

The North Carolina  
Cancer Control Plan  
2001-2006

# **The North Carolina Cancer Control Plan 2001-2006**

**June 2001**

**Advisory Committee on Cancer Coordination and Control**

# Dedication

*In memory of North Carolinians*

*who have died of cancer*

*and*

*in honor of those*

*who have survived cancer:*

*as a testimony to their courage*

*and as a commitment to*

*saving lives in North Carolina.*

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The work of the Advisory Committee is funded by the North Carolina General Assembly. The members of the Legislature have held a vision of cancer control for the citizens they represent as evidenced by many years of diverse funding for cancer control. Their aim in establishing the Advisory Committee was to provide coordination and direction for these many efforts through a single Plan for North Carolina. The creation of the Advisory Committee was the result of a joint proposal of the North Carolina Division of the American Cancer Society and the Cancer Committee of the North Carolina Medical Society.

The visionary behind this effort was Dr. John Kernodle of Burlington, who has promoted this effort tirelessly. As a pioneer in cervical cancer research and treatment, he clearly understood the potential for saving lives from cancer and the complexities involved. Dr. Kernodle served as Vice Chair of the Advisory Committee from 1993 until 1997.

The *North Carolina Cancer Control Plan 2001-2006*, as with the initial Plan, would not have been possible without the extraordinary generosity of the many, many consultants and reviewers who have assisted in its development. They provided us with a better understanding of cancer control issues and with a richer comprehension of North Carolina. Their names are listed in the section on which they worked. In addition, staff of the North Carolina Central Cancer Registry made a tremendous contribution in supplying and graphically presenting data. The American Cancer Society has provided printing support for the Plan.

The process of developing this Plan has drawn together many people and organizations to examine, very broadly and in a concerted fashion, the needs for cancer control in North Carolina. The process itself has already expanded the coordination among those who have come to offer their ideas and support. In addition, we would like to acknowledge the contributions of past Advisory Committee Members and Staff. We are grateful for the contributions of the following persons, whose names did not appear in the first or second Plan.

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This Cancer Control Plan provides a framework for action to reduce the burden of cancer in North Carolina. Its purpose is to provide statewide coordination for those cancer control and care efforts—voluntary, private, and public—that are ongoing or are needed in our state and that we know will work.

The North Carolina Advisory Committee on Cancer Coordination and Control, which was established by the General Assembly in 1993, is charged with recommending to the Secretary of Health and Human Services a coordinated, comprehensive cancer control plan for the state of North Carolina. The Committee's mission is to:

- ◆ *facilitate the reduction of cancer incidence and mortality in North Carolina and*
- ◆ *enhance access to quality treatment and support services*

through educating and advising government officials, public and private organizations, and the public.

The format of this second five-year Plan reflects the organizational structure of the Advisory Committee. Its sections address Prevention, Early Detection, Care, Evaluation, and Legislative and Education Issues, which are the responsibilities of each of the respective Subcommittees of the Advisory Committee. Each section describes the issues and provides background and information specific to North Carolina and then lists cancer control objectives and strategies selected for our state. Each of these sections was reviewed by North Carolina experts; they are listed at the beginning of each section. Thus the elements of this Plan reflect not only a scientific understanding of the issues but also an understanding of these issues from a North Carolina perspective. The Plan also includes a description of the burden of cancer on our citizens and of the evaluation process. The results of this evaluation will serve as the basis for the subsequent Plan.

This Plan has two key features. First, for each of the strategies, partner agencies have been sought. Confirmed partner agencies are listed in the Goals, Objectives, and Strategies portion of each section of the Plan. Second, ongoing evaluations and subsequent revisions are an integral component of the Plan. The objective is not simply to state worthwhile goals but

to assure that focused, concerted action is taken and real progress is made. The Plan is not a document to sit on a bookshelf; rather it should serve as a working and evolving guide to fostering, providing and coordinating essential cancer control efforts among as broad a group of institutions and agencies across North Carolina as possible.

North Carolina has long been in the forefront of cancer control. Over sixty years ago, the President of the North Carolina Medical Society appointed a committee to evaluate cancer in the state and to make recommendations for programs. This committee worked with the Women's Field Army (the forerunner of the American Cancer Society) in advocating for statewide action. Together they approached the General Assembly in 1945 and secured authorization for the Cancer Control Act to provide education about cancer, monies for diagnostic services, and funding for preventive cancer clinics across the state. This was the first such state program in the nation. A major component of the program has been the payment for both diagnostic and treatment services for financially indigent citizens.

Under the able leadership of Drs. Margaret Harker, Charles Spurr, Robert Cooper, Avery McMurry, and Lawrence Crawford, the North Carolina Medical Society Cancer Committee has played an important role in cancer control. For example, it was the primary lobbyist for the establishment of the North Carolina Central Cancer Registry, which collects vital incidence and mortality information on cancer among the state's citizens.

North Carolina has also been truly fortunate to have many excellent cancer treatment and research facilities. There are currently 23 community hospital-based cancer programs accredited by the American College of Surgeons. These programs assure multidisciplinary state-of-the-art care and access to clinical trials. The four medical schools in the state each have a cancer center. In addition, North Carolina is one of only two states in the nation with three National Cancer Institute-designated Comprehensive Cancer Centers. They are the Duke Comprehensive Cancer Center, the UNC-Lineberger Comprehensive Cancer Center, and the Comprehensive Cancer Center of Wake Forest University. Not only do these centers provide the most advanced care but also cancer control research activities, which go on across the state. Thus we have a wealth of information specific to North Carolina, and an extraordinary number of cancer

control experts leading a variety of cancer control projects, and sharing their experience and knowledge with local and state initiatives.

These assets, both human and informational, have served as the basis for a variety of collaborative cancer control efforts. Many of these efforts were undertaken during the early and mid-1990s. For example, researchers at East Carolina and UNC-Chapel Hill have worked with local health departments in five eastern counties to understand better how to increase breast cancer screening rates among older, African-American women. Duke University has collaborated with the State Division of Health Promotion's Office of Epidemiology to examine factors associated with late stage diagnosis of prostate cancer in North Carolina. The Comprehensive Cancer Center at Wake Forest University carried out a colon cancer screening project in partnership with Carolinas Medical Center. These and subsequent projects, and the knowledge and expertise they represent, have been of enormous benefit to the state.

Dozens of other organizations provide crucial efforts and energy for cancer control and for dissemination of these efforts across the state. For example, the School of Public Health at UNC-Chapel Hill has provided leadership and expertise for North Carolina cancer control efforts, especially in rural areas over the last decades. Professional cancer registrars work in hospitals across the state to collect and report incidence and treatment data. These data provide the basis for understanding the problems of cancer in North Carolina. The Breast Cancer Coalition of North Carolina, a grassroots organization, focuses on education and awareness about breast health, early detection, and treatment, as well as state and national policy issues. Efforts are currently underway to establish similar statewide coalitions for colorectal cancer and prostate cancer.

Twice in the late 1980s state leaders felt the need for a more systematic approach to cancer control. The first time was in response to the receipt of a data-based research award from the National Cancer Institute in 1987. One of the first states to receive such an award, North Carolina was empowered to develop and use state and local data to design and build local cancer control programs to match identified local needs. One outcome of the project was the realization that State public health agencies needed to work more closely with local and regional agencies and with health departments; similarly, local groups needed to work

more closely with each other in sharing knowledge, experience and materials.

The second element was the desire to tackle the high rates of cervical cancer, an essentially preventable disease, in this state. At the time, North Carolina ranked fourth worst in the country for deaths of African American women from this cancer and tenth for deaths of white women. Dr. John Kernodle and the North Carolina Division of Adult Health Promotion received funding in 1990 from the Kate B. Reynolds Health Care Trust to underwrite the activities of a Cervical Cancer Task Force, which produced a report in 1992. Perhaps most important among the Task Force's nine recommendations was the determination that cancer control efforts in North Carolina require coordination and oversight at the state level. The final recommendation of the task force thus suggested that a committee be instituted within state government to coordinate cancer control efforts and to oversee implementation of the Task Force's recommendations.

In September 1992, Senator George Daniel and the late Representative Nick Jeralds requested that the General Assembly establish a study commission on cancer. Within a year, the study commission proposed the establishment of a statewide cancer coordinating and control body. The establishment of this Advisory Committee by the General Assembly in 1993 (G.S. 130A-33.50) was an indication of the Legislature's commitment to reducing deaths and the cost of cancer in North Carolina. The Advisory Committee's first cancer control plan, the North Carolina Cancer Control Plan 1996-2001, was presented to the General Assembly in 1996.

The North Carolina Cancer Control Plan 1996-2001 served both as an invaluable model and a primary impetus for development of this second Cancer Control Plan for North Carolina. Development and implementation of the North Carolina Cancer Control Plan 1996-2001 was made possible by the leadership of Jonathan B. Howes, Joseph S. Pagano, M.D., and Marion S. White, M.S.P.H. Mr. Howes served as Chair of the Advisory Committee from 1993 until 1997. Dr. Pagano began serving as an Advisory Committee Member in 1993 and began his tenure as Chair in 1997. Dr. Pagano continues to lead the Advisory Committee. Ms. White served as Executive Director from 1993 until 2000. Under their stewardship, and through the efforts and activities of many community partners and agencies, tremendous strides have been made in bringing effective, coordinated cancer control efforts

to fruition.

Highlights of the many strategies carried out within each major area of the first Cancer Control Plan — Prevention, Early Detection, and Care— are enumerated in the introductions to those sections. As of April 2000, 76% of the strategies in the North Carolina Cancer Control Plan 1996-2001 have been implemented. This second Plan will go to press prior to the end of the five-year period.

This second cancer control plan for North Carolina is the work of the members of the Advisory Committee, of the more than 150 experts, consultants, and volunteers, and of the staff of the Committee and Subcommittees. Data have been examined, resources reviewed, experts have been interviewed and special studies have been undertaken. Cancer sites and topics were chosen based on identified needs and the ability to address those needs. Objectives and strategies in the Plan are based on research knowledge, and implementation of strategies in all Plan areas will employ research syntheses to identify successful, existing evidence-based programs.

The Centers for Disease Control and Prevention, Division of Cancer Prevention and Control defines ‘comprehensive cancer control’ as “an integrated and coordinated approach to reduce cancer incidence, morbidity, and mortality through prevention, early detection, treatment, rehabilitation, and palliation,” with the overarching goal of “maximizing categorical resources through improved coordination and integrated program planning.”<sup>1</sup> This guiding vision has provided the conceptual framework for both editions of the North Carolina Cancer Control Plan. The CDC Division of Cancer Prevention and Control has provided substantial and ongoing support for Plan strategies since 1990. That support has been crucial in allowing the Advisory Committee to integrate and coordinate statewide cancer control efforts.

The American Cancer Society, a partner of the Advisory Committee since its inception, has provided ongoing consultation for the formulation of Plan strategies. For the many strategies in this Cancer Control Plan that are consistent with the American Cancer Society, Southeast Division’s plans for activities and outcomes, the American Cancer Society has agreed to serve as a supporting partner organization.

Many of the objectives specified in Healthy Carolinians 2010<sup>2</sup> are also pertinent to cancer control. For example, particular Healthy Carolinians 2010 objectives are devoted to promoting proper nutrition and

physical activity and to reducing tobacco use among North Carolinians, all of which are priorities in this Cancer Control Plan. Healthy Carolinians 2010 objectives have also been set for improving screening rates for colorectal cancer, breast cancer, and cervical cancer, with accompanying objectives for reducing the death rates for these cancers. A listing of the Healthy Carolinians 2010 objectives that coincide with the cancer control efforts outlined in this Plan are shown in the Appendix.

Over the next five years, the Plan will be reviewed, evaluated and updated and additional studies will be conducted, to assure the best possible cancer control efforts for North Carolina. A subsequent Plan will be developed for the years 2006-2011. That Plan will include reports on and evaluation of the progress and results of each of the elements of this Plan. The creation and development of additional sources of data will be needed for successful completion of the evaluation process.

1. Abed J, Reilly B, Butler MO, Kean T, Wong F, Holman K. Comprehensive cancer control initiative of the Centers for Disease Control and Prevention: an example of participatory innovation diffusion. *Journal of Public Health Management Practice* 2000;6:79-92.
2. North Carolina Office of Healthy Carolinians, Division of Public Health, Department of Health and Human Services. *Healthy Carolinians 2010: North Carolina’s Plan for Health and Safety. Report of the Governor’s Task Force for Healthy Carolinians*. 2000.



Cancer is a devastating and increasing disease—one in every two men and one in every three women in North Carolina will be diagnosed with cancer during their life. The impact on cancer patients, on their families, and on their communities is already immeasurable. In 2000, total deaths in this state from just four cancers—lung, breast, colorectal, and prostate will number about 24,000.<sup>1</sup> The economic costs of cancer in North Carolina are estimated at \$2.9 billion annually;<sup>2</sup> the psychological and social costs are staggering.

The burden of cancer in North Carolina can be dramatically reduced if proven advances in prevention, early detection, and care are made available. Thus the goal of this Plan is to coordinate and advance specific, proven cancer control strategies across the state, by educating the public and health professionals while simultaneously increasing quality and access to care in the following areas:

## **Preventing Cancer**

Approximately 50 to 80 percent of all newly diagnosed cancers are related to personal lifestyles and behaviors. These include inadequate diet, physical inactivity, smoking and excessive exposure to ultraviolet light. For example, effective education that leads to reduction in ultraviolet exposure early in life could significantly reduce the later occurrence of malignant melanoma, the fastest increasing type of cancer.

## **Detecting Early Cancers**

Early detection programs are critical for those cancers for which a screening test exists that is proven to reduce mortality rates. Optimal colorectal cancer screening, for example, could save 550- 650 lives each year in North Carolina.\*<sup>1</sup>

\*based on an estimated mortality reduction of .35 applied to projected deaths, 2000 and 2001.

## **Caring Better for Those with Cancer**

Central to effective treatment is assuring that accessible, affordable, state-of-the-art care is available. Education about and access to new advances in pain control, for example, would have a profound effect on the productivity and quality of life of persons living with cancer who experience pain.

## **Legislative Support**

In each of these areas there will be a need for policy and funding support from the General Assembly.

For each area above, very specific goals, objectives, and strategies are enumerated in this Plan. Key are the 82 public, private, and voluntary agencies and organizations that volunteered to partner in the implementation of one or more strategies. These Plan partners will assist the Advisory Committee in creating new linkages, identifying needed resources, and building enthusiastic support for successful implementation of all Plan strategies. With the help of these organizations and the supportive efforts of the General Assembly, this Plan will serve as a guide to decreasing the substantial burden of cancer in North Carolina.

## **References**

1. North Carolina Central Cancer Registry, data projections.
2. American Cancer Society and North Carolina Division of Public Health. North Carolina Cancer Facts and Figures, 1997.
3. Mandel JS, Bond JH, Church TR, Snover DC, Bradley GM, Schuman LM, Ederer F. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. New England Journal of Medicine 1993;328:1365-7

Cancer is an increasingly common diagnosis and cause of death in North Carolina and the nation. If current trends continue, four out of every ten North Carolinians will be diagnosed with a cancer at some time in their lives. Currently, cancer is the second-ranking cause of death for North Carolinians, following heart disease.<sup>1</sup> If current trends continue, cancer may soon overtake heart disease as the primary cause of death. This is partly due to an aging population and partly to the decrease in deaths from other causes, such as heart disease and stroke. It is also, however, partly due to a variety of factors that can be modified. These include cancer-related risk factors such as poor diet, excessive sun exposure, physical inactivity, and tobacco use. Additional factors such as whether a person undergoes regular cancer screening also influence the outcomes and associated mortality rates of cancer diagnoses.

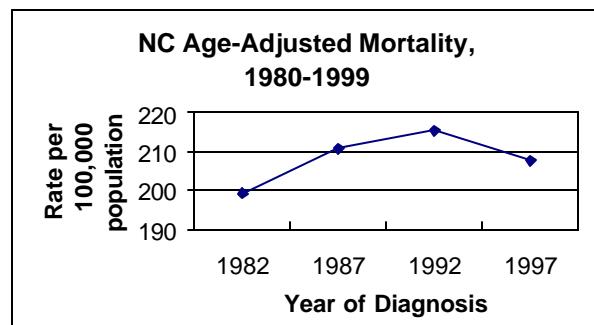
## Mortality

Over 15,000 North Carolinians die from cancer each year, an average of 41 each day. North Carolina's cancer mortality rate rose between 1980 and 1992, but between 1992 and 1999 a reversal has been observed \*<sup>2</sup> (*Figure 1*). Nationally, the trend toward increasing overall cancer death rates began to slow in the mid-1980s and subsequently reversed to a decline after 1991, with a more rapid decline after 1995.<sup>3</sup> Although these recent declines in overall cancer death rates are encouraging, for certain subgroups, death rates are rising. For example, lung cancer mortality in North Carolina is falling among men but rising among women, consistent with the more recent increase in smoking among women. There are also differences by race; for example, breast cancer mortality is rising among African American women, yet falling among white women, and the magnitude of the disparity is increasing (See *Racial, Ethnic, and Socioeconomic Disparities*, below).

Certain groups in North Carolina bear a higher overall burden in cancer mortality. The cervical cancer death rate among African American women is two and one-half times that of white women in the state.<sup>4</sup> The death rate for colorectal cancer is substantially higher among men than among women.<sup>5</sup>

\*Rates are age, race, and sex-adjusted to the 2000 U.S. population

Figure1.



Source: North Carolina Central Cancer Registry

## Incidence

Each year over 32,000 North Carolinians are diagnosed with cancer, an average of 125 each working day. This figure of 32,000 equals twice the population of Alexander County. North Carolina's overall age-adjusted rates for new cases in 1998 were 500.6 per 100,000 men and 382.2 per 100,000 women.<sup>6</sup> Age-adjusted incidence rates in North Carolina rose during the 1990s.

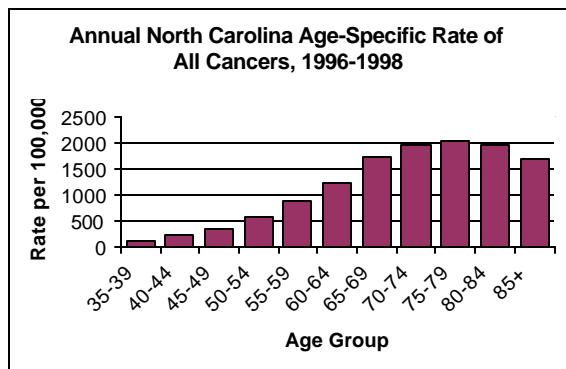
An even more dramatic increase in North Carolina's cancer incidence rates during the 1990s is apparent when rates are unadjusted for age. One reason for this increase is that cancer incidence rates increase with age (*Figure 2*) and the population is aging in North Carolina (*Figure 3*). The median age in North Carolina rose from 26.5 years in 1970 to 33.0 years in 1990, and reached 35.5 years in 1999.<sup>7</sup> A projected one-fourth of North Carolina's population will be age 65 and over by the year 2008,<sup>8</sup> reflecting both the aging of the "baby boomers" and a large influx of retirees. Because incidence rates unadjusted for age reflect the increase in cases that results from the aging of the North Carolina population, they reveal the true magnitude of the increase in the cancer burden for the state. As the proportion of the population most at risk for cancer continues to increase in North Carolina, the impact of cancer, if unmitigated, will become even greater.

