

VERMONT2007

Eradication of Cervical Cancer

Report to the Legislature on **Act 110 (2006 ADJ Session)**
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DEPARTMENT OF HEALTH
Agency of Human Services

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Executive Summary

In accordance with *Act 110*, the Vermont Department of Health convened a task force to study eradication of cervical cancer in Vermont. The legislation identified specific membership, topics for consideration and a timeline for the Commissioner of Health to report back to the General Assembly. This document is the Commissioner's report based on the Task Force's findings and recommendations regarding the prevention, detection and treatment of cervical cancer in Vermont.

This report lays out information on cervical cancer incidence and mortality, how human papillomavirus (HPV) relates to cervical cancer, prevention and early detection of cervical cancer, risk factors for cervical cancer, and cervical cancer treatment.

At the conclusion of its deliberations the Vermont Task Force to Eradicate Cervical Cancer concluded that Vermont is in a position to reduce the impact of cervical cancer among Vermont women. The task force recommended that the Vermont Department of Health provide leadership to develop approaches to work toward access to cervical cancer screening and HPV vaccine for Vermont women.

To this end, the Commissioner of Health has charged the Vermont Department of Health Cancer Control program with integrating these recommendations into the priorities and activities of the Vermont State Cancer Plan and convening appropriate workgroups of Vermont's statewide cancer coalition, Vermonters Taking Action Against Cancer (VTAAC), to develop strategies for implementation. In addition, the department will work with the Office of Vermont Health Access (OVHA), insurers and health care provider organizations to address accessibility and availability of HPV vaccine for Vermont women

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Cervical Cancer

“Cervical cancer once was the leading cause of death among women in the United States. However, in the past 4 decades, incidence [number of new cases each year] and mortality [number of deaths each year] have declined significantly, primarily because of the widespread use of the Papanicolaou (Pap) test to detect cervical abnormalities.”¹ According to the U.S. *Cancer Statistics: 2002 Incidence and Mortality Report*, more than 12,000 women were diagnosed with cervical cancer in 2002, and nearly 4,000 women died from the disease that same year.² It is estimated that more than \$2 billion per year is spent in the United States on the treatment of cervical cancer.³

Despite the adoption of widespread cervical cancer screening in the U.S., deaths from the disease occur more frequently among women who are uninsured or underinsured. Pap tests are underused by women who have less than a high school education, are older, live below the poverty level, or are members of certain racial or ethnic minority groups.⁴

Cervical Cancer Incidence and Mortality

Over the past decade cervical cancer incidence and mortality rates have declined among both Vermont and U.S. women. According to the Vermont Department of Health, each year about 31 Vermont women are diagnosed with cervical cancer each year and an average of 10 women die from the disease.

Women of all ages are at risk for cervical cancer. In Vermont, 94 percent of newly diagnosed cervical cancer cases are in women age 30 and older; 30 percent of these cases are in women 65 and older, with women aged 75-79 having the highest age-specific incidence of cervical cancer.

¹ Cervical Cancer. *NIH Consensus Statement*. April 1–3 1996;14(1):1–38.

² U.S. Department of Health and Human Services. [United States Cancer Statistics: 1999–2002 Incidence and Mortality Web-based Report](#). Atlanta: Centers for Disease Control and Prevention and National Cancer Institute; 2005.

³ Brown ML, Lipscomb J, Snyder C. The burden of illness of cancer: economic cost and quality of life. *Annual Review of Public Health* 2001;22:91–113.

⁴ U.S. Department of Health and Human Services & CDC: National Breast and Cervical Cancer Early Detection Program: Summarizing the First 12 Years of Partnerships and Progress Against Breast and Cervical Cancer. 1991-2002 National Report

Between 1999 and 2003, the incidence rates of cervical cancer in Vermont women (8.7 per 100,000 women) were statistically higher than the U.S. white female (7.2 per 100,000 women) rates.

Causes of Cervical Cancer

Cervical cancer results when cells in the lining of the cervix (the lower, narrow end of the uterus, or womb) go through abnormal changes and start to grow and spread more deeply into the cervix and to surrounding areas.

Cervical cancer may develop when a woman is infected with the human papillomavirus (HPV). Certain strains of this virus can cause cells on the cervix to change, resulting in cervical dysplasia, and over time these cells may become malignant. There are over 100 different strains of HPV and more than 30 of them are sexually transmitted. Some types of HPV are responsible for genital warts and other “high risk” strains can produce changes in the cervix that cause cancer.⁵

About 20 million men and women in the US are infected with HPV, and each year approximately 6.2 million Americans acquire a new infection. Researchers estimate that, by the age of 50, at least 80 percent of women will have been infected with HPV.⁶ Most people with an HPV infection have no symptoms, and therefore are unaware that they can transmit the virus to a sex partner.

