

**STATE OF MAINE
122nd LEGISLATURE
FIRST REGULAR SESSION**

**Initial Report of the
Task Force to Study Cervical Cancer Prevention,
Detection and Education**

December 2005

Members:

**Sen. Nancy Sullivan, Chair
Rep. Lisa Marrache, Chair
Rep. James Campbell, Sr.
Dr. Kolawole Bankole
Dr. Carrie Bolander
Dina Cole
Bob Downs
Dr. Jonathan Fanburg
Sharon Jerome
Dr. Michael Jones
Evelyn Kieltyka
Dr. Susan Miesfeldt
Janet Miles
Dr. James A. Raczek
Dr. Molly Schwenn
Dr. James Wilberg**

Staff:

**Nicole Dube, Legislative Analyst
Lucia Nixon, Legislative Analyst**

**Office of Policy & Legal Analysis
Maine Legislature
(207) 287-1670**

Table of Contents

	Page
Executive Summary	i
I. Introduction	1
II. Task Force Progress and Meetings	2
III. Agenda for Future Work	10

Appendices

- A. Authorizing Legislation; Resolve 2005, Chapter 121
- B. Task Force Membership List
- C. Agenda for November 16, 2005 Meeting
- D. Agenda for December 20, 2005 Meeting

Executive Summary

The Task Force to Study Cervical Cancer Prevention, Detection and Education (“Task Force”) was established in the First Regular Session of the 122nd Legislature by Resolves 2005, Chapter 121. The Task Force is authorized to meet over a two-year period to examine the prevalence and incidence of cervical cancer in Maine, to review preventive strategies and new technologies, to assess existing laws, programs and services, and, ultimately, to develop a statewide cervical cancer prevention plan and strategies for plan implementation and coordination. As created, the 16-member Task Force includes one member of the Senate, two members of the House of Representatives, eight members representing different medical organizations, associations and specialties, one member representing the health insurance industry, one member representing communications consultants, one member representing cervical cancer survivors and two representatives of the Maine Department of Health and Human Services.

The Task Force was convened on November 16, 2005 and held a second meeting on December 20, 2005. Task Force members received program information and data regarding screening and treatment services within the state including the Maine Cancer Registry, the Maine Breast and Cervical Health program and MaineCare coverage of cervical cancer services. The Task Force also received information regarding clinical and technology issues relating to cervical cancer screening.

In accordance with the authorizing legislation, the Task Force will not meet from December 21, 2005 to April 25, 2006. To complete its work, the Task Force anticipates holding 2 meetings between April 26, 2005 and June 30, 2006 (the end of the state fiscal year 2005-2006) and 4 meetings between July 1, 2006 and November 1, 2006. The Task Force will utilize its future meetings to:

- Further examine key clinical and technological issues related to cervical cancer prevention and detection;
- Identify and address gaps in cervical cancer prevention, detection and education; and
- Develop a statewide cervical cancer prevention plan and strategies for plan implementation and coordination.

The Task Force will then submit its findings, recommendations and any proposed legislation in its final report, due November 1, 2006, to the joint standing committee of the legislature having jurisdiction over health and human services matters.

I. Introduction

The Task Force to Study Cervical Cancer Prevention, Detection and Education (“Task Force”) was established in the First Regular Session of the 122nd Legislature by Resolves 2005, Chapter 121. A copy of the law is attached in Appendix A. As created, the 16-member Task Force includes one member of the Senate, two members of the House of Representatives, eight members representing different medical organizations, associations and specialties, one member representing the health insurance industry, one member representing communications consultants, one member representing cervical cancer survivors and two representatives of the Maine Department of Health and Human Services. The Task Force membership roster is listed in Appendix B.

