

**Cervical Cancer Prevention
and Early Detection:
Report and Recommendations**

New York State Breast and Cervical Cancer Detection and Education
Program Advisory Council

2010

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I. Executive Summary

In 2005, the New York State (NYS) Breast and Cervical Cancer Detection and Education Program Advisory Council (Council) was charged with the development of a statewide cervical cancer prevention plan to include recommendations aimed at preventing and controlling the risk of cervical cancer (Public Health Law § 2407 (3-d)) among NYS residents. Cervical cancer is one of the most preventable forms of cancer. This is due to the widespread use and adoption of the Papanicolaou (Pap) test, the growing knowledge of the link between cervical cancer and the Human Papillomavirus (HPV), as well as the development of successful treatments. Despite this progress, every year in NYS cervical cancer is diagnosed among more than 900 women and causes 280 deaths.

Risk factors for cervical cancer and its precancerous lesions include persistent high-risk HPV infection, tobacco use, immunosuppression, long-term use of oral contraceptives and high parity. Additionally, women who are rarely or never screened, defined as women who have not been screened for cervical cancer in the past or women who have not been screened in the last five years, are at high risk of developing invasive cervical cancer.

It has been established that persistent infection with high-risk, or oncogenic, types of HPV causes over 99 percent of cervical cancers. This knowledge has led to the development of two HPV vaccines recommended for females aged 9-26 as well as the development of several HPV deoxyribonucleic acid (DNA) tests which aid in the detection of high risk strains of the virus. The Advisory Committee on Immunization Practices recommends routine vaccination of females aged 11 or 12 years against HPV; vaccination is recommended for females aged 13 through 26 years who have not been vaccinated previously or who have not completed the 3-dose series.

The Pap test remains the cornerstone of cervical cancer screening; however cervical cancer screening guidelines continue to be revised. Studies have demonstrated the efficacy and safety of prolonging the interval between screenings for most women 30 years of age and older, and recently the American College of Obstetricians and Gynecologists (ACOG) changed its recommendation for women aged 21 to 29 years from annual Pap testing to every 2 years. In addition, ACOG now recommends women begin cervical cancer screening at age 21 years.

NYS receives funding from the Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and uses this funding, as well as State funding, to administer the NYS Department of Health (NYSDOH) Cancer Services Program (CSP). The CSP funds community-based contractors to coordinate screening services and access to treatment if necessary, in every county and borough in NYS. The eligible population for CSP services includes women ages 40 and older, focusing on those women 50-64 years of age who lack adequate financial resources to obtain cancer screening services, with a particular outreach focus on the rarely or never-screened population.

The Council provides the following recommendations for consideration by the NYSDOH. These recommendations stem from those identified from the National Cancer Institute's (NCI) Center to Reduce Cancer Health Disparities, the United States (US) Preventive Services Task Force's Guide to Community Preventive Services and policy initiatives identified by the Council. The Council envisions these recommendations being the shared responsibility of council members; NYSDOH cancer, immunization and women's health-related programs; the NYS Cancer Consortium; professional organizations in NYS including the American College of Obstetricians and Gynecologists (ACOG), the American Cancer Society (ACS); and community partners and stakeholders who share a vested interest in improving the health of the women of NYS.

Surveillance

- Develop a cervical cancer burden fact sheet in order to better understand disparities in cervical cancer screening, incidence, mortality and HPV vaccine use.
- Leverage existing surveillance systems to include data collection related to barriers to cervical cancer screening, follow-up, treatment and HPV vaccination.

Public Awareness

- Increase community demand for cervical cancer screening by using such resources as the NCI's 'Pink Book - Making Health Communication Programs Work' (www.cancer.gov/pinkbook), or the CDC's Guide to Community Preventive Services (www.thecommunityguide.org/index.html), to develop efforts that target areas of NYS with low rates of cervical cancer screening.
- Increase awareness of the harms of tobacco use and secondhand smoke exposure as a means of preventing cervical cancer.
- Ensure school-based and community education efforts include information about HPV vaccination, cervical cancer screening, tobacco cessation and safe sex, and ensure information is available in multiple languages.
- Develop and promote a web-based campaign promoting HPV vaccine among the target age group, using existing campaigns such as the CDC's Pre-Teen Vaccine Campaign.
- Update the NYSDOH web pages related to cervical cancer prevention and control.