Within the state there are differences in the incidence of cancer: colon cancer incidence rates, for example, are higher among men than women.<sup>9</sup> African American women are at greater risk for developing cervical cancer than white women.<sup>9</sup>

Overall cancer incidence in the nation increased slightly between 1973 and 1983, increased steadily between 1983 and 1992, and decreased steadily at a

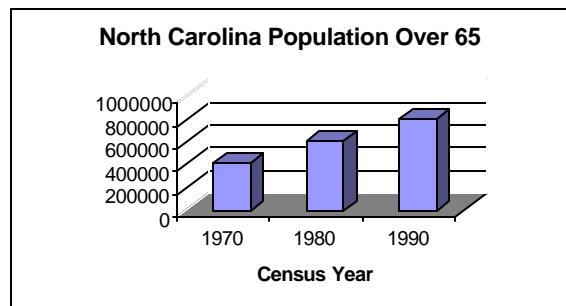
rate of -1.3% per year between 1992 and 1997.<sup>3</sup> Currently, national rates that are comparable to the North Carolina rates are not available, due to differences in the base population used for statistical calculations of rates.

Figure 2.



Source: North Carolina Central Cancer Registry

Figure 3.



Source: U.S. Bureau of the Census

## Prevalence

Over 95,000 North Carolinians are alive with cancer<sup>10</sup>—evidence of the effect of successful treatment at the state's cancer centers. Of all those diagnosed today with cancer, more than 60% will live five years or longer.<sup>11</sup> There are major differences in survival among cancer sites, however. For example, only 14 percent of lung cancer patients can be expected to survive five years, while 93 percent of prostate cancer patients live five years.<sup>12</sup> In addition, not all citizens have equal access to state-of-the-art care. Among the perceived barriers to access are a lack of understanding of combination therapies, the distance required to travel to appropriate health care, insurance coverage, and the cost of care.

## Racial, Ethnic, and Socioeconomic Disparities

The persistent disparities in health status and disease burden among different racial, ethnic, and socioeconomic groups represents one of the most important areas of public health research and practice today. Such disparities are evident for a wide range of health conditions, including cardiovascular disease, diabetes, and many types of cancer.<sup>13</sup> The agenda for the public health and medical community is to understand and address the underlying causes of health disparities. The relative roles and interplay of health behaviors, environmental and social conditions, cultural factors, and treatment variables are being studied intensively. Also critical is knowledge of the types of interventions that will be most effective for eliminating socioeconomic, racial and ethnic disparities in health.

The North Carolina Office of Minority Health has revealed major contributors to the disparity in cancer care for minorities in our state. Lifestyle/behavioral contributors such as high fat and poorly balanced diet, lack of exercise, smoking and other tobacco use, and alcohol and other drug use are shared with the non-minority population. Access issues are related to poverty, lack of insurance or comprehensive coverage if insured, affordability of cancer screening and treatment, lack of awareness of available cancer care, history of distrust of the health care system, and lack of transportation. These issues are further complicated by factors faced by minorities daily such as racism, stress, cultural beliefs and practices, and environmental hazards in our communities and workplaces.<sup>14</sup>

## Example: Colorectal Cancer

During the period 1993-1997, the incidence of colorectal cancer for African American women in North Carolina was 26% higher than that for white women, and the mortality rate for African American women was 63% higher.<sup>15</sup> While African American and white men had similar incidence of colorectal cancer, African American men had a 34% higher mortality rate.<sup>15</sup> Data are age-adjusted to the 1970 U.S. Census. Behaviors that have been found to lower the risk for colorectal cancer include consumption of five or more servings of fruits and vegetables per day, regular exercise, regular aspirin intake, and use of estrogen replacement therapy. Data from the

Behavioral Risk Factor Surveillance System, an annual, statewide telephone survey of adults in North Carolina, show that these four protective behaviors were reported less often among African American North Carolinians than among whites, and the likelihood of practicing these behaviors declined with education and income (with the exception of regular aspirin intake).<sup>16</sup>

Whether the observed differences in preventive behaviors are large enough to explain the entire racial difference in colorectal cancer incidence is unclear.<sup>16</sup> There were no racial differences in reported screening behaviors, although the only screening data available were from 1997-1999, after the incidence and mortality data were collected. The excess mortality for African American females and males could be attributable to advanced stage at diagnosis, highly aggressive tumors, or sub-optimal treatment and follow-up. African Americans are more likely to be diagnosed with later-stage disease, which may explain some of the increased mortality. However, there do not appear to be racial differences in tumor biology that would explain the increased mortality among African Americans. Data on treatment for colorectal cancer in North Carolina are not available.<sup>16</sup>

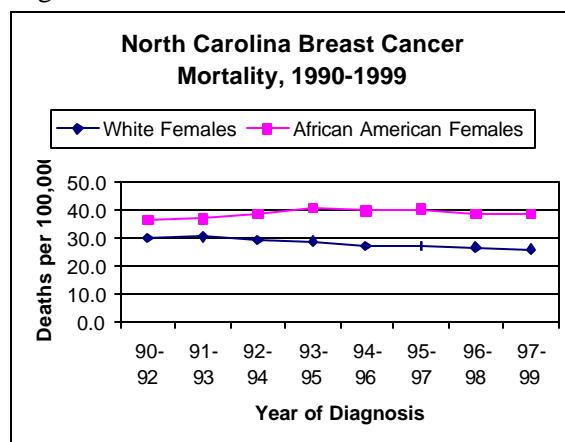
Nationally, during the period 1993-1997, the colorectal cancer mortality rate for African American women was 42% higher than that for white women. The disparity between African American men and white men during this period (34%) was similar to the disparity in North Carolina.<sup>16</sup> Data are from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) system and are age-adjusted to the 1970 U.S. Census.

### **Example: Breast Cancer**

The disparity in breast cancer mortality between African American women and white women widened throughout the 1990s in North Carolina (*Figure 4*). During the period from 1990-1992, the mortality rate for white women was 29.9 per 100,000, whereas for African American women it was 36.3 per 100,000. During the period from 1993-1995, the mortality rate for white women had dropped to 28.6 per 100,000; for African American women, the mortality rate had risen to 40.5 per 100,000. By 1997-1999, the rate for white women had decreased further, to 26.0 per 100,000; the rate for African American women had dropped only slightly, to 38.8 per 100,000.<sup>17</sup>

A racial disparity for breast cancer also exists on a national level and has received widespread attention from researchers. Data show that African American women frequently are diagnosed with later-stage breast cancer than white women.<sup>18,19</sup> Racial differences in stage at diagnosis have been found to contribute substantially to the disparity in mortality.<sup>20</sup> However, stage at diagnosis does not fully explain the racial disparity in mortality, nor does socioeconomic status; race has been found to predict breast cancer survival independent of the effects of age, income, marital status, stage at diagnosis, hormone receptor status, tumor histology, and menopausal status.<sup>18,19</sup> While multiple factors may influence the racial disparity in breast cancer mortality, it is clear that interventions to increase screening of African American women are essential so that one of the known contributing factors—stage at diagnosis—can be improved.

Figure 4.



Source: North Carolina Central Cancer Registry

### **Example: Lung Cancer**

A recent national study identified a racial disparity in treatment for non-small-cell lung cancer. African American patients were less likely than white patients to receive surgical resection, which is the recommended treatment. African American patients in the study also had lower five-year survival rates than whites. The authors attributed the lower survival rates of African Americans compared with whites to the disparity in treatment, since many variables that could influence treatment received or five-year survival were controlled for in the study. These

controlled variables were disease stage, type of insurance coverage, availability of care, socioeconomic status, age, and coexisting illnesses. Further, a possible difference in response to surgical resection did not explain the racial disparity in five-year survival rates; survival was similar for African American patients and white patients who received surgical resection. Survival was also similar for African American patients and white patients who did not receive surgical resection.<sup>21</sup> It is critical that these and other findings showing racial or ethnic disparities in care lead to careful consideration of, and attention to, the reasons for the disparity.

## **Biological Hypotheses of Racial Disparities in Health**

In 1997, the President's Cancer Panel of the National Cancer Institute reviewed research discounting the assertion, prevalent throughout U.S. history, that there is a biological basis for race. According to data presented by the Panel, 85% of all variation in gene frequencies occurs within populations (races), and the other 15% occurs between populations. The significance of this finding, as noted by the Panel's report, is that "race" (is) a social construct, rather than a biologic phenomenon that is linked to specific outcomes." The Panel concludes, "races, in the sense of genetically homogeneous populations, do not exist in the human species today, nor is there any evidence that they have ever existed in the past."<sup>22</sup>

Nevertheless, according to the Panel, "social constructions of race can and do lead to biologic differences in health," through their impact on factors including access to appropriate health care, safe employment, higher wage occupations, and healthy neighborhoods. The Panel recommends investigation of the question of whether disease disparities are mediated by biological effects of racial oppression and discrimination.<sup>22</sup>

Throughout this Cancer Control Plan, data on racial, ethnic, and socioeconomic disparities in preventive behaviors, screening, and care will be included whenever possible. It is imperative that the public health and medical community continue to study and address the reasons for racial, ethnic and socioeconomic disparities in health. Data for Hispanic and Latino persons, Asian Americans, and Native Americans are greatly needed. Programs aimed at investigating and eliminating disparities will receive

high priority in this Plan.

## **Cost**

The economic impact of cancer in North Carolina is enormous, estimated to be approximately 2.9 billion dollars per year: \$1.0 billion for medical care; \$362 million in lost productivity from those who become ill; and \$1.64 billion for future productivity losses from those who will die prematurely.<sup>23</sup>

Economic costs are only one component of the harm that befalls families when struck by this illness. These cancers also have enormous social and emotional consequences for the citizens of North Carolina. The implications for the patients, their families, friends, and communities include pain, suffering, disability and deaths, and hundreds of thousands of years of life lost prematurely. In addition to the millions of dollars lost because of illness and death, enormous numbers of human and financial resources are devoted to detection, diagnosis, and treatment.

## **Reducing the Burden**

The goal of cancer control and of this Plan is to reduce this burden. Many cases of cancer can be prevented. It is incumbent on us to provide North Carolinians with the information they need to avoid risky behaviors that increase their chances of developing cancer. Other cancers can be detected early and ameliorated, controlled, or cured. Data about these kinds of cancer and the potential to survive them once detected must be disseminated broadly. Access to high-quality screening and to state-of-the-art treatment must be available. Finally, even for cancers for which cure is impossible and from which mortality is certain, there are life-prolonging, life-enhancing, and pain-control measures to which our citizens deserve access. These are the aims of this Cancer Control Plan and they will, once achieved, reduce the burden of cancer in North Carolina.

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## **Emerging Science and Technologies**

### **Impact of Genetic Testing on Cancer Prevention and Care**

The field of genetics is having a growing impact on both the prevention and the care of cancer. The ability of genetic testing to yield greater information regarding personal risk for cancer and rapid developments taking place in the study of clinical applications of genetics for cancer care represent important areas for researchers, health care providers, and policymakers to monitor, both nationally and in North Carolina.

With regard to cancer risk, evidence to date has identified a role for genetic mutations in cancers of the breast, ovary, and colon/rectum. Although the contribution of genetic factors to population risk for cancer is thought to be relatively small when compared with behavioral and environmental factors, lifetime risk is high for those individuals who carry the relevant genetic mutations. For example, lifetime risk of breast cancer is estimated to be 85% by age 70 for those with the BRCA1 mutation, and breast cancer risk is similar for the BRCA2 mutation.<sup>1</sup>

The ability to identify genetic risk factors for particular cancer types has brought increasing attention to the clinical, ethical, and legal issues surrounding genetic testing. Increasing numbers of people are opting to undergo genetic testing to learn whether cancer-predisposing genetic mutations are present. A positive test for a cancer-predisposing genetic mutation brings with it decisions concerning whether to take preventive measures to lessen risk, such as prophylactic breast removal, prophylactic ovary removal, or long-term administration of chemopreventive agents. Significant ethical and legal issues include considerations of privacy and of discrimination in insurance and employment.

Many recent advances in cancer treatment can be attributed to both an improved knowledge of cancer pathogenesis and to technical breakthroughs in scientific disciplines, such as genetics, that have recently become more closely integrated with cancer treatment. The recognition that some individuals are predisposed to cancer offers opportunities to better understand the basic etiology of malignancy. Although to date genetics has served as an adjunct contributor rather than a primary approach to clinical care and treatment of cancer patients, genetics is poised to take on new roles in cancer care. For example, with gene

therapy, we are beginning to explore a new generation of cancer treatments. In ten years, there have been over 400 approved gene therapy clinical trials in the United States, involving more than 4000 participants.<sup>2</sup> These trials have sought new treatment alternatives for a variety of diseases. Of these trials, more than 60% have focused on cancer treatment. Gene therapy clinical trials have been conducted or are underway for cancers of the bladder, breast, colon, ovary, prostate, renal cell, glioblastoma multiforme, Hodgkin's and non-Hodgkin's lymphoma, melanoma, mesothelioma, neuroblastoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck, acute myelogenous leukemia, and chronic myelogenous leukemia.<sup>2</sup>

For a full discussion of developments and issues related to genetic testing in the contexts of cancer prevention and cancer care, refer to the *Prevention-Genetic Testing and Care-The Role of Genetics in Cancer Care* sections.

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# I. Prevention

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The goal of cancer prevention is to reduce the incidence of cancer. Not all cancers can be prevented given current knowledge, but over 80 percent of cancers may be preventable.<sup>1</sup> If these cancers were prevented, the average American would gain 2 ½ years of life expectancy or, stated another way, one fourth of Americans would live 10 years or longer.<sup>2</sup> Important gains in quality of life would also be achieved.

The effects of cancer can be overwhelming in terms of premature mortality, direct financial costs, loss of income, psychosocial costs, and decreased quality of life. The societal burden is enormous. The National Cancer Institute estimates overall costs for cancer in the year 2000 at \$180.2 billion, with \$60 billion for direct medical costs, \$15 billion for indirect morbidity costs (cost of lost productivity due to illness), and \$105.2 billion for indirect mortality costs (cost of lost productivity due to premature death).<sup>3</sup> In North Carolina, it has been estimated that the cost of cancer exceeds \$2.9 billion per year.<sup>4</sup>

Cancer is believed to be the final outcome of a series of genetic events with biological consequences that occur in steps over time, moving from a precancerous stage to fully developed invasive cancer.<sup>5</sup> The final outcome, invasive cancer, may be prevented at several earlier points, especially the precancerous stage, by modifying risk factors so that the start or progression of the disease is prevented.<sup>6</sup>

The mission of the Prevention Subcommittee is to identify gaps in present activities and develop strategies to improve cancer prevention.

## Risk Factors

A large percentage of the estimated 32,500 cancers diagnosed in North Carolina in 1998<sup>7</sup> may have been preventable, some through health-promoting lifestyle choices and others through systematic control of environmental carcinogens and societal/cultural risk factors. Epidemiologic studies of human populations have provided important information on the relation between specific cancers and identifiable risk factors.

Modifiable risk factors include elements of diet (food consumption, excess weight), physical activity, ultraviolet radiation exposure, tobacco use, and

exposure to occupational and environmental chemicals.<sup>8</sup> Dietary factors are estimated to contribute to 35 percent of cancer deaths, with an additional 30 percent caused by smoking, 10 percent by occupational exposure to carcinogens, and 7 percent by reproductive and sexual behaviors (see *Figure 1*).<sup>9,10</sup>

**High dietary fat intake** may be associated with cancers of the colon, rectum, breast, and prostate.<sup>11</sup> In addition, animal model and epidemiologic studies suggest that other carcinogens in food contribute to cancer in humans. These include benzo-a-pyrene and related compounds in smoke-cured foods, nitrates and nitrites in preserved foods, and naturally-occurring carcinogens such as aflatoxins produced by fungi.<sup>11</sup> On the other hand, the human diet also contains a number of naturally-occurring substances that may inhibit the induction of cancer in laboratory animals. These include Vitamin C, Vitamin E, selenium, and tocopherols.<sup>12,13</sup> The anti-carcinogenic effects of these compounds in humans are currently being examined, but the results will not be available for a number of years.

**Physical inactivity** is associated with increased risk for colon cancer. One study has estimated that 20 percent of colon cancer can be attributed to lack of physical activity.<sup>14</sup> Engaging in regular, sustained levels of physical activity as an adult could possibly reduce the risk of cancer of the colon by as much as 50 percent.<sup>15,16</sup> There is also epidemiologic evidence of a protective relationship between physical activity and breast cancer risk,<sup>15,17</sup> although the findings of those studies are not as conclusive as those focused on colon cancer. The level of activity needed to reduce breast cancer risk is still unclear, as is the period in life when physical activity is most important for reducing risk. Current epidemiological evidence suggests a possible relationship between physical activity and prostate cancer risk as well.<sup>15,16,18</sup>

**Skin cancers** are the most common cancers in the United States today, with one in six persons estimated to develop some type of skin cancer in their lifetime.<sup>19</sup> Approximately 80 percent of all skin cancers are preventable.<sup>20</sup> Exposure to ultraviolet radiation

through excessive exposure to the sun or man-made sources (e.g. tanning machines) is the major modifiable risk factor for melanoma, the deadliest form of skin cancer.<sup>20</sup>

**Tobacco use** is unquestionably the single most preventable cause of death in North Carolina and the United States.<sup>21</sup> Nearly 96 percent of lung cancer among men and 92 percent among women in the US was attributed to active smoking, making men 23.2 times and women 12.8 times more likely to die of lung cancer than nonsmokers.<sup>22</sup> About three-quarters of oral cancers are attributed to tobacco use, either smoked or smokeless.<sup>35</sup>

Environmental tobacco smoke is a human lung carcinogen responsible for more than 40, 000 deaths nationwide.<sup>23</sup> This is an especially important health issue since these cancers occur in people who presumably do not choose to engage in this risk-taking behavior. Environmental tobacco smoke has significant adverse health consequences on the respiratory system of children and nonsmokers.<sup>24</sup> In addition, cigarette smoke is associated with significantly increased risk of heart and lung disease and stroke.<sup>21</sup>

**Environmental and/or occupational exposures** to human carcinogens (ie., some metals, solvents, dyes, asbestos, organic and inorganic dusts, and some pesticides) have been shown to cause a small proportion of cancers. There continues to be debate about which exposures cause cancer. A number of chemicals encountered in worksites, some physical agents such as asbestos, and some production processes have been causally linked to an increased incidence of specific cancers in workers.<sup>25</sup> Most chemicals encountered in the American worksite have not been evaluated, however, and the risk of cancer from them is not known.<sup>26</sup>

While there is consensus that radon is a lung carcinogen, the degree of risk posed by chronic exposure to low levels is still being debated.<sup>27</sup> Epidemiologic evidence indicates that radon exposure substantially increases the risk of lung cancer in smokers.

The World Health Organization reported in 1994 that the potential risks associated with exposure to electromagnetic fields or water chlorination by-products (e.g. trihalomethanes) were inconclusive at that time.<sup>27</sup> Uncertainty regarding these risks remains in 2001 (personal communication, Dr. Philip Singer, UNC School of Public Health, March 7, 2001; personal

communication, Dr. David Savitz, UNC School of Public Health, March 7, 2001).

**Chemoprevention** and **genetic testing** are emerging arenas for cancer prevention. Evidence to date has identified a role for genetic mutations in cancers of the breast, ovary, and colon/rectum. A positive test for a cancer-predisposing gene brings with it decisions concerning whether to take preventive measures to lessen risk. For example, some women who test positive for the cancer-predisposing genes BRCA1 or BRCA2 have chosen to undergo prophylactic breast removal or prophylactic ovary removal. Possible agents for chemoprevention, the use of natural or synthetic agents that will prevent, halt, or reverse the development or progression of cancers, are being studied intensively.<sup>28</sup> Basic research on the cellular and molecular mechanisms of carcinogenesis and the genetics of cancer is underway and will provide additional strategies for cancer prevention in the future.<sup>29</sup> Advances in understanding the genetic contribution to cancer susceptibility will lead to more precise targeting of prevention activities to high-risk populations or individuals.