The Task Force was established to examine the prevalence and incidence of cervical cancer in Maine, to review preventive strategies and new technologies, to assess existing laws, programs and services, and, ultimately, to develop a statewide cervical cancer prevention plan and strategies for plan implementation and coordination. Specifically, the Task Force was charged with the following six duties:

1. Review statistical and qualitative data on the prevalence and incidence of cervical cancer in Maine;
2. Review preventive strategies and new technologies, including newly introduced vaccines and their effectiveness in preventing and controlling the risk of cervical cancer, as well as their relative costs;
3. Identify and examine the strengths and limitations of existing laws, regulations, programs and services regarding coverage and awareness of cervical cancer;
4. Consider reports and testimony from individuals, local health departments, community-based organizations, voluntary health organizations and other public and private organizations statewide to learn more about their contributions to cervical cancer diagnosis, prevention and treatment and their ideas for improving prevention, diagnosis and treatment in Maine;
5. Develop, in consultation with the Department of Health and Human Services, a statewide comprehensive cervical cancer prevention plan and strategies for plan implementation and for promoting the plan and awareness of the causes, risk factors, prevention, early detection and treatment of cervical cancer to the general public, state and local elected officials and various public and private organizations, associations, businesses, industries and agencies; and
6. Recommend strategies for coordination and communication among state and local agencies and organizations regarding their involvement in achieving the aims of the cervical cancer prevention plan.

Resolves 2005, chapter 121 requires the Task Force to submit two reports:

1. An initial report to the Joint Standing Committee on Health and Human Services and to the Governor in December 2005;¹ and
2. A final report to the Joint Standing Committee on Health and Human Services by November 1, 2006.

The resolve authorizes the joint standing committee of the Legislature having jurisdiction over health and human services matters in the First Regular Session of the 123rd Legislature to report out legislation on cervical cancer prevention, detection and education.

II. Task Force Progress and Meetings

Appointments to the Task Force were completed on October 19, 2005, and the Task Force convened for its first meeting on November 16, 2005. The Task Force held a second meeting on December 20, 2005.

A. First Meeting of the Task Force

The first meeting focused on laying the foundation for the work of the Task Force. The meeting included three main components:

1. A review of the authorizing legislation and Task Force goals,
2. An overview of cervical cancer initiatives within the Maine Department of Health and Human Services, and
3. An opportunity to discuss and identify priorities for the Task Force within the context of its required duties.

1. Authorizing Legislation and Task Force Goals

Task Force members reviewed the authorizing legislation, Resolves 2005, chapter 121, with particular focus on the duties and reporting requirements described in the Introduction above (see also Appendix A). Members discussed the motivation and underlying goals for the Task Force and identified the following justifications for undertaking this work:

- While Maine is doing relatively well in the areas of cervical cancer prevention, detection and education, there is an opportunity for the State to further reduce the rate of cervical cancer given the current technology and to move toward complete eradication of cervical cancer with the development and introduction of new technology, and

¹ The deadline for the initial report in Resolves 2005, chapter 121, was December 7, 2005. The Task Force requested an extension of the reporting deadline from the Legislative Council to December 23, 2005; that extension was approved by the Council on November 28, 2005.

- There are gaps in the current system of cervical cancer prevention, detection and education in the State that need to be addressed.

2. Cervical Cancer Initiatives within DHHS

The Task Force invited representatives of the Maine Department of Health and Human Services to present information on the Maine Cancer Registry and the Maine Breast and Cervical Health Program.

a. Maine Cancer Registry

The Maine Cancer Registry (MCR) is a statewide population-based cancer surveillance system established by the Legislature in 1983 (22 MRSA, Chapter 255). MCR collects patient demographic, diagnosis and initial treatment information on all cancer cases diagnosed in Maine, except for basal cell and squamous cell carcinoma of the skin. Information is collected from hospitals, health care facilities, physicians and other health care providers who diagnose or treat cancer patients. The law requires these individuals and facilities to report new cases to the MCR within 6 months of seeing the patient. MCR is partially funded by the National Program of Cancer Registries, a program of the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC).

MCR issues a “Cancer Incidence and Mortality Report” which includes statistical comparisons between cancer incidence and mortality rates in Maine and the nation for various cancer types, including cervical cancer. This information is used to monitor and evaluate cancer incidence trends in Maine, to identify areas in need of public health interventions and to improve cancer prevention, treatment and control. The latest data from the MCR shows that the rates of cervical cancer incidence and mortality in Maine are similar to the rest of the nation:²

Table 1
Cervical Cancer Age-Adjusted Incidence and Mortality Rates

Year	Incidence Rate per 100,000		Mortality Rate per 100,000	
	Maine	National	Maine	National
2000	6.5	7.3	1.8	2.5
2001	9.2	7.3	1.6	2.4
2002	7.1	6.8	2.2	2.3

b. Maine Breast and Cervical Health Program

² The differences in rates of cervical cancer incidence and mortality in Maine compared with the nation are not statistically significant. The National Cancer Institute’s Surveillance, Epidemiology and End Results (SEER) collects cancer information from 13 population based registries representing approximately 14% of the U.S. Population. Because the population in Maine is 98% white, the Maine Cancer Registry uses the SEER White data as a national comparison.

