is key to identifying precancerous lesions at their earliest stages, when they can be monitored for change or removed before they develop into cancer.
- A vaccine that can prevent precancerous lesions of the cervix in women has been licensed and is recommended by the major medical professional organizations for girls 9 to 26. However, not all health plans cover the vaccine. It is important to note that the vaccine does not take the place of Pap tests or guard against sexually transmitted diseases. Women should keep following their health care provider's advice on getting Pap tests.
- Health care professionals often lack the necessary knowledge and skills to promote prevention efforts. Just as public health messages must be tailored to specific cultural groups, health care providers must be trained to discuss immunization, screening, and behavioral change in a culturally sensitive and responsive manner that uses principles of health literacy.
- A significant layer of complexity is the inconsistencies that exist between insurance companies regarding reimbursement for immunization and Pap test screening.
- Significant barriers exist that must be addressed before we can effectively prevent all cervical cancer and pre-cancerous lesions. The Task Force acknowledges that there are at least two major issues that must be addressed in the future. First is the role of males as transmitters of HPV and engaging them as partners in preventing its spread. Second is accessible preventive health care that establishes consent standards of care across geographic, economic, and racial lines.

Key Recommendations:

- Public Education: Develop and implement a multi-media public education campaign to deliver cervical cancer prevention and screening information to women across the state, especially in underserved areas (rural and urban). This would include intensifying outreach to women who have rarely or never been screened for cervical cancer and ensure women know that a Pap test should be part of their regular health checkup
- Health Provider Training: Ensure that health care providers have access to current training on cervical cancer and HPV to facilitate the successful education of and care for their patients.
- Legislation: Introduce legislation that facilitates the administration of the HPV vaccine to females age nine through 26 through reimbursement by insurers
- Funding: Secure funding for cervical cancer outreach efforts, maintain and expand existing screening programs and provide coverage of the HPV vaccine.

Purpose and Process

Every year in the United States, women die from cervical cancer. This is of concern because cervical cancer is one of the most preventable cancers, and when detected early and treated, the prognosis is excellent. In Pennsylvania, a total of 510 invasive cervical cancers were diagnosed in 2003. These figures represent the lowest annual number of cases reported during the ten-year period of 1994-2003.[1] However, the average annual age-adjusted incidence rate for invasive cervical cancer during 1999-2003 was 56 percent higher for Blacks compared to White females and the death rate among Black women was over twice as high as the rate for Whites.[2] All cases of cervical cancer represent missed opportunities for screening, early diagnosis, and treatment.

During the past four decades, incidence and mortality from cervical cancer have declined significantly. However, cervical cancer and the Human Papillomavirus (HPV), the cause of genital warts and most cases of cervical cancer, continue to be major public health concerns affecting women in every demographic of American life, with the incidence and mortality rate of cervical cancer highest among Black and Hispanic women. The true burden of cervical cancer is not only measured in human costs, as evident in the number of deaths per year, but also in the financial costs associated with this disease. The prevention and treatment of genital warts and cervical HPV-related disease imposes an estimated burden of $4 billion or more (2004 dollars) in direct costs in the United States each year. Of this, approximately $200 million is attributable to the management of genital warts; $300-$400 million to invasive cervical cancer; and the remainder to routine cervical cancer screening, the follow-up of abnormal Pap tests, and pre-invasive cervical cancer.[3]

Public health early detection programs for breast and cervical cancer have been responsible for identifying thousands of cancers in early stages when treatment is more effective and less expensive. For example, treatment of cervical cancer at an early stage costs $2,000, while diagnosis at a late stage means more intense treatment that may not be as effective and costs $30,000.[4]

The Cervical Cancer Education and Prevention Act, Act 74 of 2005, authorized and directed the Pennsylvania Department of Health to establish a Cervical Cancer Task Force (Task Force) to evaluate and make recommendations for education and prevention of cervical cancer. A Task Force focusing on cervical cancer, as opposed to other cancers, was established because of the preventive nature of this disease and the potential to make a tremendous impact on cervical cancer incidence and mortality due to recent technological advances in cervical cancer screening. The Task Force recognized that through effective outreach, education, screening, and treatment, cervical cancer morbidity and mortality could be eliminated in Pennsylvania.

Cervical Cancer Task Force Duties

- Develop, using existing resources, a plan to raise public awareness and educate women about the prevention, early screening, and detection of cervical cancer and its relation to HPV.
- Identify new technologies, including newly introduced diagnostics and preventive therapies that are effective in preventing and controlling the risk of cervical cancer.
- Make recommendations concerning existing laws, regulations, programs, and services relating to cervical cancer.
- Receive and consider reports and testimony from individuals, local health departments, community-based organizations, voluntary health organizations, and other public and private organizations statewide regarding education and prevention of cervical cancer, to learn more about their contributions to cervical cancer diagnosis, prevention and treatment, and their ideas for improving cervical cancer prevention, diagnosis, and treatment in this Commonwealth.
- Facilitate coordination of and communication among state and local agencies and organizations to promote education and prevention of cervical cancer.

Cancer of the cervix is the second most common cancer in women worldwide, with about 500,000 new cases and 250,000 deaths each year. Almost 80 percent of cases occur in low-income countries, where cervical cancer is the most common cancer in women. In the United States, cervical cancer is the third most common gynecologic malignancy. Cervical cancer is a relatively slow progressing disease that affects the lining of the cervix (the organ connecting the uterus and vagina) of the female reproductive system. It may present with vaginal bleeding but symptoms may be absent until the cancer is in its advanced stages, which has made cervical cancer the focus of intense screening efforts utilizing the Pap test.

Signs and symptoms of cervical cancer

- Unusual vaginal discharge
- Bleeding that starts and stops between regular menstrual periods
- Bleeding during sexual intercourse, douching, or a pelvic exam
- Menstrual bleeding that lasts longer or is heavier than usual
- Bleeding after menopause

All of these symptoms do not appear until cervical cells become cancerous.

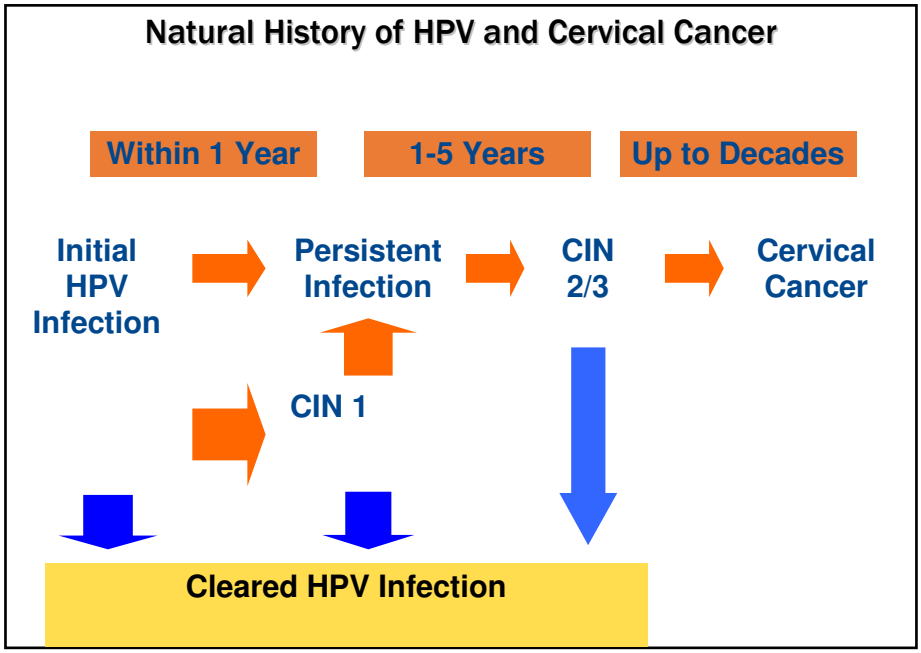
HPV is the most common sexually transmitted viral infection of the reproductive tract and the major cause of the two types of cervical cancer - squamous cell cancer and adenocarcinoma. It is sometimes called the wart virus or genital wart virus as some types of HPV cause genital warts. However, the types of this virus that cause warts (types 6 and 11) are not the types that cause cervical cancer. Virtually all cervical cancer cases (99.7 percent) are linked to genital infection with certain types of the HPV.

More than 100 HPV types are recognized, and more than 50 of these affect the genital tract. HPV is transmitted through sexual contact and often has no signs or symptoms. As a result, women may not be aware that they are infected. The Centers for Disease Control and Prevention (CDC) estimates that 80 percent of women will have had genital HPV by age 50. Approximately 80-90 percent of infections will clear on their own within two years, with an average duration of infection of 8-12 months.

There are “low-risk” (non-cancer associated) HPV types that are virtually never found in cervical cancer. These are HPV types 6, 11, 42, 43, 44, 54, 61, 70, 72, and 81. The HPV types considered to be “high-risk” for developing cancers of the cervix, vagina, vulva, anus, and penis are types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82. If a woman has persistent or frequent infections with any of these high-risk types, she is more at risk of developing pre-cancerous cervical cells or cervical cancer.

Although only a small proportion of women have persistent infection (approximately ten percent), persistent infection with high-risk types of HPV is the main risk factor for cervical

cancer. Of the fifteen high-risk HPV types, HPV 16 is the most prevalent and accounts for 50 to 60 percent of cervical cancer cases. HPV 16 infections tend to persist longer than infection with other HPV types, but still most HPV 16 infections become undetectable within two years.[5] HPV 18, the second most prevalent type, accounts for 10 to 12 percent of cervical cancers.[6] Thus, HPV types 16 and 18 together account for approximately 70 percent of persistent and high-risk HPV infections.



Source: CDC. Current issues in Immunization, NetConference, July 6, 2006

Research suggests that persistent HPV infections are the most critical for later development of cervical cancer.[7] The figure above depicts the natural history of HPV infection. It shows that the majority (80 percent) of HPV infections regress spontaneously. Additionally, studies show that 91 percent of new HPV infections will clear within two years; however, in a small minority of women the infection persists and may result in genital warts, cervical dysplasia or cervical cancer. Furthermore, cervical dysplasia (CIN1, CIN II, or CIN III) resulting from HPV infections is also more likely to regress or persist unchanged than to progress to invasive cancer.[8] It is important to note that once HPV infection is present, there is no medical treatment to rid the body of the virus. The treatments that are provided are directed at addressing the precancerous conditions or genital warts resulting from HPV infection.

