
Cervical Cancer Prevention Plan

Report to:
Governor of Tennessee and
Members of the 2008 General Assembly

In fulfillment of Public Acts 2006, Chapter No. 921

Tennessee Cervical Cancer Elimination Subcommittee
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April 1, 2008

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Executive Summary

In May 2006, the Tennessee General Assembly established a task force to study the prevalence and burden of cervical cancer in Tennessee to develop strategies for the education of the public and health care providers about cervical cancer prevention and detection and to publish a statewide cervical cancer elimination plan. The task force is called the Tennessee Cervical Cancer Elimination Subcommittee. The 19-member group has worked for two years to produce concrete recommendations for eliminating cervical cancer in Tennessee. The report is presented in three chapters, which mirror the duties assigned by the legislature:

- **Chapter 1:** A Review of statistical and qualitative data on the prevalence and burden of cervical cancer;
- **Chapter 2:** Strategies to raise public awareness, value of prevention and early detection, and physician education;
- **Chapter 3:** A Statewide Comprehensive Cervical Cancer Prevention Plan.

No woman in the U.S. should develop or die from cervical cancer. This disease is preventable through regular screening and treatable if detected early. Cervical cancer is caused by infection with the human papillomavirus (HPV), which is the most common sexually transmitted infection in the US. While most HPV infections have no symptoms and resolve without treatment, HPV is of public health importance because persistent infection with certain high-risk types can lead to cervical cancer. Annually in Tennessee, cervical cancer is diagnosed in approximately 250 women and 100 die of the disease, with a greater disease burden experienced by black women.

In June 2006, an HPV vaccine was licensed by the Food and Drug Administration (FDA) for use in females, ages 9-26 years. HPV vaccination is effective and has been shown to decrease cervical cancer rates. It will take many years before the impact of the HPV vaccine is felt; therefore, efforts to detect and treat cervical abnormalities and cervical cancer at early stages must continue and intensify.

The overall recommendations of the Subcommittee are condensed on the following page and explained in depth in the body of the report. The recommendations highlight the importance of providing awareness and education to both the lay public and healthcare providers concerning the importance of preventive screening and HPV vaccination. The overall recommendations are provided as a strategy to eliminate cervical cancer in Tennessee by 2040.

SUBCOMMITTEE RECOMMENDATIONS

To develop and promote a comprehensive statewide prevention plan for cervical cancer, the Subcommittee met over the course of two years, created a plan and compiled these recommendations for cervical cancer control in Tennessee.

- Promote continued Pap testing and routine HPV vaccination of all girls and young women, in accordance with established CDC guidelines, to eliminate the primary biologic cause of cervical cancer.
- Maximize the use of federal Vaccines for Children (VFC) Program to vaccinate all eligible young women 11 through 18 years of age against HPV.
- Adopt strategies to make HPV vaccine affordable to uninsured or underinsured young women ages 19-26, including appropriation of State funds to purchase vaccine for these women.
- Appropriate state funds to fully vaccinate (3 doses at approximately \$126 per dose) 14,000 young women annually in health departments who are ACIP-recommended to receive HPV vaccine, but are not eligible for VFC. Cost estimate: \$5 million/year for 10 years.
- Establish an on-going Cervical Cancer Elimination Advisory Committee for oversight and consultation on cervical cancer elimination that will conduct a three-year pilot program to educate the 10 Tennessee counties with the highest incidence rate for cervical cancer. The pilot will be an adaptation of Team-Up Tennessee and feature culturally appropriate, messages and materials provided by the Tennessee Department of Health and the Centers for Disease Control and Prevention (CDC). Cost estimate: \$280,000/year for three years.
- Take the pilot education project statewide to educate all Tennesseans about cervical cancer prevention and screening and the importance of the vaccine. Cost estimate: \$655,000/year.
- Implement methods for collection of cervical cancer data from primary care providers throughout the State of Tennessee, including the appropriation of funds to establish two new cancer registrar positions within the Tennessee Cancer Registry. Change the cancer reporting laws and rules to enable the collection of precancerous lesions that is currently not permitted.
- Advocate the use of liquid-based cytology versus conventional Pap-based slides due to the improved sensitivity achieved in using liquid-based cytology. This would have the effect of capturing more cases, hence improving surveillance.
- Encourage healthcare providers to promote strategies that facilitate easy access for the second and third doses in the vaccine series to increase the timeliness of series completion.
- Promote effective strategies to increase both appropriate cervical cancer screening and follow-up for abnormal screenings in accordance with established standards of practice.
- Provide professional education programs and information for physicians and allied health professionals regarding cervical cancer screening, current standards of care for women with abnormal Pap tests and current information about the vaccine.

Introduction

THE PROBLEM

The reduction in deaths from cervical cancer in the U.S. is a success story in the history of cancer control. Since screening programs using the Papanicolaou test (Pap test) were implemented widely more than 50 years ago, cervical cancer deaths have declined approximately 75 percent in the U.S. Yet despite the proven benefits of screening, in Tennessee approximately 250 women are diagnosed with and approximately 100 die from cervical cancer each year. Many of the deaths from cervical cancer occur in economically disadvantaged or underserved women. The Human Papillomavirus (HPV) is recognized as the cause of almost all cervical cancers, and a vaccine found to be effective at preventing infection with certain HPV types has recently been recommended by CDC for use among all young women aged 9 through 26 years. The HPV vaccine has the potential to complement the already proven effectiveness of Pap testing making feasible the elimination of cervical cancer in Tennessee by 2040. This goal can only be realized if women are educated about the benefits of regular screening and vaccination and if vaccination and Pap testing are equally available to all women, including economically disadvantaged and underserved women.

TENNESSEE CERVICAL CANCER ELIMINATION SUBCOMMITTEE

To address this problem, on May 26, 2006, Tennessee Code Annotated, Title 68, Chapter 1, Part 18 was amended establishing the Tennessee Cervical Cancer Elimination Task Force, which became Public Chapter Number 921 of 2006. The task force was created for the purpose of eliminating cervical cancer in Tennessee and designated it to be called the Tennessee Cervical Cancer Elimination Subcommittee, hereafter referred to as the Subcommittee, of the Tennessee Comprehensive Cancer Control Coalition. The law required the Subcommittee to complete the following tasks:

- (1) Obtain from the Tennessee Comprehensive Cancer Control Subcommittee on Surveillance a review of statistical and qualitative data on the prevalence and burden of cervical cancer;
- (2) Develop a strategy to raise public awareness on the causes and nature of cervical cancer, value of prevention and early detection, and physician education;
- (3) Publish a statewide comprehensive cervical cancer prevention plan for public distribution, state and local elected officials, and various public and private organizations.