In 1990, Congress enacted the Breast and Cervical Cancer Mortality Prevention Act which established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), the first and only national cancer screening program. This program, which is administered by CDC, provides free breast and cervical cancer screening and related diagnostic services for low income and uninsured women. The federal law does not authorize the CDC to pay for treatment services for those women diagnosed with breast or cervical cancer.

Maine is one of over 60 states and tribal organizations that has received funding from the CDC to implement a comprehensive breast and cervical cancer program. Established in 1994, the Maine Breast and Cervical Health Program (MBCHP) is administered through the Maine Department of Health and Human Services in collaboration with Medical Care Development, Inc. Key features of the program are as follows:

- **Funding.** Currently, Maine receives \$1.8 million annually from the CDC for this program. These federal funds are supplemented with approximately \$381,000 in state General Fund dollars.
- **Eligibility.** To be eligible for MBCHP, a woman must: be age 40 years and older; have income at or below 250% of the federal poverty level; be uninsured or underinsured; and be a resident of Maine or New Hampshire.³
- **Enrollment.** Since its inception, MBCHP has enrolled over 15,000 women and provided 23,349 Pap tests and diagnosed 57 cases of cervical cancer. As of December 7, 2005, there were 5,321 women currently enrolled in MBCHP. Of these women, 33% were 40-49 years of age, 64% were 50-59 years and 3% were 65 years or older. The MBCHP enrollment rate by county ranged from a low of 6.8% of eligible women enrolled in Cumberland County to a high of 38.5% of eligible women enrolled in Washington County.⁴
- **Covered clinical services.** For enrollees, the MBCHP provides an annual exam, including a clinical breast exam, pelvic exam, Pap test and HPV testing. Cancer treatment is not covered by MBCHP but, in most cases, is covered by MaineCare (Medicaid) pursuant to the federal Breast and Cervical Treatment Act of 2000.
- **Service delivery system and outreach.** MBCHP funds nearly 300 sites to provide clinical and educational services. These include: primary care provider sites which provide clinical exams and pap tests; other health care professionals who provide diagnostic services on referral; laboratory facilities that provide cytology and pathology services; and community partnerships that provide public education and other support services. In 2005, the MBCHP distributed 70,000 program brochures and 1,900 posters to 441 sites across the state.

³ The CDC gives the option of eligibility starting at age 18; due to the limited funding for MBCHP and the availability of family planning services for younger women, Maine decided to begin eligibility at age 40.

⁴ Source: Maine Department of Health and Human Services, Maine Breast and Cervical Health Program.

3. Task Force Priorities

Throughout its first meeting, the Task Force relied on the expertise of its members to identify priorities to guide the group in the remainder of its work to address cervical cancer prevention, detection and education. At the meeting, members specifically identified the following priorities:

- Examine key clinical and technological issues related to cervical cancer prevention and detection, as follows:
 - Review national clinical guidelines for cervical cancer screening,
 - Evaluate existing Pap test technologies: thin prep and traditional pap,
 - Examine HPV testing issues, and
 - Track the development of new HPV vaccines; and
- Identify and address gaps in cervical cancer prevention, detection and education, as follows:
 - Develop strategies to address unmet needs of two distinct populations: (1) women who are not getting screened, and (2) women who are screened but for whom screening fails,
 - Explore opportunities to address the needs of women under 40 years, who are presently ineligible for MBCHP, and
 - Assess existing public education and outreach strategies and develop new strategies to improve access to screening and treatment services, including outreach to immigrant and minority populations.

B. Second Meeting of the Task Force

The second meeting of the Task Force, on December 20, 2005, focused on clinical issues relating to cervical cancer screening and gathering additional information on screening and treatment services within the state, including MaineCare coverage of cervical cancer services.