Early Intraepithelial Disease/Dysplasia

Before cancer appears in the cervix, the cells of the cervix go through precancerous changes known as dysplasia. Recognition of these pre-cancerous pathological changes in the cervix is important in order to understand the burden of disease related to cervical cancer. Two types of dysplasia are recognized: low-grade squamous intraepithelial lesions (LGSIL) also known as cervical intraepithelial neoplasia (CIN 1) and high-grade squamous intraepithelial lesions (HGSIL) that encompasses carcinoma in situ CIS, CIN 2 and CIN 3. The abnormal cells present in LGSIL usually return to normal on their own within 18 to 24 months, but the HGSIL cells, if not treated, can progress to cancer of the cervix. As depicted in the natural history of HPV infection, a persistent infection may lead to the development of HGSIL cervical dysplasia. While statistics on incidence of cervical dysplasia in Pennsylvania are not readily available, national figures indicate that more than 700,000 cases of high-grade cervical dysplasia occur each year in the United States[9]. Roughly 500,000 to one million women are estimated to develop high-grade cervical cancer precursors each year, and all will need treatment. Identification of these precursors causes considerable physical and psychological morbidity and expense.

The following stages are used to group cancer cases for all primary sites (excluding Hodgkin and non-Hodgkin lymphomas) and are referenced throughout this report:

- **In Situ** – Cancer has not penetrated or spread beyond the basement membrane of the epithelial tissue involved.
- **Local** – An invasive cancer that is confined entirely to the organ of origin.
- **Regional** – Cancer has extended beyond the limits of the organ of origin and there is no evidence of distant metastasis.
- **Distant** – Cancer cells have broken away from the primary cancer, traveled to other parts of the body, and begun to grow at the new location.
- **Unknown** – Insufficient or no information available to determine stage.
- **Early stage** – The combination of both In Situ and Local stages.
- **Late stage** – The combination of both Regional and Distant stages.

A risk factor is anything that increases a person's chance of getting a disease such as cancer. Several risk factors increase the chance of developing cervical cancer. Women without any of these risk factors rarely develop cervical cancer. Both modifiable and non-modifiable risk factors for cervical cancer are presented in this section, as well as data from the 2004 Survey from the Behavioral Risk Factor Surveillance System (BRFSS). The BRFSS is an ongoing telephone health surveillance survey conducted each month to assess the behavioral risk factors associated with cervical cancer prevention and screening.

Cervical Cancer Risk Factors Include:

- HPV Infection
- Health Disparities
- Sexual Activity
- Smoking
- Human Immunodeficiency Virus (HIV) and other Immunodeficiencies
- Age
- Not Receiving Appropriate Screening

HPV Infection

HPV is transmitted through sexual contact and often has no signs or symptoms. As a result, women may not be aware that they are infected. It is the most common sexually transmitted disease. Most cases clear on their own; however, cases left untreated may develop into cervical cancer. As a result, it is important for women to receive regular Pap tests to screen for HPV.

Health Disparities

Women suffering high cervical cancer mortality tend not to have a usual source of healthcare; are less likely to receive preventive health services, including cancer screening; have low incomes and educational attainment; and have high rates of breast cancer, colorectal cancer, cerebrovascular disease, and infant mortality. Black females are at greater risk of death from cervical cancer because their incidence rates are higher and cases are diagnosed at more advanced stages as compared to White females. The persistent disparity has been attributed to several factors, including differences in the prevalence of risk factors for cervical cancer; differences in screening, diagnostic evaluation, and treatment; and differences in the stage of disease at diagnosis.[10]

Low Socioeconomic Status –Women least likely to have recommended cervical cancer screening are those who have no health insurance and/or no usual source of healthcare or are recent immigrants. Reasons for not being screened vary considerably across populations, but efforts to identify and encourage women to be screened requires culturally and community-sensitive education and methods to facilitate informed decision making about preventive health in general and cervical cancer screening specifically.[11]

Sexual Activity

Number of sexual partners – An increased number of sexual partners increases the risk of acquiring an HPV infection. There is also evidence that uncircumcised males have an increased risk of penile HPV infection and, in the case of men with a history of multiple sexual partners, an increased risk of cervical cancer in their current female partners.[12]

Sexual activity at a young age – Sexual contact, not limited to vaginal intercourse, before age 18 increases the risk of persistent HPV infection, which subsequently increases the risk of developing cervical cancer.[13] It is not yet entirely clear why, but immature cervical cells are more susceptible to HPV infection as well as the pre-cancerous changes it can cause. Some believe it is the anatomical differences, while others blame adolescents' less-developed immune system.

Other vaginal infections – A recent study found that having both herpes and HPV infection nearly doubled the risk of squamous cell cervical cancer. This research took account of the number of sex partners women had, as well as their use of the pill.[14] A recent study looked at concurrent infection with HPV and Chlamydia trachomatis and found that risk of squamous cell cervical cancer is increased by about 60 percent.[15]

Smoking

Cigarette smoking is associated with an increased risk of developing squamous cell cervical cancer.[16] Cancer causing chemicals (benzyrene) from cigarette smoke have been found in cervical mucus of women who smoke. These chemicals damage the cells of the cervix and contribute to the development of cancer.[17] There are cells in the lining of the cervix called Langerhans cells that specifically help fight against disease and their function is impaired in smokers. If a woman has a high-risk HPV infection and smokes, she is twice as likely to get cervical cancer.[18]

Human Immunodeficiency Virus (HIV) and other Immunodeficiencies

A weakened immune system (from HIV, AIDS, chronic steroid therapy, etc.) increases the risk of HPV infection and subsequent risk of cervical cancer.[19] Large observational studies of HIV-positive women have demonstrated a strong and consistent relationship between coinfection with HIV and HPV and cervical dysplasia.[20] [21]

Age

The risk of cervical cancer rises with age and, when first diagnosed, cervical cancer in older women tends to be more advanced. Although cervical cancer is most often diagnosed in women over the age of 40, with proper screening and or vaccination of younger women, the precancerous lesions are diagnosed or obviated and progression to cancer is averted.

Not Receiving Appropriate Screening

Women who have never been screened, or are inappropriately no longer being screened because they are post-menopausal or "beyond reproductive years" are at a significantly increased risk of cervical cancer because their lesions are not discovered until advanced stages. Approximately half of all cervical cancer cases are in women who have never been screened.[22], [23]

Results from 2004 BRFSS survey conducted by the Pennsylvania Department of Health showed that 95 percent of women age 18 and older reported having received a Pap test in their lifetime, and the percentage was the same for White (non Hispanic) and Black (non Hispanic) resident females. Hispanic females were not included in the analysis due to small numbers. Of women 18 and older, 84 percent reported to have had a Pap test in the previous three years.

Results from the 2004 Behavioral Risk Factor Surveillance System (BRFSS) Survey

- The age of increased risk of not receiving proper screening followed a bimodal distribution with women ages 18-29 and ≥ 65 having significantly lower rates of ever receiving a Pap test (91 percent and 88 percent, respectively) compared to women ages 30-44 and 45-64 (97 percent and 98 percent, respectively).

- Women with some college education had significantly higher rates of having received at least one Pap test (some college education, 97 percent; college degree, 96 percent) compared to women with less than a high school education (88 percent).

- Significantly higher percentages were seen for women with household incomes of $50,000+ for having ever received a Pap test ($50,000-$74,999, 99 percent; $75,000+, 97 percent) compared to women with household incomes less than $15,000 (89 percent).

- No significant difference was seen by race/ethnicity.

The trend in reporting ever having a pap test over the years in Pennsylvania adult females compared with the Healthy People 2010 target is depicted in the figure below:

Figure 1

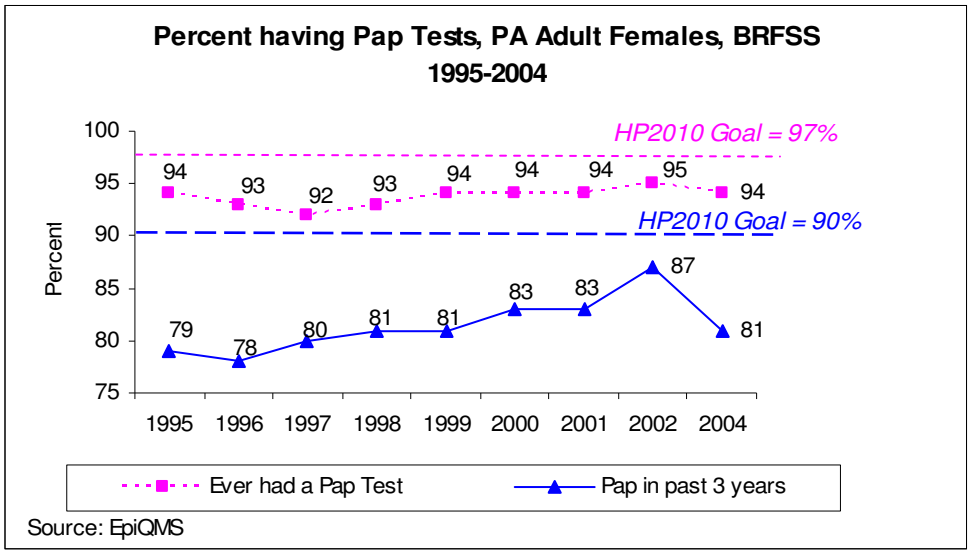


Figure 1 indicates that the percentage of women who reported ever having a pap test has remained more or less static since 1994; while those reported having pap test in last three years rose steadily from 79 percent in 1994 to 87 percent in 2002 then sharply declined to 81 percent in 2004 survey respondents. These results suggest that more efforts are needed to improve the cervical screening practices of adult women in Pennsylvania. However, limitations such as self-reporting bias, exclusion of incarcerated individuals, access to telephone, and voluntary participation in BRFSS survey should be considered when interpreting these results.

According to the American Cancer Society, the major barriers to accessing care for prevention, screening and treatment of cervical cancer are lack of health insurance, poverty, and the resultant shift in priorities. A woman who has no home and/or can't feed her family may have little interest in getting a Pap test even for free. The Task Force is dedicated to addressing these barriers, as cervical cancer is a preventable disease.

In addition, cervical cancer is more likely to occur in middle-aged and older women who have not been screened, or not screened in the previous five years. After child bearing, women often stop seeing a healthcare provider or gynecologist and stop getting Pap tests. Healthcare providers are less likely to screen older versus younger women for cervical cancer. [24]

Summary of Barriers to Care

- **Lack of Health Insurance** – In Pennsylvania, seven percent of females do not have health insurance and 18-34 year olds are more likely to be uninsured.[25]
- **Socioeconomic Status** – Women of lower socioeconomic status are more likely to be underinsured, and are less likely to seek screening or preventive services.
- **Cultural Sensitivity** – Some perceptions and cultural beliefs of both women and healthcare providers may impede women from accessing care.
- **Age** – Younger women often deal with issues of parental consent and experience a conflict of interest regarding informing their parents. Also, they may not have access to preventive services. Older women (beyond reproductive age) may not have access to screening services and are more likely to be omitted from screening.
- **Geographic Disparities** – Rural areas are less likely to have sufficient services and providers.
- **Payment for Preventive Services** – Coverage is still lacking for some cancer-related services. Previous studies have shown that preventive care like mammography often is not sought when insurance coverage is inadequate; women without insurance are less likely to get these important screening tests than women who are covered[26].
- **Healthcare System Limitations** – Issues such as low reimbursement rates, language barriers, and lack of cultural competency may prevent women from obtaining screening services.