The Subcommittee is composed of representatives from both the Tennessee House of Representatives and the Senate, American Academy of Pediatrics, Tennessee affiliate of the American Cancer Society, American College of Obstetrics and Gynecology, Tennessee Breast and Cervical Cancer Screening Program, Tennessee Immunization Program, Tennessee Family Planning Program, American Academy of Family Physicians, the general public and the health insurance industry. The Tennessee Department of Health Commissioner and Bureau of TennCare Director are ex officio members of the Subcommittee. Members of the Subcommittee are listed on the following page.

Subcommittee Members

Task Force Chair	Stephan L. Foster, Pharm.D., FAPhA College of Pharmacy, University of Tennessee (UT), Memphis
Representatives of the American College of Obstetrics and Gynecology	Dineo Khabele, M.D., Director of Gynecology Oncology Meharry Medical College, Nashville
	Howard W. Jones, III, M.D., Director of Gynecology Oncology Vanderbilt University Medical Center, Nashville
	Joseph T. Santoso, M.D., UT College of Medicine, Memphis
Representative of Tennessee Immunization Program	Kelly L. Moore, M.D., M.P.H. Tennessee Department of Health (TDOH), Nashville
Representative of the Tennessee Breast & Cervical Cancer Early Detection Program	Mary Jane Dewey, M.P.A., Director Tennessee Breast & Cervical Cancer Early Detection Program, TDOH, Nashville
Representative of Tennessee Family Planning	Deana Vaughn, CNM, MSN Nursing Consultant Women's Health, TDOH, Nashville
Representatives of the American Academy of Family Physicians	Lee Marvin Carter, M.D., Private Practice, Huntington Beth Anne Fox, M.D., M.P.H., Associate Program Director College of Medicine, East Tennessee State University, Kingsport
Representative of the Health Insurance Industry	Richard Mark Lachiver, M.D., M.P.H
Representative of the American Academy of Pediatrics	Naomi N. Duke, M.D., Pediatrics, Vanderbilt Clinic, Nashville
Representatives of the General Public	Navita W. Gunter, Cervical Cancer Coalition of Tennessee, Nashville
	Sadie P. Hutson, PhD, RN, WHNP, Hematology/Oncology East Tennessee State University, Johnson City
	Nadem Zafar, M.D., UT College of Medicine, Memphis
Representative of Tennessee House	The Honorable JoAnne Favors, D - Chattanooga
Representative of Tennessee Senate	The Honorable Charlotte Burks, D - Monterey
Representative of the American Cancer Society	Angel G. Strange, MSW, Nashville
Representative of Director of TennCare	David L. Collier, M.D., Associate Medical Director, Nashville
Resource Member	Barbara P. Clarke, PhD., R.D., Extension Health Specialist & Co-Director, Center for Public Health Literacy
	The University of Tennessee Extension, Knoxville

Tennessee Department Of Health Personnel

Paula Taylor, MS	Director, Office of Policy, Planning and Assessment, TDOH
Martin Whiteside, DC, PhD, MSPH	Director, Office of Cancer Surveillance (OCS), TDOH
Trudy Stein-Hart, MS	Program Manager, Tennessee Comprehensive Cancer Control Program, TDOH
Jill Thomas	State Cervical Cancer Coordinator, Middle Tennessee State University, Murfreesboro
Kathy Childress	OCS, TDOH

Chapter 1

Review of Statistical and Qualitative Data on the Prevalence and Burden of Cervical Cancer

Cervical Cancer in Tennessee

“I am 37 years old now. With a life expectancy of less than six months, I am on a mission to help others. I am asking that parents who have daughters get them the Human Papillomavirus (HPV) vaccine. This vaccine can prevent HPV, a sexually transmitted disease that can lead to cervical cancer. I have taken my two daughters for vaccinations because I don’t want them to go through what I have experienced.”

Sharon Holley, diagnosed with cervical cancer at age 35
Now deceased

Review of statistical and qualitative data on the prevalence and burden of cervical cancer

Risk Factors for Cervical Cancer

Cervical cancer is a major public health problem throughout the world, with developing nations sharing a larger disease burden compared with more developed regions of the world. Infection by any of the many types of so-called “high-risk” HPVs, but especially HPV-16 and HPV-18, is associated with almost all cervical cancers and is generally recognized as the principle cause of cervical cancer. Other established risk factors include: cigarette smoking; not being screened for cervical cancer and pre-cancer; high-risk sexual behavior, such as having multiple sex partners; and long-term use of oral contraceptive agents. Women who consume low amounts of fruits and vegetables have also been shown to be at increased risk in some studies. Women who bear large numbers of children are also at increased risk of cervical cancer.

Prevention of Cervical Cancer

Avoiding the above risk factors has the potential to substantially reduce the burden of cervical cancer. A well established screening mechanism, the Pap test, has been available for over 50 years that enables healthcare practitioners to effectively detect precancerous lesions before they develop into invasive cancer. Those countries routinely providing screening using the Pap test have the lowest number of new cervical cancer cases per total population of women in any specific year or time period. For example, the number of new cases of cervical cancer in the U.S., where Pap screening is widespread, is 4 times less than that reported in India, where Pap screening is only available to a limited number of women. The number of new cases of cervical cancer has been adjusted to compensate for differences in the age distribution of the populations compared and is called an age-adjusted incidence rate. Because most cases of cancer occur in older individuals, populations with larger numbers of older people will be expected to have larger numbers of people with cancer. To make valid comparisons, all incidence and mortality rates presented in this report are age-adjusted to the U.S. 2000 standard population.