1. Cervical Cancer Screening

a. Screening Guidelines

Task Force members reviewed and discussed the current cervical cancer screening guidelines provided by three groups: (1) the American Cancer Society (ACS), (2) the U.S. Preventive Services Task Force⁵ (USPSTF), and (3) the American College of Obstetricians and

⁵ The USPSTF, sponsored by the U.S. DHHS Agency for Healthcare Research and Quality (AHRQ), is an independent panel of experts in primary care and prevention that reviews the scientific evidence of effectiveness and develops recommendations for clinical preventive services.

Gynecologists (ACOG). As shown in Table 2, the recommended starting point for screening is similar across the three groups, but the recommendations for how often to screen for cervical cancer and when to stop screening differ across the groups. Task force members noted that these differences in the recommendations were not surprising given that each group had its own process and methodology for developing its guidelines.

Table 2
Cervical Cancer Screening Guidelines⁶

Recommendation	American Cancer Society (Nov. 2002)	U.S. Preventive Services Task Force (Jan. 2003)	American College of Obstetricians and Gynecologists (Aug. 2003)
When to Start Screening	Approximately 3 years after onset of vaginal intercourse, but no later than age 21	Within 3 years of onset of sexual activity or age 21, whichever comes first	Approximately 3 years after onset of sexual intercourse, but no later than age 21
Screening Interval			
If conventional Pap smear test	a) Annually b) Every 2-3 years for women ≥ 30 yrs with 3 negative cytology tests	At least every 3 years	a) Annually b) Every 2-3 years for women ≥ 30 yrs with 3 negative cytology tests
If liquid-based cytology test	a) Every 2 years b) Every 2-3 years for women ≥ 30 yrs with 3 negative cytology tests	Insufficient evidence	a) Annually b) Every 2-3 years for women ≥ 30 yrs with 3 negative cytology tests
If HPV testing used	Every 3 years if HPV negative, cytology negative	Insufficient evidence	Every 3 years if HPV negative, cytology negative
When to Stop Screening	Women ≥ 70 yrs with ≥ 3 recent, consecutive negative tests and no abnormal tests in prior 10 years	Women > 65 yrs with negative tests, who are not otherwise at high risk for cervical cancer	Inconclusive evidence to establish upper age limit

b. Understanding Cervical Cancer Screening Failure

The Task Force reviewed information regarding the factors that contribute to the failure of cervical cancer screening to prevent the development of cervical cancer. Given the existing screening technology, it is estimated that 95% of cervical cancer could be prevented under

⁶ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, <http://www.cdc.gov/std/HPV/ScreeningTables.pdf>

perfect conditions.⁷ In reality, 30% of cervical cancer cases are not prevented as a result of imperfections, or failures, in the screening system. Screening failures can be divided into two major types:

1. *Insufficient screening.* Approximately 65-70% of screening failures are the result of women not being screened, including women who are never screened and women who are not meeting the recommended guidelines for onset and frequency of screening; and
2. *False negative screening.* Approximately 30-35% of screening failures are the result of “false negative” screening, in which a woman is screened but still develops cervical cancer.

c. Cervical Cancer Screening Technology – Conventional Pap Smear and Thin Prep

To understand the state of current cervical cancer screening technology, the Task Force reviewed the differences between the conventional Pap smear and the newer ThinPrep Pap test. A number of advantages of the ThinPrep technology were identified, including:

- More effective than conventional Pap smear in detecting low-grade and high-grade lesions (specifically squamous intraepithelial lesions, or SILs);
- Provides higher quality sample than conventional Pap smear (ease of sample collection is a contributing factor); and
- The sample is good for 30 days and can be used for follow-up testing for Human Papillomavirus (HPV) without requiring the patient to return for another test.

Despite the advantages of the ThinPrep Pap test, it was noted that the ThinPrep does cost significantly more than the conventional Pap test and given the current lack of scientific evidence as to whether the ThinPrep will result in reductions in cervical cancer mortality, it is still unclear whether the additional cost is warranted. Nonetheless, it is clear that practitioners are increasingly using the ThinPrep instead of the conventional Pap test.