INCIDENCE

Incidence is the number of new cases diagnosed in a given period of time, usually a year. Cervical cancer is a relatively uncommon cancer. It is projected that there will be 435 new cases of invasive cervical cancer diagnosed in Pennsylvania in 2006. This represents a significant public health problem, and most importantly, it is preventable. More frequently diagnosed cancers are breast, lung, colon-rectum, uterine, and non-Hodgkin's lymphoma. These account for nearly 22,000 or 64 percent of all new cases annually. Table 1 describes the incidence rates for leading cancers, expressed per 100,000 women. For each type, the incidence rate for Pennsylvania compares favorably with the United States.

Table 1

Age adjusted Incidence Rates of Common Cancers among Females, Pennsylvania[27]* and the United States[28]**

Site	Pennsylvania	United States
Breast	128.7	124.9
Lung and Bronchus	53.3	53.7
Colon and Rectum	50.9	44.9
Corpus and uterus	30.1	22.8
Non-Hodgkin's Lymphoma	16.8	15.5
Ovary	15.5	13.1
Melanoma of Skin	12.8	13.6
Thyroid	16.5	12.1
Cervix	8.5	8.7
Pancreas	9.7	9.5
Urinary Bladder	11.5	9.4

Pennsylvania*: 1999-2003 average annual age-adjusted rates and US 2002 rates**; 2000 US standard

Figure 2 depicts the cervical cancer rate in Pennsylvania relative to other states reporting cervical cancer incidence in 2002. The state's risk was about 24 percent lower compared to women in the highest risk areas, Alabama and Washington, D.C. (10.6 and 10.4 per 100,000, respectively, compared to 8.1 per 100,000 for Pennsylvania). Yet it is about average compared to the U.S: 8.5 per 100,000, slightly below the national average of 8.7 as shown in Table 1.

Figure 2

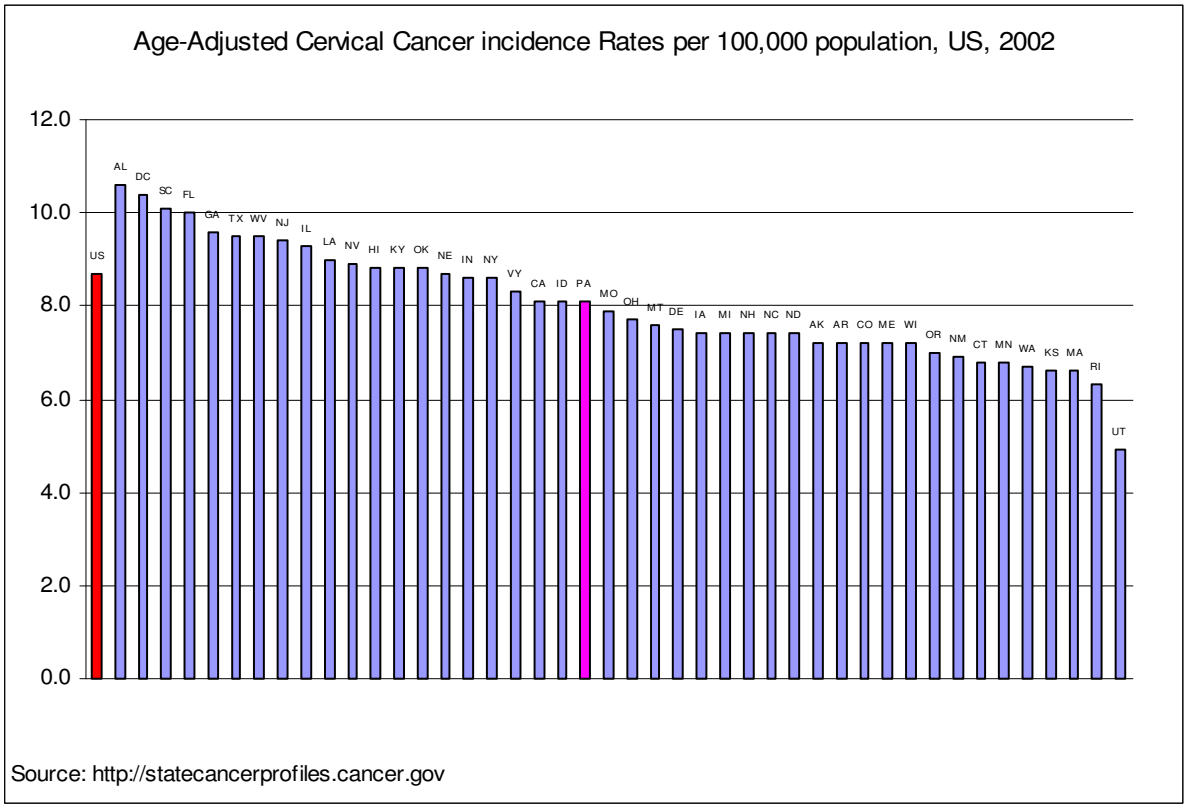


Figure 3 shows the average annual age adjusted incidence rates for cervical cancer by race/ethnicity for 2002-2004 described in the Pennsylvania Cancer Registry's latest statistics.[29] The rate for Black women is over 50 percent higher than White women and lowest for Asian women. The stage at diagnosis of invasive cervical cancer also differs by race as shown in Figure 3; more than 50 percent of cervical cancers are diagnosed at a late stage in non-White minority women, compared to 45 percent in Whites.

Figure 3

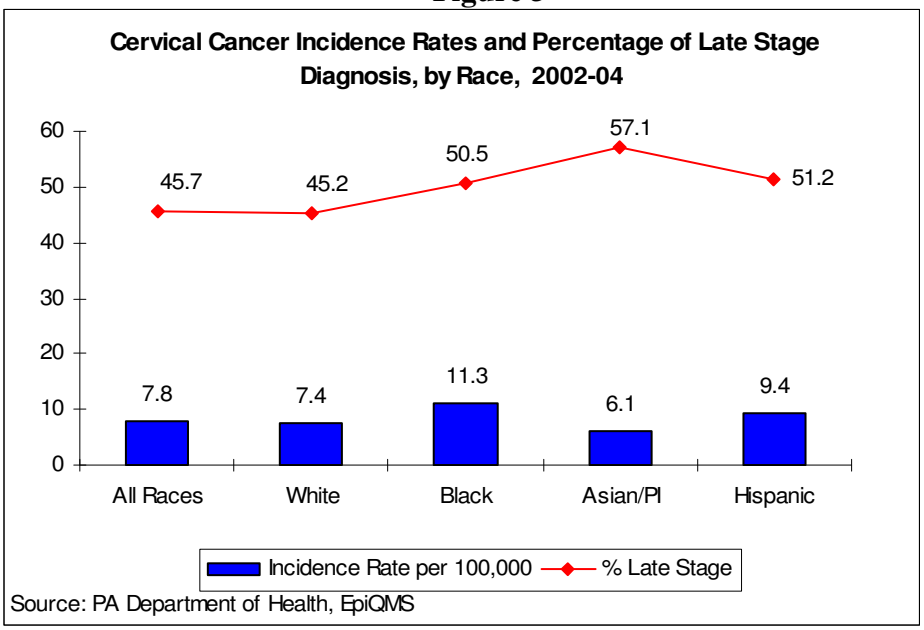


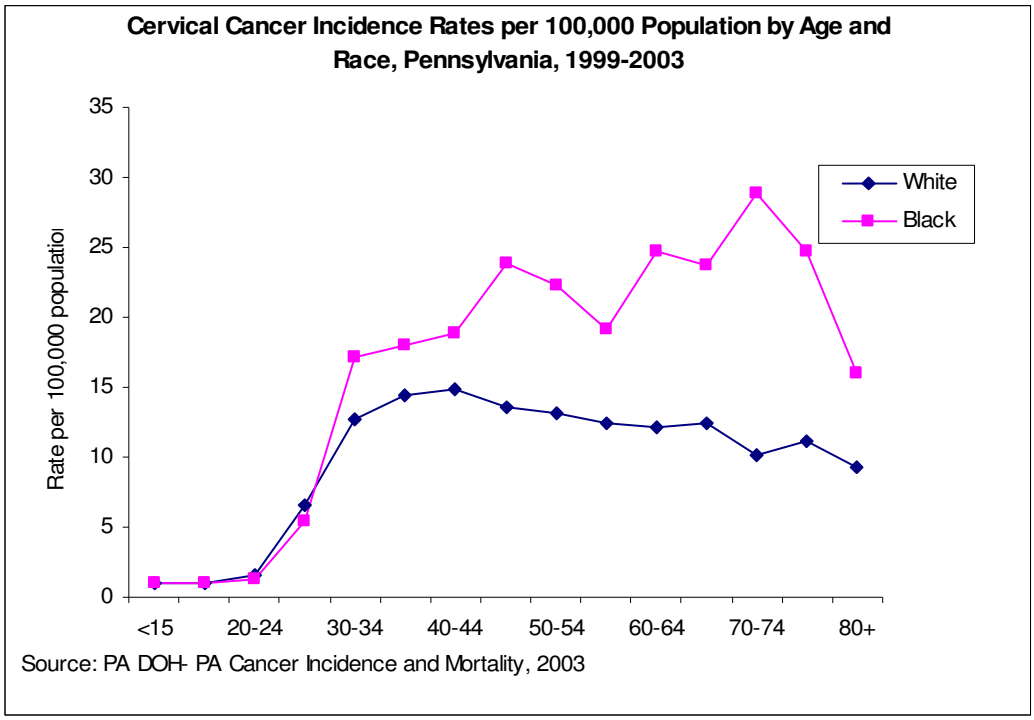
Table 2

Cervical Cancer Cases and Incidence Rates by Age Group and Race
Pennsylvania, 1998 – 2002[30]

	All Races		White		Black	
Age Group	**Rate**	**Count**	**Rate**	**Count**	**Rate**	**Count**
0 – 19	0.1	5	0.1	4	0.1	1
20 - 29	4.2	156	4.2	128	3.9	18
30 – 39	14.5	616	14.1	512	17.0	82
40 - 49	15.0	726	14.1	596	22.4	108
50 - 59	13.8	537	12.8	442	20.3	70
60 - 69	14.2	399	12.8	323	26.8	62
70 – 79	13.2	344	11.4	276	28.3	50
80 +	11.2	196	10.4	170	18.6	19

Table 2 and Figure 4 describe the risk of developing cancer with increasing age for the years 2002-2004. Among White women, the rates rise to ages 40-44 and gradually decline thereafter. For Blacks, it continues to rise throughout life, peaking about age 70, and then declines sharply. These trends reflect both the period of exposure to the virus, and the latency period from infection to disease.