Early Detection of Cervical Cancer

The Pap test is an effective screening tool for cervical cancer and pre-cancerous conditions. In 2005, 83 percent of Vermont women over the age of 18 reported having had a Pap test within the past three years. Women who are not being regularly screened tend to be older than 65 years old, have no regular source of health care, have less than a high school diploma, and/or do not have health insurance.

The Vermont State Cancer Plan includes an objective to “Increase the percentage of women (age 18+) who have had a Pap test in the past 3 years” to 90 percent by 2010. Vermonters Taking Action Against Cancer (VTAAC), the statewide cancer control coalition which includes the

⁵ American Cancer Society. *What Every Woman Should Know About Cervical Cancer and the Human Papilloma Virus*. <http://www.cancer.org>. July 10, 2006.

⁶ Centers for Disease Control and Prevention. *Fact Sheet: HPV Vaccine Questions and Answers*. <http://www.cdc.gov>.

Vermont Department of Health, is forming a workgroup to develop strategies to achieve this objective.

New Technologies: Liquid-based Cytology and HPV Vaccines

New laboratory technologies have been approved recently to improve our ability to screen for and identify cervical cancer and pre-cancerous conditions. In addition, two vaccines have been developed to prevent infection with HPV strains that cause the majority of cervical cancer and genital warts. Widespread use of these vaccines, coupled with regular screening, has the potential to significantly impact rates of cervical cancer in the U.S. over the next several decades.

HPV Prevention

Cervical cancer results from infection with one of the cancer-causing strains of HPV, the human papillomavirus. There are over 100 strains of HPV, and many are sexually transmitted. Some strains of HPV can cause changes to the cells of the cervix, which can lead to genital warts, cervical cancer or other problems.⁷ HPV infection is very common, and up to 80 percent of women age 50 and older have had an HPV infection during their lifetime. Despite the large numbers of women with HPV infection relatively few develop cervical cancer. This is because not all strains of HPV cause cervical cancer and most women's bodies can effectively fight the virus.

Safer Sexual Practices

Cervical cancers can result from HPV infections, which are generally sexually transmitted. Sexual abstinence is the only way to virtually eliminate cervical cancer risk. However, for individuals who are sexually active, safer sex (consistent condom use) will help to reduce overall risk. Additional strategies to reduce risk include delaying age at first sexual contact, limiting the number of sexual partners or being in a long-term, mutually monogamous relationship with an uninfected partner.⁸

HPV Vaccines

In June of 2006, the U.S. Food & Drug Administration (FDA) licensed the first vaccine to prevent HPV infection in women. This vaccine, named Gardasil®, protects against four types of HPV, two of which are known to lead to about 70 percent of cervical cancers. The two other strains account for 90 percent of genital warts. A second vaccine, effective against the two HPV strains that cause the most cervical cancers, is currently awaiting FDA approval.

In 2006, the Advisory Committee on Immunization Practices (ACIP), a group of 15 experts chosen by the Secretary of the U.S. Department of Health and Human Services, made recommendations to the Centers for Disease Control and Prevention (CDC) on the most effective ways to prevent vaccine-appropriate diseases. The national ACIP committee recommended HPV vaccine for all 11-12 year old girls, and for 13-26 year old girls and women who have not

⁸ Centers for Disease Control and Prevention. Fact Sheet: Genital HPV Infection. <http://www.cdc.gov>

received it. It can also be given to girls as young as age 9.⁹ The vaccine is currently not approved for use in males or women older than age 26 years, due to limited testing with these groups.

Costs and Insurance Coverage for HPV Prevention

At this time Gardasil® retails at a cost of \$120 per dose. The currently approved immunization protocol requires a series of three injections over the course of one year, for a cost of approximately \$360 per person in addition to the doctor's fee or the cost of giving injections.¹⁰

The Vermont Department of Health Immunization program is able to purchase a limited amount of HPV vaccine at a cost of \$96 per dose through a contract negotiated between the CDC and the vaccine manufacturer. Although funding for some part of this may be available through the federal Vaccines for Children program, it would potentially impact the state's ability to provide other needed childhood vaccines currently purchased with these federal dollars.