## Prevention Potential

Epidemiologic evidence on the primary causes of two cancers is irrefutable: smoking causes lung cancer and oral cancer, and exposure to ultraviolet radiation causes skin cancer. Since there is consensus about the causes of these cancers, there have been significant research and educational efforts focused on how to prevent them.

There are many examples of successful education and behavior change programs implemented throughout North Carolina at local health departments, cancer centers, community health centers, in communities, and within health systems, such as health maintenance organizations. These programs, funded with a combination of local, state, and federal funds, make an important contribution to cancer control in the state.

## North Carolina Cancer Control Plan 1996-2001

Implementation of the strategies in the first edition of this Plan, the *North Carolina Cancer Control Plan 1996-2001*, has also contributed significantly to the efforts in the state to prevent cancer. These projects, carried out by the North Carolina Advisory Committee

on Cancer Coordination and Control in concert with its many partners statewide, have sought to reduce known risk factors for cancer, using strategies supported by research knowledge.

**Diet:** The National 5 A day for Better Health Program approaches Americans with a simple, positive message to eat 5 or more servings of vegetables and fruits daily for better health. As a participant in the program, between 1997 and 2000 North Carolina implemented a multifaceted campaign designed to meet the objectives set by the national program. A recent report to the NCI Board of Scientific Advisors by the 5 A Day Evaluation Group concluded that continuation of the program is warranted based on additional evidence of the benefits of a diet rich in fruits and vegetables for reducing cancer risk.

**Ultraviolet Radiation Exposure:** To aid in the completion of the ultraviolet radiation protection strategies outlined in the *North Carolina Cancer Control Plan 2001-2006*, a UV Radiation Protection Partners Workgroup was established in 1997. This group is composed of dermatologists, educators, and representatives from various state agencies, park and recreation professionals, and skin cancer survivors. Since its formation, the workgroup has provided minigrants to 29 local health departments to hold skin cancer screenings and outreach in their communities, collaborated with the North Carolina Daycare Association and other partner organizations to develop and distribute skin cancer prevention and education materials to day care workers, and joined with the North Carolina Division of Radiation Protection to commission a study of tanning facility use. In 1999, the Workgroup spearheaded the Shade Project, which raises awareness of skin cancer protective behaviors through community-wide plantings of tree seedlings coupled with skin cancer prevention education.

**Tobacco Use:** The Environmental Tobacco Smoke (ETS) Education and Mobilization Project is one example of the successful tobacco control initiatives that have been implemented during the last five years. The project included a statewide assessment of public attitudes and policies on ETS exposure in enclosed public places and dissemination of the survey findings to the owners/managers of all North Carolina enclosed malls and bowling alleys as a way to promote education and awareness. The development of stronger, statewide coalitions for ETS protection for smoke-sensitive adults and children is another highlight of tobacco control efforts. Partnerships

between the North Carolina Tobacco Prevention and Control Branch and North Carolina youth have resulted in remarkable progress in achieving 100% tobacco free schools in the state.

The strategies outlined in this second edition of the *North Carolina Cancer Control Plan* are designed to build upon the accomplishments of the last five years. Physical activity, chemoprevention, and genetic testing represent new arenas of effort and inquiry for the Prevention Subcommittee of the North Carolina Advisory Committee on Cancer Coordination and Control.

With recent advances in molecular biology and molecular epidemiology, it is reasonable to anticipate the identification of an array of new biomarkers for cancer that are both sensitive and specific. Biomarkers that identify genetic and host susceptibility, tissue levels of metabolic products of carcinogens, and/or sequential events in the carcinogenic process hold great promise for the prevention and early detection of cancer.<sup>30</sup>

As these avenues of cancer prevention develop, their findings will be incorporated into future Cancer Control Plans for North Carolina.

## Barriers to Preventing Cancer

Although gains in cancer control have been made through both basic and applied community interventions in recent decades, there are a number of problems inherent in changing cancer-promoting behaviors. Reducing tobacco use, for example, is very difficult. Tobacco is a legal product, youth are vulnerable to advertising, tobacco is addictive to users, and its use is reinforced by many social and economic supports in today's society. Likewise, altering diets and physical activity levels to reduce the risk of cancer not only involves personal motivation to eat wisely, exercise, and maintain appropriate weight, but also requires fundamental changes in the food industry and in individual choices and entrenched cultural preferences.

Related social issues in the prevention of cancer that are difficult to change are poverty and inadequate access to health-related knowledge and medical care. One study found that for all cancer sites combined, cancer incidence was higher in less-educated and low-income groups.<sup>31</sup> Education and income influence, in some cases, knowledge of preventive behaviors, stage of disease at diagnosis, and resources for treatment.<sup>32</sup>

<sup>34</sup> One researcher summarized a large body of literature suggesting that much of what has appeared to be racial differences in cancer incidence and mortality in the United States is actually a function of poverty and its associated risks.<sup>32</sup>

When cancer risks are reduced through preventive strategies, it takes many years to observe their impact on cancer rates. The gradual reduction of smoking rates among men beginning in the mid-1960s was not reflected in a lower rate of lung cancer incidence among this group until the late 1980s. Conversely, the increase in lung cancer due to the increase in smoking by women in the 1950s was not reflected until 20-25 years later. Among cancers with dietary risk factors, the results of preventive efforts are more difficult to measure given multiple risk factors in the foods eaten, patterns of physical activity, and lag time between exposure to risk and diagnosis of disease. This delay is also a barrier to assessing prevention efforts directed at the cancers attributed to environmental factors.

Despite these difficulties, the existence of strong epidemiologic evidence linking specific cancers to risks demands action to reduce these risk factors. Such actions, if successfully implemented, will reduce the incidence of cancer. One major barrier to fully understanding the problem of cancer and the effectiveness of proposed solutions is the lack of valid and appropriate data to describe completely population behavior on important risk factors for cancer. The lack of data must be addressed in the future.

## Strategies

Preventing cancer requires comprehensive approaches. Programs should be designed and implemented using methods known to be effective. Such programs should:

- 1) use multiple strategies to reduce specific risks;
- 2) reinforce positive attitudes toward the prevention of cancer and build skills for practicing preventive behaviors;
- 3) encourage behaviors among children and young adults that will achieve risk reduction early in life;
- 4) involve public and private partnerships to make the best use of resources;

- 5) target activities toward vulnerable populations, such as minorities, those with low income, and those who lack knowledge of healthy lifestyles;
- 6) develop support across social, cultural, and political lines to reduce socio-cultural barriers to behavior change;
- 7) stimulate community-based ownership in planning and sponsoring programs; and
- 8) include cost-efficient means of evaluating impact.

## Summary

The objectives and strategies have been chosen to target the most preventable risk factors identified above; inadequate diet, physical inactivity, tobacco use, and ultraviolet exposure. Most efforts focus primarily on reducing the risks among younger persons in order to gain the greatest impact, although some strategies appropriately target all segments of the state's population. As research suggests other areas appropriate for prevention activities, these will be specified in future plans. Efforts to alleviate racial, ethnic, socioeconomic, and age-related disparities in screening, and in the factors that influence screening, will remain central to the mission of the Prevention Subcommittee.

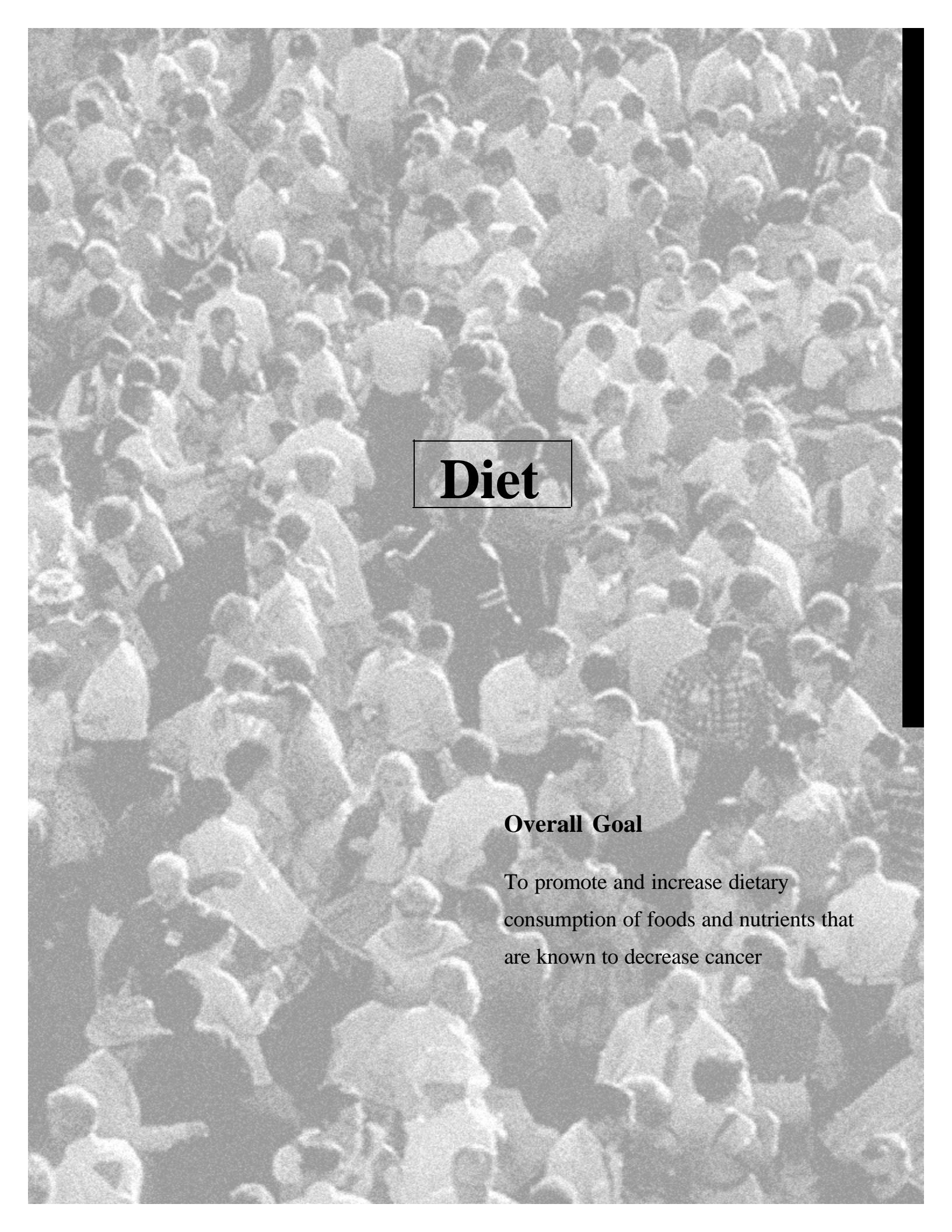
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# Diet

## Overall Goal

To promote and increase dietary consumption of foods and nutrients that are known to decrease cancer



*Cancer is a complex disease, with many causes. A large proportion of cancer incidence can be linked to environmental factors, of which the most important are tobacco, diet, and factors related to diet, including body mass and physical activity, and exposures in the workplace and elsewhere. Much of the cancer burden could be reduced if people did not smoke, practiced appropriate dietary and physical activity habits, and reduced other environmental exposures.*<sup>1,2,3</sup>

An international interdisciplinary panel convened by the World Cancer Research Fund (WCRF) and the American Institute for Cancer Research (AICR) has published the most extensive review of diet and cancer to date.<sup>1</sup> The project involved review of more than 4,500 research studies by an expert panel of 15 international researchers in diet and cancer, more than 100 peer reviewers, and participants from the World Health Organization (WHO), the U.S. National Cancer Institute (NCI) and the International Agency for Research on Cancer (IARC). In the published report, *Food, Nutrition and the Prevention of Cancer: A Global Perspective*, the panel found that current data continues to support previous findings that dietary imbalances may be responsible for approximately one-third of all cancer deaths. The panel concluded that the incidence of cancer could be reduced by as much as 30-40% by recommended feasible changes in diets, combined with maintenance of physical activity and appropriate body mass.

According to the WCRF/AICR report, the most convincing data concerning dietary prevention of cancer support the protective effect of fruits and vegetables. "Overall, when cancers of all anatomical sites are taken together, 78 percent have shown a significant decrease in risk for higher intake of at least one vegetable and/or fruit examined" (p. 441). Whereas the preponderance of epidemiological evidence is consistent for a protective effect of fruits and vegetables, recent data from studies such as the Nurses' Health study and Polyp Prevention trial have not found a protective effect of fruits and vegetables.<sup>4</sup> Therefore, the observed relationship between high fruit and vegetable intake and lowered cancer risk in populations is in need of further research.

Reviews in 1998 by the British Department of Health<sup>2</sup> and in 1999 by the American Cancer Society's Advisory Group on Diet, Physical Activity and Cancer<sup>3</sup> also confirmed that dietary practices, adequate physical activity, and avoidance of tobacco use and occupational carcinogens are important factors in the prevention of cancer.<sup>3</sup>

Evidence (convincing or probable) that fruits and vegetables are protective exists for cancers of the mouth and pharynx, esophagus, lung, stomach, colon and rectum, larynx, pancreas, and bladder. Evidence that alcohol increases cancer risk is convincing for cancers of the mouth and pharynx, larynx, esophagus, and liver, and probable for cancers of the breast, colon and rectum. There are also convincing data to indicate that high body mass index increases risk for cancer of the endometrium, with increased risk probable for breast cancer. There are convincing data to show that

refrigeration of food protects against stomach cancer and probable evidence that consumption of salt and salted foods increases risk. Diets high in meats probably increase risk for colon cancer.

**Dietary imbalances  
may be responsible  
for approximately  
one-third of all  
cancer deaths.**

Many mechanisms could explain the associations of diet with cancer risk. Some nutrition researchers have indicated that a plant-based diet is particularly well suited to reducing cancer risk.<sup>5</sup> Most importantly, fruits and vegetables contain naturally-occurring components termed "phytochemicals." Phytochemicals can act as antioxidants, protecting DNA from damage, or in other ways can protect against unregulated cell growth. The American Dietetic Association supports the view that an "appropriately planned vegetarian diet" is nutritionally adequate and beneficial for the prevention and treatment of certain diseases, including some types of cancer.<sup>6</sup>

## Epidemiological Evidence

### Breast Cancer

Several of the factors that influence risk for breast cancer are those that affect circulating hormone levels throughout life. These include age at menarche, obesity, number of pregnancies, breast feeding and physical activity. Rapid early growth and early menarche, two of the main determinants of breast cancer risk that are related to diet, may have the greatest effect during the first two decades of life. The most consistent relationships between risk of breast cancer and dietary factors are increased risk with alcohol intake and decreased risk with vegetable and fruit consumption. The evidence for a decreased risk with vegetable and fruit consumption is much weaker for breast cancer than for other cancer sites.<sup>1,7,8</sup>

Epidemiological data suggest that consumption of 1-3 alcohol drinks per day is associated with a 20 to 50 percent increased risk of breast cancer.<sup>9</sup> High body mass probably increases the risk after menopause. The WCRF/AICR panel judged that plant-based diets, and the avoidance of alcohol, together with the maintenance of recommended body mass and regular physical activity, may decrease the incidence of breast cancer by 33 to 50 percent. This is consistent with the American Cancer Society's (ACS) advice to limit intake of alcoholic beverages, eat a diet rich in fruits and vegetables, be physically active, and avoid obesity to reduce the risk of breast cancer.<sup>3</sup>

### Colorectal Cancer

Colorectal cancer is the second leading cause of cancer death among Americans. Migrant and temporal trend studies suggest that colon and rectal cancers are determined largely by environmental exposures. Diet has long been regarded as the most important environmental influence. Incidence in persons emigrating from low risk areas such as Africa, Asia, Central and South America tends to rise to the high risk rates of the United States within one to two generations, or even as early as within the migrating generation itself. Colorectal cancer and stomach cancer are the two major cancers for which risks can be reduced mainly by diet.<sup>1,2</sup>

Although the mechanism for the effect of diet on colorectal carcinogenesis is not fully understood, biological hypotheses involving mucosal damage to

epithelial cells are widely accepted. Diets high in fats may elevate risk by increasing bile acid production. Dietary fiber may decrease risk by binding bile acids, as well as by increasing stool bulk and, as a result, diluting carcinogens. Vegetables may be protective by providing the colon with fiber, or with a number of anticarcinogenic compounds, such as vitamin C, folic acid, organosulfides, isothiocyanates, and protease inhibitors.<sup>1,10,11</sup>

There is evidence that diets high in vegetables, in combination with regular physical activity, can decrease the risk of colorectal cancer. Evidence is weakly suggestive that diets high in fiber decrease risk but there is lack of clarity about which constituents of high-fiber foodsCnamely, vegetables, fruits, cereals, and seedsCcontributes to the lowering of risk. Alcohol consumption and intake of saturated fat and red meat, which are difficult to differentiate from that of total fat in the western diet, have been regarded as factors that probably increase the risk of colorectal cancer. The WCRF/AICR panel judged that diets high in vegetables and low in meat, together with regular physical activity and the avoidance of alcohol, may decrease the incidence of colorectal cancer by 66-75 percent. This is consistent with the American Cancer Society's advice to consume fewer high-fat foods, limit intake of red meats, eat more vegetables, fruits, and whole grains, and be physically active to reduce risk for colorectal cancer.<sup>3</sup>

### Stomach Cancer

Infection of the stomach by the bacterium *helicobacter pylori* is a non-dietary cause of stomach cancer, but the persistence of this infection and its role in carcinogenesis may be modified by dietary factors. Several correlational and case-control studies have shown a positive association between stomach cancer and the consumption of salted, smoked, grilled, and pickled foods, whereas diets high in fruits, vegetables and refrigerated perishable foods protect against cancer. The WCRF/AICR panel judged the evidence regarding these associations to be convincing and concluded that diets high in vegetables and fruits, together with the use of freezing and refrigeration and a low consumption of salt and salted foods, may prevent 66-75 percent of stomach cancer cases. Vitamin C contained in fruits and vegetables is probably protective. The American Cancer Society recommends eating at least five servings of fruits and

vegetables to reduce the risk of stomach cancer.<sup>1,3,12</sup>

## Oral and Esophageal Cancers

Tobacco is an established cause of oral and esophageal cancers. There is convincing evidence that alcohol increases the risk of oral and of the squamous (epithelial) cell type of esophageal cancer. Nine of 10 cohort studies and 18 of 21 case-control studies show increased risk for esophageal cancer with consumption of all types of alcoholic drinks. Most evidence suggests a dose-response relationship; that is, risk for esophageal cancer increases with increased intake of alcohol. Tobacco and alcohol, singly and together, increase the risks for cancers of the mouth, pharynx, larynx and esophagus (squamous or epithelial cell type). For drinkers of alcohol who also smoke, the risk is further increased. There is convincing evidence that consumption of fruits and vegetables decreases the risk of oral cancer and that consumption of vegetables decreases the risk of esophageal adenocarcinoma, the second type of esophageal cancer. Adenocarcinoma incidence is also strongly associated with obesity and with fat consumption.