Figure 4



However, these racial disparities are not unique to Pennsylvania. A 2002 report prepared by the North Carolina State Center of Health Statistics found that the age-adjusted cervical cancer incidence rate for Black women is 1.5 times that of White women and this disparity was greatest among women ages 65 and older, where the incidence rate for Black women is three times that for White women.[31]

Figure 5

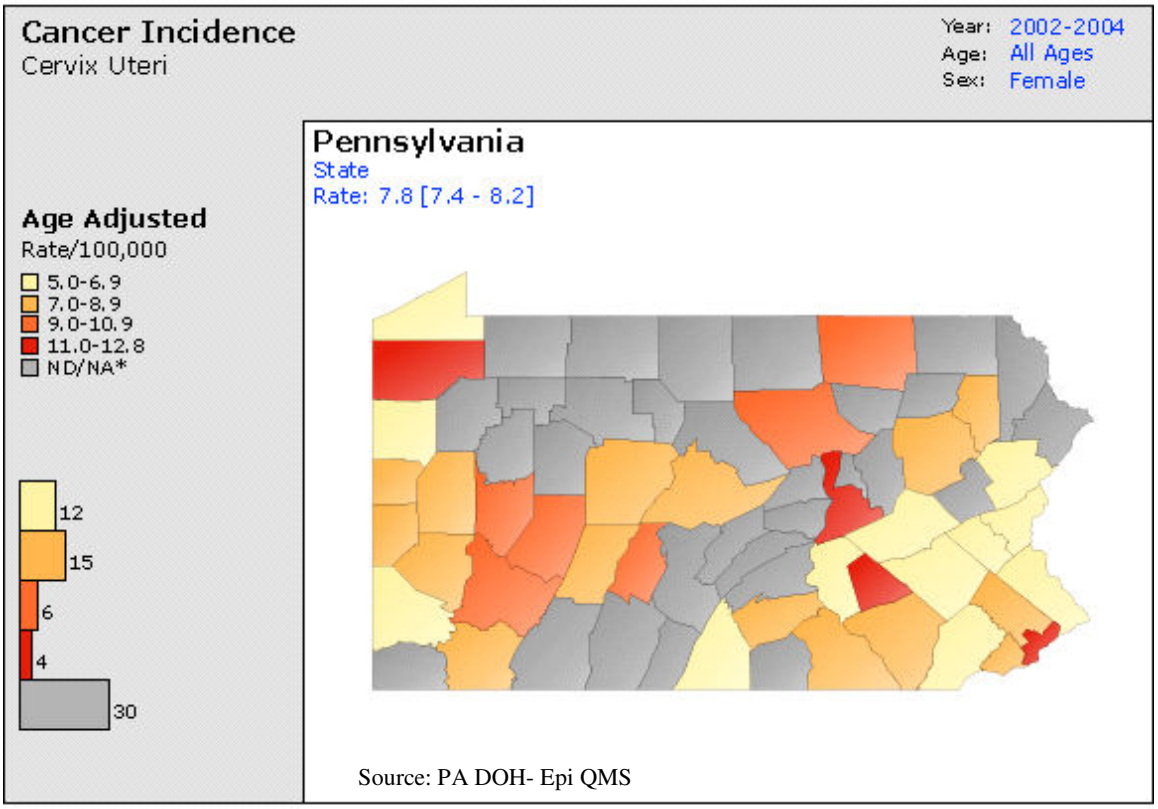


Figure 5 shows a map of Pennsylvania and the distribution of invasive cervical cancer rates by counties for the years 2002-2004.[32] The overall average age-adjusted rate for the state was 7.8 per 100,000. Variation in age-adjusted incidence rates for invasive cervical cancer among counties indicated Philadelphia County to have a significantly higher rate at 11.8 per 100,000 compared to the other counties. Rates were also higher than the overall state rate for 16 other counties with populations above 500,000. For about half of the Pennsylvania counties (30 out of 67) data was either not available or the numbers of cases were too small for calculations. These counties appear in grey in the map. Many of these counties are in the rural areas of the state.

Prevention is the best way to control incidence and mortality, while screening leads to diagnoses at early stages and improves patient outcomes, therefore, screening is the major approach used for controlling cervical cancer. Cervical cancer survival for women with pre-invasive lesions is almost 100 percent. For invasive cervical cancer, the five-year survival is 92.2 percent if the lesion is localized (i.e., an invasive malignant cancer confined entirely to the uterine cervix), and 53.3 percent if there is regional spread (i.e., a malignant cancer that has

extended beyond the cervix into surrounding organs or tissues, and/or involves regional lymph nodes). With distant metastasis, however, the five-year survival is only 16.8 percent.[33] Low income women tend to have their diagnosis delayed, which may lead to more advanced disease at the time of treatment and consequently, to poorer survival.[34]

Figure 6

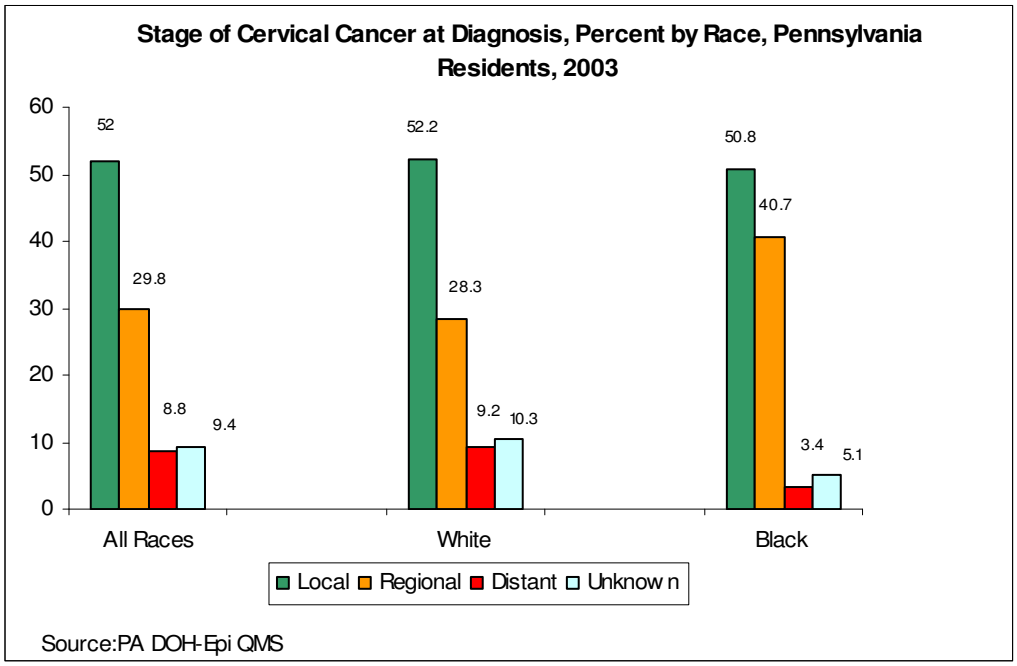
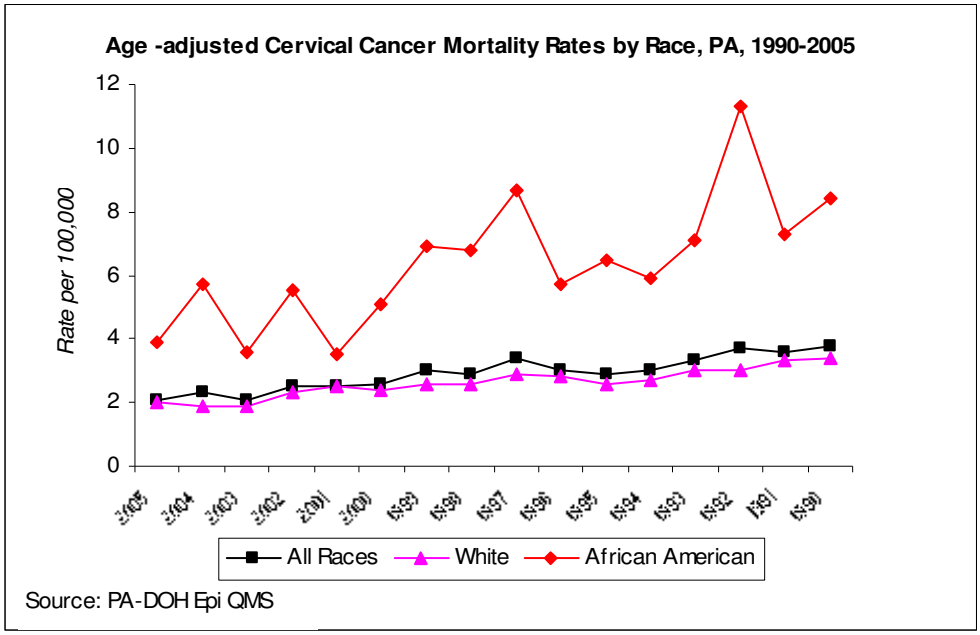


Figure 6 illustrates the percent of cervical cases reported by diagnosis stage (local, regional, distant, and unknown) in 2003. For women of both race categories (White and Black), the percent of women diagnosed at a local stage was 52 and 51 percent, respectively. The more significant differences are observed in the later stages of the disease; 41 percent of Black cervical cancer patients were diagnosed at the regional stage compared to 28 percent of White patients. Late-stage cancer (defined as the distant spread of cancer) diagnoses accounted for 9 percent in White cases and 3 percent in Black cases.