Health insurance companies will often cover the costs of new vaccines and the cost of administration, but there is often a lag time between vaccine approval and coverage by health plans.¹¹

Vermont is currently looking into cost and funding issues related to HPV vaccine.

⁹ Centers for Disease Control and Prevention. *HPV and HPV Vaccine Information for Health Care Providers*. <http://www.cdc.gov>. August 2006.

¹⁰ Ibid 1

¹¹ Ibid 2

Early Detection

Early detection increases the chances of long-term survival by diagnosing the cancer at an early and more treatable stage. Cervical cancer is one of the few cancers that can actually be prevented by receiving screening tests. Abnormalities can be detected and treated before they progress to cancer.

Cervical Cancer Screening

Both the incidence of, and mortality from, cervical cancer have dropped significantly in the U.S. over the past 40 years, mostly because of the widespread use of Papanicolaou (Pap) test to detect cervical abnormalities (dysplasia). Since few women with cervical cancer have any symptoms or signs that indicate a problem, widespread screening for early detection is critical.

“In the United States, approximately 50 million women undergo a Pap test each year. Of those, about 7-8 percent will have an abnormal result. ... About 2 million women have atypical squamous cells (ASC), 1.25 million have low-grade abnormalities (LSIL), about 300,000 have high-grade abnormalities (HSIL) and about 12,000 have cervical cancer each year. ... Fortunately, the most common abnormal findings on a Pap are minimally abnormal changes or low-grade abnormalities with the high-grade pre-cancer or cancer changes being much less frequent.”¹²

The Pap test includes the traditional smear and the new liquid-based cytology, both done by a health care provider. During a pelvic exam the clinician scrapes cells from the woman’s cervix and then sends them to the laboratory to identify changes or abnormalities. The cost of an annual gynecological exam and Pap test is a fraction of the cost for cancer treatment.

The primary limitation of the Pap smear is poor sensitivity (high false negative rates) caused by sampling and interpretation errors.¹³ New technologies have been introduced to improve the accuracy of the Pap test including: AutoPap, PapNet, and ThinPrep. AutoPap and PapNet are computer-based systems that are used to assess Pap smear slides. ThinPrep is an FDA-approved

¹² Gynecologic Cancer Foundation, undated, Powerpoint presentation, slide #31, Cervical Cancer: Screening: Evaluation: Treatment

¹³ Woolf, Steven H., *The Effectiveness of Screening for Cancer and Its Unfulfilled Potential in the United States: A Review of the Evidence*. A Report for the National Cancer Policy Board. February 19, 2004.

system that could potentially replace the conventional Pap test¹⁴ as it has improved accuracy by 10 percent or more. When the Thin Prep is used, HPV testing can be done if results are atypical.

When the Pap test results indicate that there have been cellular changes further diagnostic tests are performed to determine if cancer is present and how far it has spread. These diagnostic tests include:¹⁵

Colposcopy: Clinicians can get a closer look at the cervix with a colposcope. If any abnormal tissue in the cervix is noted, a sample is biopsied.

Biopsy: Tissue samples are taken from the cervix and tested by a pathologist to diagnose whether pre-cancer or cancer is present. If cancer is present, then further tests will be done to determine the extent or spread of the disease. These tests include: cystoscopy which looks for cancer of the bladder, colonoscopy which checks for cancer of the colon and rectum, chest x-ray to see if it is in the lungs, and other imaging tests.

Detection of cervical cancer in its earliest stages is essential given that the chances of survival decrease when cancer is diagnosed at a later stage of the disease. Although 92 percent of women will survive 5 years when the cancer is localized in the cervix, only 13 percent will survive when the cancer has spread to other parts of the body. Studies have found that within three years of implementing a screening program, the cervical cancer rates can be reduced by 60-90 percent, which can reduce mortality by 20-60 percent.¹⁶

Screening Schedules

There is general agreement among standard setting organizations for when to begin screening for cervical cancer and frequency. However, there is disagreement as to when regular screenings can be ended. In 2002, the American Cancer Society (ACS), along with the American College of Obstetricians and Gynecologists (ACOG) issued formal recommendations about cervical cancer screening, which included: “Pap tests should be started within three years of vaginal intercourse, or at least by age 21, in order to detect and treat the disease early.” According to ACOG, “Pap tests should be done annually until age 30. After 30, if a healthy woman has had three