Despite the importance of regular Pap testing to cervical cancer prevention, a recent report indicates fewer women may be undergoing screening for cervical cancer. The National Cancer Institute’s “Cancer Trends Progress Report–2007 Update” reported that the percentage of U.S. women, 18 years of age and older, who received a Pap test within the three years prior to being surveyed in 2005 had decreased compared with that reported in 2003. Approximately 75-80 percent of women were undergoing screening using the Pap test in the 2005 survey; though more recent data seems to indicate increasing screening levels (Table 2). Given the proven effectiveness of the Pap test for reducing the burden of cervical cancer, these percentages should be closer to 100 percent; therefore, women should be better educated about the importance of undergoing Pap screening for cervical cancer and precancer. The U.S. Government’s Department of Health and Human Service’s (HHS) Healthy People 2010 established the goal to increase to 90 percent the proportion of women aged 18 and older who have received a Pap test within the past 3 years. At current screening levels, as a nation, that goal may not be met.

Burden of Cervical Cancer in Tennessee

Table 1 displays the incidence and mortality rates for cervical cancer in Tennessee with a comparison to the overall rates for U.S. women. Rates are given for all women, white women and black women. Rates are average annual rates during the 5-year period, 2000-2004, and are per 100,000 women.

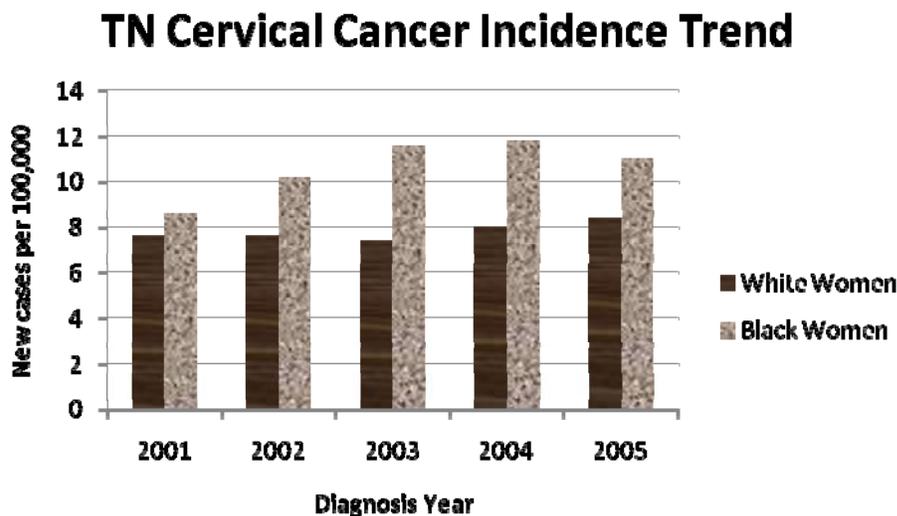
Table 1. 2000-2004 Average Annual Cervical Cancer Incidence and Mortality Rates (per 100,000 Women)

	TN All	TN White	TN Black	U.S. All	U.S. White	U.S. Black
Incidence Rate	8.1	7.7	10.8	8.8	8.4	12.3
Mortality Rate	3.2	2.7	6.9	2.6	2.3	4.9

Source: Cancer in North America, 2000-2004, North American Association of Central Cancer Registries (NAACCR)

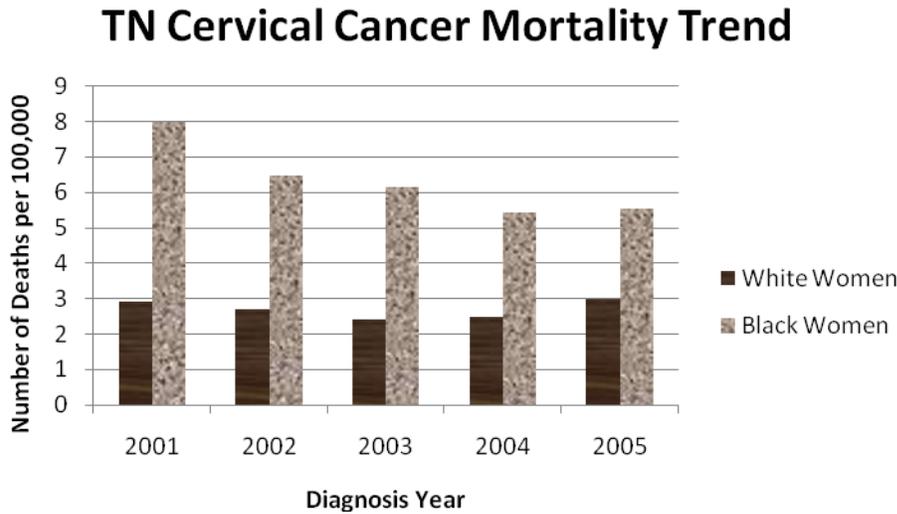
Figures 1 and 2 display the 5-year trends, from 2001-2005, in cervical cancer incidence and mortality, respectively. The data are presented for black and white women separately. Interpret with caution the statistics presented for incidence since data collected by the Tennessee Cancer Registry was incomplete prior to the 2004 diagnosis year. The increase in incidence rates observed for black women over the 5-year period may be due to improvements in cancer reporting.

Figure 1.



Data are presented as the number of new cases per 100,000 women in the Tennessee population. For black women, new diagnoses have increased substantially over the 5-year period, whereas for white women rates have been relatively stable.

Figure 2.



Data are presented as the number of invasive cervical cancer-related deaths per 100,000 women in the Tennessee population. For black women, mortality has decreased substantially over the 5-year period, whereas for white women rates have been relatively stable.

Black women, both nationally and in Tennessee, display the greatest burden of cervical cancer for both incidence and mortality. The reason for this greater disease burden in black women is not fully understood, but does not appear to be due to differences in screening. Table 2 presents the screening prevalence (percentage) for all women, white women and black women for both TN and the U.S. Interestingly, the percentage of black women in Tennessee who reported undergoing screening for cervical cancer within the past 3 years when surveyed in 2006 met the 90% goal established by Healthy People 2010.

Table 2.

	TN All	TN White	TN Black	U.S. All	U.S. White	U.S. Black
Screening Prevalence	85.9	84.9	91.4	84.0	84.9	88.2

Source: 2006 Behavioral Risk Factor Surveillance System, Centers for Disease Control and Prevention (CDC)

Table 3 presents the 10 Tennessee counties with the highest cervical cancer incidence and mortality. Note that a county may be in the top 10 for incidence but not mortality and vice versa. The incidence and mortality rate for Tennessee is listed in the first row for comparison. New cases and deaths represent the total number of women diagnosed with and dying from cervical cancer, respectively, over the 5-year period from 2001-2005. Incidence rates are the averages for the same time period. Only Lauderdale and Carroll counties are in the top 10 for both incidence and mortality.