MORTALITY

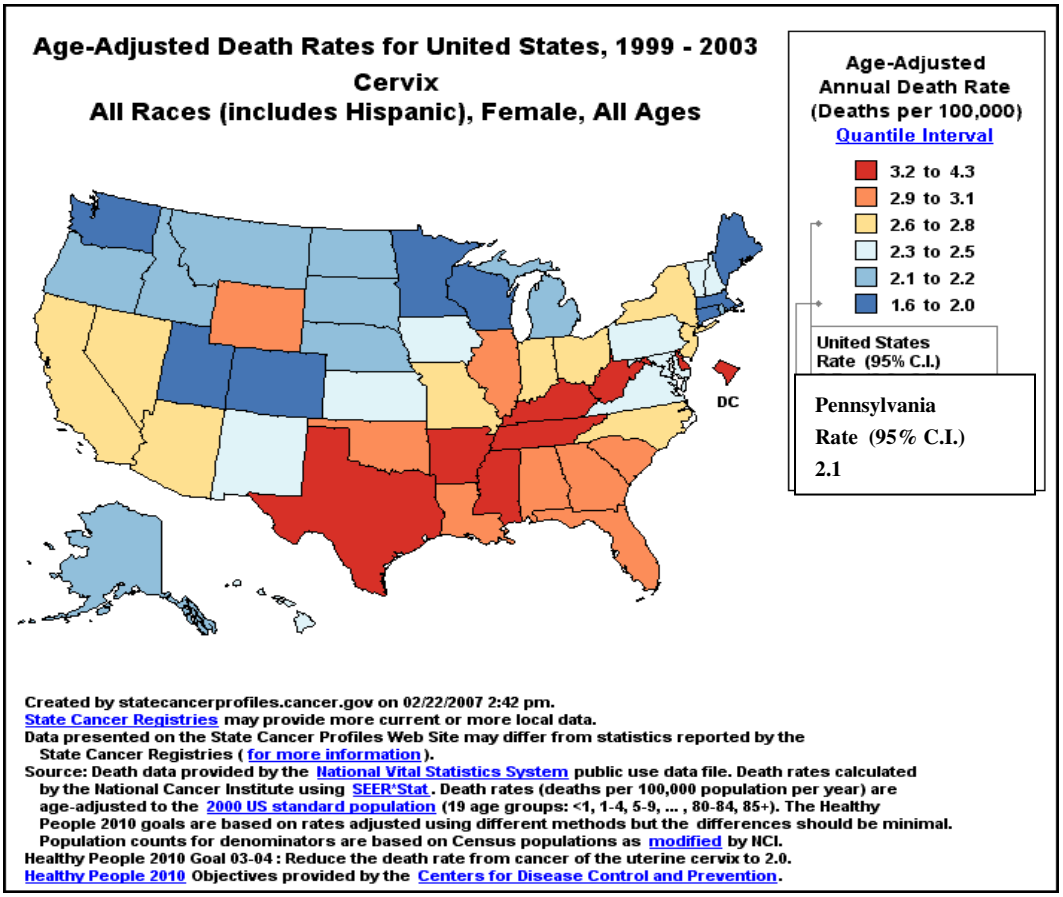
The cervical cancer mortality pattern in Pennsylvania parallels the U.S.: death rates have declined significantly for both Black and White women from 1990 to 2005, from 8.4 to 3.9 per 100,000 for Blacks and from 3.4 to 2.0 for Whites. In the U.S., cervical cancer incidence rates have decreased approximately 75 percent and death rates approximately 70 percent since the 1950s largely due to the introduction of pap testing[35]. However, all deaths related to cervical cancer should be considered to be preventable. Moreover, substantial differences exist in the incidence and mortality by ethnic and racial groups. In Pennsylvania, 156 women died of cervical cancer in 2005, representing an age-adjusted death rate of 2.1 per 100,000 women (16 percent of the 156 women were Black). Among Black women, the rate was 3.9, about twice the rate for White women. Additionally, the five-year survival rate for Black women in the U.S. is only 66 percent, while the rate for White women is 74 percent. In 1990 the Black:White cervical cancer mortality rate ratio in Pennsylvania was approximately 2.5 (8.4/3.4 = approximately 2.5). In 2005, the rate ratio was approximately 2.0 (3.9/2 = approximately2.0). Black females remain at greater risk of death from cervical cancer because their incidence rates are higher and cases are diagnosed at more advanced stages as compared to White females. Age adjusted cervical cancer mortality trends for Pennsylvania by race for the period 1990–2005 appears in Figure 7.

Figure 7



The overall U.S. cervical cancer death rate in 2003 was 2.5 deaths per 100,000 population, and for Pennsylvania was 2.1/100,000, which was below the U.S. rate. Pennsylvania has the 29th highest cervical cancer death rates among the 50 states and the District of Columbia.

Figure 8



As depicted in Figure 8, the age-adjusted death rates for cervical cancer during 1999-2003 for both U.S. and Pennsylvania were higher than the Healthy People 2010 goal of 2.0 per 100,000.

While cervical cancer is not very prevalent or a leading cause of mortality when compared to other cancers, it is still a significant public health issue. Most importantly, this is a preventable cancer. In Pennsylvania, as these data show, there are substantial racial disparities regarding incidence and mortality from cervical cancer. These rates appear to be highest in regions that are the most depressed economically and have large minority populations.

Once infected with HPV, there is no treatment available to rid the body of the virus. The infected cells begin to undergo precancerous changes, called dysplasia. This process, beginning with HPV infection, leading to dysplasia and ultimately, cervical cancer, takes approximately 10-20 years; therefore, regular screening for cervical cancer is the key to preventing and ending this disease. Again, approximately half of all cervical cancer cases are in women who have never been screened.[5] Pap tests, combined with pelvic examinations can reveal abnormal cells in the cervix caused by HPV. These tests can save a woman's life because they can detect pre-cancerous cells early, when they can be treated more successfully.

Both conventional Pap tests (smear on glass slide) and a new liquid-based cytology (cervical cells are exfoliated and collected into a liquid medium) can be used to screen for cervical cancer. The major problem with the conventional Pap test is its variably low sensitivity, which produces a high rate of false-negatives. However, with the liquid-based preparations there is a relatively higher sensitivity and lower false-negative rate, easier sampling procedure, and the ability to perform additional testing on the sample, thus this technique has established itself as the predominant means of sampling cervical cells for dysplasia.[36]

In the past, it was recommended that all women receive a conventional Pap test every year. New technology has changed screening guidelines and new recommendations have resulted. The Pennsylvania Department of Health follows the guidelines set forth by the American Cancer Society:

Guidelines for Prevention and Early Detection of Cervical Cancer

- All women should begin cervical cancer screening within three years after they begin having sexual intercourse, but no later than 21 years old. Testing should be done every year with regular Pap tests or every two years with the new liquid-based Pap tests.
- Beginning at age 30, women who have had three normal test results in a row can get screened every two to three years.
- Women over 30 can also choose to get screened every three years (but not more often) with either the regular or liquid-based Pap test, plus the HPV deoxyribonucleic acid (DNA) test. The HPV DNA test can show high-risk types of HPV in cell DNA before any changes to cervical cells are noticed.
- Women with diethylstilbestrol (DES) exposure before birth, Human Immunodeficiency Virus (HIV) infection, or a weak immune system due to organ transplant, chemotherapy, or chronic steroid use should get screened every year.
- Women 70 years of age or older who have had three or more normal tests in a row (and no abnormal tests in the last 10 years) may choose to stop having the test. But women who have had cervical cancer or who have other risk factors (as mentioned above) should continue screening.
- Women who have had a total hysterectomy (removal of the uterus and cervix) for reasons other than having cancer or a precancerous lesion may also choose to stop having the test. Women who have had a hysterectomy (with preservation of the cervix) should continue to follow the guidelines above.

Today, women must be notified that they have options regarding cervical cancer screenings. In all cases, women should consult their healthcare provider when in doubt about screening recommendations.

Currently, tests are available to determine whether a lesion contains a high-risk HPV type. Tests that utilize solution hybridization, are approved by the Food and Drug Administration (FDA) for the following indications: assisting clinicians to further typify abnormal Pap or liquid-based tests, and as an adjuvant screening tool for women over 30 years of age. This HPV DNA test is designed to detect high-risk types of HPV (Types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68). The HPV DNA test detects whether one or more types of HPV are present but it does not identify individual HPV types. The principal utility of the test is in identifying women with high-risk HPV who are thus at risk for having or developing pre-cancerous or cancerous changes.[37]

A test is available to detect low-risk types of HPV, but this test is not approved by the FDA and there are no clinical indications for this test. Currently no FDA-approved HPV DNA test exists for males, nor is HPV testing of males recommended because infection does not indicate increased risk of disease for the man or his partner. While HPV is common in men, HPV-associated cancers are rare.[38]

There are no routine methods for culturing HPV. Serologic (blood) tests are available for HPV, but these tests are used only in research settings. Many persons with detectable HPV DNA do not have antibodies, so these tests are not a good method to indicate infection with HPV.[39]

The recent development of a new vaccine approved by the FDA and the continuation of Pap tests will improve efforts to prevent cervical cancer. On June 8, 2006, the FDA licensed the first vaccine developed to prevent cervical cancer and other diseases in females caused by certain types of genital HPV. The quadrivalent vaccine protects against four types of HPV (6, 11, 16, 18), which are responsible for 70 percent of cervical cancers and 90 percent of genital warts. On June 29, 2006, the CDC's Advisory Committee on Immunization Practices (ACIP) voted to recommend use of this vaccine in females age 9-26 years. This prophylactic vaccine, made from non-infectious HPV virus-like particles (VLP), offers a promising new approach to the prevention of HPV and associated conditions. However, this vaccine should not replace other standard prevention strategies (pelvic exam and Pap test) since it will not work for all genital HPV types. At this time, new and different HPV vaccines are in production. The Pennsylvania Department of Health does not support one vaccination over another.

Available treatments are directed at either surgically or pharmacologically removing the precancerous growths or genital warts resulting from HPV infection.

HealthyWoman Program

The purpose of Pennsylvania's HealthyWoman Program (HWP) is to reduce breast and cervical cancer morbidity and mortality through screening, referral and follow-up, public education and outreach, professional education, quality assurance, surveillance, evaluation partnership development, and community involvement. The HWP is funded by the CDC and the Pennsylvania Department of Health (Department). The Department contracts with one grantee, the Alliance of Pennsylvania Councils, Inc. who in turn subcontracts with over 300 service delivery sites. The HWP provides breast and cervical cancer screening and diagnostic services to eligible women, age 40 to 64, who are uninsured, or are under-insured, and have incomes that are 250 percent of the Federal Poverty Income Guidelines or less. These services are also available to eligible women under age 40 that present with symptoms or problems indicative of cancer or a pre-cancerous condition of the breast or cervix.

Since the program's inception in 1994 through June 2006, more than 48,000 women have been screened for breast and cervical cancer; over 1,000 breast and 55 invasive cervical cancers have been detected as a result of these screenings. Eligible women enrolled in the HWP who have a positive diagnosis for cancer or a pre-cancerous condition of the breast or cervix are eligible for comprehensive healthcare coverage under the Commonwealth's Medical Assistance Program, through the Breast and Cervical Cancer Prevention and Treatment (BCCPT) Program.

The Pennsylvania Breast and Cervical Cancer Early Screening Act

On November 22, 2005, Governor Edward G. Rendell signed Act 74 of 2005, the Pennsylvania Breast and Cervical Cancer Early Screening Act. On July 1, 2006, the Pennsylvania Department of Health began providing funding for free breast and cervical cancer screenings to low income, uninsured and underinsured women ages 40-49. This additional funding enabled the HWP Contractor to offer breast and cervical cancer screening services to more women across the Commonwealth. In state fiscal year 2006-2007, the State Legislature appropriated $1.7 million to be used for breast and cervical cancer services offered through this program. This resulted in an expansion of the HealthyWoman Program, which previously provided the same services to women ages 50-64. Because of Act 74 funding, an estimated 4,200 additional women will receive HWP services in 2006-07 as a result of the state-funded program expansion.

Breast and Cervical Cancer Research Initiative

Act 7 of 1997 established an income tax provision to allow individuals to donate all or part of their state income tax refund for breast and cervical cancer research. These identified funds or personal donations to the Pennsylvania Department of Health are used for grants that are awarded to individuals conducting breast and cervical cancer research each year. Through a Request for Application (RFA) process, the Department of Health solicits research applications on breast or cervical cancer from Pennsylvania institutions and organizations. The overall goal of this funding is to promote research directed toward reducing the incidence of and mortality associated with breast or cervical cancer.

As of May 31, 2007, the total revenues collected for breast and cervical cancer research through donations from Pennsylvania personal income tax returns and private contributions totaled $2,057,500. The amount of donations received for the Breast and Cervical Cancer Research Grants fund during the 2006 tax year was $136,196. Expenditures for research studies have amounted to $1,139,122 and the current available balance for the fund is $580,532.