There is evidence that vitamin C and carotenoids may be the components of fruits and vegetables that are responsible for reducing risk for oral and esophageal cancers. The most effective way to prevent oral and esophageal cancers is not to use tobacco, avoid or limit alcohol intake, and consume a varied diet rich in fruits and vegetables.<sup>1,3,13,14,15</sup>

## Prostate Cancer

Prostate cancer is the most common cancer among American men, other than skin cancer. The cancer is related to male hormones, but the exact mechanism is unclear. To date, evidence does not demonstrate that any dietary factors modify risk for prostate cancer. However, there is a growing body of evidence to show that vegetables are protective. The WCRF/AICR panel noted that diets high in vegetables are possibly protective and that regular consumption of fat, saturated/animal fat, red meat and dairy products may increase risk. Current evidence suggests that the most effective dietary means of preventing prostate cancer is to consume a diet high in fruits and vegetables and limit intake of foods from animal sources, especially saturated fats and red meats.<sup>1,3,16</sup> However, more research is needed to confirm this.

## Endometrial Cancer

There is convincing evidence that high body mass index increases the risk of endometrial cancer. The association may be due to the increase in estrogen levels that occurs among postmenopausal women who are overweight. This evidence suggests that maintenance of body weight within recommended levels through healthy food choices and regular physical activity may be effective for preventing endometrial cancer.<sup>1,3,17</sup>

## Lung Cancer

The overwhelming cause of lung cancer is smoking of tobacco. Over 80% of lung cancer cases occur as a result of tobacco smoking. There is convincing evidence that diets high in vegetables and fruits protect against lung cancer. The WCRF/AICR panel judged that 20-30 percent of cases of lung cancer in both smokers and non-smokers may be prevented by diets high in a variety of fruits and vegetables. Currently, it is not known which components of fruits and vegetables are protective. This question is under very active investigation. Carotenoids, found in plant foods, have been studied to determine whether they may be protective. Two large prevention trials found, unexpectedly, that consumption of a combination of beta-carotene and retinyl palmitate,<sup>18</sup> or beta-carotene alone,<sup>19</sup> resulted in an *increase* in lung cancer incidence.<sup>20</sup> Nevertheless, even among smokers, increased consumption of fruits and vegetables does decrease risk.

## Risk Factor Prevalence

### Fruit and Vegetable Consumption

Despite evidence associating consumption of fruits and vegetables with decreased risk for cancer and other chronic diseases such as cardiovascular disease, national surveys show consumption of these foods remains lower than recommended. A report of national data collected through The Behavioral Risk Factor Surveillance System (BFRSS), Centers for Disease Control and Prevention (CDC), revealed that fruit and vegetable consumption increased between 1990 and 1994 by 0.14 servings per day, with no further increases between 1994 and 1998.<sup>21</sup> National Five-A-

Day surveys demonstrated an increase of 0.2 servings between 1991 and 1997.<sup>22</sup>

For each of the three BRFSS reporting years, 1994, 1996 and 1998, consumption in North Carolina was below the national average. In 1996, only 16.4% of North Carolina's adults reported eating at least 5 servings of fruits and vegetables, a decrease from 18.9% reported in 1994. In 1998, the percentage of adults reporting consumption of at least 5 servings of fruits and vegetables daily was 26.1% nationally and 21.3% for North Carolina, with an average of 3.8 servings per day. The mean for North Carolina for the three reporting years (1994, 1996, 1998) was 18.9%, ranking North Carolina as the 5<sup>th</sup> lowest in the nation for prevalence of fruit and vegetable consumption.

### **The 5 A Day For Better Health Program of the National Cancer Institute**

The National 5 A day for Better Health Program approaches Americans with a simple, positive message to eat 5 or more servings of vegetables and fruits daily for better health. As a participant in the program, during 1999 and 2000 North Carolina implemented a multifaceted campaign designed to meet the objectives set by the national program. A recent report to the NCI Board of Scientific Advisors by the 5 A Day Evaluation Group concluded that continuation of the program is warranted based on additional evidence of the benefits of a diet rich in fruits and vegetables for reducing cancer risk.<sup>22</sup>

### **Overweight and Obesity**

There has been an alarming increase in the number of overweight and obese individuals during the last decade.<sup>23</sup> Body Mass Index (BMI) describes body weight relative to height. It is equal to weight in kilograms divided by height in meters squared. Overweight for adults is defined as BMI of 25 to 29.9 and obesity is defined as BMI of 30 and above. A BMI of 30 in most cases means an individual is about 30 pounds overweight. The Third National Health and Nutrition Examination Survey showed that the number of overweight Americans increased from 25 percent (1976-80) to 33 percent (1988-94) of adults. According to the 1999 Behavioral Risk Factor Surveillance Study (BRFSS), 36.4 percent of North Carolina adults are overweight; 21.5 percent are obese.

Dr. Jeffery Koplan, Director of the Centers for Disease Control and Prevention, cites the continuing epidemic of obesity as a critical public health problem. Obesity rose 6 percent nationally between 1998 and 1999, with the largest increase (7%) found among whites. Children with BMI of greater than or equal to the 85<sup>th</sup> percentile but less than the 95<sup>th</sup> percentile for age and gender, based on growth charts, are considered at risk for overweight; children with BMI greater than or equal to the 95<sup>th</sup> percentile are considered overweight. Data from the North Carolina Health Services Information System show that in 1999, using the newly revised children growth chart cut points for BMI, 12.3 percent of 2 through 4 year olds, 17.8 percent of 5 through 11 year olds and 22.5 percent of 12 through 18 year olds have a BMI at or above the 95<sup>th</sup> percentile for gender and age. In all age groups, North Carolina has a higher prevalence of overweight than the national average.<sup>21,23,24</sup>

### **Summary**

About one-third of the 500,000 cancer deaths that occur in the United States each year have been linked to dietary factors. Recommended feasible changes in diet, together with maintenance of physical activity and appropriate body mass, can reduce the incidence of cancer by 30-40 percent. Evidence (convincing or probable) of dietary protection against cancer (mouth and pharynx, esophagus, lung, stomach, colon and rectum, larynx, pancreas, and bladder) is strongest and most consistent for diets high in vegetables and fruits. Fruits and vegetables should be consumed in their natural form, as food sources, since synthetic sources of the nutrients contained in fruits and vegetables have not been shown to reduce cancer risk. Diets high in meats probably increase the risk of colon cancers. Alcohol consumption increases the risk of oral and esophageal cancers. Appropriate refrigeration of food, along with reduction of salt and salted foods, protect against stomach cancer. High body mass increases the risk of endometrial cancer and probably breast cancer.

Despite evidence linking greater consumption of fruits and vegetables with decreased cancer and chronic disease risk, consumption patterns in North Carolina have remained low and relatively unchanged, ranking North Carolina as the 5<sup>th</sup> lowest among all states. The prevalence of overweight and obesity is rising at alarming rates. Eating patterns, along with

other behaviors such as physical activity, are complex and require challenging intervention strategies. The dietary intervention components that are most efficacious for promoting a diet to reduce the risk of cancer vary by population and setting. In general, however, it appears that interventions including food-related activities (such as food tasting), social support, goal setting, and culturally sensitive intervention designs are the most effective in promoting dietary change.<sup>25</sup>

To change both dietary practices and physical activity levels, the Institute of Medicine recommends use of a social ecological intervention model; such a model would provide the necessary framework for intervening at multiple levels (individual, interpersonal, institutional, community, and policy) and with multiple approaches (e.g., education, social support, incentives, laws, policies).<sup>26</sup>

The Prevention Subcommittee strongly supports multi-level dietary interventions to reduce cancer incidence in North Carolina. The Subcommittee has selected the following objectives and strategies to accomplish that aim.

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## *Diet Goals, Objectives, and Strategies*

### **Goal 1:**

**To promote and increase dietary consumption of foods and nutrients that are known to decrease cancer.**

#### **Targets for Change by 2006:**

1. Increase to 35% the proportion of North Carolina adults 18 and older who consume at least five servings of fruits and vegetables each day. (Data Source: Behavioral Risk Factor Survey, 1998 Baseline: 21.3%)
2. Increase the proportion of North Carolina middle school students who consume at least five servings of fruits and vegetables each day. (Data Source: Youth Risk Behavior Survey, Item to be developed – Baseline to be established in 2001)
3. Increase the proportion of North Carolina high school students who consume at least five servings of fruits and vegetables each day. (Data Source: Youth Risk Behavior Survey, Item to be developed – Baseline to be established in 2001)
4. Increase to 50% the proportion of North Carolina adults 18 and older with BMI below 25.0. (Data Source: Behavioral Risk Factor Survey, 1999 Baseline 42.1%)
5. Increase to 90 percent the proportion of North Carolina children 2-18 years of age with Body Mass Index (BMI) less than the 95<sup>th</sup> percentile for age and gender. (Data Source: NC HSIS, 1999 Baseline 85.9%; Data Source: Youth Risk Behavior Survey, Item to be developed – Baseline to be established in 2001).
6. Increase to 85% the proportion of North Carolina high school students who report not initiating alcohol use (“other than a few sips”) before 13 years of age. (Data Source: Youth Risk Behavior Survey, 1997 Baseline 68.9%).
7. Increase the proportion of North Carolina adults 18 and older who report restricting fat intake (particularly saturated fat) to 30 % or less of recommended caloric intake. (Data Source to be developed).

**Note:** During the next five years, efforts to improve rates of consumption of at least five servings of fruits and vegetables each day among African-Americans and Hispanics will receive priority attention, since rates among these groups currently are lower than those for other populations.

**On the following pages,**

**\*\*indicates objectives or strategies that are focused on racial, ethnic, socioeconomic, educational or age-related disparities**

### **Objective 1**

To increase the proportion of North Carolinians who eat five or more servings of fruits and vegetables each day.

### **Strategies**

1. Develop and implement a multi-faceted, statewide intervention program to increase the intake of fruits and vegetables and limit fat consumption, particularly from animal sources. Intervention program will include promotion of the Institute of Medicine's recommendation that the mandatory school-health curriculum include health topics, including nutrition.
2. Secure stable, core funding for local programs and build/maintain central state-level capacity.
3. Increase the number of culturally appropriate cues and messages regarding the protective effect of fruit and vegetable consumption in the reduction of risk for cancer.

### **Objective 2**

To increase the proportion of North Carolinians who achieve and maintain a healthy body weight/body mass.

### **Strategies**

1. Develop and distribute the North Carolina Strategic Plan for the Prevention of Child and Adolescent Overweight and Related Chronic Disease Risk Factors.
2. Develop and implement enhancements to the North Carolina Pediatric Nutrition Surveillance System to monitor the prevalence of relevant nutrition and physical activity behaviors among children.
3. Develop and implement Women Infants and Children Program (WIC) and the Child and Adult Care Food Program (CACFP) policy changes that support dietary and physical activity behavior changes in low-income and minority children 2-5 years of age participating in WIC and CACFP.
4. Create environmental supports for healthy eating and physical activity in regulated childcare settings through a nutrition and physical activity environmental rating scale.

### **Objective 3**

To prevent initiation of alcohol use by North Carolina youth.

### **Strategies**

1. Implement interventions to increase awareness of the relationship between alcohol use and increased risks for cancer.
2. Identify and work with commissions, task forces, funders and providers of alcohol prevention services to incorporate strategies and activities to prevent initiation of alcohol use.

### **Objective 4**

To reduce consumption of high-fat foods, particularly from animal sources, among North Carolinians.

### **Strategies**

1. Identify, or develop, and implement a multi-faceted, statewide intervention program to increase the intake of fruit and vegetables and limit fat consumption, particularly from animal sources.

2. Secure stable, core funding for local programs and build/maintain central state-level capacity.
3. Increase the number of culturally appropriate cues and messages regarding the detrimental effect of fat consumption in the risk for cancer.

### **Objective 5**

To eliminate disparities in reported dietary practices by improving health related factors and norms of populations more adversely affected by poor diet. \*\*

#### **Strategies**

1. Actively engage underserved and vulnerable ethnic and cultural groups in the development and implementation of operational strategies aimed at understanding and reducing disparities among ethnic groups and across educational and socioeconomic differences. \*\*
2. Identify, or develop, and implement effective, culturally appropriate interventions in addressing each of the stated objectives areas, i.e. increase fruits and vegetables intake, achieve and maintain a healthy body weight, prevent initiation of alcohol use by youth, reduce consumption of high-fat foods. \*\*

#### **Goal 2: To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state (See Coordination)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

Alice Aycock Poe Center for Health Education: 1.3

American Cancer Society: 1.3, 2.2, 2.3, 2.4, 5.1, 5.2

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention Subcommittee: 1.3, 1.2, 5.1, 5.2

North Carolina Cooperative Extension Service: 1.1, 1.3, 2.1, 2.3, 4.1, 4.2, 4.3

North Carolina Department of Public Instruction: 1.1, 1.3, 4.1, 4.2, 4.3

North Carolina Dietetic Association: 1.3, 5.1, 5.2

North Carolina Health Promotion and Disease Prevention Section: 2.1, 2.2, 2.3, 2.4

North Carolina Health Promotion and Disease Prevention Section-Cardiovascular Health Program: 5.1, 5.2

North Carolina Health Promotion and Disease Prevention Section-Physical Activity and Nutrition Unit:  
1.1P\*, 1.2P, 1.3P, 4.1P, 4.2P, 4.3P, 5.1P, 5.2P

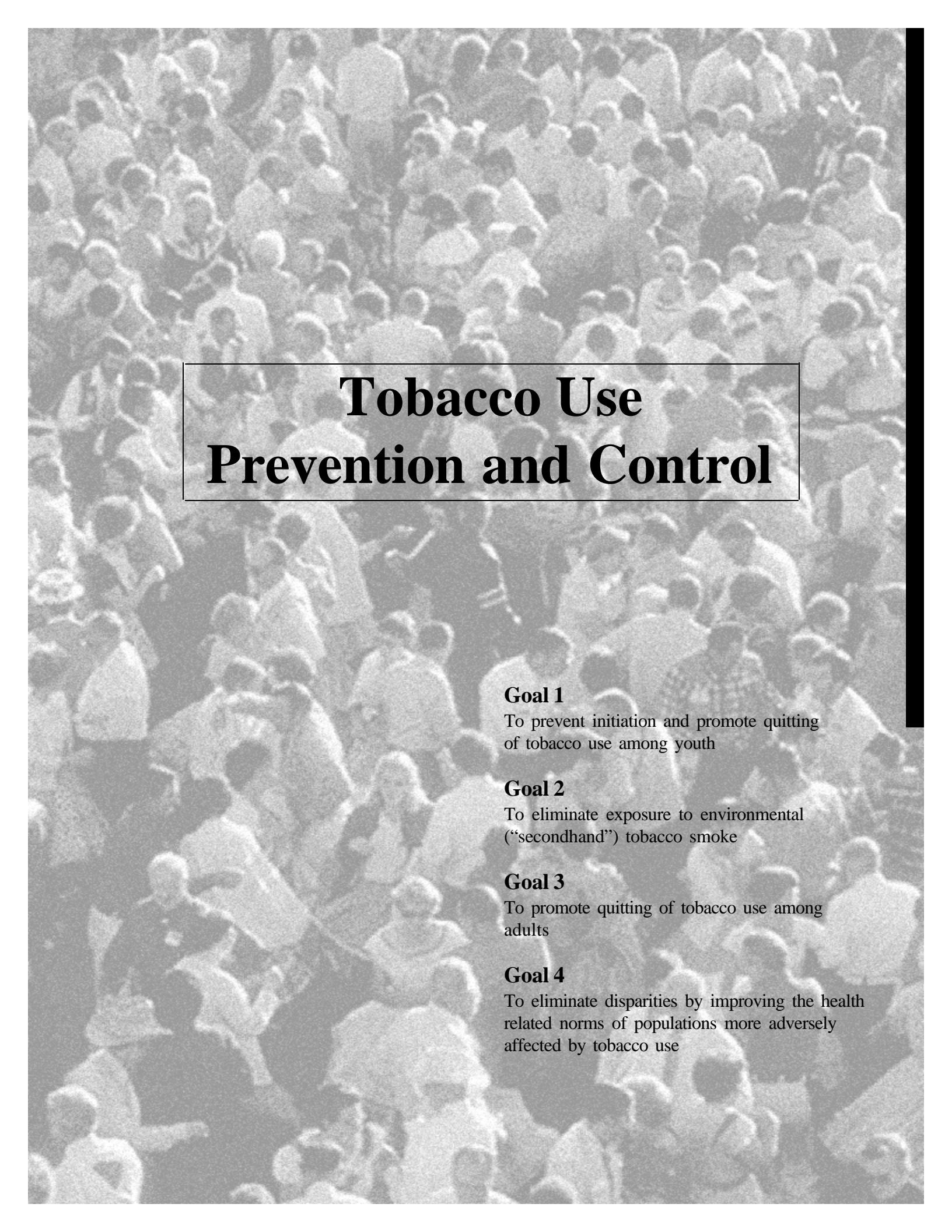
North Carolina Nutrition Network: 1.1, 1.3, 4.1, 4.2, 4.3

North Carolina Office of Minority Health and Health Disparities: 5.1, 5.2

North Carolina Prevention Partners: 1.1, 1.3, 2.1, 2.4, 4.1, 4.2, 4.3

North Carolina Women's and Children's Health Section: 2.1P, 2.2P, 2.3P, 2.4P

\* P indicates Principal Agency



# **Tobacco Use Prevention and Control**

## **Goal 1**

To prevent initiation and promote quitting of tobacco use among youth

## **Goal 2**

To eliminate exposure to environmental (“secondhand”) tobacco smoke

## **Goal 3**

To promote quitting of tobacco use among adults

## **Goal 4**

To eliminate disparities by improving the health related norms of populations more adversely affected by tobacco use



*Tobacco use is the number one preventable cause of premature death and disease in North Carolina and the nation.<sup>1,2</sup> It is estimated that 21% of the deaths in our state are associated with tobacco use — more than 14,500 in 1999.<sup>3</sup> Nearly 96% of lung cancers among men and 92% among women in the U.S. were attributed to active smoking, making male smokers 23 times and female smokers 13 times more likely to die of lung cancer than nonsmoking men and women, respectively.<sup>2</sup>*

The National Cancer Institute recently revealed that among active smokers, 57% of all deaths among men and nearly half of deaths among women were attributable to smoking.<sup>5</sup> About three-quarters of oral cancers are attributed to tobacco use, either smoked or smokeless.<sup>6</sup>

Smoking kills more people than alcohol, AIDS, car crashes, illegal drugs, murders and suicides combined. Thousands more die from other tobacco-related causes, such as exposure to secondhand smoke (more than 40,000 deaths nationwide),<sup>7</sup> health consequences of spit tobacco use<sup>7</sup>, and fires caused by smoking (more than 1000 deaths per year nationwide).<sup>7</sup>

### **Tobacco Use Prevalence**

Despite the well-established relationship between smoking and lung cancer, a quarter of North Carolina's adults, 14% of pregnant women, and nearly 40% of youth in high school smoke, all above national rates.<sup>4,8</sup> Data from the Behavioral Risk Factor Surveillance System show that, in 1999, prevalence of smoking among adults in North Carolina was 25.2%. This smoking rate is higher than the national estimate of 24.1%. However, the preceding statistics have a margin of error large enough that North Carolina's rate may not be meaningfully different from the national estimate. Only nine states reported a larger percentage of male adults smoking than North Carolina, and only 14 states reported a larger percentage of female adults smoking.