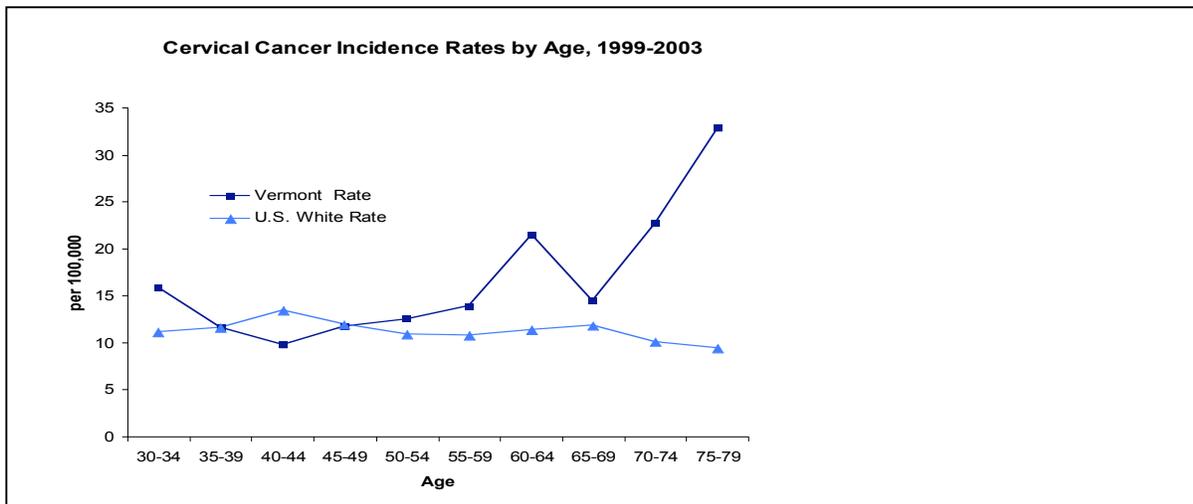
¹⁴ American Cancer Society. *New Pap Test Screenings are Controversial*. www.cancer.org. August 26, 1998.

¹⁵ American Cancer Society. *Overview: Cervical Cancer – How is Cancer of the Cervix Found?* <http://www.cancer.org>. November 17, 2005.

¹⁶ U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services, Third Edition: Screening for Cervical Cancer*. <http://www.ahrq.gov/clinic/3rduspstf/cervcan/cervcanrr.pdf>

completely normal and satisfactory Pap tests, she may be able to increase the test interval to every two to three years (but should still see a gynecologist every year for an exam).”¹⁷

Shortly following the ACS and ACOG recommendations, the United States Preventive Services Task Force released updated recommendations on screening for cervical cancer. These recommendations are used as guidelines for women’s health care providers across the United States.¹⁸ The document states that the “Majority of cases of invasive cervical cancer occur in women who are not adequately screened. Clinicians, hospitals, and health plans should develop systems to identify and screen the subgroup of women who have had no screening or who have had inadequate past screening.”¹⁹



Among Vermont women, cervical cancer incidence increases after the age of 40 and is significantly higher among women age 60-64 and 70-79, as shown in the following graph. This points to the need to continue screening women beyond the age of 65 for cervical cancer, and to examine for other gynecological health issues.²⁰

HPV Testing

The HPV test, approved in 2000, examines cervical cells for DNA of 13 high-risk strains of HPV associated with cervical cancer. This test was originally used only for women with abnormal Pap tests to determine the need for more testing. In March 2003, the U.S. Federal Drug Administration approved the use of the HPV test in combination with a Pap test for screening

¹⁷ Killackey, Maureen. *New Cervical Cancer Screening Guidelines: Do The Right Thing*. <http://www.acog.org>

¹⁸ U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services, Third Edition: Screening for Cervical Cancer*. <http://www.ahrq.gov/clinic/3rduspstf/cervcan/cervcanrr.pdf>

¹⁹ Ibid 3

²⁰ Vermont Department of Health. *Eradicating Cervical Cancer in Vermont*. Presentation, October 5, 2005.

women over 30 years of age, along with a complete medical history and an evaluation of other risk factors.²¹

The US Preventative Services Task Force was unable to make recommendations regarding the routine use of new technologies to screen for cervical cancer or HPV testing as an adjunct or alternative to regular Pap smear screening.²² The reasons are that these new tests are costly, and have not been available long enough for researchers to conduct prospective studies. The CDC is currently undertaking a large cost-benefit analysis of the use of HPV testing as a primary screening tool. Preliminary results are expected in the next 2 years.