Statewide Cervical Cancer Screening Program

Since 2002, the Pennsylvania Department of Health has provided funding to the Family Planning Council (FPC), Inc. to administer a statewide cervical cancer program to educate, screen, diagnose, and provide limited treatment to women who are uninsured or whose insurance does not cover these services. This program served women who are not eligible for the Department of Health's HealthyWoman Program. In 2007, the Pennsylvania State Legislature did not appropriate funding for this program. In the future, it is critical that such funding for women age 18-39 be obtained on a permanent basis.

FPC, Inc. provided services through a grant agreement with the Department within its family planning region of the state (Southeast). In addition, three subgrantees provided services within their respective family planning regions of the state. The subgrantees and their respective service areas are.

- Adagio Health – Western region
- Family Health Council of Central Pennsylvania, Inc. – Central region
- Maternal and Family Health Services, Inc. – Northeast region

The first component of the Statewide Cervical Cancer Screening Program is an educational risk assessment service which consists of assessing a patient's risk for cervical cancer and education on these risks and the importance of receiving regular screening for cervical cancer. All patients under 50 years of age, regardless of insurance status, receive this education.

The program also provides traditional cervical Pap tests to low-income women under 40 years of age who are not covered by any other source of payment. If the results of an initial Pap test indicate that a patient should receive a repeat Pap, this repeat Pap can be done using the new liquid based Pap test. If the results of the liquid based Pap test indicate an Atypical Squamous Cells of Undetermined Significance (ASCUS or ASC-US) or a Low Grade Squamous Intraepithelial Lesion (LGSIL), the specimen will be subjected to the Digene Hybrid Capture test, to determine the strain of Human Papillomavirus (HPV) involved. This information enables the clinical staff to better counsel the patient regarding her risk for developing cervical cancer.

Finally, the following additional diagnostic and limited treatment procedures are provided to uninsured women: colposcopy without biopsy, colposcopy with biopsy, cryosurgery, and Loop Electrosurgical Excision Procedure (LEEP).

Cervical cancer strikes women younger than 40 and the rate rises rapidly between the ages of 20-39 (Figure 4 of this report). We must address the issue of cervical cancer screening and follow-up care for women under 40 who will continue to need screening even if they have

received the HPV vaccine. In calendar years 2002-2006, the FPC, Inc. provided 360,000 traditional Pap tests, liquid-based screenings and HPV typing as well as cervical cancer education and 10,800 colposcopies, biopsies, LEEP and cryosurgeries to treat precancerous conditions.

Cervical cancer mortality is a public health concern nationwide. This Task Force was presented with a tremendous and timely opportunity to address concerns and develop strategies directed at the prevention of HPV and early detection of precancerous conditions for women in the Commonwealth. In 2004, the Pennsylvania Department of Health released the first Comprehensive Cancer Control Plan (CCCP) for Pennsylvania. The recommendations of this Task Force align with many of the CCCP goals. Recently, the National Cancer Institute (NCI) Center to Reduce Cancer Health Disparities developed specific recommendations to eliminate cervical cancer mortalities and improve healthcare to underserved women. The recommendations developed by this Task Force also align with many of the NCI recommendations.

The following recommendations were developed to raise public awareness on the prevention, early screening and detection of cervical cancer and reduce the occurrence of cervical cancer in women in this Commonwealth. Included with each Task Force recommendation is reference to, if applicable, aligning Pennsylvania CCCP and NCI recommendations.

Recommendation 1: Public Education

Develop and implement a multi-media public education campaign to deliver cervical cancer prevention and screening information to women across the state, especially in rural and underserved areas.

State and National Recommendations

PA CCCP: Prevention Objective H1: Increase the proportion of women in Pennsylvania who understand the importance of being screened for cervical cancer on a regular basis throughout their lifetime and who have knowledge of cervical cancer screening guidelines; and Prevention Goal H: All women in Pennsylvania at higher risk for cervical cancer will have the knowledge and the resources to have Pap tests according to evidence-based guidelines and to receive appropriate follow-up of abnormal screening results.

NCI: Intensify outreach to women who have rarely or never been screened for cervical, breast, or colon cancer and other screenable/treatable diseases; Improve awareness and knowledge about cervical cancer through the development and provision of linguistically and culturally appropriate information; and Conduct social/behavioral, health services, and intervention research to better understand high-risk populations and develop interventions to improve their care.

Implementation Strategy

Outreach/Education

Outreach efforts must be presented in a culturally sensitive manner and be tailored to the specific population they are attempting to reach.

Media

A multi-media campaign will be the most effective way to inform women about cervical cancer prevention. Media efforts should reach women through mediums such as television, radio, and outdoor and transportation ads that convey the following messages: 1) Most cases of cervical cancer are caused by a virus, HPV; 2) Cervical cancer can be prevented through regular screening; 3) There are newly-developed vaccines to prevent HPV; and 4) HPV is not a sexually transmitted disease.

Limitations

If a HPV vaccine media campaign is developed and implemented, it must be ensured that an adequate supply of the vaccine is available. Sources of the HPV vaccine include the Vaccines For Children Program for girls age 18 and under who meet eligibility guidelines and manufacturers of the vaccine.

Tactics (including but not limited to):

Develop and evaluate multi-media efforts that reach women through avenues including but not limited to: Penn State Cooperative Extension, universities, Women, Infants and Children (WIC) sites, annual conferences across the state that specifically target women, community centers, churches, and beauty salons.

Audience: The public (women of all ages, men)

Responsible party: Pennsylvania Department of Health

Recommendation 2: Healthcare Provider Training

Ensure healthcare providers have access to current training on cervical cancer and HPV to facilitate the successful education of and care for their patients.

State and National Recommendations

PA CCCP: Prevention Objective H3: Promote updated educational campaigns targeting healthcare providers and family planning professionals about HPV prevention messages, new developments in testing and treatment, and patient counseling for sexually active patients, especially those with HPV infections and their partners; Information Objective B2: Ensure that every healthcare provider has access to the latest evidenced-based guidelines and Information Goal B: Provide all Pennsylvania healthcare providers with access to accurate, up-to-date, age- and culture-appropriate information about cancer prevention, risk reduction, screening, diagnosis, treatment, and end-of-life.

NCI: Improve provider-patient communication through provider education and availability of language translation; Develop, implement, and evaluate education and training programs designed to create a diverse and culturally competent cancer care workforce; and Improve medical records maintenance and retrieval systems through the use of rapidly evolving information technology.

Implementation Strategy

Healthcare providers should receive current, accurate information on cervical cancer on a

regular basis and have access to resources and technical assistance if needed. Some of the training topics to be addressed include but are not limited to: 1) Evaluating clinical practice guidelines and providing guidance on how to effectively talk to patients and their families about cervical cancer, HPV, and the HPV vaccine; 2) How to address the issue of obtaining consent for women under the age of 18 to receive a Pap test and/or the HPV vaccine; 3) Ensuring the HPV vaccine is available and administering the vaccine without concerns related to liability and difficulty, ensuring that women routinely receive all three vaccinations; 4) Continued review and updates to providers of recommendations for screening for cervical cancer and management of abnormal Pap tests; 5) Minimizing the paperwork associated with screening and vaccine administration; and 6) Facilitating culturally sensitive care.

Many opportunities for technical assistance exist through organizations such as the Pennsylvania Chapter of the American Academy of Pediatrics, the Pennsylvania Academy of Family Physicians, and the Pennsylvania Medical Society.

Limitations

There should be adequate reimbursement of the HPV vaccine and administration of the vaccine.

Tactics (including but not limited to):

1) Partner with the organizations listed above to develop, implement, and evaluate CME for healthcare professionals, nurses, and nurse practitioners
   Audience: Healthcare professionals
   Responsible party: Pennsylvania Department of Health
2) Partner with the organizations listed above to develop and evaluate a tool kit for use by medical and nursing schools
   Audience: Medical and nursing students
   Responsible party: Pennsylvania Department of Health; Pennsylvania medical and nursing schools
3) Develop a Speaker's Bureau of healthcare providers, nurses, and nurse practitioners to address professional associations and/or community groups
   Audience: Healthcare providers; nurses; nurse practitioners
   Responsible party: Professional organizations listed above

Recommendation 3: Legislation

Create legislation that facilitates the administration of the HPV vaccine to females age 9-26 through reimbursement by insurers.

State and National Recommendations

PA CCCP: Information Goal E: Enhance collaboration among diverse cancer control organizations and engage other public- and private-sector organizations in the coordinated dissemination and utilization of cancer information for the public, patients, providers, researchers, program planners, and policymakers.

NCI: Improve coverage and reimbursement for cancer-related services and optimize HPV testing and HPV vaccine development to eliminate the primary biologic cause of cervical cancer.

Implementation Strategy

All insurers should cover the costs of tests that healthcare providers deem to be necessary, including the HPV vaccine. This would enable more women to be able to receive the vaccine. It is important that all costs associated with administration of the vaccine be covered at an adequate level. It must be ensured that there is adequate coverage for appropriate screening, vaccine administration, and follow-up. In addition to creating legislation to remove barriers to services, other legislative issues to consider include mandated Pap tests and reimbursement for HPV sub-typing on Pap tests. HPV testing should be covered for payment.

Limitations

The HPV vaccine is covered by Medical Assistance but not covered by CHIP. Unless coverage of the vaccine is mandated, it will be optional for private insurers to cover as well. The Pennsylvania Department of Health has a prescribed list of immunizations that should be covered and the HPV vaccination should be included. Pennsylvania's Cancer Control, Prevention, and Research Advisory Board supports the availability of the HPV vaccine to all eligible females who meet vaccine guidelines.

Coverage for HPV testing depends on the HPV testing procedure code, and many codes exist. Currently, Medical Assistance only covers one code (infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified). However, if the Federal Government recognizes another code, a provider may request an exception in order for it to be covered. Nothing prohibits coverage of a HPV test if it is considered medically necessary. HPV testing is covered, however, if done in conjunction with a liquid-based Pap test, as the HPV test is readily available to a woman if she receives a this type of Pap test. It is recommended that this type of Pap test become the standard so that HPV testing can be easily conducted if necessary.

Tactics (including but not limited to):

1) Obtain clarification on the rights of mature minors to consent to public health services.
   Audience: All eligible females; healthcare providers
   Responsible party: Department of Health Legal Office
2) Set the standard of insurance coverage through Medicaid and encourage that other insurance providers will follow.
   Audience: All eligible women
   Responsible party: Health insurers
3) Pass legislation that establishes liquid-based cytology as standard cervical cancer screening for all women.
   Audience: Pennsylvania General Assembly
   Responsible party: Women's health advocates; healthcare provider community

Recommendation 4: Funding

Secure funding for cervical cancer outreach efforts, maintain and expand existing screening programs, and provide coverage of the HPV vaccine.