Whites and African Americans reported the highest smoking rates, 25.2% and 24.6 % respectively. By comparison, only 22.7% of Hispanics reported

smoking. Persons aged 25-44 are most likely to be smokers; in fact, over 35% of young adults are smokers. Cigarette smoking is most prevalent among persons with less than a high school diploma, with 34% reporting smoking in 1999.<sup>4</sup> North Carolina has one of the highest rates of smokeless tobacco use in the country, particularly among racial and ethnic minority groups, and it has the highest rate of female smokeless tobacco use.<sup>9</sup>

### **Smoking kills more people than alcohol, AIDS, car crashes, illegal drugs, murders and suicides combined.**

Tobacco use among teens in North Carolina is also higher than the nation, especially among middle school aged youth.<sup>8, 10</sup> In 1999, more than 18% of North Carolina middle school children reported some form of tobacco use in the past month, as compared to less than 13% for the nation (*Figure 1*). Trends were similar for cigarette smoking among middle school students; 15% of North Carolina middle school children reported cigarette smoking in the past month, as compared to 9.2% nationally. Among high school youth, the percentages were 38.3% for North Carolina and 34.8% in the nation for overall tobacco use in the past month, and 31.6% to 28.4% for cigarette use in the past month.<sup>11</sup> In 1999, 14.0% of high school males and 1.8% of high school females reported using smokeless tobacco in the past month.<sup>10</sup> Youth from rural areas were more likely to report tobacco use than teens in urban settings, 41.2% to 35.2%.<sup>8</sup>

### **Middle School Students:**

#### **Percentage of middle school students reporting use of some form of tobacco in the past month.**

North Carolina	18.4%
National	12.8%

#### **Percentage of middle school students reporting cigarette smoking in the past month.**

North Carolina	15.0 %
National	9.2 %

### **High School Students:**

#### **Percentage of high school students reporting use of some form of tobacco in the past month.**

North Carolina	38.3%
National	34.8%

#### **Percentage of high school students reporting cigarette smoking in the past month.**

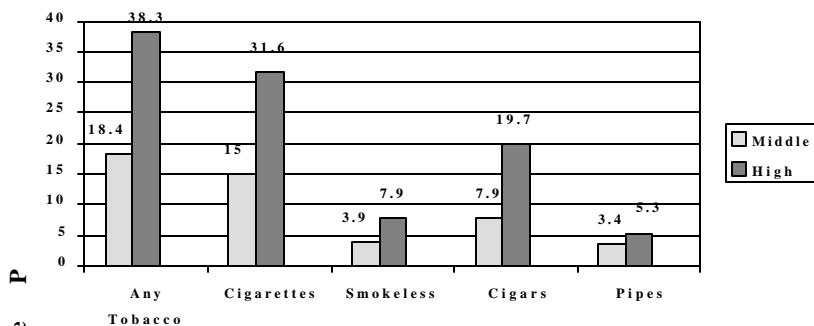
North Carolina	31.6 %
National	28.4%

Current\* Cigarette Smoking Among Middle School and High School Students by Race and Ethnicity—North Carolina Youth Tobacco Survey (NCYTS) Compared to the National YTS Data, 1999

\*Used cigarettes on 1 or more of the past 30 days preceding the survey.

### **Percentage of North Carolina Students Who Report Tobacco Use**

\*Tobacco Use by Product and by School Level



\*Used cigarettes on 1 or more of the past 30 days preceding the survey

Early adolescence is when young people are most likely to experiment with smoking.<sup>12</sup> Nearly one of three youths who begin smoking in childhood will die prematurely from some smoking-related illness. Children and adolescents who smoke are at greater risk for asthma, coughing, wheezing, slowed rate of lung growth, and other respiratory problems.<sup>13</sup>

## Exposure to Environmental Tobacco Smoke

Exposure to second-hand smoke is known to be a major health problem, causing 30 times as many lung cancer deaths as all other regulated pollutants. Each year 3,000 nonsmoker deaths and 300,000 lung infections are caused by exposure to environmental tobacco smoke.<sup>14</sup>

A 1999 survey of North Carolina youth showed that almost half of North Carolina middle school students (48.8%) and high school students (46.0%) live with someone who smokes. 88.9% of middle school students and 91.3% of high school students believe that the smoke from other people's cigarettes is harmful to them.<sup>11</sup>

## Tobacco's Toll on Health

The Cancer Prevention Study II in 1988 examined the relative risk of various diseases known to be associated with cigarette smoking. As shown in Table I, cigarette smokers face higher relative risk of death than do nonsmokers. Smokers are at especially high risk for dying of lung cancer and respiratory disease, yet the numbers of smoking-attributable

deaths due to heart disease are higher.

In 1999, more than 4,600 people died of lung cancer in North Carolina. Other conditions associated with smoking also had large numbers of deaths: chronic obstructive pulmonary disease, 3,586 deaths; coronary heart disease, 14,593 deaths; cerebrovascular disease, 5,597 deaths; pancreatic cancer, 800 deaths; cancer of kidney and renal organs, 342 deaths; and bladder cancer, 318 deaths.<sup>3</sup>

Pregnant women who smoke have an increased risk of stillbirths and neonatal deaths. Children of mothers who smoke also average 200 grams less at birth than children of women who do not smoke.<sup>15</sup> Women suffer additional risks of cervical cancer, premature menopause, impaired fertility and pregnancy complications.<sup>16</sup> According to a report by the U.S. Surgeon General in 1990, between 17% and 26% of low birthweight can be attributed to maternal smoking.<sup>17</sup> Of women in North Carolina who gave birth in 1999, 14.3% reported smoking.<sup>18</sup>

## Disparities Among Population Groups

Certain population groups have higher tobacco use rates. Adult minority populations in the North Carolina reported a slightly lower rate of smoking than the white population. Yet the rate of smoking-attributable years of life lost for African Americans was twice that of whites (the sum of the number of years lost from premature deaths under age 65).<sup>19</sup> Nearly 25% of African American adults in North Carolina reported smoking, while 22.7% of Hispanics, 23.3% of other other minorities, and 25.2% of white adults reported

**Table 1. Relative Risk for Cigarette-related Mortality, Cancer Prevention Study II, 1988**

	Males	Females
Overall deaths	2.3	1.9
Lung Cancer	23.2	12.8
Coronary Heart Disease	1.9	1.8
Chronic Obstructive Pulmonary Disease	11.7	12.8
Stroke	1.9	1.8
Other Smoking-related Cancers*	3.5	2.6

\*Sites include larynx, oral cavity, esophagus, bladder, kidney, other urinary tract organs, and pancreas.  
National Cancer Institute, National Institutes of Health, Bethesda, Maryland, February, 1997, xi

Source: Changes in Cigarette-Related Disease Risks and Their Implication for Prevention and Control, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, February 1997, xi

smoking.<sup>4</sup>

High school students show the same trends, but among middle school students, 19.8% of African Americans and 20.5% of Hispanics smoked compared to 16.8% of whites.<sup>8</sup>

Nationally, the 1998 Surgeon General's report on tobacco use among U.S. racial/ethnic minority groups summarizes data on smoking prevalence among African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics, presented below.

**African Americans:** The data show that prevalence of cigarette smoking among African Americans decreased from 37.3% in 1978-80 to 26.5% in 1994-1995.<sup>20</sup> Smoking declined for both African American men and African American women but remained higher among men than women throughout this time period.

**American Indians and Alaska Natives:** Data on smoking prevalence among American Indians and Alaska natives are limited but the data that are available show that smoking rates for both men and women in these groups have been higher than for any other population subgroup in the United States. The Surgeon General's report cites a nationally representative survey conducted in 1991 that found a smoking rate of 32.8% among respondents. The report cites a survey conducted in the early 1990s on reservations that found rates of cigarette smoking prevalence to be 40.5% for men and 29.2% for women.<sup>20</sup>

**Asian Americans and Pacific Islanders:** National Health Interview Survey data presented in the Surgeon General's report show that, between 1978 and 1995, smoking prevalence among Asian Americans and Pacific Islanders decreased from 23.8% to 15.3%; the decline was much greater for women (60%) than for men (23%).<sup>20</sup>

**Hispanics:** Among Hispanics, smoking prevalence declined from 30.1% in 1978 to 18.9% in 1995 but prevalence was higher among men than among women throughout this time period.<sup>20</sup>

*Table 2* (Page 56) shows mortality rates for malignant diseases of the respiratory system by race / ethnicity and gender between 1950 and 1995. For population groups for whom data prior to 1980 is available (African Americans and Whites), mortality

rates rose and then declined slightly between 1950 and 1995. For all other population groups, mortality rates rose moderately or remained approximately stable between 1980 and 1995.

## The Cost of Tobacco Diseases and Death

It has been estimated that in direct and indirect costs, smoking costs smokers and non-smokers alike in the U.S. between \$213 and \$353 per person per year (in 1993 dollars).<sup>21</sup> These estimates include direct costs such as treatment and prevention services, as well as lost productivity due to illness or premature death. In 1987 (the most recent year available), 43.3% of medical care expenditures associated with smoking were paid for by public funding sources, such as Medicare and Medicaid.<sup>22</sup>

Each year during 1990-1994, data showed an average of 14.7 years of life lost due to smoking among North Carolinians. North Carolina's annual Medicaid payments directly related to tobacco are estimated at \$200 million.<sup>37</sup> Overall medical costs alone due to smoking in North Carolina during 1993 (latest year for available figures) were estimated at \$1.2 billion.<sup>23</sup>

## Tobacco Advertising and Promotions

In 1998, cigarette companies spent about \$6.73 billion on cigarette advertisements. It is estimated that at least \$145 million of these advertising dollars targeted North Carolinians.<sup>24</sup> Children and youth make up the largest proportion of new smokers. Documents revealed by the Master Settlement Agreement with the state Attorneys General showed that much of the industry's advertising and promotion strategies have been aimed at young people.<sup>25</sup> The three top brands reportedly smoked by adolescent smokers are the three most heavily advertised brands of cigarettes in the U.S.<sup>12</sup> These include Marlboro, Camel and Newport.

Two studies released May 17, 2000 showed that the tobacco companies increased magazine advertising aimed at youth since signing the Master Settlement in November 1998. These studies showed that the tobacco companies dramatically increased their advertising spending in magazines read by large numbers of youth at the frequency needed to make a significant impact.<sup>8</sup> One recent example of tobacco promotions affecting tobacco use among young persons is seen with the 1999 data from the Youth Tobacco Survey. 21.9% of all North Carolina middle school students and 41.6% of

middle school students who currently used tobacco reported owning a personal item (e.g., book jacket, cap) with a tobacco company name or logo on it.<sup>11</sup>

**Table 2. Death rates per 100,000 U.S. residents for malignant diseases of the respiratory system, by race/ethnicity and gender, United States, 1950-1995,\* selected years**

Race/ethnicity and gender	1950 <sup>^</sup>	1960 <sup>^</sup>	1970	1980	1985	1990	1993	1995
<b>African American men</b>								
All ages, age-adjusted	16.9	36.6	60.8	82.0	87.7	91.0	86.0	80.5
All ages, crude	14.3	31.1	51.2	70.8	75.7	77.8	74.7	71.2
<b>American Indian or Alaska Native men **</b>								
All ages, age-adjusted	NA	NA	NA	23.2	28.4	29.7	31.0	32.7
All ages, crude	NA	NA	NA	15.7	19.6	21.1	23.1	25.1
<b>Asian American or Pacific Islander men †</b>								
All ages, age-adjusted	NA	NA	NA	27.6	26.9	26.8	28.4	25.8
All ages, crude	NA	NA	NA	22.9	21.3	21.7	23.9	22.4
<b>Hispanic men Φ</b>								
All ages, age-adjusted	NA	NA	NA	NA	24.0	27.7	25.1	25.2
All ages, crude	NA	NA	NA	NA	13.9	17.4	16.5	16.9
<b>White men</b>								
All ages, age-adjusted	21.6	34.6	49.9	58.0	58.7	59.0	56.3	53.7
All ages, crude	24.1	39.6	58.3	73.4	77.6	81.0	79.7	77.8
<b>African American women</b>								
All ages, age-adjusted	4.1	5.5	10.9	19.5	22.8	27.5	27.3	27.8
All ages, crude	3.4	4.9	10.1	19.3	23.5	29.2	30.2	31.3
<b>American Indian or Alaska Native women 9</b>								
All ages, age-adjusted	NA	NA	NA	8.1	11.1	13.5	16.1	16.4
All ages, crude	NA	NA	NA	6.4	9.2	11.3	14.6	15.5
<b>Asian American or Pacific Islander women ***</b>								
All ages, age-adjusted	NA	NA	NA	9.5	9.2	11.3	11.7	13.0
All ages, crude	NA	NA	NA	8.4	8.2	10.6	11.7	13.6
<b>Hispanic women ≈</b>								
All ages, age-adjusted	NA	NA	NA	NA	6.7	8.7	8.2	8.2
All ages, crude	NA	NA	NA	NA	5.2	7.5	7.3	7.5
<b>White women</b>								
All ages, age-adjusted	4.6	5.1	10.1	18.2	22.7	26.5	27.6	27.9
All ages, crude	5.4	6.4	13.1	26.5	34.8	43.4	47.3	48.9

Note: Data in the table on African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and whites include persons of Hispanic and non-Hispanic origin. Conversely, in this table, the data on Hispanic origin may include persons of any race.

\* Age-adjusted to the 1940 U.S. standard population. Cause-of-death data are based on classifications from the then current *International Classification of Diseases* (e.g., cause-of-death codes 160-165 for the Ninth Revision). Data for the 1980s are based on intercensal population estimates.

H Includes deaths of nonresidents of the United States.

\*\* Interpretation of trends should consider that population estimates for American Indians and Alaska Natives increased by 45 % between 1980 and 1990 (because of better enumeration techniques in 1990 and an increased tendency for people to denote themselves as American Indian in 1990).

' Interpretation of trends should consider that the Asian population in the United States more than doubled between 1980 and 1990, primarily because of immigration.

Φ Because of incomplete data, the National Center for Health Statistics (NCHS) reports 1985 death certificate data on decedents of Hispanic origin for only 17 states and the District of Columbia. By 1990, data for 47 states and the District of Columbia were reported. NCHS estimates that the 1990 reporting area encompassed 99.6 % of the U.S. Hispanic population. After 1992, only Oklahoma did not provide information on Hispanic origin.

NA = data not available.

Source: Adapted from National Center for Health Statistics. U.S. Department of Health and Human Services. Tobacco Use among U.S. racial/ethnic minority groups-African Americans American Indians and Alaska Natives, Asian Americans and Pacific Islanders, and Hispanics: A report of the Surgeon General (DHHS Publication No. (CDC) 89-8411: Washington, DC). Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. 1999.

## What Can Be Done?

Several strategies have the potential to reduce tobacco use in North Carolina.

### ***Increase the Number of Smoke Free Air Policies***

North Carolina's law G.S. 143-595 requires that 20% of state-controlled buildings be set aside for smoking, and preempts local governments from passing stricter ordinances since 1993.<sup>24</sup> North Carolina does not allow municipalities or counties to enact smoke-free laws. This represents an enormous barrier for local communities because it greatly limits their ability to protect public health and safety. Voluntary adoptions of workplace nonsmoking policies have resulted in a 95.3% increase in workers who are covered.<sup>26</sup>

Schools are exempt from G.S. 143-595, and last year former Governor Jim Hunt strongly supported 100% tobacco free schools by sending a letter to all North Carolina schools indicating his support. Recently, Michael F. Easley and Mike Ward, State Superintendent of Public Instruction have promoted 100% tobacco-free schools. Currently 13 school districts have adopted 100% smoke free environments.<sup>27</sup>

### ***Increase Price***

Taxation is the most effective measure to reduce tobacco use demand; higher taxes induce quitting, reduce consumption and prevent starting. It is estimated that a 10% increase in price reduces consumption by four to eight percent.<sup>28</sup> Studies of smokeless tobacco show similar trends.<sup>12</sup>

North Carolina's tax rate is 5 cents per cigarette pack, the third lowest in the nation. The smokeless tobacco tax is 2% of cost.<sup>21</sup> The last time North Carolina raised the cigarette tax was 1991. That year the General Assembly increased the excise tax on cigarettes by 3 cents per pack. The legislature passed the tax because the State was experiencing a major budget deficit.

### ***Reduce Youth Access to Tobacco***

Today, there is widespread support to reduce youth access to tobacco products. Some studies that have reduced illegal tobacco sales to minors have shown reductions in youth smoking, whereas others have failed to document any reduction.<sup>29</sup> Aggressive enforcement is required to maintain low rates of tobacco sales to minors.<sup>30,31</sup>

The federal Synar Amendment stepped up local efforts to reduce tobacco sales to minors. The Synar

Amendment requires the North Carolina Department of Health and Human Services, Division of Mental Health, Developmental Disabilities and Substance Abuse Services to significantly reduce the rate that underage youth are able to buy tobacco products in over-the-counter retail outlets and vending machines.<sup>32</sup> Failure to comply with the requirements of the federal Synar Amendment could result in a 40 % or approximately \$13 million reduction in the State's Substance Abuse Prevention and Treatment Block Grant.

Since 1996, local law enforcement, the North Carolina Division of Alcohol Law Enforcement, the North Carolina Substance Abuse Services Section, local ASSIST Coalitions, and the North Carolina Tobacco Prevention and Control Branch have worked cooperatively to reduce the rate at which minors can purchase tobacco products by 50%. The North Carolina General Assembly passed a new enforceable youth access to tobacco law effective December 1, 1997. In response, Governor Hunt signed Executive Order 123, which designated the North Carolina Division of Alcohol Law Enforcement (ALE) as the lead agency to implement model enforcement and education on prohibiting tobacco sales to minors. Since 1996, combined enforcement and educational efforts of the North Carolina Substance Abuse Services Section, ALE, local law enforcement, North Carolina Tobacco Prevention and Control Branch and its local ASSIST coalitions have reduced the rate at which minors can purchase tobacco products to 20%—more than a 50% reduction.

Active enforcement, combined with public and merchant education, is the only strategy proven to reduce youth access to tobacco products. Current gaps in manpower and funding for active statewide enforcement threaten continued progress. Resources are needed to sustain active enforcement and merchant education. Under federal law, North Carolina must continue to reduce tobacco sales to minors at a rate to meet predetermined performance targets.

### Promote Tobacco Use Cessation

Seventy percent of smokers want to quit and 70% of smokers see a physician each year.<sup>33</sup> Data indicate that only 67% of doctors give smokers advice to quit, though that advice alone increases quit rates by one third.<sup>34</sup> Helping people quit smoking can yield significant health benefits. The 1990 Surgeon

General's report cites these findings: After one year of not smoking, the risk of heart disease is cut in half; in 5-15 years the risk of stroke returns to the same as non-smokers; all race-sex groups add years to their life expectancy.<sup>35</sup>

Effective strategies for treating nicotine addiction include brief advice by a medical care provider, counseling and pharmacotherapies. Advancements in treating tobacco use cessation are summarized in the recent guideline, Treating Tobacco Use and Dependence, A Clinical Practice Guideline, published by the Public Health Services and available on-line at [www.surgeongeneral.gov/tobacco/default.htm](http://www.surgeongeneral.gov/tobacco/default.htm)

In 1998, only one HMO and one Public Health Plan in North Carolina provided tobacco cessation as a benefit. Recent gains were made in this arena, and by 2000, 60% (8 of 14) offered a cessation benefit, rider, or product. The Public Health Plan continues to offer these services. As a result, cessation services are available to more North Carolinians than before through their routine medical care.<sup>36</sup>

### Summary

Tobacco use is the single most preventable cause of premature death in North Carolina. In the areas of tobacco education, prevention, cessation, and policy making there is much to be done to improve the health of North Carolina's citizens. There is good scientific evidence on how to affect tobacco use. The Centers for Disease Control and Prevention, National Cancer Institute, Institute of Medicine, Substance Abuse and Mental Health Services Administration (SAMHA), Center for Substance Abuse Prevention, American Medical Association, American Cancer Society, American Heart Association and American Lung Association agree that a multi-strategy approach involving public education, policy, and programmatic efforts at the state and local community levels is essential to reduce and prevent tobacco use among teens and other priority populations.<sup>38</sup>

Effective population-based programs first began in California (from 1989), then Massachusetts (from 1993), Arizona (from 1994), and Oregon (from 1996). In addition, Florida began a comprehensive program in 1997. In the past decade these five states have seen reductions in adult and/or teen tobacco use while, quite the contrary, the remainder of the nation has seen no declines in adults and dramatic increases in teen

tobacco use.<sup>38</sup> Over the past 10 year period, California has reduced the percent of smoking to less than 18 percent and has had a 14 percent reduction in lung cancer.<sup>38</sup> It is evident that a well-funded, comprehensive tobacco prevention and control plan can make a significant impact on the lives and well-being of North Carolinians.