2. HPV and Cervical Cancer

The Task Force also briefly reviewed the relationship between Human Papillomavirus (HPV) and cervical cancer and issues related to HPV testing. Research has shown the presence of HPV in over 93% of cervical cancers.⁸ Only certain types of HPV have been linked to the development of cervical cancer, including HPV 16 which is estimated to account for 50% of cervical cancer, and HPV 18, 31 and 45, which together are estimated to account for 30% of cervical cancer.⁹ While HPV is known to lead to cervical cancer, it is important to note that most HPV infections are “transient” and will resolve on their own without medical intervention

⁷ Presentation of Dr. Michael Jones to the Task Force on December 20, 2005.

⁸ National Cancer Institute. Cervical Cancer: Background. <http://rex.nci.nih.gov/massmedia/backgrounders/cervical.html>

⁹ Shah, Keerti V. (1997). “Human Papillomaviruses and Anogenital Cancers.” *The New England Journal of Medicine*, 337(19), 1386-1388.

and will *not* develop into cervical cancer.¹⁰ Because most cases of HPV will not lead to cervical cancer, positive HPV test results provide less information (have less predictive value) than negative HPV test results.

HPV testing is increasingly being used to further evaluate Atypical Squamous Cells of Undetermined Significance (ASCUS) results from a routine Pap test and determine whether to proceed to a colposcopy, a visual examination of the outer portion of the cervix using a colposcope to magnify and illuminate the area. Other drivers behind the use of the HPV test include its relatively high sensitivity for detection of high-grade intraepithelial lesion (HSIL) and the opportunity it presents to extend the screening interval for women 30 years or older who have a negative HPV test result (see Table 2).

3. HPV Vaccines

The Task Force reviewed information regarding the status of HPV vaccine development and related issues. It is anticipated that the introduction of HPV vaccines may significantly advance cervical cancer prevention. At the same time, it is important to recognize that there will be a significant lag period between the introduction of the vaccines and a reduction in cervical cancer mortality rates, due to the latency associated with this disease.

Two HPV vaccines are currently in the pipeline for licensure by the U.S. Food and Drug Administration (FDA):

- **Gardasil**, being developed by Merck, targets HPV types 6, 11, 16 and 18. Merck submitted its Biologics License Application (BLA) to the FDA in December 2005; and
- **Cervarix**, being developed by GlaxoSmithKline(GSK), targets HPV types 16 and 18. Phase III clinical trials are currently in progress and GSK intends to submit its BLA in 2006.

Both Gardasil and Cervarix have been shown to be highly effective in preventing persistent HPV infection and 100% effective in preventing HPV type-specific associated lesions.¹¹ Task Force members noted that while the efficacy of these vaccines is clear, acceptance of the vaccines among health care providers, parents and patients is an important practical challenge that will need to be addressed to fully realize the potential of these vaccines.

4. “At Your Cervix” Program

The Task Force invited Tri-County Health Services (TCHS) to present information regarding its new cervical cancer prevention program, At Your Cervix. TCHS, a program of the Western Maine Community Action agency, provides reproductive health services and education to residents of Androscoggin, Franklin and Oxford counties. With a two-year grant from the

¹⁰ Presentation of Dr. Michael Jones to the Task Force on December 20, 2005.

¹¹ Diane M. Harper, MD, MPH, MS. Presentation to “The Status Cervical Cancer Vaccine Research” conference, Women’s Policy, Inc., Washington, DC, December 6, 2005.

Maine Health Access Foundation, TCHS launched At Your Cervix in July 2005 to enhance and expand its cervical cancer prevention effort. As part of At Your Cervix, TCHS has been able to:

- Switch from conventional Pap tests to liquid based Pap tests at no extra charge to clients,
- Provide HPV testing for all atypical Pap test results,
- Provide significant discounts for colposcopy, cryosurgery and cervical biopsy procedures,
- Purchase equipment to perform colposcopies in all three counties,
- Train a clinician in the Loop Electrical Excision Procedure (LEEP), a procedure to remove tissue from the cervix, and
- Initiate new community outreach services including providing information to local providers (gynecologists and family practice physicians), distributing At Your Cervix information along with heating assistance program applications and hiring a Somali outreach worker for the Lewiston-Auburn area.