State and National Recommendations

PA CCCP: Information Goal D: Influence policy-makers, government, and private industry to increase funding opportunities that focus on cancer information development, management, and dissemination and Information Objective D1: Develop a method for tracking funding opportunities for cancer information development, management, and dissemination activities through governmental and private sources.

NCI: Develop and implement an agenda to provide and sustain funding for coalitions, partnerships, and community-based quality health services, education, and prevention programs; Improve coverage and reimbursement for cancer-related services; Ensure that populations at highest risk have access to age- and gender-appropriate screening and follow-up services; and Collaborate with the private and voluntary health sectors to ensure that all Americans receive the full range of lifesaving information, services, and quality care.

Implementation Strategy

Since there are different types of funding available through a variety of organizations, a thorough assessment of potential funding should be completed. Funding can be obtained from organizations including, but not limited to, public/private partnerships, federal grants, and pharmaceutical corporations.

Current federal funding received by the Pennsylvania Department of Health to provide breast and cervical cancer screening services through the HealthyWoman Program only serves 8 percent of the eligible population. Additional funding must be secured to maintain screenings for women age 40-49 and expand screenings for women age 50-64. There are only enough funds for a finite number of women at this time, and since they must be seen on an annual basis, the ability to accept new patients is limited. Cervical cancer screenings for women under age 40 must be funded. Such funding can be obtained through legislation that is linked to an existing screening program, such as the HealthyWoman Program. This relates to public education, since there must be adequate services and an adequate means to pay for these services if outreach is conducted.

In order to obtain funding to cover the costs of the HPV vaccine, a cost analysis should be conducted to identify the impact of the vaccine as well as cost of the vaccine as it relates to cervical cancer morality. It will be important to identify a reasonable charge for the administration of the vaccine in order to determine the financial impact of the recommendation. Also, although younger women will get the vaccine, they still need to be screened. Since cervical cancer affects women much younger than 40, it must be ensured that all women are covered for screening and follow-up care.

Finally, insurance companies should be educated about the HPV vaccine and encouraged to offer the vaccine to all eligible women and mandate coverage. Pharmaceutical corporations

should be engaged in the discussion of the cost of the vaccine and be encouraged to consider reimbursement rates that will eliminate any barriers to administration of the vaccine. All insurers should cover all recommended screening tests and make the tests part of their available services.

Limitations

Given the inadequate amount of funding available to screen and treat uninsured women of all ages, we must be mindful about recruiting women to nonexistent or overburdened services for which they cannot pay.

Tactics (including but not limited to):

1) Assess costs of vaccine and HPV testing on the impact on insurers (ERISA)
   Audience: Insurers; General Assembly
   Responsible party: Healthcare Cost Containment Council; Legislative Budget and Finance Committee
2) Document the Return on Investment of early detection and prevention to determine the economic burden of cervical cancer; evaluate state expenditures for cervical cancer and conduct an analysis of the current cost for the state
   Audience: Insurers, General Assembly
   Responsible party: Insurers; Legislative Budget and Finance Committee; Healthcare Costs Containment Council
3) Assess the cost of state and federal funds for detection, screening and treatment; request state funding for the vaccine that will complement current federal funds
   Audience: General Assembly
   Responsible party: Pennsylvania Department of Public Welfare; Pennsylvania Insurance Department

Cervical Cancer Task Force Members

Required Representative	Member(s)	Organization
Chairperson	Joanne Corte Grossi Deputy Secretary for Health Promotion and Disease Prevention	Department of Health, Commonwealth of Pennsylvania
A representative of the HealthyWoman Program in the Department	Susan George, Director, Division of Cancer Prevention and Control	Bureau of Health Promotion and Risk Reduction, Department of Health, Commonwealth of Pennsylvania
A representative of the Breast and Cervical Cancer Treatment Program in the Department of Public Welfare	Donald Yearsley, Director	Bureau of Policy Budget and Planning, Office of Medical Assistance Programs, Department of Public Welfare; Commonwealth of Pennsylvania
A Gynecology Oncologist	Joel Noumoff, M.D. Chief, Division of Gynecologic Oncology; Chair, Pennsylvania Cancer Advisory Board	Crozer-Chester Medical Center, Wynnewood, PA
An Epidemiologist	Zeenat Rahman, MBBS, MPH Epidemiologist	Division of Community Epidemiology, Bureau of Epidemiology, Department of Health, Commonwealth of Pennsylvania
A Public Health Professional	Evelyn Talbot, DrPH, MPH, Professor	Graduate School of Public Health, University of Pittsburgh
Two representatives of Women's Community Health Services	Bette Cox Saxton, Executive Director/CEO	Maternal and Family Health Services, Inc.
	Sheila Dow-Ford, Senior Vice President and Chief Counsel; President of the Board at the YWCA of Greater Harrisburg	Pennsylvania Higher Education Assistance Agency (PHEAA)
Two representatives of Women's Outreach and Social Services	Leslie Stiles, Executive Director	Pennsylvania Commission for Women
	Lisa Davis, MHA, Director	Pennsylvania Office of Rural Health
Two representatives of Health Concerns of Minority Women	Rosa Myers, ARNP, MSN, Regional Women's Health Coordinator	Office on Women's Health, Health Resources and Services Administration
A Pediatrician	Jonathan Pletcher, M.D.	The Pediatric Specialty Care Center at Lehigh Valley Hospital

Authorizing Legislation

PRINTER'S NO. 963

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 801 Session of 2005

INTRODUCED BY HARHART, BALDWIN, BEBKO-JONES, BELARDI, BISHOP, CALTAGIRONE, CAPPELLI, CAWLEY, CRAHALLA, CREIGHTON, CURRY, DeWEESE, FRANKEL, GOOD, GOODMAN, GRUCELA, HARPER, HENNESSEY, HERMAN, JOSEPHS, KIRKLAND, LEDERER, MANN, McILHATTAN, McILHINNEY, MELIO, MYERS, O'NEILL, PHILLIPS, READSHAW, REICHLEY, SAINATO, SAYLOR, SCHRODER, STERN, E. Z. TAYLOR, TIGUE, WATSON, WHEATLEY, YOUNGBLOOD, GEIST, R. STEVENSON, PICKETT, S. MILLER, STABACK, FREEMAN, DENLINGER, LEACH, B. SMITH AND DeLUCA, MARCH 14, 2005

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, MARCH 14, 2005

AN ACT

1 Authorizing and directing the Department of Health to establish
2 a Cervical Cancer Task Force to evaluate and make
3 recommendations for education, prevention and detection of
4 cervical cancer.

5 The General Assembly finds and declares as follows:
6 (1) According to Federal statistics, cervical cancer is
7 the third most commonly diagnosed gynecological cancer among
8 American women.
9 (2) In 2003, the Centers for Disease Control reported
10 that an estimated 12,200 new cases of cervical cancer were
11 diagnosed and an estimated 4,100 women would die of this
12 disease.
13 (3) In Pennsylvania, the rate of cervical cancer is
14 slightly lower than the national average.
15 (4) Cervical cancer disproportionately affects minority

1 women and women with lower incomes because they are less
2 likely to have access to routine screening.
3 (5) Human papillomavirus (HPV) is a primary cause of
4 cervical cancer.
5 (6) Each year more than 5 million people acquire human
6 papillomavirus, which is linked to cervical cancer in high-

7 risk cases.
8 (7) With regular and accurate screening, cervical cancer
9 is highly preventable.
10 (8) When found early, cervical cancer is highly curable,
11 but testing is required for early detection.
12 (9) Approximately half of all cervical cancer cases are
13 in women who have never been screened and 10% of cases are in
14 women who have not been screened within five years.
15 (10) Cervical cancer cases in the United States are
16 generally attributed to a lack of education, a reduction of
17 access available to regular cervical cancer screening and a
18 lack of screening accuracy.
19 (11) The public's widespread recognition of breast
20 cancer can overshadow the significance of cervical cancer.
21 The General Assembly of the Commonwealth of Pennsylvania
22 hereby enacts as follows:
23 Section 1. Short title.
24 This act shall be known and may be cited as the Cervical
25 Cancer Education, Prevention and Detection Act.
26 Section 2. Legislative intent.
27 The purpose of this act is to provide for education,
28 detection and treatment of cervical cancer separate from breast
29 cancer.
30 Section 3. Definitions.
20050H0801B0963

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1 The following words and phrases when used in this act shall
2 have the meanings given to them in this section unless the
3 context clearly indicates otherwise:
4 "Department." The Department of Health of the Commonwealth.
5 "Plan." The Cervical Cancer Education, Prevention and
6 Detection Plan.
7 "Task force." The Cervical Cancer Task Force established
8 under section 4 (relating to Cervical Cancer Task Force.
9 Section 4. Cervical Cancer Task Force.
10 (a) Establishment.--The Cervical Cancer Task Force is
11 established in the department.
12 (b) Composition.--The task force shall be determined by the
13 department and shall include individuals with expertise in
14 women's health, including, but not limited to, gynecological
15 oncology, epidemiology, social services and outreach to women
16 and minorities, and shall also include a representative of the
17 department's Healthy Women Project and a representative of the
18 Department of Public Welfare's Breast and Cervical Cancer
19 Treatment Project. The task force shall reflect the composition
20 of the State population with regard to ethnicity, race and age.
21 Section 5. Meetings.
22 The task force shall convene within 90 days after the
23 appointments are made and published and meet at least quarterly.
24 Section 6. Compensation and expenses.
25 The members of the task force shall receive no compensation
26 for their services but shall be allowed their actual and
27 necessary expenses incurred in performance of their duties. Such
28 reimbursement shall be provided for through the department.
29 Section 7. Duties.

30 The task force shall have the following duties:
20050H0801B0963

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1 (1) To obtain from the department statistical and
2 qualitative data on the prevalence and incidence of cervical
3 cancer.
4 (2) In collaboration with the department, to raise
5 public awareness on the causes and nature of cervical cancer,
6 personal risk factors, value of prevention, early detection,
7 options for testing, treatment costs, new technology, medical
8 care reimbursement and health provider.
9 (3) To identify priority strategies and new
10 technologies, including newly introduced diagnostics and
11 preventive therapies that are effective in preventing and
12 controlling the risk of cervical cancer.
13 (4) To identify and examine the limitations of existing
14 laws, regulations, programs and services with regard to
15 coverage and awareness issues for cervical cancer.
16 (5) In consultation with the department and the
17 Pennsylvania Cancer Control Consortium, to develop a
18 Statewide comprehensive Cervical Cancer Education, Prevention
19 and Detection Plan and develop strategies for implementing
20 and promoting the plan to the general public, State and local
21 elected officials and various public and private
22 organizations, associations, businesses, industries and
23 agencies.
24 (6) To identify strategies to facilitate specific
25 commitments to help implement the plan from the entities
26 listed in paragraph (8).
27 (7) To facilitate coordination of and communication
28 among State and local agencies and organizations regarding
29 current or future involvement in achieving the aims of the
30 plan.
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1 (8) To receive and consider reports and testimony from
2 individuals, local health departments, community-based
3 organizations, voluntary health organizations and other
4 public and private organizations Statewide to learn more
5 about their contributions to cervical cancer diagnosis,
6 prevention and treatment and their ideas for improving
7 cervical cancer prevention, diagnosis and treatment in this
8 Commonwealth.
9 Section 8. Report.
10 Beginning November 30, 2005, and on November 30 each year
11 thereafter, the task force shall present a report to the
12 chairman of the Public Health and Welfare Committee of the
13 Senate and the chairman of the Health and Human Services
14 Committee of the House of Representatives. The annual report
15 shall present its findings and recommendations including:
16 (1) The anticipated time frame for completion of the
17 plan.
18 (2) Recommendations on human and financial resources
19 required to implement the plan.
20 (3) Recommended strategies or actions to reduce the
21 occurrence of cervical cancer in women in this Commonwealth.