Health Disparities and Barriers to Cervical Cancer Screening

In the U.S., most women are aware of the importance of cervical cancer screening and the need for regular Pap tests and pelvic examinations,²³ but many do not have adequate access to recommended screening resources. Deaths from cervical cancer occur more frequently among women who are uninsured or underinsured. Pap tests are underused by women who have less than a high school education, are older, live below the poverty level, or are members of certain racial or ethnic minority groups. Asian Americans and Pacific Islanders are less likely to have had a Pap test within the past three years than Whites, African Americans, Hispanics and American Indians.

In Vermont, based on data from the 2005 Behavioral Risk Factor Surveillance System, 83 percent of women 18 and older reported being screened for cervical cancer in the past three years. However, certain populations report lower rates of cervical cancer screening. Variables related to primary care, health insurance, age and education are significant predictors of cervical cancer screening.

Primary Care: Women with a primary care provider are more likely to get screened for cervical cancer than those without a specific primary care provider, about 83.8 percent vs. 65.9 percent, respectively.

²¹ US Food and Drug Administration. *FDA Approves Expanded Use of HPV Test*. www.fda.gov/bbs/topics/NEWS/2003/NEW00890.html. March 31, 2003.

²² *Ibid* 2

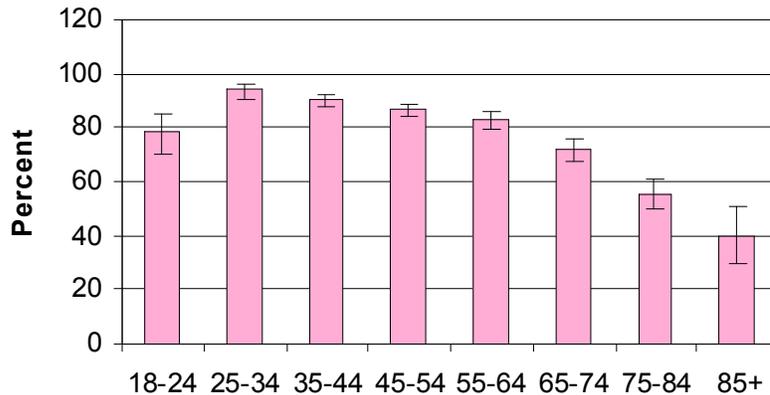
²³ Institute of Medicine, National Research Council. *Fulfilling the Potential of Cancer Prevention and Early Detection*. The National Academies Press. 2003, Washington, D.C.

Health Insurance: Women with health insurance are more likely to get screened for cervical cancer than those without insurance, about 84.1 percent vs. 73.7 percent, respectively.

Education: Cervical cancer screening rates increase with education. Only about 70 percent of women who did not finish high school have had a Pap test in the past three years compared to 87.2 percent of women who have completed college.

Age: Women between the ages of 25-44 have the highest rates of cervical cancer screening. Only about half of Vermont women age 65 and older report having a Pap test in the past three years.

Percentage of Vermont women meeting the recommendations for cervical cancer screening (Pap tests) by AGE, 2005



Programs Addressing Barriers to Cervical Cancer Screenings

The Vermont Department of Health Ladies First program provides low-income, uninsured, and underserved women access to timely, high-quality screening and diagnostic services to detect breast and cervical cancer at the earliest stages. This program is funded by the Center for Disease Control's (CDC) National Breast and Cervical Cancer Early Detection Program. Based on federal guidelines, the program provides services to uninsured and underinsured women at or below 250 percent of the federal poverty line.

The Vermont program provides cervical screening to women age 18-64 years. Between July 1999 and June 2004, the Ladies First program provided cervical cancer screening to 3,410 Vermont women. Of those women, 7 were diagnosed with cervical cancer, and 116 were diagnosed with cervical dysplasia (pre-cancer changes in cervical cells).

Nationally, poor and minority women find it more difficult to access traditional screening programs. A 1997 study published in the American Journal of Public Health examined the “costs and effects of cervical and breast cancer screening in a public hospital emergency room.”²⁴ Overall, the researchers determined that cervical cancer screening in the emergency room at a public hospital was cost-effective. The results of this study were most strongly influenced by the numbers of women screened, and the rates of follow-up after an abnormal screening test result. This type of an approach may warrant further investigation and is an example of innovative thinking that is needed to address barriers to screening.

²⁴ Mandelblatt, J. et al. *The Costs and Effects of Cervical and Breast Cancer Screening in a Public Hospital Emergency Room*. American Journal of Public Health, 87(7) July 1997, pp. 1182-1189.