Table 3.

County	New Cases	Incidence Rate	County	Deaths	Mortality Rate
Tennessee	1282	8.2	Tennessee	507	3.2
Lewis	7	22.7	Lauderdale	6	9.0
Macon	11	20.0	Marion	7	8.6
Meigs	6	18.7	Carroll	7	8.2
Dyer	18	17.8	Hardeman	6	7.7
Robertson	24	16.0	Gibson	9	5.1
Lauderdale	10	15.9	Monroe	6	5.1
Chester	6	15.3	Hamblen	9	5.0
Humphreys	7	15.0	Shelby	111	4.8
Cocke	14	14.9	McMinn	7	4.7
Carroll	10	13.7	Roane	8	4.7

Figures 3 and 4 show the regional distribution of the counties presented in Table 3. Figure 3.

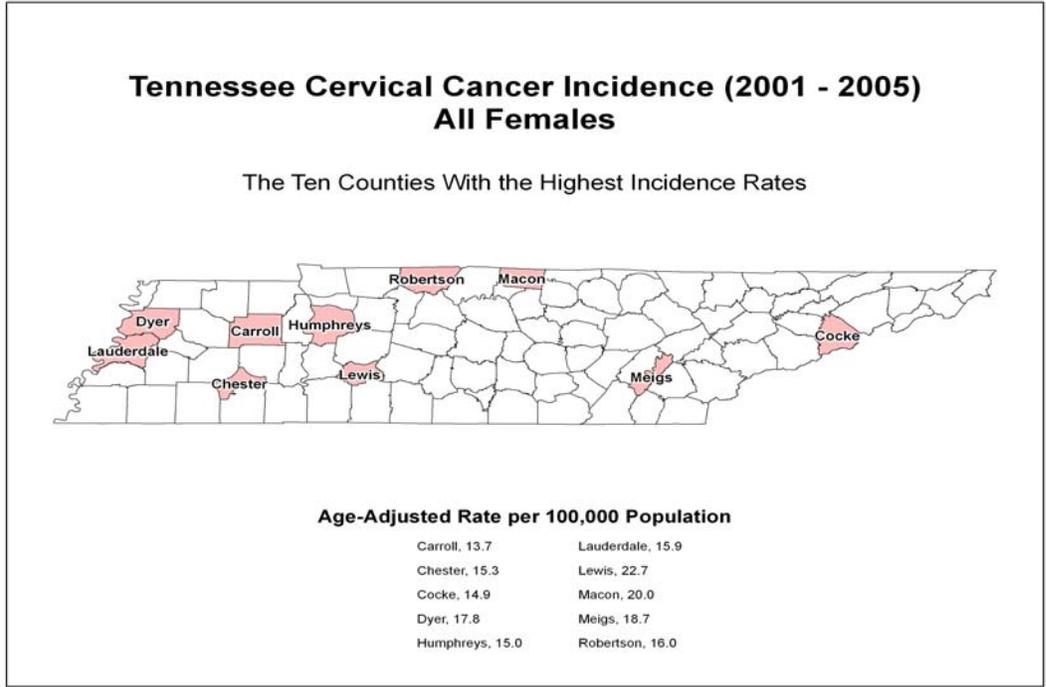
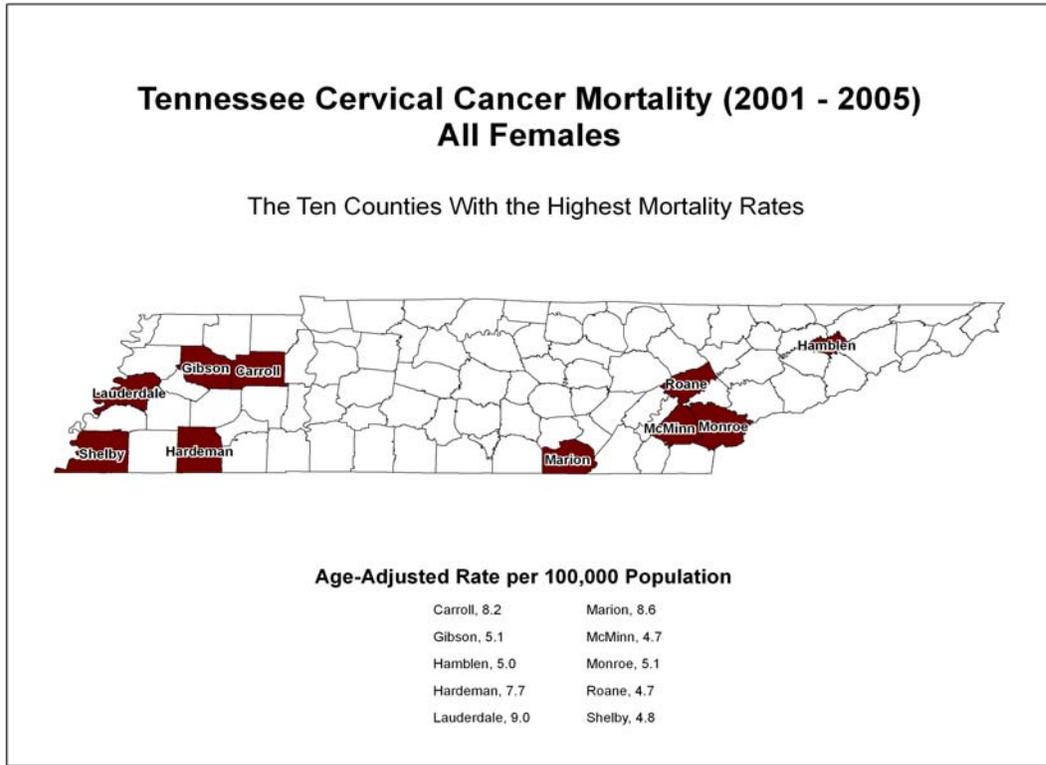


Figure 4.



Chapter 2

Strategies to Raise Public Awareness of Cervical Cancer, Value of Prevention and Early Detection, and Physician Education

Cervical Cancer in Tennessee

“I am not a cervical cancer survivor but I am a close friend of one who was recently diagnosed with the beginning stages of cervical cancer. Luckily, the doctors caught it in time and she is healthy now. As a result of this experience, my service and sisterhood organization has been on a campaign to educate young women about the importance of annual Pap tests and getting the HPV vaccine. That’s what we have been educating college students about – getting the vaccine and getting Pap tests. We can wipe out cervical cancer in our lifetime!”