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## **Tobacco Use Prevention and Control Goals, Objectives, and Strategies**

The following Targets, Goals, Objectives, and Strategies reflect *Vision 2010: North Carolina's Comprehensive Plan to Prevent and Reduce the Effects of Tobacco Use*.<sup>1</sup>

### **Targets by 2006\***

1. Decrease overall teen tobacco use in North Carolina from 38.3% to 26.8%  
(Data Source: North Carolina Youth Tobacco Survey, 1999)
2. Decrease the proportion of North Carolina adults who smoke from 25% to 17.2%  
(Data Source: North Carolina Behavioral Risk Factor Survey, 1999)
3. Reduce the proportion of pregnant women who smoke in North Carolina from 15.2% to 12.1%  
(Data Source: North Carolina State Center for Health Statistics, Vital Statistics/Birth Certificate Data, 1998)

**Note:** These Targets are based on those set for Healthy Carolinians 2010. They have been prorated to 60% for this *Cancer Control Plan*.

**Note:** During the next five years, efforts to decrease rates of tobacco use by African-American, Hispanic, and rural middle school students and by adults with less than high school educational attainment will receive priority attention, since rates among these groups currently are higher than those for other groups.

**On the following pages,**

**\*\* indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities**

## **Goal 1: To prevent initiation and promote quitting of tobacco use among youth**

### **Objective 1**

To increase from 29.8% to 47.9% the proportion of young people in high school who have never smoked.  
(Source: YTS 1999)

### **Objective 2a**

To decrease the proportion of middle school students who use tobacco products from 18.4% to 12.9% and high school students who use tobacco products from 38.3% to 26.8% (Source: YTS 1999).

### **Objective 2b**

To decrease the proportion of middle school students who smoke from 15% to 10.5% and high school students who smoke from 31.6% to 22.1% (Source: YTS 1999).

### **Objective 3**

To increase from 5.1% to 62% the proportion of schools in North Carolina that are 100% tobacco free for students, staff and visitors in school buildings, the campus, and in school-related events (Baseline: 6 of 117 school districts in 2000; *DPI/DHHS survey 1999*).

## **Objective 4**

To decrease the rate of illegal sales of tobacco products to minors at retail stores and vending machines from 20% to 11%. (Source: *DHHS, Substance Abuse Services Section 2000 Annual Synar Survey*).

### **Strategies**

1. Empower youth as tobacco prevention and control advocates.
2. Empower youth as peer counselors for cessation.
3. Deglamourize tobacco use and increase public awareness through paid advertising and public relations.
4. Earn pro-health media coverage.
5. Provide media literacy education and training.
6. Promote effective tobacco use prevention and control policies in schools and communities.
7. Assure a comprehensive approach to tobacco use prevention and control in all schools grades K-12.
8. Promote and provide access to effective cessation services to all youth and adults.
9. Increase merchants' understanding of and commitment to reducing youth access to tobacco products through the delivery of an effective statewide merchant education program.
10. Increase compliance with the State's Youth Access Law through the development and implementation of a sustained statewide enforcement program.

## **Goal 2: To eliminate exposure to environmental (“Secondhand”) tobacco smoke**

### **Objective 1**

To increase from 5.1% to 64.1% the number of schools in North Carolina that are 100% tobacco free for students, staff and visitors in school buildings, the campus, vehicles, and in school events. (Baseline: 6 of 117 school districts in 1999, *DPI/DHHS survey 1999*).

### **Objective 2a**

To increase from 60.7% to 84.3% the proportion of North Carolina workers covered by a formal smoking policy that prohibits smoking entirely or limits it to separately ventilated non-essential portions of the workplace (Baseline: CPS 1999).

### **Objective 2b**

To increase smoke-free policies in the following public indoor recreational sites in North Carolina: (UNC Dept of Family Medicine, 1999)

- Indoor malls from baseline of 58% to 83.2%.
- Commercial airports from baseline of 55% to 82%.
- Roller/ice skating rinks from baseline of 91% to 96.4%.
- Bowling centers from baseline of 7% to 62.8%.
- Indoor spectator facilities from baseline of 82% to 92.8%.

### **Objective 3**

To increase the percentage of North Carolinians reporting smoke-free homes from 52.5% (1998/99 CPS data) to 65.4%.

### **Objective 4a**

To decrease from 48.8% to 34.2% the percentage of middle school students reporting living with someone who smokes. (Baseline: YTS 1999)

### **Objective 4b**

To decrease from 46.0% to 32.2% the percentage of high school students reporting living with someone who smokes. (Baseline: YTS 1999)

### **Strategies**

1. Promote adoption of nonsmoking policies in:
  - Homes
  - Child Care Facilities
  - Schools
  - Restaurants
  - Family oriented businesses, e.g. shopping malls, recreational facilities, bowling alleys, hair salons barbershops, sports arenas, etc.
  - Workplaces
  - Public Places
2. Earn pro-health media coverage.
3. Develop and run paid media on the health risks.
4. Promote nonsmoking establishments through the web, paid media, and earned media.
5. Raise public awareness of the risks of secondhand smoke related to asthma.
6. Provide in-home inspections and tobacco use cessation services for families of asthmatics.

## **Goal 3: To promote quitting of tobacco use among adults**

### **Objective 1**

To decrease proportion of adults who smoke from 25% to 17.2%. (HP2010 national target)

### **Objective 2**

To decrease the proportion of young adults, ages 18-24, who use spit tobacco from 5.0% to 4.3%. (Data Source BRFSS).

### **Objective 3**

To decrease proportion of pregnant women who smoke from 15.2% to 12.1%. (*SCHS 1998 Vital Statistics/Birth Certificate data*)

## **Objective 4**

To increase from 8% to 63.2% the public and private health plans in NC that include the clinical practice guidelines for treating tobacco use and dependence as a covered benefit in their most basic benefits package. (Data Source: 1 out of 14 HMO's currently meet this criteria; North Carolina Prevention Partners, 2000)

### **Strategies**

1. Promote and provide access to effective cessation services for all adults and youth who want to quit by developing a multi-level NC Quitting Infrastructure.
2. Develop state-level position with oversight authority/accountability for cessation services and programs.
3. Continue to support voluntary insurance reform initiative and partnerships with NC public and private health plans to expand coverage of comprehensive smoking cessation benefits (behavioral and pharmacological).
4. Increase level of employer and public purchasers requesting and paying for cessation benefits.
5. Develop resource for demonstrating how health facilities can implement current practice guidelines. Increase the proportion of, and maintain updated resource directory of health care facilities (hospitals, health departments, medical care practices) in NC that have a quitting program that follows the Clinical Practice Guidelines for smoking cessation.
6. Develop health professional training program and provide training and technical assistance to health professionals and health professional students on evidence-based guidelines.
7. Develop and promote programs for special populations, and develop and promote tools to treat tobacco use as a vital sign. \*\*
8. Establish and promote a NC culturally and linguistically appropriate 24 hour NC Quit-line and on-line quitting programs. \*\*
9. Develop and promote consumer utilization of quitting programs through NC tailored public awareness quitting campaign.
10. Establish financial incentives for health agencies to develop quitting infrastructure through partnerships with NC foundations and other funding resources.
11. Establish a cessation market research and evaluation program that informs the development of interventions to motivate health plans, employers, health facilities, health professionals, and consumers and evaluates effectiveness of cessation strategies and progress towards cessation goals.

## **Goal 4: To eliminate disparities by improving the health related norms of populations more adversely affected by tobacco use.**

### **Objective 1**

To decrease tobacco use among all NC middle school students to 12.9% from the current rates of: African American students (19.8%), Hispanic students (20.5%) White students (16.8%), rural middle school students (20.2%), and urban middle school students (15.9%) (Source: 1999 NC YTS).

## **Objective 2**

To decrease tobacco use among all NC high school students to 26.8% from the current rates of: Whites (42.5%), Hispanics (33.9%), African Americans (28.7%), rural (41.2%) and urban (35.2%). (Source: 1999 NC YTS)

## **Objective 3**

To decrease cigarette smoking among all NC adults to 17.2%.

- a) Current rates for ethnic groups are:  
White adults (25.2%), North Carolina African American adults (24.6%), North Carolina Hispanic adults (22.7%) and other minorities (23.3%) [which includes Native Americans and Asians] (Source: 1999 NC BRFSS).
- b) Current rates for education levels are: adults with less than a high school diploma (34%), adults with some college education (18.8%). (Source: 1999 NC BRFSS)
- c) Current rates by gender are: adult males who smoke (27.5%), female adults who smoke (22.7%). (Source: 1999 BRFSS)

## **Objective 4**

To decrease the proportion of all pregnant women who smoke from an average of 15.2% to 12.1% (16.8% of white women; 11.2% of African American women and 11.4% of other minorities). Maintain the low rate of Hispanic women who smoke during pregnancy (2.1%). (Source: 1998 Vital Statistics)

### **Strategies: Incorporate diversity in all 4 goal areas**

#### **Strategies for Goal 1: Prevent initiation and promote quitting among youth**

1. Increase the number of diverse youth leaders, community groups and organizations representing underserved populations actively involved in tobacco use prevention and control. \*\*
2. Increase the number of schools with large proportion of minority populations that adopt 100% tobacco free policy. \*\*
3. Train diverse youth as peer counselors for cessation. \*\*
4. Develop culturally appropriate youth leadership models and implement training such as the “UJIMA” model for African American youth. Promote African American youth leadership using the “UJIMA” model across the state. \*\*

#### **Strategies for Goal 2: Eliminate exposure to environmental tobacco smoke**

1. Incorporate role modeling in educational strategies. Emphasize the influence of parents, educators and adult youth leaders on youth initiation to tobacco use, especially in ethnic communities. \*\*

#### **Strategies for Goal 3: Promote quitting of tobacco use among adults**

1. Develop and implement culturally appropriate cessation services and training such as the “Pathways to Freedom” for African Americans. Increase the availability of the “Pathways to Freedom” across the state. \*\*

#### **Strategies for Goal 4: Eliminate disparities related to tobacco use**

1. Promote tobacco prevention and control efforts through culturally appropriate paid advertising and public relations. Increase the proportion of pro-health media coverage in culturally appropriate media. \*\*

2. Obtain tobacco prevalence data reflecting a more accurate representation of diverse ethnic and cultural groups such as Native Americans, Hispanic/ Latinos and Asian Americans. \*\*
3. Address cultural use of tobacco among Native Americans through education on the difference between culturally relevant ceremonial use and addictive use of manufactured tobacco. Raise public awareness to processing and manufacturing of tobacco (chemical additives) especially among Native American communities. \*\*

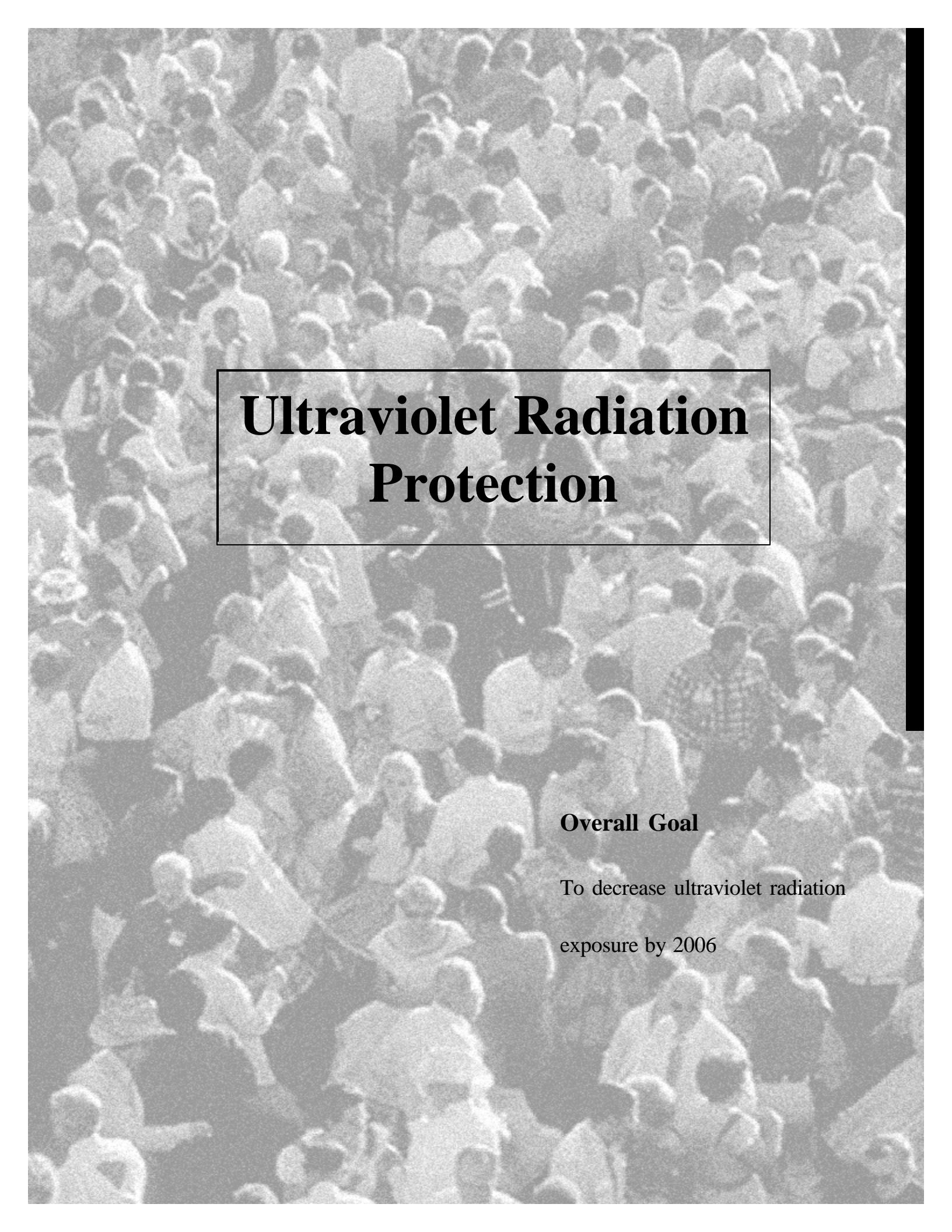
**Goal 5: To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See Coordination)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Strategy)

American Cancer Society: 1.4, 1.8, 2.1, 2.2, 2.4, 3.1  
American Lung Association of North Carolina: 1.2, 1.4, 1.8, 2.1, 2.2, 2.4, 2.5, 2.6, 3.1  
Governor's Institute on Alcohol and Substance Abuse Prevention: 1.5  
Historically Black Colleges and Universities (HBCU) Health Promotion Alliance: 4.1.1  
National African American Tobacco Prevention Network: 3.1.1  
North Carolina Association of Local Health Directors: 1.1, 1.3, 1.6, 1.8, 2.1, 2.2, 2.4, 2.5, 4.1.4  
North Carolina Cardiovascular Health Program: 2.1, 2.2, 2.4, 3.1, 3.3, 3.4, 3.5, 3.7  
North Carolina Commission of Indian Affairs: 4.1.1, 4.4.3  
North Carolina Department of Public Instruction: 1.1, 1.2, 1.6, 1.7, 2.1, 2.2, 2.4, 4.1.2  
North Carolina Division of Alcohol Law Enforcement: 1.9, 1.10P\*  
North Carolina Division of Mental Health, Developmental Disabilities, and Substance Abuse Services: 1.6, 1.8, 1.9, 1.10P, 2.1, 2.2  
North Carolina Heart Disease and Stroke Prevention Task Force: 1.6, 2.1, 2.2, 2.4  
North Carolina Medical Society: 3.7  
North Carolina Office of Minority Health: 4.1.1  
North Carolina Prevention Partners: 1.4, 2.1, 2.2, 2.4, 1.8, 1.10, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 3.10, 3.11  
North Carolina Tobacco Prevention and Control Branch: 1.1P, 1.2P, 1.3P, 1.4P, 1.5P, 1.6P, 1.7P, 1.8P, 1.9P, 1.10, 2.1P, 2.2P, 2.3P, 2.4P, 2.5P, 2.6P, 3.1P, 3.2P, 3.3, 3.4P, 3.5, 3.6, 3.7P, 3.8P, 3.9P, 3.10P, 3.11, 4.1.1P, 4.1.2P, 4.1.3P, 4.1.4P, 4.2.1P, 4.3.1P, 4.4.1P, 4.4.2P, 4.4.3P  
North Carolina Women's and Children's Health Section-Children and Youth Branch-Asthma Program: 2.5, 2.6  
North Carolina Women's and Children's Health Section-Women's Health Branch: 3.1, 3.4, 3.6, 3.7  
Survivors and Victims of Tobacco Empowerment Project: 2.1, 2.2, 2.4  
UNC Center for Health Promotion and Disease Prevention: 1.1, 4.1.1, 4.4.2, 4.4.3  
UNC School of Medicine-Department of Family Medicine: 2.1, 2.2, 2.4  
UNC School of Public Health-Department of Health Behavior and Health Education: 1.1  
UNC School of Public Health-Office of Epidemiology: 2.5

\* P indicates Principal Agency





# **Ultraviolet Radiation Protection**

## **Overall Goal**

To decrease ultraviolet radiation

exposure by 2006



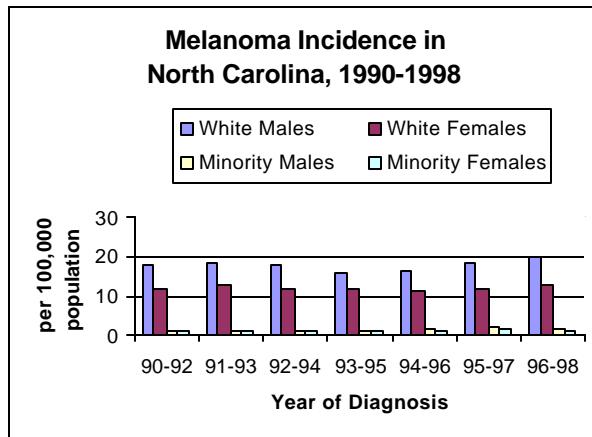
*For a discussion of early detection of malignant melanoma, please refer to the Early Detection-Malignant Melanoma section.*

*Despite the fact that approximately 80 percent of all skin cancers are preventable, skin cancer is the most common malignancy in the United States today.<sup>1</sup> In fact, skin cancer cases make up half of all new cancers that are diagnosed.<sup>2</sup> There are three main types of skin cancer: basal cell and squamous cell carcinoma, which are non-melanoma skin cancers, and malignant melanoma, the most serious and aggressive form of skin cancer.*

The American Cancer Society estimated that 1.3 million new cases of basal and squamous cell carcinoma would be detected in the United States in the year 2000; although rarely lethal, 1,900 deaths are attributed to these cancers. It was estimated that 47,700 new cases of malignant melanoma would be diagnosed, and 7,700 deaths would be attributed to this far more serious type of cancer.<sup>2</sup>

In North Carolina, projections for the year 2000 show an estimated 1,220 new cases of malignant melanoma and an estimated 225 deaths from the disease.<sup>3</sup> The incidence of melanoma in North Carolina rose between 1990 and 1998 (Figure 1).