Access to Care

- Identify new, and enhance existing, systems that enable women who rely on publicly funded health services to have a usual source of health care.
- Support, develop and advocate for policies that eliminate financial barriers to cervical cancer screening and HPV vaccine provision.
- Increase promotion and awareness of the NYSDOH CSP Partnerships among local stakeholders, worksites and other partners.

- Maximize the use of the federal Vaccines for Children Program to vaccinate eligible young women 9 through 18 years of age against HPV.
- Maximize the uptake of available and affordable HPV vaccine to uninsured and underinsured women aged 19-26.

Clinical Practice

- Identify, develop and support policies that decrease barriers to cervical cancer screening and promote use of guideline concordant care.
- Promote the use of quality improvement resources such as the Health Resources and Services Administration's Cancer Collaborative Toolkit in health care settings. The toolkit is an evidence-based initiative developed in 2008 by the Health Resources and Services Administration to help Federally Qualified Health Centers improve the quality of cancer screening and follow-up care through a systematic process of organizational change.
- Assess compliance with, and increase awareness of, hospital regulation 10 NYCRR 405.9(b)(12)(i), which requires complete history and physical examinations be performed and documented on all patients admitted to the hospital, including a 'screening uterine cytology smear on women 21 years of age and over, unless such test is medically contraindicated or has been performed within the previous three years.'
- Support and leverage NYS health information technology efforts related to the meaningful use of electronic health records in improving cervical cancer screening rates.
- Work with key partners to develop and promote online and in-person continuing education opportunities for health practitioners related to cervical cancer screening guidelines, current standards of care for women with abnormal Pap tests and current information about the available HPV vaccines.

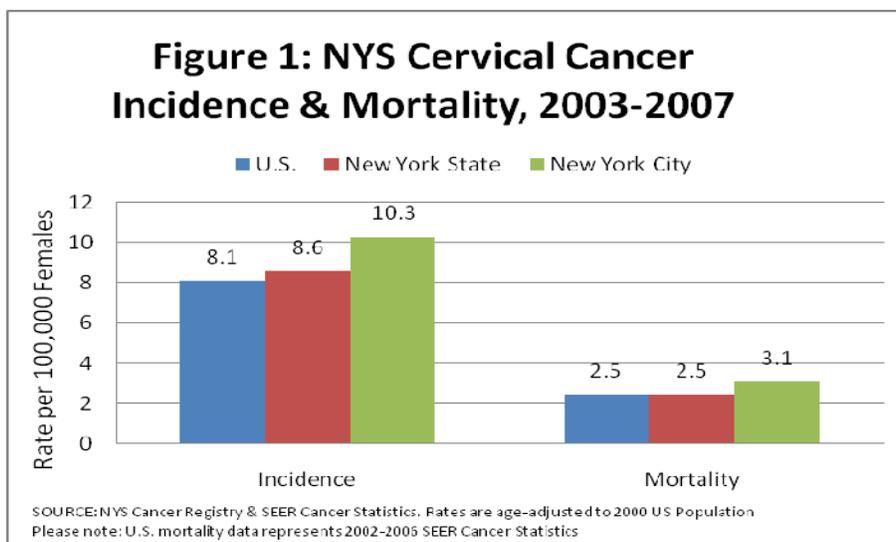
II. Authorization and Charge

Section 2407 of the Public Health Law authorized the creation of the Council. Originally, the Council was created to address breast cancer detection and education. In 2005, the law was revised to expand the Council's responsibility to include cervical cancer and charged the Council with the development of a statewide cervical cancer prevention plan. Specifically, "*The advisory council shall develop with the department a statewide comprehensive cervical cancer prevention plan and identify priority strategies and new technologies, which are effective in preventing and controlling the risk of cervical cancer.*"