5. MaineCare Coverage of Cervical Cancer

a. Cervical Cancer Services and Expenditures

The Task Force invited representatives of DHHS to present information regarding MaineCare services and expenditures related to cervical cancer. As summarized in Table 3, DHHS provided data organized by diagnosis code (the client's diagnosis) and other data organized by procedure code (the clinical procedure performed).

Table 3
MaineCare Expenditures Related to Cervical Cancer
State Fiscal Year 2004¹²

	# Distinct Claims	# Distinct Members	Total Paid
By Diagnosis Code (ICD-9)¹³			
Routine Pap/Gynecological exam	31,850	23,546	\$1,510,609
Treatment/Evaluation of Abnormal Pap	37,801	21,304	\$2,101,414
Human Papillomavirus (HPV)	1,517	1,256	\$131,101
Cervical cancer treatment or care	1,755	564	\$832,836
By Procedure Code			
Cytopathology for Pap smear	39,290	33,320	\$579,418
Colposcopy/Biopsy/LEEP	2,113	1,825	\$118,675
HPV testing	2,069	1,964	\$27,642

b. MaineCare Coverage under the Treatment Act

¹² Source: Maine Department of Human Services, MMDSS

¹³ ICD-9 stands for the International Classification of Diseases, 9th Revision, Clinical Modification, which is a listing of diagnoses and identifying codes used by physicians for reporting patient diagnoses to health plans.

In accordance with the federal Breast and Cervical Cancer Prevention and Treatment Act of 2000 (the Treatment Act), Maine enacted Public Law 2001, chapter 439, Part TT to require the state's Department of Health and Human Services to amend its rules to provide full MaineCare coverage to women diagnosed with breast or cervical cancer under the Maine Breast and Cervical Health Program. Approximately two years following this rule change, Maine applied for and received federal approval to also provide MaineCare coverage to those women who are not enrolled in MBCHP but who: (a) meet MBCHP eligibility requirements and (b) are diagnosed with breast or cervical cancer at a Federally Qualified Health Center participating in the MBCHP,¹⁴ a less restrictive option allowed under the federal Treatment Act.

To be eligible for MaineCare under the above Treatment Act provisions, a woman must be under age 65, not covered by credible health insurance, and have income less than 250% of the federal poverty level.¹⁵ MaineCare coverage under these rules is continuous for one year as long as the woman is receiving cancer treatment. Since 2001, 88 women with cervical cancer or a pre-cancerous cervical cancer condition have been enrolled in MaineCare under these rules. Of these women, 64% entered MaineCare with a diagnosis of cervical cancer and 36% entered with a pre-cancerous condition.

III. Agenda for Future Work

In accordance with the authorizing legislation, the Task Force will not meet from December 21, 2005 to April 25, 2006. To complete its work, the Task Force anticipates holding 2 meetings between April 26, 2005 and June 30, 2006 (the end of the state fiscal year 2005-2006) and 4 meetings between July 1, 2006 and November 1, 2006.

Task Force members have identified the following three areas to address at the next meeting:

- Continue to monitor the development of cervical cancer vaccines and invite representatives from the U.S. Centers for Disease Control and pharmaceutical companies (Merck, GlaxoSmithKline) to brief the Task Force on the vaccines;
- Examine available data on the geographic distribution of women in Maine who are not receiving sufficient cervical cancer screening services (including follow-up services after an abnormal Pap) and discuss potential strategies to reach these women; and
- Examine available data from the Maine Health Data Organization on cervical cancer screening and treatment service utilization and expenditures in both public and private health care systems in Maine.

¹⁴ This change was motivated by LD 143, Resolve, to Improve Access to Breast and Cervical Cancer Treatment, which was proposed in the 121st legislature. Ultimately, the LD 143 was not enacted after the department agreed to make the changes without legislation.

¹⁵ Specifically the individual must have no "credible coverage" as defined in Section 2701(a) of the federal Public Health Service Act.

More broadly, the Task Force will utilize its future meetings to:

- Further examine key clinical and technological issues related to cervical cancer prevention and detection;
- Identify and address gaps in cervical cancer prevention, detection and education; and
- Develop a statewide cervical cancer prevention plan and strategies for plan implementation and coordination.

The Task Force will then submit its findings, recommendations and any proposed legislation in its final report, due November 1, 2006, to the joint standing committee of the legislature having jurisdiction over health and human services matters.