Sherrae Hayes

Strategies to raise public awareness of cervical cancer, value of prevention and early detection, and physician education

The HPV vaccine is an important breakthrough in women's health and the elimination of cervical cancer in Tennessee. However, it must be combined with continued screening to be effective. The Subcommittee recommends three major objectives to reduce and eventually eliminate cervical cancer:

1. Implement a model community education project based on the infrastructure of Team Up Tennessee (See Appendix 3, Fact Sheet, page 24) to educate all Tennesseans about cervical cancer prevention and screening and the importance of the vaccine.
2. Establish an on-going Cervical Cancer Elimination Advisory Committee for oversight and consultation on cervical cancer elimination.
3. Develop professional education programs and information for physicians and allied health professionals regarding cervical cancer screening, current standards of care for women with abnormal Pap tests and current information about the vaccine.

Public Awareness and Early Detection

Team-Up Tennessee is a successful breast and cervical cancer community education program implemented by the University of Tennessee Extension Service that educates women about risks, signs and symptoms and referral sources for screening or vaccinations. This pilot program will be developed in the 10 Tennessee counties (see Chapter 1) with the highest incidence rates for cervical cancer, using culturally appropriate, bilingual, low-literacy messages and materials provided by the Tennessee Department of Health and the Centers for Disease Control and Prevention (CDC). Some of the community education will focus on the Vaccines for Children Program (over 40 percent of Tennessee children are eligible). This will assure that parents are exposed to information published by the CDC informing them the HPV vaccine is recommended for use among all young women aged 9 through 26 years (or to age 26 for those with TennCare).

Through the Team-Up community education efforts, public awareness on the role of HPV in cervical cancer, the benefits of HPV vaccination, and the benefits of early cervical cancer detection through Pap tests will be emphasized. Parents, teens, and young adults will be targeted for these community education efforts, as will women over the age of 26 who need to continue to seek annual exams and Pap tests for good preventive health.

The pilot program will be reviewed by the Advisory Committee at least every 6 months with the goal of developing an effective educational program for cervical cancer prevention and early detection to be implemented statewide within 3 years.

Advisory Committee

As proposed in this Plan, the Cervical Cancer Elimination Advisory Committee is charged with the responsibility of guiding the state's activities to eliminate cervical cancer, and monitoring progress at least on a semi-annual basis. The committee should be staffed by a full-time state funded clinician and full-time health educator. At least one representative from each of the following is recommended for membership:

- Tennessee Breast and Cervical Cancer Screening Program representative
- University of Tennessee Extension representative
- Department of Health regional health officer
- Coordinated School Health representative
- State immunization program representative
- Regional Health Council representative
- Tennessee Comprehensive Cancer Control Program/Coalition representative
- American Cancer Society

In addition, two members should be appointed by the Commissioner of Health from each state of the three grand regions of the state East, Middle and West.

Physician and Provider Education

The Subcommittee recommends that the Advisory Committee review and approve a multi-pronged cervical cancer education program for Tennessee medical providers and allied health professionals to assure that the professional community is up-to-date on cervical cancer prevention and early detection. The educational material will include vaccine information and lifestyle issues, specifically sexual transmission and smoking, which increase the risk of cervical cancer. Articles on cervical cancer elimination will be written and featured in HMO, TennCare and medical association publications and newsletters. Part of the educational material would also inform providers of the Vaccines for Children Program (VFC) that provides free vaccine to eligible children and the Tennessee Breast and Cervical Cancer Screening Programs. Emphasis will be placed on recruiting additional providers from Family Medicine and Obstetrics and Gynecology residencies and advanced nursing programs. Internet links and resources for public and provider education on HPV and cervical cancer screening should be posted and maintained on the Tennessee Cancer Website. (See Appendix 4)

The budget proposed to implement and continue the recommendations of the Subcommittee with regard to community education/social marketing is on the following page.

**PROPOSED IMPLEMENTATION BUDGET FOR SOCIAL
MARKETING OF THE CERVICAL CANCER ELIMINATION
STATE PLAN**

Year 1 – Initiate program development by establishing the Cervical Cancer Elimination Advisory Committee; hiring project staff and developing social marketing materials; beginning implementation in selected pilot counties

TOTAL \$262,900

Year 2 – Implementation of Outreach and Education in 10 the Pilot Counties; continuation of Advisory Committee and staffing

TOTAL \$294,700

Year 3 - Final Year for Implementation and Evaluation in the 10 Pilot Counties

TOTAL \$293,900

Year 4 - Statewide Implementation – Expand to all 95 counties

TOTAL \$654,750

Implementation Costs for 4 years

GRAND TOTAL \$1,506,250

Each additional year of implementation would require \$654,750 for staffing, materials, Advisory Committee meetings, general office expenses, etc.

The Subcommittee recommends that the Governor reconvene this Subcommittee in April 2009 and each April thereafter for four years to analyze and report on the state’s progress toward the goals and objectives of this plan. If this proposal is accepted, an additional appropriation of approximately \$5,000 will be needed each year for travel and support expenses.

Chapter 3

Statewide Comprehensive Cervical Cancer Prevention Plan

Cervical Cancer in Tennessee

During a routine physical with a Pap test, Navita Gunter's doctor discovered a problem, took a biopsy and had her wait in his office for the results.

“He told me it was cancer and I lost my hearing from that point on. When I regained my hearing I heard him say; ‘This is early enough to beat.’ ”

Navita Gunter, 8-year cervical cancer survivor
Founder of Cervical Cancer Coalition of Tennessee

Statewide Comprehensive Cervical Cancer Prevention Plan

The Subcommittee recommendations are as follows:

1. All health care providers should emphasize the importance of continued Pap tests for all women.
2. Young women (11 -12 year olds) should be vaccinated following national guidelines.
3. Young women over the age of 12 should receive vaccination as soon as possible.
4. All means of providing the vaccination should be utilized including the Vaccines for Children Program, Merck's dose replacement assistance program, mandatory coverage by state health insurers and state funds for vaccine purchase when necessary.