III. Cervical Cancer

Burden

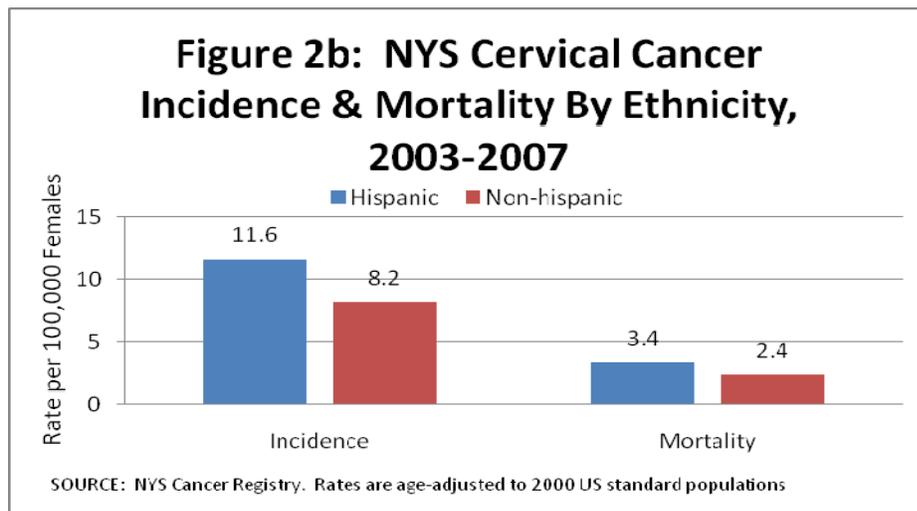
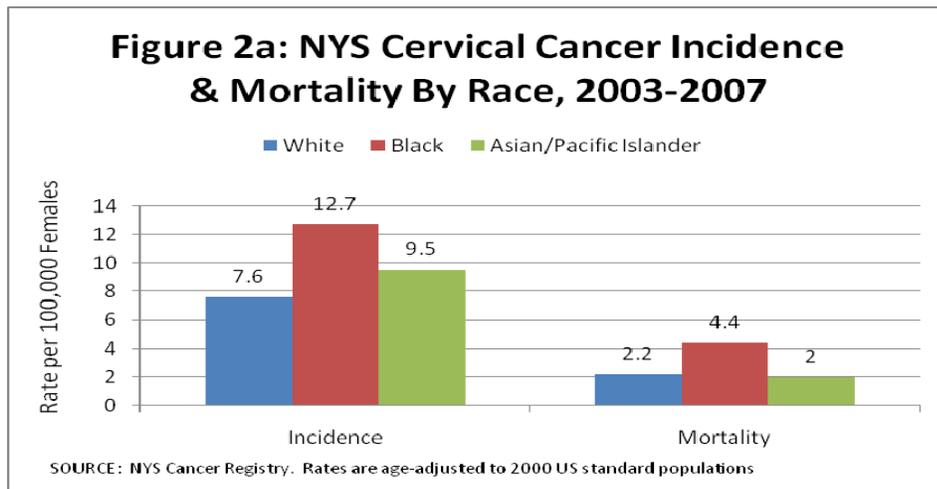
Cervical cancer is an uncontrolled growth of abnormal cells arising from the cervix, which is the opening of the uterus. According to the ACS, the number of cervical cancer deaths in the US dropped by 74 percent between 1955 and 1992. Despite this promising trend, an estimated 11,000 new cervical cancer cases were diagnosed and over 4,000 cervical cancer deaths occurred across the country in 2009 (NCI, 2009). In NYS, cervical cancer is diagnosed in more than 900 women, and over 280 women die of cervical cancer every year (NYS Cancer Registry, 2003-2007). The cervical cancer incidence and mortality rates for the US, NYS (including New York City [NYC]) and NYC alone are shown in Figure 1. This figure shows a higher incidence and mortality rate in the NYC region as compared to both the US and NYS.



Cervical cancer is one of the most preventable forms of cancer, due to the widespread use and adoption of the Papanicolaou (Pap) test, as well as the development of successful treatments for precancerous lesions. The growing knowledge of the link of cervical cancer and precancerous lesions to the HPV has led to the development of new technologies that test for the presence of high-risk HPV, which help guide screening and treatment decisions, and the development of HPV vaccines, which help prevent the main cause of cervical cancer. The combination of these advances has led to a dramatic decline in the burden of cervical cancer. Despite the potentially avoidable nature of this cancer type, however, cervical cancer incidence and mortality rates have persisted.