RISK FACTORS

While screening for cervical cancer through the use of the Pap test is the most effective way of decreasing the risk of progression to cervical cancer, it is important to note that some women are at increased risk of progression from HPV infection to cervical cancer due to the following risk factors:

Weakened Immune System: Women with Human Immunodeficiency Virus (HIV) infection have a suppressed immune system, which makes it hard to fight infections such as HPV, and early cancers.

Age: While HPV infection is less prevalent in older women, if present it can progress to cervical cancer more readily. In Vermont, women aged 65 and older have the highest age-specific incidence of cervical cancer. Age-adjusted rates of late stage diagnosis are statistically higher among Vermont women age 75-79 compared to the U.S. This points to the need to continue screening women beyond the age of 65 for cervical cancer, and to examine for other gynecological health issues.

Smoking: Women who smoke cigarettes are about twice as likely to get cervical cancer as non-smokers. The carcinogenic chemicals in tobacco can damage the DNA in cervical cells, making smokers more prone to developing cancer. In addition, current smokers in Vermont report lower rates of screening for cervical cancer than non-smokers.

Exposure to DES (diethylstilbestrol): Between 1940 and 1971, health care providers prescribed DES to women who were vulnerable to miscarriage. The daughters of women who took DES have a slightly increased risk of vaginal or cervical cancer.

TREATMENT

The treatment plan for cervical cancer depends on the stage or severity of disease. Like most cancers, there are three main treatment strategies: surgery, radiation, and chemotherapy. Surgery is used to remove the malignant area. Radiation therapy is used to shrink or kill cancer cells, and chemotherapy uses potent drugs to destroy cancer cells.

The Cervical Cancer Task Force made no specific comments on treatment standards, except that women of all ages and backgrounds should have equal access to best practices and standards of care for treating HPV, pre-cancerous conditions and cervical cancer.

Costs and Insurance Coverage Issues

Diagnosis and treatment of cervical cancer is costly, and many private health insurance plans will pay a percentage of the fees. However, these costs are insurmountable for the millions of Americans who are uninsured. In recognition of the complexity of the issue of treatment costs, coverage and access to care, the United States Congress passed the Breast and Cervical Cancer Prevention and Treatment Act in 2000.

In addition to providing funds for screening and diagnostic testing, the “Medicaid Treatment Act” allows states to provide medical assistance through Medicaid to eligible women who were screened through a CDC program like Ladies First, if they were found to have breast or cervical cancer or pre-cancerous conditions. Vermont passed legislation in 2001 to adopt this Act, and established the Ladies First program. In order for a woman to be eligible for Medicaid under this Act, she must have been screened for and found to have breast or cervical cancer (including precancerous conditions) through Ladies First, be under age 65, and be uninsured and otherwise not eligible for Medicaid.

RECOMMENDATIONS

The Vermont Task Force to Eradicate Cervical Cancer concluded that Vermont is in a position to reduce the impact of cervical cancer among women. The task force recommended that the Vermont Department of Health provide leadership to develop approaches to work toward access to cervical cancer screening and HPV vaccine for all women who would benefit from them.

The Commissioner of Health has accepted the task force recommendations as follows:

- Assure that clinicians are informed about and apply best practice standards and guidelines regarding HPV vaccinations and testing, cervical cancer screening for women of all ages, treating precancerous conditions and treating cervical cancer.
- Assure that women and their families are informed, have the resources and necessary supports to actively manage their own care in collaboration with the primary care physician and other members of their health care team. This includes understanding causes of HPV infection and cervical cancer, the importance of screening, and the roles of HPV vaccination and testing.
- Assure that policies and practices of regulators, insurers, and healthcare providers remove barriers to affordable and appropriate healthcare for women of all ages, economic, ethnic and cultural groups. These services include vaccination, screening, treatment of precancerous conditions and cervical cancer, and follow-up care for cervical cancer survivors.

The Commissioner of Health has charged the Vermont Department of Health Cancer Control program with integrating these recommendations into the priorities and activities of the Vermont State Cancer Plan²⁵ and convening appropriate workgroups of Vermont's statewide cancer coalition, Vermonters Taking Action Against Cancer (VTAAC) to develop strategies for implementation. In addition, the department will work with the Office of Vermont Health Access (OVHA), insurers and health care provider organizations to address accessibility and availability of HPV vaccine for Vermont women

²⁵ Vermont Department of Health. Vermont State Cancer Plan, 2006-2010; page 20. December 15, 2005.

Appendix

Vermont Task Force on the Eradication of Cervical Cancer

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