Vaccine and Health Care Recommendations

The Subcommittee recommends state health provider organizations promote the Advisory Committee on Immunization Practices (ACIP) guidelines for HPV vaccine and current cervical cancer screening guidelines. Pap test screening recommendations for women are unlikely to change in the short term, for both women who are vaccinated and those who are not. Women and providers need to be educated on the need for continued Pap testing.

The Subcommittee recommends that all healthcare providers including nursing and pharmacy professional organizations emphasize the importance of vaccinating young women against HPV on time (starting at age 11-12 years, or as soon as possible, if older) in order to help assure that the 3-dose series is complete before sexual activity starts. ACIP recommendations emphasize routine vaccination with the current Food and Drug Administration approved HPV vaccine at ages 11-12, and also stresses catch-up vaccination of all young women for whom the vaccine is recommended from ages 9 to 26. Vaccination at early ages has proven to provide increased clinical efficacy of the vaccine. Other key health care partners include, but may not be limited to: the Tennessee Medical Association (TMA), Tennessee Academy of Family Practitioners (TNAFP), Tennessee College of Obstetricians and Gynecologists, and Tennessee's chapter of the American Academy of Pediatrics (TNAAP).

Because the vaccine is not a substitute for screening, the Subcommittee wants to ensure women understand the message that screening remains an important part of cervical cancer prevention even if they have had the vaccine. The Subcommittee recommends the State continue to fund and promote cervical cancer screening to identify women already affected or at risk while at the same time provides funding for HPV vaccine to prevent future cases of cancer. This dual strategy is recommended to assure that all women have access to vaccination and screening.

Funding Recommendations

Because of the cost of this vaccine, affordability must be addressed once parents and young women understand the need for HPV vaccination. The Subcommittee recommends the following steps to improve access to the vaccine and overcome the financial barriers that affect the decisions of providers about whether to make the vaccine available to their patients:

- Maximize the awareness of and participation in the federal Vaccines for Children (VFC) Program. This program will provide all CDC-recommended routine vaccines at no cost to the provider or patient, including HPV vaccine, to all eligible children through age 18. Eligible children are those without insurance, on TennCare, of

American Indian or Alaskan Native ethnicity, or [in health departments and Federally Qualified or Rural Health Centers] those whose health insurance does not cover vaccinations.

- Raise awareness of VFC eligibility among parents so they know that cost is not a barrier for eligible girls at participating providers or health departments, but that eligibility ends at age 19.
 - Raise awareness and increase VFC enrollment among healthcare providers who give primary care to preteens and teens.
- Adopt other strategies to make vaccine affordable to young women facing out of pocket expenditures (ages 19-26 without insurance coverage and those of any age with high insurance deductibles)
 - Provide state funds to fully vaccinate (3 doses at approximately \$126 per dose) 14,000 young women annually in health departments who are ACIP-recommended to receive HPV vaccine, but are not eligible for VFC. This would cost approximately \$5 million/year for 10 years. After approximately 10 years, the state program could be phased out as young women without insurance coverage of HPV are vaccinated routinely as preteens or young teens, while eligible for the federal VFC Program.
- Access the dose replacement plan offered by Merck, the HPV vaccine manufacturer, so private healthcare providers who administer HPV vaccine to an eligible woman whose income is less than 200 percent of the poverty level have an incentive for providing the vaccine. While this program helps providers by replacing doses pre-approved for administration to such women, the quarterly dose replacement (not factoring in up-front purchasing costs) and pre-approval process necessary before each dose are likely to limit the number of women vaccinated through this program. The program also is not available to public sector clinics at this time.
- Negotiate with TennCare's Managed Care Organizations (MCO) to pay the maximum allowable vaccine administration fee (\$13.70 per dose) for this and other vaccines to reduce financial losses faced by providers who vaccinate TennCare enrolled children. The vaccine administration fee paid to healthcare providers falls far below the actual costs incurred by the provider to store, handle and administer vaccine. Currently, TennCare MCOs reimburse providers less than the maximum allowable reimbursement of \$13.70. This \$13.70 fee was established by federal Medicaid in 1994 and has not changed since; of note, this maximum is lower than the minimum allowable reimbursement for influenza vaccine administration under Medicare, which exceeds \$18 in Tennessee.
- Mandate that insurers reimburse providers 100 percent of the cost of ACIP recommended vaccines, plus administration. In many cases, with HPV vaccine, providers are being reimbursed less than their cost to purchase the vaccine – which is a disincentive to offer the vaccine.
- Do not cover vaccine costs under capped wellness rider benefits on insurance plans (vaccine cost quickly exceeds the cap, forcing choices between vaccine and other preventive medical services). Vaccine coverage should be a standard benefit.

- The Subcommittee encourages healthcare providers to facilitate easy access for the second and third doses in the vaccine series to increase the timeliness of series completion. Examples of strategies include walk-in vaccination without an office visit or writing a prescription for follow-up doses to be administered by a pharmacist.

APPENDICES

Appendix 1. Facts About The HPV Vaccine

In June 2006, the Food and Drug Administration (FDA) approved for young women ages 9 through 26 the first vaccine to prevent cervical cancer. This vaccine, Gardasil[®] (by Merck) is a “quadrivalent” vaccine, which means it protects against four common strains of human papillomavirus (HPV). Two of the four strains (HPV 16 and 18) cause about 70% of all cases of cervical cancer in the United States; the other two strains (HPV 6 and 11) cause 90% of genital warts. In June 2006, after reviewing the safety and effectiveness of Gardasil[®], the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended this vaccine be administered routinely to all young women aged 11-12 years and to all young women aged 13 through 26 not previously vaccinated. In addition to Gardasil[®], GSK also has applied to FDA for licensure of Cervarix[®], a bivalent cervical cancer vaccine against HPV 16 and 18; Cervarix[®] is expected to offer another option for cervical cancer prevention, but will not be discussed further, since it is not yet FDA approved and recommendations for its use do not exist at this time.

The quadrivalent HPV vaccine (Gardasil[®]) is administered in three doses at 0, 2, and 6 month intervals. It is unknown whether recipients will ever need a booster dose, but protection is expected to last at least several years. The CDC recommendation to administer the vaccine series during the preteen years was made for at least three practical reasons. First, vaccination before the beginning of any sexual activity is critical to assure that the young woman has the best possible protection: the vaccine cannot treat existing HPV infections. Second, two other vaccines (meningococcal meningitis vaccine and a booster against tetanus, diphtheria and pertussis) are already routinely given at this age. Third, most adolescents infrequently visit their primary care providers and may miss opportunities to complete the 3-dose series for protection later in their teen years.