In 2005, the NCI reported continuing patterns of cervical cancer mortality in particular populations, geographic areas and socioeconomic groups in a report entitled, 'Excess Cervical Cancer Mortality: A Marker for Low Access to Health Care in Poor Communities.' The report concluded that cervical cancer in America is overwhelmingly a disease of poor women with low

educational attainment, and noted rural NYS as one area of the country with higher than average cervical cancer mortality rates. The report also points out that high rates of cervical cancer are an indicator of larger issues facing the health care system and need to be addressed by multiple partners working on cancer control initiatives. Specifically, the report highlights the following disparities: Hispanic/Latino women have the highest cervical cancer incidence rate; white women living in Northern Appalachia have higher incidence rates than white women living in other areas; compared to white women, African American women are more likely to be diagnosed with cervical cancer; and women living in rural and suburban areas have higher cervical cancer mortality rates than women living in urban locations. Incidence and mortality rates in NYS by race and ethnicity are shown in Figures 2a and 2b.



Risk Factors for Cervical Cancer

The following factors increase a woman's risk of developing cervical cancer:

- HPV infection: Persistent infection with high-risk HPV subtypes increases a woman's risk for cervical cancer. HPV infection is more common in women who initiate sexual intercourse at young ages and who have had multiple sexual partners. It should be noted, however, that not all women with HPV infection develop cervical cancer.
- Smoking: Both active smoking and second hand cigarette smoke increase the risk of cervical cancer. Among women with HPV, current and former smokers have a two- to three-fold increased risk of cervical cancer compared to women who have never smoked.
- High Parity: Women who have had multiple full-term pregnancies have been found to have a higher risk of cervical cancer compared to women who have had given birth less frequently. This association remains, even among women with HPV infection.
- Long-term use of oral contraceptives: Studies have found a three- to four-fold increased risk of cervical cancer in women who have been taking oral contraceptives for five to nine and more than ten years, respectively. As with high parity, this association remains even among women with HPV infection.
- Compromised immune systems: The overall strength of the immune system appears to play a role in a woman's susceptibility to cervical dysplasia, which is an abnormal development of cervical cells. Recent reports suggest that the prevalence of cervical dysplasia is higher among HIV-infected women. Cervical cancer is listed as an AIDS-defining condition by the CDC.

In addition to the above risk factors for cervical cancer, women who have not been screened for cervical cancer in the past and women with long intervals between screenings (not screened within the past five years) are at increased risk of developing invasive cervical cancer. Such populations of women are often referred to as rarely or never screened. These often include women who:

- Have Pap tests infrequently or do not have them at all.
- Do not receive adequate and appropriate follow-up to abnormal cervical cancer screening tests.
- Do not have a usual source of health care.
- Are past child-bearing age.
- Are 50 years of age and older.
- Are African American.

Human Papillomavirus (HPV)

HPV types 16 and 18 are the cause of about 70 percent of cervical cancers worldwide. More than 100 HPV types have been identified, approximately 30 percent of which are sexually transmitted. The CDC reports that there are an estimated 20 million Americans currently infected with HPV, with roughly six million people becoming infected annually. Most sexually active women have had or will have HPV infection at some point in their lives. It is estimated that 80 percent of women will have acquired HPV infection by age 50.

HPV is transmitted sexually through skin-to-skin contact, with mucosal skin being most receptive to infection. The majority of HPV infections is transient and cleared by the immune system; 70-90 percent of infections will clear within one to two years. When the immune system does not clear the infection, however, HPV becomes persistent and may cause changes that lead to the development of abnormal cervical cells (cervical dysplasia) or cervical cancer.

Methods for preventing HPV infection include abstinence from sexual activity, limiting the number of sexual partners, use of latex condoms and vaccination, as recommended by the Advisory Committee on Immunization Practices (ACIP).