Figure 1



Source: North Carolina Central Cancer Registry

Malignant melanoma is increasing in incidence more rapidly than any form of cancer.<sup>4</sup> Since 1930, the incidence of melanoma has increased by 2000 percent.<sup>5</sup> Currently, it is the sixth most common cancer in men and the seventh most common cancer in

women.<sup>2</sup> Data from the National Cancer Institute indicate, however, that the relative five-year survival rate for malignant melanoma increased from 81 percent in 1976 to 87 percent in 1992.<sup>6</sup> This is due in part to detection of thinner lesions, which have a better prognosis. Despite the increase in survival, mortality from melanoma continues to rise due to its increasing incidence. North Carolina ranked fifteenth in the United States in malignant melanoma mortality for the period 1992-1996.<sup>6</sup>

In contrast to most other common cancers, death from melanoma tends to occur relatively early in adult life, resulting in a disproportionately high premature mortality and the concomitant loss of many productive years of life among young and middle-aged people. In the United States, the lifetime probability of developing melanoma is now 1 in 74.<sup>5</sup>

Although melanoma is clearly the most aggressive and potentially fatal of all the skin cancers, it accounts for only 4 percent of skin cancers.<sup>5</sup> The remaining 96 percent of skin malignancies are primarily basal cell or squamous cell carcinoma (non-melanoma skin cancer) which, though rarely fatal, result in substantial treatment costs and physical and psychological morbidity. Other, rarer forms of skin cancer include sarcomas and lymphomas.

## Risk Factors

There are several risk factors associated with the development of skin cancer, including age, a family history of skin cancer, precursor lesions, race, and exposure to ultraviolet (UV) radiation (especially acute sunburn in some types of melanoma).<sup>7</sup>

Age is a risk factor because of the cumulative exposure to the sun. About half of all melanomas occur in people over the age of 50;<sup>7</sup> however, people under the age of 20 have been diagnosed with melanoma.<sup>8</sup> Although melanoma in children is rare, it has been reported that it appears to be increasing in frequency.<sup>8</sup>

Risk for melanoma is greater in individuals who have a first degree relative who has had melanoma. The risk of melanoma can be up to eight times greater for people with a family history of melanoma, compared to people without a family history.<sup>7</sup>

Some types of skin conditions may lead to skin cancer. For example, actinic keratoses are multiple small scaly spots on a reddish base most common on sun-exposed areas such as the face, lower arms and back of the hands. Actinic keratoses do not tend to heal spontaneously and may become skin cancers if they are not treated.<sup>7</sup>

The risk of skin cancer is over twenty times higher for whites than for dark-skinned African Americans. The lower risk among dark-skinned African Americans is due to the protective effects of melanin, the pigment that gives skin its color.<sup>7</sup> Although light-skinned people are more likely to get skin cancer, dark-skinned people such as Hispanics, Asians, and African Americans are more likely to be diagnosed at a later stage of the disease.<sup>9</sup>

Exposure to UV radiation is an important risk factor for skin cancer. The risk of developing malignant melanoma is linked to intermittent, intense UV exposure causing painful or blistering sunburns during childhood and adolescence. Exposure in the first twenty years is a more important determinant of melanoma incidence than exposure later in life. One study indicated that a single severe sunburn may increase the risk of malignant melanoma twofold.<sup>10</sup> For non-melanoma skin cancer, the major risk factor is chronic, cumulative sun exposure. One factor potentially contributing to the problem of exposure to UV radiation is the depletion of the atmospheric ozone layer, which filters out some of the excessive and harmful ultraviolet solar radiation.<sup>4,11</sup>

Besides exposure to UV radiation from outdoor sun-tanning and leisure activities, the problem is made worse by the use of artificial ultraviolet sources, especially tanning salons. Today, tanning beds are a \$2 billion dollar per year industry in the United States, with over 25,000 tanning salons

in operation.<sup>5</sup> Evidence suggests that frequent use of these tanning devices is leading to increased numbers of pre-cancerous and cancerous skin lesions, including malignant melanoma, earlier in life.<sup>12</sup> To compound the problem, a study of tanning facilities in North Carolina indicated that the majority violated specific state and federal requirements for safety.<sup>13</sup> This situation continues to exist despite regulatory efforts to correct these violations. If operated incorrectly or if utilized by individuals with photosensitive diseases or taking photosensitive drugs, tanning machines may be extremely hazardous. One study found that persons who used tanning machines more than ten times per year had more than eight times the risk of melanoma as persons who did not.<sup>14</sup>

In summary, there are many factors that may contribute to the development of skin cancer. Although risk factors such as an individual's age, family history, and race cannot be changed, exposure to UV radiation is an important risk factor that can be reduced or prevented.<sup>10</sup>

## Skin Cancer Prevention

Preventive strategies to reduce UV exposure should result in a significant decrease in the incidence of skin cancer. These strategies include: (1) avoiding sun exposure during the peak ultraviolet hours from 10 a.m. to 3 p.m.; (2) wearing protective clothing such as wide-brimmed hats, long-sleeve shirts, and UV protective sunglasses; (3) using shade from trees, umbrellas, and canopies; and (4) applying sunscreens and sunblocks with an SPF of at least 15 or higher, preferably a complete UVB/A sunscreen.

Given that excessive ultraviolet exposure is one of the major factors contributing to the development of skin cancer, and since it is estimated that at least 80 percent of lifetime sun exposure may occur during childhood and adolescence,<sup>5</sup> preventive action needs to start early in life. A rational approach to early primary prevention should include public education targeting young children, adolescents, their parents, and caregivers. Such efforts should concentrate on increasing knowledge regarding the potential hazards of ultraviolet radiation, as well as shaping or changing attitudes and behaviors toward more sun-safe practices. In addition to these educational efforts, supportive policies (e.g., requiring children to wear hats or sunscreen on the

playground) and environmental supports (e.g., providing shade on playgrounds) are also necessary to reduce exposure to ultraviolet radiation.

Occupational exposure to ultraviolet radiation is another important context for prevention efforts. There is evidence that while melanoma and basal carcinoma are associated more strongly with non-occupational ultraviolet radiation exposure than with occupational exposure, squamous cell carcinoma is associated more strongly with total exposure, both occupational and non-occupational.<sup>15</sup> Outdoor workers need to be an intervention focus.

## Barriers to Prevention

At present, use of sun protection behaviors in the United States is not very encouraging. Only 30-50 percent of parents reported that they usually wore sunscreen while 60 percent of children and 9-37 percent of adolescents usually wear sunscreen when outdoors.<sup>16,17,18</sup> In addition, from 1986 to 1996, the use of tanning beds increased from 2 percent to 6 percent, and the incidence of sun-burns increased from 30 percent to 39 percent.<sup>19</sup> Surveys indicate that barriers to sun protection include thinking that sunscreen and protective clothes are too expensive and too burdensome to use, as well as believing that basking in the sun is relaxing and makes a person more attractive.<sup>20,21</sup>

In the United States, there is still a strong perception in adults, adolescents, and children that tanned skin is attractive. In one study, 10 percent of children ages 4-6 already perceive a tan as attractive.<sup>22</sup> In another study, approximately 50 percent of teenagers indicated intentionally working on tans.<sup>23</sup>

Surveys sponsored by the American Academy of Dermatology demonstrated that only one third of teens knew that excessive sun exposure causes skin cancer, and only one third of adults (and 5 percent of teens) knew that melanoma was a form of skin cancer.<sup>23,24</sup> By comparison, more than 95 percent of the population in Australia<sup>25</sup> knew about melanoma following public health education efforts, which suggests that knowledge in the United States can be increased. Common misperceptions about skin cancer in the United States include the belief that sun exposure is not harmful if you “build up” a tan, that there is not a risk from the sun during the winter,<sup>16</sup> and that dark-skinned individuals cannot

get skin cancer.

## Public Education

Currently, public education programs about skin cancer exist in many countries, including the United States, Australia, Canada, and Sweden. In the United States, public education programs for skin cancer prevention have been developed by the American Academy of Dermatology, the American Cancer Society, and the Centers for Disease Control and Prevention. Additionally, at least 17 states have developed, implemented and evaluated public education programs for skin cancer prevention. A review of the published skin cancer prevention programs during the last decade suggests that certain types of programs are more successful at changing knowledge, attitudes, and beliefs. Ideally, education programs should be multi-component, community-wide, ongoing (rather than short duration), and matched to the age and culture of the target group.

In North Carolina, school courses on the structure and function of the skin generally do not address the major health issues, namely, the effects of ultraviolet exposure. Although several small pilot programs have been implemented in North Carolina, at this time there are no formal, comprehensive programs being undertaken to teach young people about sun protection and skin cancer. According to a study in North Carolina, many teachers indicated multiple problems with skin cancer education programs, including administrative and time constraints for the teacher.<sup>26</sup> In addition, there are multiple barriers to implementing policy and environmental changes that are needed to support these educational programs.

In terms of secondary prevention, the North Carolina Dermatologic Association and the American Academy of Dermatology support and promote free skin cancer screening clinics across the state. These programs provide public education, screening, and early detection of skin cancers by targeting adults, not children, who are at risk. Guidelines for the early detection of melanoma promote the “ABCD” approach to pigmented lesion assessment.<sup>27</sup> This assessment tool recommends that people regularly examine moles or pigmented spots on their skin and consult a physician if any show Asymmetry, Border irregularity, Color variation from one area to another, or Diameter larger than 6

mm. Results from a study in Connecticut suggest that people who perform skin self-examination are more likely to detect melanoma in an earlier, more curable stage of the disease.<sup>28</sup>

## **Summary**

In order to decrease the incidence of, and mortality from, skin cancer (especially malignant melanoma), primary prevention efforts need to be focused on the highest-risk groups: children and adolescents. Educational programs to change knowledge, attitudes, and behaviors must be supported by policy and environmental changes that promote sun protection behaviors. At the same time, secondary prevention efforts should continue to encourage and support skin examination for the early detection of melanoma and other skin cancers.

The Prevention Subcommittee strongly supports multi-level interventions designed to reduce ultraviolet radiation exposure in North Carolina. The Subcommittee has selected the following objectives and strategies to accomplish that aim.

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## ***Ultraviolet Radiation Protection Goals, Objectives, and Strategies***

### **Goal 1: To decrease ultraviolet radiation exposure by 2006.**

#### **Targets by 2006:**

1. To decrease from 21% to 15% or less the proportion of North Carolinians who report trying to get a suntan in the last 12 months (Data Source: Behavioral Risk Factor Surveillance System, 1999).
2. To increase from 48% to at least 55% the proportion of North Carolinians who report always or nearly always using sunscreen or protective clothing (Data Source: Behavioral Risk Factor Surveillance System, 1999).
3. To increase to at least 10% above baseline the proportion of North Carolinians who report using shade as a form of sun protection. [See Objective 5, Strategy 1]  
(Data Source: North Carolina Cancer Survey, baseline and specific target to be established in 2001).
4. To increase from 71% to at least 85% the proportion of North Carolinians with children under 13 who report always or nearly always using sunscreen or protective clothing with their children (Data Source: Behavioral Risk Factor Surveillance System, 1999).
5. To increase to at least 10% above baseline the proportion of North Carolinians with children under 13 who report using shade as a form of sun protection for their children. [See Objective 5, Strategy 1]  
(Data Source: North Carolina Cancer Survey, baseline and specific target to be established in 2001).
6. To decrease from 24% to 19% or less the proportion of North Carolinians who report having a sunburn in the last 12 months (Data Source: Behavioral Risk Factor Surveillance System, 1999).
7. To decrease the proportion of North Carolinians under 18 who report having a sunburn in the last 12 months. (Data Source NC Cancer Survey, baseline and specific target to be established in 2001).
8. To decrease the proportion of North Carolinians who report using tanning beds in the last 12 months.  
(Data Source NC Cancer Survey, baseline and specific target to be established in 2001).

#### **Objective 1**

To increase to at least 15% above baseline the knowledge in the general population about the hazards of UV light and about early detection of skin cancer.

#### **Strategies**

1. Identify, or develop, and disseminate targeted educational messages about the hazards of UV exposure.
2. Identify, or develop, and disseminate targeted educational messages about the early detection of skin cancer at such events as skin cancer screenings and other prevention programs.
3. Identify, or develop, and disseminate patient educational messages for use in medical settings.
4. Identify and implement continuing medical education programs for primary care providers and ancillary health personnel on skin cancer prevention techniques for patients.

## **Objective 2**

To increase the adoption of sun-protective behaviors and reduce the number of sunburns among person under age 18 by:

- ❖ increasing the use of shade for extended (1/2 hour or more) exposure periods among persons under 18,
- ❖ increasing the use of sunscreens or sunblocks (with a sun protection factor of 15 or higher) for extended (1/2 hour or more) exposure periods among persons under 18,
- ❖ increasing the use of photoprotective clothing (including UV-protective sunglasses) for extended (1/2 hour or more) exposure periods among persons under 18,
- ❖ reducing the unprotected sun exposure from 10 a.m. to 4 p.m. (standard time) among persons under 18
- ❖ increasing the number of environmental supports that provide shade areas for persons under 18, and
- ❖ increasing the number of school and recreational policies that support sun protective behaviors for persons under 18.

## **Strategies**

1. Identify, or develop, and disseminate targeted educational messages about sun-protective behaviors targeted to youth under age 13 and to parents and caregivers of children under age 13.
2. Identify, or develop, and disseminate targeted educational messages about sun-protective behaviors targeted to youth ages 13 to 18.
3. Identify and implement education programs about skin cancer and UV exposure for children under age 13 targeted for such settings as schools, camps, child care facilities, and scouts.
4. Identify and implement education programs about skin cancer and UV exposure for youth ages 13 to 18 targeted for such settings as schools, camps, and pools.
5. Encourage organizations, businesses, and schools to plant trees and/or erect shade structures in playgrounds and other areas frequented by children under age 13 through educational messages, programs, and other initiatives.
6. Encourage organizations, businesses, and schools to plant trees and/or erect shade structures in outdoor recreational and social areas frequented by youth ages 13 to 18 through educational messages, programs, and other initiatives.
7. Encourage child care facilities and schools to set policies that promote sun protective behaviors such as sunscreen use, protective clothing, and reducing prolonged unprotected outdoor exposure during the hours when UV radiation is highest (between 10:00 a.m. and 4:00 p.m. standard time) for children under 13 through educational messages, programs, and other initiatives.
8. Encourage schools and athletic leagues to set policies that promote sun protective behaviors such as sunscreen use, protective clothing, and reducing prolonged unprotected outdoor exposure during the hours when UV radiation is highest (between 10:00 a.m. and 4:00 p.m. standard time) for youth ages 13 to 18 through educational messages, programs, and other initiatives.

### **Objective 3**

To increase the adoption of sun-protective behaviors and reduce the number of sunburns among outdoor workers by:

- ❖ increasing the use of shade for extended (1/2 hour or more) exposure periods,
- ❖ increasing the use of sunscreens or sunblocks (with a sun protection factor of 15 or higher) for extended (1/2 hour or more) exposure periods,
- ❖ increasing the use of photoprotective clothing (including UV-protective sunglasses) for extended (1/2 hour or more) exposure periods,
- ❖ reducing the unprotected sun exposure from 10 a.m. to 4 p.m. (standard time)
- ❖ increasing the number of environmental supports that provide shade areas
- ❖ increasing the number of business policies that support sun protective behaviors.

### **Strategies**

1. Develop and disseminate targeted educational messages about sun-protective behaviors for outdoor workers.
2. Identify and implement education programs about skin cancer and UV exposure targeted for outdoor workers, such as parks and recreation, highway, and agricultural workers.
3. Encourage organizations and businesses to implement environmental supports such as erecting shade structures in areas where outdoor workers labor, when these are safe and feasible, through educational messages, programs, and other initiatives.
4. Encourage organizations and businesses to set policies on sun protective behaviors through educational messages, programs, and other initiatives.

### **Objective 4**

To decrease skin damage from tanning machines and other forms of recreational tanning.

### **Strategies**

1. Develop and disseminate targeted educational messages to youths and to parents and caregivers regarding the dangers of tanning machines in order to impact attitudes and norms about tans.
2. Assure that tanning machines in North Carolina meet existing regulations and safety standards.
3. Strengthen warning, consumer information, and educational messages about tanning machines through policy changes.
4. Encourage organizations and businesses to implement environmental supports such as erecting shade structures in areas where people recreationally tan through educational messages, programs, and other initiatives.
5. Develop and disseminate targeted educational messages to youths and to parents and caregivers regarding the dangers of recreational tanning in order to recraft attitudes and norms about tans.

## **Objective 5**

To collect needed data to assess a baseline for objectives and to evaluate effectiveness of interventions.