22 (4) Recommended strategies or actions to reduce the
23 costs of cervical cancer.
24 (5) Progress being made in fulfilling the duties of the
25 task force and in developing and implementing the plan.
26 Section 9. Expiration.
27 The task force shall expire November 30, 2009, or upon
28 submission of the task force's final report to the General
29 Assembly.
30 Section 10. Effective date.
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1 This act shall take effect in 30 days.

Definitions

Breast and Cervical Cancer Prevention and Treatment (BCCPT) Program
On January 1, 2002, the Pennsylvania Department of Public Welfare implemented the Breast and Cervical Cancer Prevention and Treatment (BCCPT) Program. The BCCPT Program provides full healthcare benefits to women needing treatment for breast or cervical cancer, or a pre-cancerous condition of the breast or cervix, who are:

- Screened and diagnosed under the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection Program
- Uninsured or having no creditable insurance
- Under age 65
- U.S. citizen or eligible alien resident of Pennsylvania

HealthyWoman Program (HWP)
Women who qualify for this coverage can receive free healthcare (except for nominal co-payments), including healthcare for medical needs unrelated to a breast or cervical cancer diagnosis, throughout their course of treatment for cancer or a pre-cancerous condition of the breast or cervix.

To qualify for this comprehensive healthcare coverage, a woman must be screened and diagnosed with breast or cervical cancer, or a pre-cancerous condition of the breast or cervix, through the Department of Health's HealthyWoman Program. The Department of Health imposes a 250 percent income limit based upon the Federal Poverty Income Guidelines, which are updated annually.

The HealthyWoman Program provides free:

- mammograms
- clinical breast and pelvic exams
- Pap tests

HealthyWoman has a simple application for women to apply for free services through the HealthyWoman Program and healthcare coverage under the BCCPT Program. HealthyWoman will provide each woman with a brochure describing the BCCPT Program, forward the woman's application for the BCCPT Program to the local County Assistance Office for determination of eligibility, and if diagnosed with breast or cervical cancer or a pre-cancerous condition of the breast or cervix, provide the woman with a folder of information about the BCCPT Program, including how to access healthcare.

To learn more about the HealthyWoman Program, access the web at http://www.PAHealthyWoman.com. Or call 1-800-215-7494 to find the closest HealthyWoman Program provider.

Human Papillomavirus (HPV)
HPVs are members of the family of viruses, Papillomaviridae. More than 100 HPV types are recognized, and more than 30 of these viruses are transmitted sexually and can subsequently affect the genital tract. Most people who become infected with HPV will not have any symptoms and will clear the infection on their own. HPV Infection is discovered by an abnormality on a screening Pap test.

Although only a small proportion of women have persistent infection, persistent infection with high-risk types of HPV is the main risk factor for cervical cancer. Recent studies have shown that high-risk HPV is present in at least 99.7 percent of cervical cancer cases globally. (#8 Illinois Report) Of the approximately one dozen high-risk HPV types, type 16 accounts for about half of all cervical cancer cases. Types 18, 31, 33 and 44 combined account for another estimated 20 percent.

Genital HPV infections are thought to be the most prevalent sexually transmitted infections in the U.S., with approximately 20 million people currently infected. Of those, between 50-75 percent are infected with high-risk types of HPV.

Request for Application (RFA)
Request for Application (also called Request for Proposals or Request for Assistance) is a document released by a funder or vendor to parties who might have an interest in applying for the described funds. The RFA delineates the requirements of the funder, which can vary from rather simple (usually local or private funders), to highly complex (state and especially federal funders).

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References

[1] Pennsylvania Department of Health, Bureau of Health Statistics and Research. *Pennsylvania Cancer Incidence and Mortality 2003.*
[2] Pennsylvania Department of Health, Pennsylvania Cancer Incidence and Mortality 2003
[3] Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR), Vol. 56, RR-2, March 23, 2007.
[4] American Cancer Society, Cancer Facts and Figures 2005.
[5] Ho GY, Bierman R, Beardsley L, et al. Natural history of cervicovaginal papillomavirus infection as measured by repeated DNA testing in adolescent and young women. N Engl J Med. 1998;338(7):423- 428.
[6] Bosch FX, de Sanjose S. Chapter 1: Human papillomavirus and cervical cancer—burden and assessment of causality. *J Natl Cancer Inst Monogr.* 2003;3:3-13.
[7] Centers for Disease Control and Prevention (CDC), *Cancer Prevention and Control: Cervical Cancer HealthAwareness,* May 10, 2005
[8] Waxman A. Human papillomavirus DNA testing in office practice. The Female Patient 2005; 30:28)
[9] CDC. Results from the National Breast and Cervical Cancer Early Detection Program, October31, 1991-September 30, 1993. MMWR Morb Mortal Wkly Rep 1994;43:530-4.
[10] Centers for Disease Control and Prevention. Implementing Recommendations for the Early Detection of Breast and Cervical Cancer Among Low-Income Women. Morbidity and Mortality Weekly Report (MMWR), Vol. 49, RR02, March 31, 2000.
[11] Association of Reproductive Health Professionals. Cervical Cancer Prevention and HPV DNA Testing. *Health & Sexuality.* Volume 10(1). January 2005.
[12] Castellsagué X et al. Male Circumcision, Penile Human Papillomavirus Infection, and Cervical Cancer in Female Partners. *N Engl J Med*, 2002, 346(15):1105-1112.
[13] NCI, Cancer Topics: Cervical Cancer Prevention, April 2004, http://www.cancer.gov/cancer topics/pdq/prevention/cervical/Patient/page2 (July13, 2005).
[14] Smith JS et al. Herpes Simplex Virus-2 as a Human Papillomavirus Cofactor in the Etiology of Invasive Cervical Cancer. *Journal of the National Cancer Institute* 2002 94(21):1604-1613.
[15] Madeleine MM et al. Risk of cervical cancer associated with Chlamydia trachomatis antibodies by histology, HPV type and HPV cofactors. *International Journal of Cancer*, 2007, 120(3):650-655.
[16] Lambert EC. College student's knowledge of human papillomavirus and effectiveness of a brief educational intervention. *The Journal of the Board of Family Practice* 2001; 14(3):178-183.
[17] ACS, Cancer Reference Information: Detailed Guide Cervical Cancer, August 2004, http://www.cancer.org/docroot/CRI/content/CRI_2_4_2X_What are_the_risk_factors_for cervical_cancer_8.asp?sitearea= (July 13, 2005).
[18] Green J, Berrington de Gonzalez A, Sweetland S, Beral et al. Risk factors for adenocarcinoma and squamous cell carcinoma of the cervix in women aged 20-44 years: the UK National Case-Control Study of Cervical Cancer. *British Journal of Cancer*, 2003, Dec 1; 89(11):2078-86.
[19] Sun XW, Kuhn L, Ellerbrock TV, Chiasson MA, Bush TJ, Wright TC Jr. Human papillomavirus infection in women infected with the human immunodeficiency virus. *N Engl J Med* 1997; 337:1343-9.

[20] Wright TC Jr, Ellerbrock TV, Chiasson MA, Van Devanter N, Sun XW. Cervical intraepithelial neoplasia in women infected with human immunodeficiency virus: prevalence, risk factors, and validity of Papanicolaou smears. New York Cervical Disease Study. *Obstet Gynecol* 1994; 84:591-7.
[21] Conley LJ, Ellerbrock TV, Bush TJ, Chiasson MA, Sawo D, Wright TC. HIV-1 infection and risk of vulvovaginal and perianal condylomata acuminata and intraepithelial neoplasia: a prospective cohort study. *Lancet* 2002; 359:108-13.
[22] Pennsylvania Department of Health HealthyWoman Program Web-based Data System.
[23] Stenkvist B, Bergstrom R, Eklund G, Fox CH. Papanicolaou smear screening and cervical cancer. What can you expect? J Am Med Assoc 1984;252:1423-6.
[24] Dr. Debbie Saslow, American Cancer Society
[25] Pennsylvania's Health Insurance Status Survey, Pennsylvania Insurance Department, May 2005
[26] American Cancer Society. Uninsured Diagnosed More Often with Advanced Cancer: ACS Calls for Adequate, Affordable Insurance Coverage, June 11, 2007
[27] www.health.state.pa.us/stats/
[28] SEER
[29] http://app2.health.state.pa.us/epiqms
[30] PCR 2005; Rates per 100,000 and age-adjusted to 2000 US standard
[31] Edwards JM, Buescher PA. Cervical Cancer disparities between African-American women and white women in North Carolina 1995-1998. *North Carolina Department of Health and Human Services, State Center for HealthStatistics.* 2002;134: 1-6.
[32] http://app2.health.state.pa.us/epiqms/Asp/Showmap_Cancer.asp
[33] American Cancer Society, *supra* note 1, page 21.
[34] Franco EL, Duarte-Franco E, Ferenczy A. Cervical cancer: epidemiology, prevention and the role of human papillomavirus infection. *Canadian Medical Association Journal* 2001;164(7): 1017-1025.
[35] CDC. Quadrivalent Human Papillomavirus Vaccine, MMWR, March 23, 2007;Vol 56/RR-2.
[36] Belinson J, Qiao YL, Pretorius Rea. Shanxi province cervical cancer screening study: a cross-sectional comparative trial of multiple techniques to detect cervical neoplasia. Gynecol Oncol.2001;83:439-444. AND Kulasingam SL, Hughes JP, Kiviat NB, et al. Evaluation of human papillomavirus testing in primary screening for cervical abnormalities: comparison of sensitivity, specificity, and frequency of referral. JAMA. 2002;288(14):1749-1757.
[37] Human Papilloma Virus: HPV Information for Clinicians. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. http://www.cdc.gov/std/HPV/common-infection/CDC_HPV_ClinicianBro_LR.pdf
[38] Human Papilloma Virus: HPV Information for Clinicians. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. http://www.cdc.gov/std/HPV/common-infection/CDC_HPV_ClinicianBro_LR.pdf
[39] Gerberding, JL. Report to Congress: Human Papillomavirus: Surveillance and Prevention Research. Aug 2003. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. http://www.cdc.gov/std/HPV/2004HPVpercent20Report.pdf.