HPV Vaccine: In June 2006, the US Food and Drug Administration (FDA) approved a quadrivalent HPV vaccine (provides immunity against HPV types 16, 18, 6, 11) for females aged 9–26 years (HPV4; Gardasil, Merck & Co, Inc.). A second bivalent vaccine (provides immunity against HPV types 16 and 18) was approved by the FDA in October 2009 for females aged 10-25 years (HPV2; Cervarix, GlaxoSmithKline). The ACIP recommends routine vaccination of females aged 11 or 12 years with three doses of either HPV2 or HPV4; vaccination is recommended for females aged 13 through 26 years who have not been vaccinated previously or who have not completed the 3-dose series. Both vaccines are most effective when given before any exposure to HPV infection, however sexually active adolescents and women may also benefit from the vaccine because vaccination can provide protection against infection with HPV vaccine types not already acquired. The HPV vaccine is not recommended for pregnant women, but can be given to women who are breastfeeding. While the exact duration of immunity from the vaccine has not been determined, studies to date indicate immunity for at least six years. The need for booster vaccination has not been established. Cervical cancer screening with appropriate interval Pap testing continues to be recommended for all women, regardless of their vaccination status.

In October 2009, the FDA licensed HPV4 for use in males aged 9 through 26 years for prevention of genital warts caused by HPV types 6 and 11; the ACIP provided guidance soon thereafter that HPV4 may be given to males in this age group to reduce their likelihood of acquiring genital warts, but does not recommend HPV4 for routine use in males.

HPV DNA Testing: The Hybrid Capture II® is an FDA-approved test for the detection of high-risk HPV DNA (a marker of HPV infection with high risk strains of the virus). The test has been approved by the FDA for two purposes:

- Primary screening for women aged 30 and older. Current recommendations are to perform both a Pap test and a high-risk HPV DNA test as a primary cancer screening for women aged 30 years and older. The use of primary HPV testing in addition to a Pap test in this population has been shown to increase the sensitivity of detecting cervical dysplasia from 60 to 95 percent. Due to the high prevalence of HPV infection in women younger than 30 years of age, co-testing using both Pap and HPV DNA testing is not recommended as a primary screening strategy in this younger population.
- Triage of Atypical Squamous Cells of Undetermined Significance (ASC-US). ASC-US is the most commonly diagnosed Pap test abnormality. In order to determine the need for additional testing (e.g., colposcopy), current recommendations are to perform a “reflex” HPV DNA test on Pap test results of ASC-US and, if positive, refer the patient for additional testing.

Screening and Early Detection

The Pap test remains the cornerstone of cervical cancer screening. The Pap test is a quick and effective method to detect cervical cell abnormalities. Until recently, health professionals generally agreed that Pap testing should commence within three years of women’s initial sexual activity, or when they reach age 21 (whichever comes first). Recent clinical management guidelines released by the ACOG in December 2009, however, recommend that Pap testing begin at age 21. This recommendation is based on the understanding that while HPV infection is common in sexually active young adults, these infections are most commonly cleared by the immune system within two years, without causing cancerous changes to the cervix. The recommendation for beginning Pap testing at age 21 is also supported by study findings that report the treatment for cervical dysplasia (e.g., excisional procedures) can increase a woman’s risk of premature births.

Until recently, it was recommended that women receive annual Pap tests. A better understanding of the natural history of precancerous cervical changes and cervical cancer, the acknowledgement of HPV as the major cause of cervical cancer, the introduction of high-risk HPV DNA testing and improved screening technologies, have led to revised screening guidelines by national organizations such as the ACS, ACOG and the US Preventive Services Task Force (USPSTF). Organizations now generally agree that women aged 30 years and older who have had three consecutive cervical cytology test results that are negative for dysplasia and cancer may be screened every three years. Additionally, women aged 30 years and older with both a normal Pap test and a negative high-risk HPV DNA test are at very low risk of developing abnormalities over the next 4-6 years, therefore such women should also be rescreened no sooner

than three years from that primary screening. For women aged 21-29 years, the ACOG’s December 2009 recommendations include every two year screening with either conventional or liquid-based Pap testing, rather than annual screening. The longer screening intervals reflect a movement towards a reduction in unnecessary Pap testing in order to reduce diagnostic follow-up for false positive findings that may result from more frequent screening. These longer screening intervals do not apply, however, to women who are immunocompromised, who are infected with HIV, who were exposed in utero to diethylstilbestrol (DES) or who have been treated for Cervical Intraepithelial Neoplasia 2 or 3 (CIN 2 or 3) or cervical cancer. Such women should continue to be screened annually.