The quadrivalent HPV vaccine offers the best chance for protection if given before sexual activity begins; however, previous sexual activity, HPV infections or abnormal cervical examinations are not factors in deciding whether the vaccine should be given. The vaccine offers at least partial protection to almost all sexually active young women in the recommended age groups. Even though HPV is the most common sexually transmitted infection, studies have shown that the vaccine could protect about 90% of sexually active women from at least 3 of the 4 HPV strains in the vaccine. Because HPV vaccine may be given after a woman is already infected and because it does not protect against every cervical cancer-causing HPV strain, vaccinated women still need routine Pap tests and gynecologic examinations.

The 3-dose HPV vaccine is expensive, costing approximately \$126 per dose (\$378 for entire series), excluding administration or office fees. Many, but not all, private and public sector payers will cover the vaccine, but policies about who will be covered and what amount will be paid vary and, in some cases, are still being determined. The vaccine is included in the federal Vaccines for Children (VFC) Program that provides federally-funded vaccine to eligible children (such as the uninsured and those on TennCare) through age 18 years – roughly 40% of children nationwide.

**Appendix 2. Tennessee Breast And Cervical Screening Program (TBCSP)
Fact Sheet**

Implemented: 1997
Managed By: Tennessee Department of Health – Bureau of Health Services (4/2002)
Funding Source: Centers for Disease Control – (NBCCEDP)

Number of Staff: Six full time staff including the Program Director, Administrative Assistant, Account Administrator, 2 Nurse Consultants, a Data Manager and thirteen regional coordinators, one in each public health region.

Services Provided: This statewide program provides breast and cervical screening to eligible women and diagnostic follow up tests for those with suspicious results. Women diagnosed with breast or cervical cancer or pre-cancerous conditions for these cancers are enrolled in Presumptive Eligibility for treatment coverage through the state’s TennCare Program. **All women for any service (screening, diagnosis or treatment) must meet the general eligibility guidelines for the program.**

Eligibility Requirements: Age between 40 and 64
Income 250%FPL or less
Insurance uninsured or underinsured

Mammograms are only available for women 50-64 unless there is family history (40-49). Women younger than 40 who meet these general eligibility requirements can be enrolled for diagnosis and/or treatment services when they have suspicious results from screening services. The estimated number of women in TENNESSEE eligible for the program is over 65,000 women. (CDC 2004)

Summary of Program Structure: Over 100 sites including most county health departments and affiliated free standing primary care centers serve as the point of entry enrolling eligible women in the program and providing basic screening services. These sites also provide referral and case management services for women needing diagnostic or treatment services through a regional network of referral providers. Over 350 specialty providers accept our patients upon referral for further diagnostic tests. Providers are reimbursed for services based on the state Medicare rate for specific procedures related to breast and cervical cancer diagnosis.

Any woman who meets the general eligibility guidelines and receives any service from TBCSP is eligible for TennCare coverage for treatment services. The state waiver for this special Medicaid category was approved for implementation in July 2002.

Program Statistics:

Number served in FY 2001	1,069
Number Served in FY 2004	4,825
Number Served in FY 2007	13,762

Services Provided in FY 2007

Breast Screening	6,789	Breast Cancer Diagnosed	181 / 98 invasive
Cervical Screening	6,580	Cervical Cancer Diagnosed*	440 / 23 invasive
		(* CIN II or greater)	

September 2007

Appendix 3. Team-Up Tennessee Fact Sheet



Rural Outreach Makes a Difference: *Increasing Breast and Cervical Screening among Rural Appalachian Women*



Abstract

- ***Innovative partnership*** in 11 rural Appalachian counties results in an increase in the number of women seeking age appropriate breast and cervical cancer screenings.
- ***Target group:*** women aged 50 through 64 who were under or uninsured and had rarely or never been screened.
- ***Recognized barriers to screening:*** insurance, access to medical services, Appalachian culture, rurality, low income, lack of understanding about the importance of annual screenings, perceived level of risk for these cancers, and lack of knowledge about availability of screening services through the county health department.
- ***Pilot counties:*** Blount, Campbell, Carter, DeKalb, Fentress, Greene, Loudon, Overton, Scott, Smith and Warren.

Background

- ***State Partnership:*** Tennessee Breast and Cervical Screening Program (TBCSP), University of Tennessee (UT) Extension, American Cancer Society's (ACS) Mid-South Division, National Cancer Institute's (NCI) Mid-South Cancer Information Service and the Knoxville Affiliate of the Susan G. Komen for the Cure partnered in 2003 to address the higher than average mortality rates for breast and cervical cancer in 11 rural Appalachian counties.
- ***Part of a National Partnership*** created with ACS, Centers for Disease Control and Prevention, NCI, USDA and 8 states: Alabama, Georgia, Illinois, Kentucky, Mississippi, Missouri, South Carolina and Tennessee.
- ***County UT Extension educators*** skilled in outreach interventions and understanding of screening barriers unique to women in their respective counties.
- ***County health departments*** provide enrollment and screening to eligible women. Women referred for mammograms and Pap test follow-up if needed.

Methods

- Educational materials developed and/or identified.
- County UT Extension educators trained in basics of breast and cervical cancer, value of early screening for cancer and role/services of the TBCSP.
- County UT Extension educators facilitated county partnerships/coalitions with representatives from state partner organizations and community stakeholders.
- County partnerships used evidence-based outreach interventions or developed outreach interventions unique to reaching women in their respective counties.
- Seven counties advertised a "free" screening day.
 - Pelvic, Paps and clinical breast exams were provided to all.
 - Eligible women enrolled in the TBCSP were referred for mammograms.

- TBCSP screening data from 2003 was used for the baseline in each county along with control counties.
- Detailed information about screening and diagnostics were gathered from the data file of women enrolled in the TBCSP.
- Funding Sources: TBCSP, UT Extension, Susan G. Komen for the Cure, National Cancer Institute.