New York State Cervical Cancer Screening Rates

According to the Behavioral Risk Factor Surveillance System (BRFSS), 83.3 percent of women living in NYS aged 18 and older reported having had a Pap test within the past three years in 2008. This is compared to a nationwide screening rate of 82.8 percent. Screening rates among particular populations of women reveal that 1) women between the ages of 25 and 54 are more likely to be screened for cervical cancer than older women (Figure 3); 2) women with lower educational attainment are less likely to be screened than women who have completed some post-high school education or college (Figure 4); and 3) women with lower incomes are less likely to be screened than women with higher incomes (Figure 5).

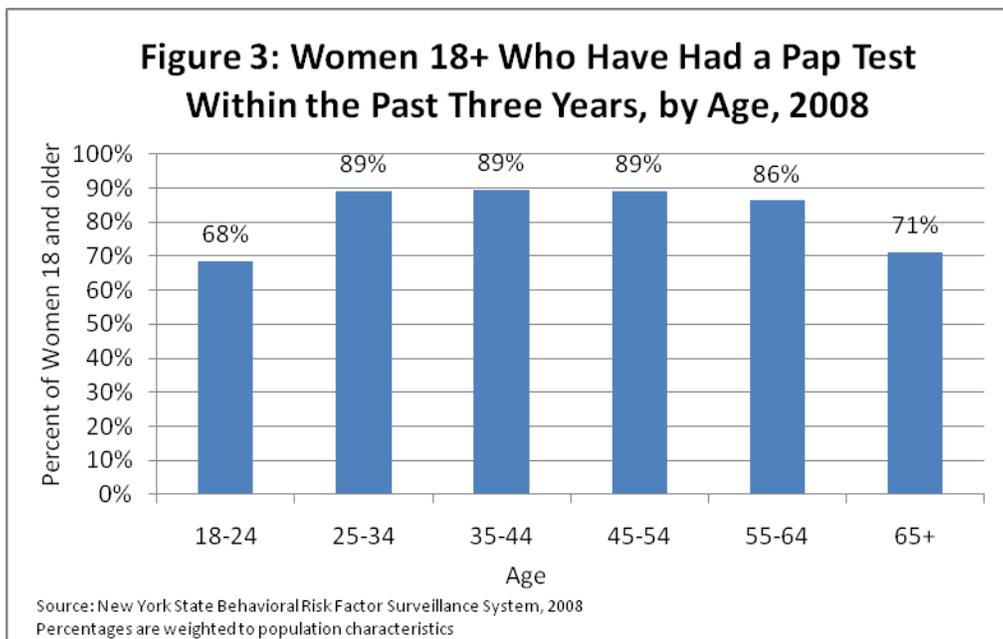
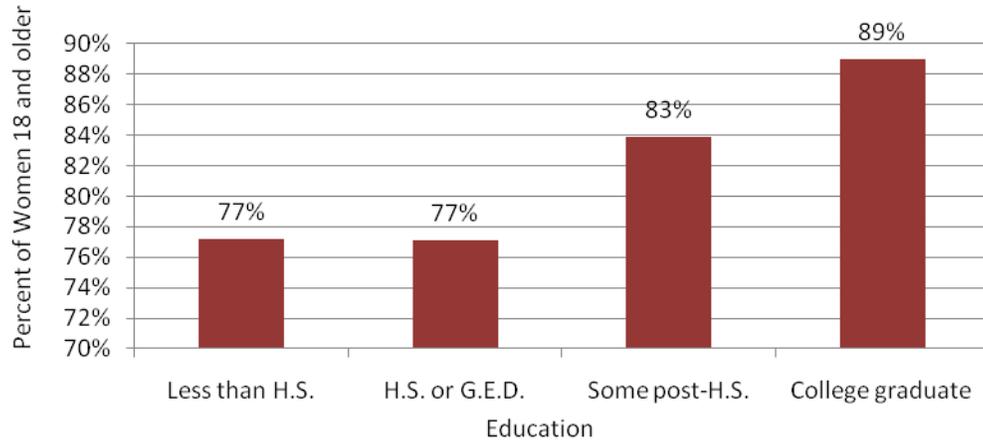
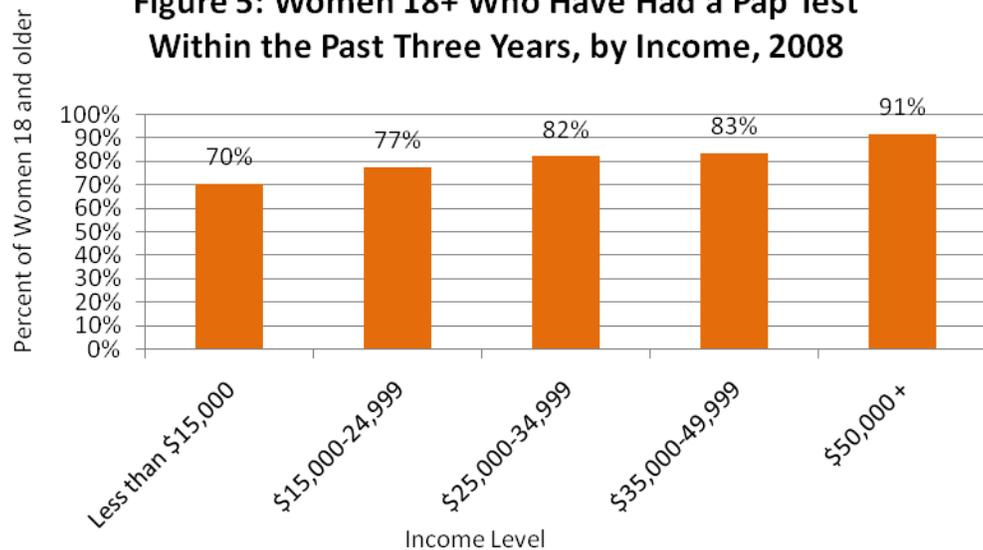


Figure 4: Women 18+ Who Have Had a Pap Test Within the Past Three Years, by Education, 2008



Source: New York State Behavioral Risk Factor Surveillance System, 2008
 Percentages are weighted to population characteristics

Figure 5: Women 18+ Who Have Had a Pap Test Within the Past Three Years, by Income, 2008



Source: New York State Behavioral Risk Factor Surveillance System, 2008
 Percentages are weighted to population characteristics

New York State Cancer Services Program

The CDC's NBCCEDP provides access to breast and cervical cancer screening services to underserved women in all 50 states, the District of Columbia, five U.S. territories, and 12 tribes. NYS uses funding from the NBCCEDP, as well as state funding, to administer the NYSDOH CSP. The CSP funds community-based contractors, referred to as CSP partnerships, to coordinate screening services in every county and borough in NYS. The CSP supports the provision of age-appropriate, comprehensive breast, cervical and colorectal cancer screening services for uninsured and underinsured eligible women and men using evidence-based, clinical guidelines from the USPSTF and other national organizations.

The eligible population that can receive cervical cancer screening and diagnostic services through the CSP includes those women aged 40 and older who lack adequate financial resources to obtain cancer screening and detection services. These persons may lack health insurance, have inadequate health insurance coverage, or be unable to meet their deductible obligations for purposes of accessing coverage under their health insurance. Eligible women are provided with bi-manual pelvic examinations and Pap tests (conventional or liquid based) and high-risk HPV DNA testing, as appropriate.

Certain sub-groups, or priority populations, of CSP clients who are disproportionately affected by cervical cancer are the focus of outreach, recruitment and screening efforts. CSP priority populations include:

- Uninsured or underinsured persons aged 50 – 64.
- Women who are never or rarely screened for cervical cancer.
- Persons who are geographically or culturally isolated.
- Persons who are medically unserved or underserved.
- Members of racial, ethnic and cultural minority populations.