Results

- All counties experienced a significant increase in screening rates for women aged 50 through 64 as compared to control counties.
- Fourteen free screening days attracted women in the target group as well as women with insurance.
- In 2006, UT Extension educators with county partners conducted 283 educational programs/events reaching 2,850 women.
 - Outreach programs included Mother/Daughter Teas, Women's Teas, African American Church Service Programs, Women's Day Fairs, Church Delivered Educational Programs, Health Fairs
- In 2006, promotional strategies were used to reach women with messages about the benefits of breast and cervical cancer screening using exhibits (39), newspaper articles (39), radio programs (29) and TV programs (5).
 - 340,479 community contacts made

Discussion

- TEAM UP Tennessee reached the never and rarely screened woman.
- TEAM UP Tennessee interventions increased screening rates among the target audience - women aged 50 through 64.
- County partnerships do work in expanding outreach to rural Appalachian women with education and screening services.
- Combining the outreach capacity of UT Extension with the service delivery of TBCSP, rural Appalachian women are increasing their understanding about the need for screening and are seeking screening services in their communities.

Conclusion

- Women will seek breast and cervical cancer screening services if made convenient, culturally sensitive and with no additional cost to them.
- Women will seek screening services if they understand the benefits to their health.
- Interventions focusing on social and religious settings have allowed TEAM UP Tennessee to reach older women, African American women and Latino women in rural Appalachia.
- External funding is critical for program coordination, travel, and purchasing incentives and educational materials to attract community participation in education and screening events.

For Further Information, Contact TEAM UP Tennessee Steering Committee Co-Chairs:

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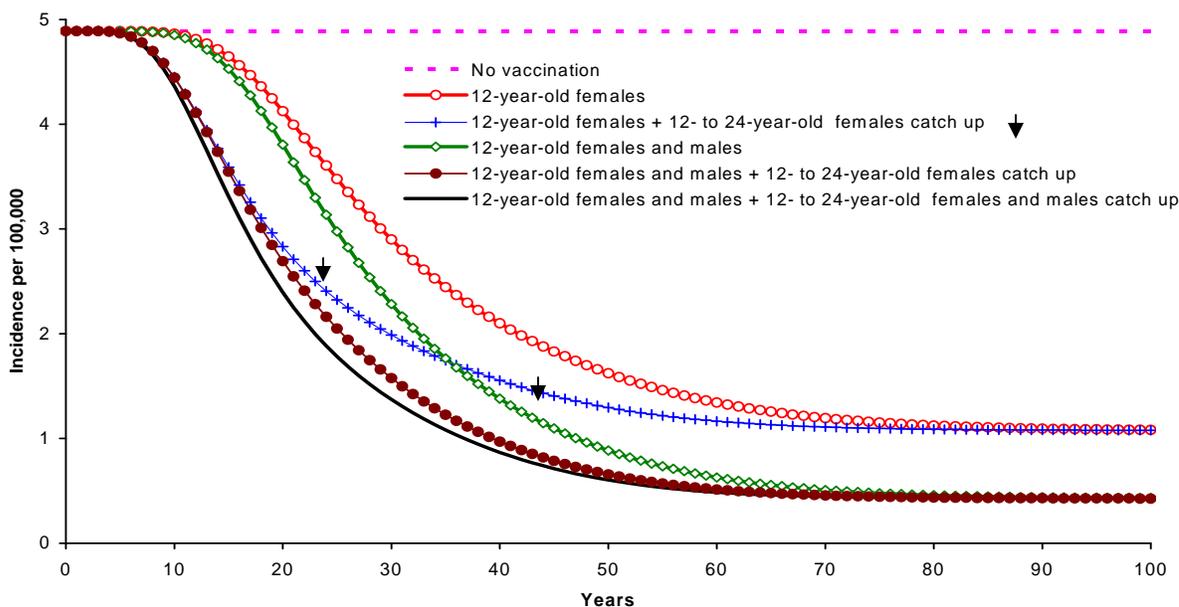
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Appendix 4. Projected Impact Of HPV Vaccination On Cervical Cancer Rates Over Time

From: Elbasha EH, Dasbach EJ, Insinga RP. Model for Assessing Human Papillomavirus Vaccination Strategies. *Emerg Infect Dis.* 2007 Jan;13(1):28-41.



This figure, published in the journal *Emerging Infectious Diseases* in 2007, shows the rates of new vaccine-preventable cervical cancer among girls and women over age 12, using several different kinds of national HPV immunization strategies.

The Centers for Disease Control and Prevention (CDC) currently recommends that all young women ages 11 through 26 years be vaccinated against HPV. This study estimated that, if 70% of young women ages 12 to 24 years were vaccinated (line marked with arrows), the number of women diagnosed with vaccine-preventable cervical cancer would begin to drop within 10 years and continue to drop to just over one case per 100,000 women. Because cervical cancer usually results from HPV infections that occurred years earlier, the vaccine must be in widespread use for several years before its impact on new cancer cases is seen.

Note: Although some options in the figure refer to the projected benefit of vaccinating young men, a decision by the Food and Drug Administration to license HPV vaccine for males is pending; it is licensed and recommended only for use in females at this time.

Appendix 5. Cervical Cancer Internet Resources

Organizational Recommendations

American Society for Colposcopy & Cervical Pathology

www.asccp.org

American College of Obstetrics & Gynecology

www.acog.org

Advisory Committee Immunization Practices (Centers for Disease Control and Prevention)

<http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>

American Academy of Family Physicians

www.aafp.org

General Information Resources

Prospects for cervical cancer prevention by HPV vaccination.

Abstract, Schiller JT, Lowy DR Cancer Res. 2006 Nov 1; 66 (21):10229-32.

<http://cancerres.aacrjournals.org/cgi/reprint/66/21/10229>

What Parents of Preteens/Adolescents Should Know About the HPV Vaccine

<http://www.cdc.gov/std/hpv/common-clinicians/InsertParents.pdf>

HPV Information for Clinicians, in English and Spanish

<http://www.cdc.gov/std/hpv/hpv-clinicians-brochure.htm>

What Women Should Know Before They Get a Pap and HPV Test

<http://www.cdc.gov/std/hpv/common-clinicians/InsertPap.pdf>

What Women with a Positive HPV Test Result Should Know

<http://www.cdc.gov/std/hpv/common-clinicians/InsertPos.pdf>

Women Reaching Out Against Cervical Cancer

www.wrocc.org

American Cancer Society

www.cancer.org

Merck, Manufacture of the HPV Vaccine

www.merckvaccines.com

National Cancer Institute

www.cancer.gov

Tennessee Comprehensive Cancer Control Program

www.health.state.tn.us/cccp/index.htm