Women diagnosed with precancerous cervical conditions or cervical cancer may be eligible to obtain treatment coverage through the NYS Medicaid Cancer Treatment Program (MCTP). Since the MCTP began in October 2002, over 2,150 eligible women diagnosed with precancerous cervical conditions and cervical cancers received full Medicaid coverage for their entire treatment periods.

IV. Recommendations

The Council acknowledges and supports the NYSDOH Prevention Agenda toward the Healthiest State and specifically the following goals related to cervical cancer:

- By 2013, reduce the age-adjusted cervical cancer mortality rate to no more than 2.0 per 100,000 females (Baseline 2.6/100,000, NYS Cancer Registry).

- By 2013, increase the percentage of cervical cancer cases diagnosed at an early stage of disease in New York residents to at least 65% (Baseline 52 percent, NYS Cancer Registry).

The Council provides the following recommendations for consideration by the NYSDOH. These recommendations stem from those identified from the NCI Center to Reduce Cancer Health Disparities, the USPSTF's Guide to Community Preventive Services and policy initiatives identified by the Council. The Council envisions these recommendations being the shared responsibility of council members; NYSDOH cancer, immunization and women's health-related programs; the NYS Cancer Consortium; professional organizations in NYS including the ACOG, the ACS; and community partners and stakeholders who share a vested interest in improving the health of the women of NYS.

Surveillance

- Develop a cervical cancer burden fact sheet in order to better understand disparities in cervical cancer screening, incidence, mortality and HPV vaccine use.
- Leverage existing surveillance systems to include data collection related to barriers to cervical cancer screening, follow-up, treatment and HPV vaccination.

Public Awareness

- Increase community demand for cervical cancer screening by using such resources as the NCI's 'Pink Book - Making Health Communication Programs Work' (www.cancer.gov/pinkbook), or the CDC's Guide to Community Preventive Services (www.thecommunityguide.org/index.html), to develop efforts that target areas of NYS with low rates of cervical cancer screening.
- Increase awareness of the harms of tobacco use and secondhand smoke exposure as a means of preventing cervical cancer.
- Ensure school-based and community education efforts include information about HPV vaccination, cervical cancer screening, tobacco cessation and safe sex, and ensure information is available in multiple languages.
- Develop and promote a web-based campaign promoting HPV vaccine among the target age group, using existing campaigns such as the CDC's Pre-Teen Vaccine Campaign.
- Update the NYSDOH web pages related to cervical cancer prevention and control.

Access to Care

- Identify new, and enhance existing, systems that enable women who rely on publicly funded health services to have a usual source of health care.
- Support, develop and advocate for policies that eliminate financial barriers to cervical cancer screening and HPV vaccine provision.

- Increase promotion and awareness of the NYSDOH CSP Partnerships among local stakeholders, worksites and other partners.
- Maximize the use of the federal Vaccines for Children Program to vaccinate eligible young women nine through 18 years of age against HPV.
- Maximize the uptake of available and affordable HPV vaccine to uninsured and underinsured women aged 19-26.

Clinical Practice

- Identify, develop and support policies that decrease barriers to cervical cancer screening and promote use of guideline concordant care.
- Promote the use of quality improvement resources such as the Health Resources and Services Administration's Cancer Collaborative Toolkit in health care settings. The toolkit is an evidence-based initiative developed in 2008 by the Health Resources and Services Administration to help Federally Qualified Health Centers improve the quality of cancer screening and follow-up care through a systematic process of organizational change.
- Assess compliance with, and increase awareness of, hospital regulation 10 NYCRR 405.9(b)(12)(i) which requires complete history and physical examinations be performed and documented on all patients admitted to the hospital, including a 'screening uterine cytology smear on women 21 years of age and over, unless such test is medically contraindicated or has been performed within the previous three years.'
- Support and leverage NYS health information technology efforts related to the meaningful use of electronic health records in improving cervical cancer screening rates.
- Work with key partners to develop and promote online and in-person continuing education opportunities for health practitioners related to cervical cancer screening guidelines, current standards of care for women with abnormal Pap tests and current information about the available HPV vaccines.

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