### **Strategies**

1. Revise BRFSS and North Carolina Cancer Survey questions related to skin cancer prevention.

### **Goal 2: To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

American Cancer Society: 3.1P\*, 3.3P, 4.3P, 4.5P

Blue Ridge Cancer Coalition: 1.2, 4.1, 4.5

Center for Corporate Health: 2.1, 2.2, 2.3P, 2.4P, 2.5, 2.6, 3.1, 3.2, 3.3, 4.1, 4.4, 4.5

Eastern Carolina Cancer Coalition: 1.2, 4.5

North Carolina Academy of Family Physicians: 1.1P, 1.3P, 1.4P, 2.1, 2.2, 4.1, 4.3P, 4.5

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention Subcommittee: 2.5, 2.6, 2.7, 5.1

North Carolina Cancer Control Program: 1.2P, 2.7P, 2.8P, 3.1P, 4.1, 4.4P, 5.1P

North Carolina Cooperative Extension Service: 1.2, 3.1, 3.2

North Carolina Council for Women: 1.1, 1.2, 1.3

North Carolina Day Care Association: 2.1, 2.3, 2.7

North Carolina Department of Public Instruction: 1.2, 2.1P, 2.2, 2.5P, 2.6P, 2.8, 4.1, 4.5

North Carolina Department of Transportation: 3.4

North Carolina Department of Environment and Natural Resources-Division of Parks and Recreation: 1.1, 3.1, 3.2, 4.5

North Carolina Division of Child Development-Workforce Section: 1.1, 1.2, 2.3, 4.1, 4.5

North Carolina Division of Forest Resources: 2.5

North Carolina Division of Radiation Protection: 2.2, 2.7, 3.1, 4.1, 4.2P, 5.1

North Carolina Farmworkers Health Alliance: 1.2, 3.1P

North Carolina Health Promotion and Disease Prevention Section: 1.1, 2.3, 2.4, 2.7P, 4.1, 4.5

North Carolina High School Athletic Association: 2.8

North Carolina Local Health Services Section: 2.3, 2.4

North Carolina Office of Healthy Carolinians: 1.1, 3.1, 3.2, 3.3, 4.4, 4.5

North Carolina Office of Healthy Carolinians: 2.3P, 2.4P, 3.3P, 4.3P

North Carolina Office of Public Health Nursing: 1.4P

North Carolina Pediatric Society: 1.4, 2.1

North Carolina Prevention Partners: 2.1

North Carolina Recreation and Parks Society, Inc.: 1.1, 3.1, 3.2, 3.3, 4.1, 4.5

North Carolina State University-Natural Learning Initiative: 2.5, 2.6

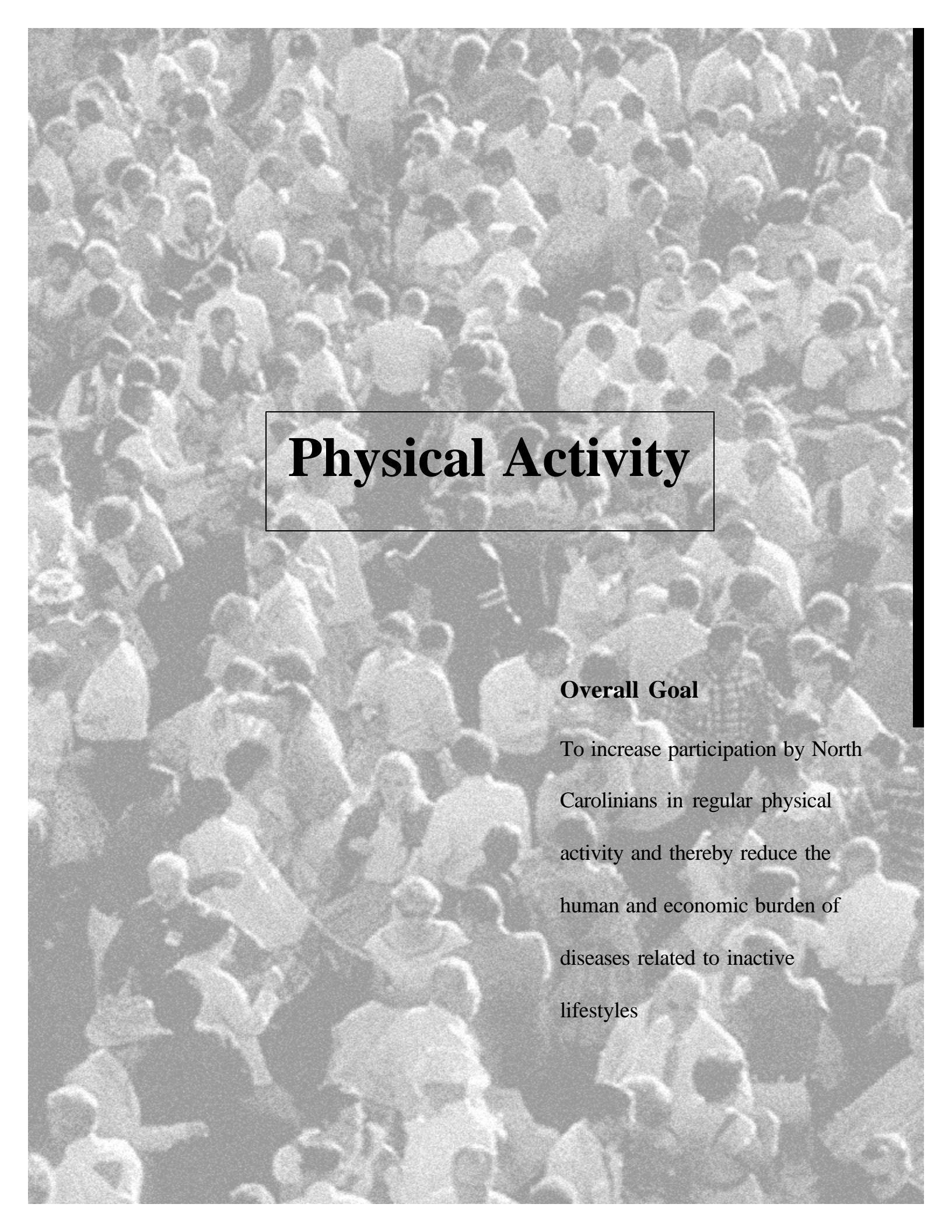
North Carolina State University-Recreation Resources Service: 1.1, 3.1, 3.2, 3.3, 4.1, 4.5

North Carolina Women's and Children's Health Section-Children and Youth Branch: 2.1P, 2.3, 2.4

UNC School of Public Health: 1.4

YMCA: 2.3, 2.4

\* P indicates Principal Agency



# **Physical Activity**

## **Overall Goal**

To increase participation by North Carolinians in regular physical activity and thereby reduce the human and economic burden of diseases related to inactive lifestyles



*According to the U.S. Surgeon General's 1996 Report on Physical Activity and Health, physical activity can substantially reduce the risk of developing or dying from colon cancer and other major health problems such as heart disease, high blood pressure, and diabetes.<sup>1</sup>*

The epidemiological evidence of an association between physical activity levels and cancer varies with the tumor site. Engaging in regular, sustained levels of physical activity as an adult could possibly reduce the risk of cancer of the colon by as much as 50 percent.<sup>2,3,4,5</sup> A similar inverse relationship appears likely with breast cancer<sup>6</sup> and possibly with prostate cancer.<sup>5</sup> That is, as activity levels increase there is a concomitant decrease in the risk of cancer. For other tumor sites, the evidence is less convincing or incomplete.

Another key issue is related to the energy balance between caloric intake and expenditure in maintaining body weight. There is convincing evidence that obesity/high body mass, itself caused by a combination of energy-dense diets, excess caloric intake, and lack of sufficient physical activity, increases the risk of endometrial cancer. Obesity probably increases the risk of postmenopausal breast cancer and possibly increases the risk of colon cancer.<sup>7</sup>

One of the most serious consequences of overweight in children is that it tends to persist into adulthood when it is associated with many adverse health outcomes, including heart disease, hypertension, diabetes, gallbladder disease, osteoarthritis, and some cancers.<sup>8</sup>

The biological mechanism for a protective effect of physical activity on cancer risk varies with the tumor site. Proposed mechanisms that are common to many cancer sites include: maintenance of optimal weight; prevention of weight gain or reduction of abdominal fat mass; promotion of optimal levels of metabolic hormones and growth factors; alteration of endogenous sex hormones levels; and enhanced immunologic response.<sup>9,10,11</sup>

**There has been  
an alarming  
increase in the  
number of  
overweight and  
obese individuals  
during the last  
decade.**

## Epidemiological Evidence

Following is a brief summary of the epidemiologic evidence on the role of physical activity in reducing the risk of cancers of the colon, breast, and prostate. Studies on other tumor sites, including the lung, testes, ovary, and endometrium, although promising, are scant and inconsistent; more research on these cancers is clearly needed.<sup>3,4</sup> Further, there is little or no data on the issue among African Americans, who have higher cancer mortality rates but lower levels of recreational activity than whites.

### Colon Cancer

One study has estimated 20 percent of colon cancer can be attributed to lack of physical activity.<sup>9</sup> The epidemiological evidence for a reduced risk of colon cancer in relation to recreational or occupational activity levels is convincing.<sup>2,3,4,11,13</sup> Numerous studies have been published showing a 20 to 70 percent decrease in risk among the most physically active men and women. The studies that evaluated a possible trend in risk observed an inverse dose-response relationship – as activity levels increased there was an associated decrease in the risk of colon cancer. Given the strength and consistency of this association along with data indicating that it does not appear to be attributable to other factors related to a healthy lifestyle, the evidence is compelling that physical activity independently protects against colon cancer.<sup>2,3,4,13</sup> In contrast, most research has found physical activity to be unrelated to risk for rectal cancer.<sup>5,14-16</sup>

In addition to the suggested biological pathways common to all cancers, some investigators have

suggested that increased physical activity levels may specifically decrease colon cancer risk by decreasing stool transit time and thereby reducing the time the colon is exposed to carcinogens in the stool. More scientific evidence is needed, however on the specific biological mechanisms underlying the association between physical activity and reduced colon cancer risk. Intervention studies that evaluate whether the introduction of moderate physical activity levels among sedentary adult populations will decrease the incidence of colon cancer have not been published.<sup>3,4</sup>

## Breast Cancer

Breast cancer rates differ greatly around the world. Epidemiological data indicate that these differences are most likely due to multiple factors including diet, physical activity, obesity, alcohol intake, and reproductive patterns.<sup>17</sup> Greater childhood weight gain lowers the age at menstruation, which in turn increases the years of ovulation and possibly the risk of breast cancer.<sup>18</sup> The epidemiological evidence on the association between recreational and occupational physical activity levels and breast cancer risk is supportive of a probable protective relationship.<sup>6,7</sup> However, the results of these studies are not as conclusive as those examining the relationship between physical activity and colon cancer.<sup>4,10</sup> Of the 36 studies published, 25 reported an inverse association between increased physical activity and the risk of both pre and post menopausal breast cancer, with risk reductions ranging from 10 to 70 percent and an average reduction of 40 to 50 percent. The level of activity needed to reduce risk is still unclear. Some studies have suggested that moderate activity is sufficient. A few studies that examined a possible trend in risk reported that increasing levels of physical activity actually increase one's risk for breast cancer. Mixed results have been found with regard to whether activity is protective when undertaken during teen-age years versus as an adult.

The proposed underlying biological mechanisms for a protective effect of physical activity on breast cancer development are compelling.<sup>9,10</sup> Possible pathways include: balancing caloric intake with energy expenditure, decreasing exposure to female hormones by promoting anovulation, preventing weight gain or abdominal obesity during adulthood, and improving immune function.

## Prostate Cancer

Prostate cancer is the second leading cause of cancer death in men and the most frequently diagnosed cancer among men in the U.S.<sup>19</sup> The epidemiological evidence suggests a possible relationship between physical activity and prostate cancer. The results of published studies are much more uncertain than studies conducted of breast and colon cancer.<sup>3,4,20</sup> Of the 23 published studies, only 13 showed a decrease in risk with an average reduction of 10 to 30 percent. Among the studies that examined the trend in risk, about one-half observed a lower risk of prostate cancer at higher levels of physical activity. Because the natural history of prostate carcinogenesis is poorly understood, biological mechanisms for a relationship with physical activity are not clear.<sup>3,4</sup> No intervention studies have been published on physical activity and prostate cancer.

## Risk Factor Prevalence

### Physical Activity Levels in North Carolina

Physical activity holds promise as one of the few interventions that can be undertaken by adults to reduce their risk of cancer. In addition, regular physical activity can help reduce risks for cardiovascular diseases which with cancers are the leading causes of death in North Carolina and nationally. However, since the early 1980's, the level of physical activity has been decreasing nationally. By 1992, 28 percent of American adults age 18 years and older reported that they did not engage in any leisure-time physical activity. In North Carolina, data from the Behavioral Risk Factor Surveillance System (BRFSS) show that participation in physical activity is below the national average, with only 18.5 percent of adults reporting in 1998 that they participated in 30 minutes of physical activity at least five times per week. This means that 81.5 percent of adults were not achieving the recommended level of activity; data of the same year for older adults show that 84 percent of North Carolinians age 65 or older were not achieving the recommended level of activity.

Nationally, self-reported participation in vigorous physical activity among youth has decreased slightly from 66 percent in 1991 to 64 percent in 1997.<sup>21</sup> The same year in North Carolina, only 55 percent of students reported participating in vigorous physical

activity.<sup>21</sup> Consistent findings over time suggest that girls are less active than boys, teenagers are less active than younger children, and African American girls are the least active of all.

## Prevalence of Overweight and Obesity

There has been an alarming increase in the number of overweight and obese individuals during the last decade. Body Mass Index (BMI) describes body weight relative to height. It is equal to weight in kilograms divided by height in meters squared. Overweight is defined as BMI of 25 to 29.9 and obesity as a BMI of 30 and above. A BMI of 30 in most cases means an individual is about 30 pounds overweight. The Third National Health and Nutrition Examination Survey showed that the number of overweight Americans increased from 25 percent (1976-80) to 33 percent (1988-94) of adults.

According to the 1999 Behavioral Risk Factor Surveillance Study (BRFSS), 36.4 percent of North Carolina adults are overweight; 21.5 % are obese. Dr. Jeffery Koplan, Director of the Centers for Disease Control and Prevention, states that the continuing epidemic of obesity is a critical public health problem. Obesity rose 6 percent nationally between 1998 and 1999 with the largest increase found among whites, who had a 7 percent increase.<sup>22</sup> Data from the North Carolina Health Services Information System show that in 1999, using the newly revised children growth chart cut points for BMI, 12.3 percent of 2 through 4 year olds, 17.8 percent of 5 through 11 year olds and 22.5 percent of 12 through 18 year olds have a BMI at or above the 95<sup>th</sup> percentile for gender and age.<sup>3,8</sup> In all age groups, North Carolina has a higher prevalence of overweight than the national average.

## Summary

A growing body of research indicates that physical activity is one of the few interventions that can help prevent cancer, particularly cancer of the colon, breast and possibly prostate. These tumor sites are among the most frequently diagnosed cancers in the US and in North Carolina. Nationally, it appears that there is an epidemic of inactivity with up to 60 percent of adults getting little or no physical activity. The prevalence of obesity is rising at an alarming rate. In North Carolina, participation in physical activity is below the national average. Lifestyle behaviors such as

physical activity patterns are complex and behavior change interventions are challenging. In *Promoting Health: Intervention Strategies from Social and Behavioral Research*, the Institute of Medicine recommends use of a social ecological model, which would provide the necessary framework for intervening at multiple levels (individual, interpersonal, institutional, community, and policy) and with multiple approaches (e.g., education, social support, incentives, laws, policies).<sup>23</sup> An increased intervention focus on environmental and institutional barriers should be considered. Research that evaluates the impact of increased physical activity on the risk of these tumors is needed, as are studies that identify the strategies that will be most effective in promoting regular physical activity.

The Prevention Subcommittee strongly supports multi-level interventions designed to increase physical activity and reduce cancer incidence in North Carolina. The Subcommittee has selected the following objectives and strategies to accomplish that aim.

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## ***Physical Activity Goals, Objectives, and Strategies***

### **Goal 1:**

**To increase participation by North Carolinians in regular physical activity and thereby reduce the human and economic burden of diseases related to inactive lifestyles.**

#### **Targets by 2006:**

1. Increase the proportion of North Carolina adults 18 and older who report participating in any leisure time physical activity to more than 85%. (Data Source: Behavioral Risk Factor Survey, 1998. Baseline, 1998: 72.3%)
2. Increase the proportion of North Carolina adults 65 and older who report participating in any leisure time physical activity to more than 71%. (Data Source: Behavioral Risk Factor Survey, 1998. Baseline, 1998: 61.1%).
3. Increase the proportion of North Carolina youth grades 9-12 who report participating in either moderate (30 minutes, 5 times per week) or vigorous (20 minutes, 3 times per week) physical activity. (Data Source: Youth Risk Behavior Survey beginning 2001. Baseline will be set with YRBS 2001 data when they become available).

**Note:** During the next five years, efforts to improve rates of physical activity among African Americans and among lower income groups will receive priority attention, since rates among these groups currently are lower than those for other populations.

The following objectives are supported by the published *Plan to Increase Physical Activity in North Carolina 1999-2003*. (Copy Available Upon Request from the North Carolina Health Promotion and Disease Prevention Section-Physical Activity and Nutrition Unit)

**On the following pages,**

**\*\* indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

### **Objective 1**

To increase the number of NC adults who are aware of and practice the Surgeon General's recommendations on physical activity (an accumulation of 30 minutes per day of moderate physical activity on most days of the week to produce health benefits).

### **Strategies**

1. Develop skills for conducting groundwork activities such as partnership and coalition building, assessment, community planning, etc. for the delivery of environmental and policy interventions.
2. Develop media and social marketing campaigns addressing diverse populations and groups as well as media advocacy interventions to support policy level change. \*\*

3. Conduct policy analysis and develop or modify public, private and organizational policies to support physical activity.

## **Objective 2**

To increase the number of worksites that provide opportunities for physical activity and policies that promote physical activity.

### **Strategies**

1. Identify, or develop, and promote or develop worksite intervention models proven to be effective with respect to increasing physical activity opportunities.
2. Conduct worksite policy analysis and assist worksites in developing or modifying policies that support physical activity opportunities.

## **Objective 3**

To increase the number of local communities that provide physical activity opportunities and adopt policies that promote physical activity.

### **Strategies**

1. Develop skills for conducting groundwork activities such as partnership and coalition building, assessment, community planning, etc. for the delivery of environmental and policy interventions.
2. Develop media and social marketing campaigns for addressing communities and media advocacy interventions to support policy level change.
3. Conduct local policy analysis and develop or modify public, private and organizational policies to support physical activity.

## **Objective 4**

To increase the number of schools that provide physical activity opportunities and adopt policies that promote physical activity.

### **Strategies**

1. Develop regular communications to students, faculty and staff about the need for physical activity, opportunities for physical activity, and the recommended levels of physical activity.
2. Work collaboratively with the Department of Public Instruction to conduct a policy analysis examining physical activity opportunities for youth.
3. Establish quality physical education curriculums and policies that provide physical activity opportunities for students and establish lifelong physical activity routines.
4. Post signage about on-site physical activity opportunities (e.g. using stairs, joining clubs, walking to school).

## **Objective 5**

In collaboration with faith communities, to increase opportunities for physical activity within those communities.

### **Strategies**

1. Develop skills for conducting groundwork activities such as developing linkages with faith communities, conducting participatory planning, assessment of needs and assets, and partnering to develop and evaluate programs.

## **Objective 6**

To eliminate disparities in reported physical activity by improving health related factors and norms of populations more adversely affected by inadequate physical activity. \*\*

### **Strategies**

1. Actively engage underserved and vulnerable ethnic and cultural groups in the development and implementation of operational strategies aimed at understanding and reducing disparities among ethnic groups and across educational and socioeconomic differences. \*\*
2. Develop and implement effective, culturally appropriate interventions in addressing each of the stated objectives areas. \*\*

## **Goal 2: To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

Alice Aycock Poe Center for Health Education: 1.2, 1.3

American Cancer Society: 6.1, 6.2

Center for Corporate Health: 2.1, 2.2

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention Subcommittee: 3.2P\*,  
3.3P, 5.1, 5.2P, 5.3P

North Carolina Cardiovascular Health Program: 1.3, 2.1, 2.2, 3.1, 4.2, 6.1, 6.2

North Carolina Cooperative Extension Service: 1.1, 1.2, 1.3, 3.2, 3.3

North Carolina Department of Public Instruction: 1.1, 1.2, 1.3, 3.2, 3.3, 4.1P, 4.2, 4.3P, 4.4

North Carolina Health Promotion and Disease Prevention Section-Injury and Violence Prevention Unit

North Carolina Health Promotion and Disease Prevention Section-Physical Activity and Nutrition Unit/  
Governor's Council on Physical Fitness and Health: 1.1P, 1.2P, 1.3P, 2.1P, 2.2P, 3.1P, 3.2P, 3.3P, 4.2P,  
4.4P, 5.1P, 6.1P, 6.2P

North Carolina Nutrition Network: 1.1, 1.2, 1.3, 3.2, 3.3

North Carolina Office of Minority Health: 1.1P, 1.2P, 1.3P, 3.2P, 3.3P, 6.1, 6.2

North Carolina Prevention Partners: 1.1, 1.2, 1.3, 2.1, 2.2, 3.2, 3.3

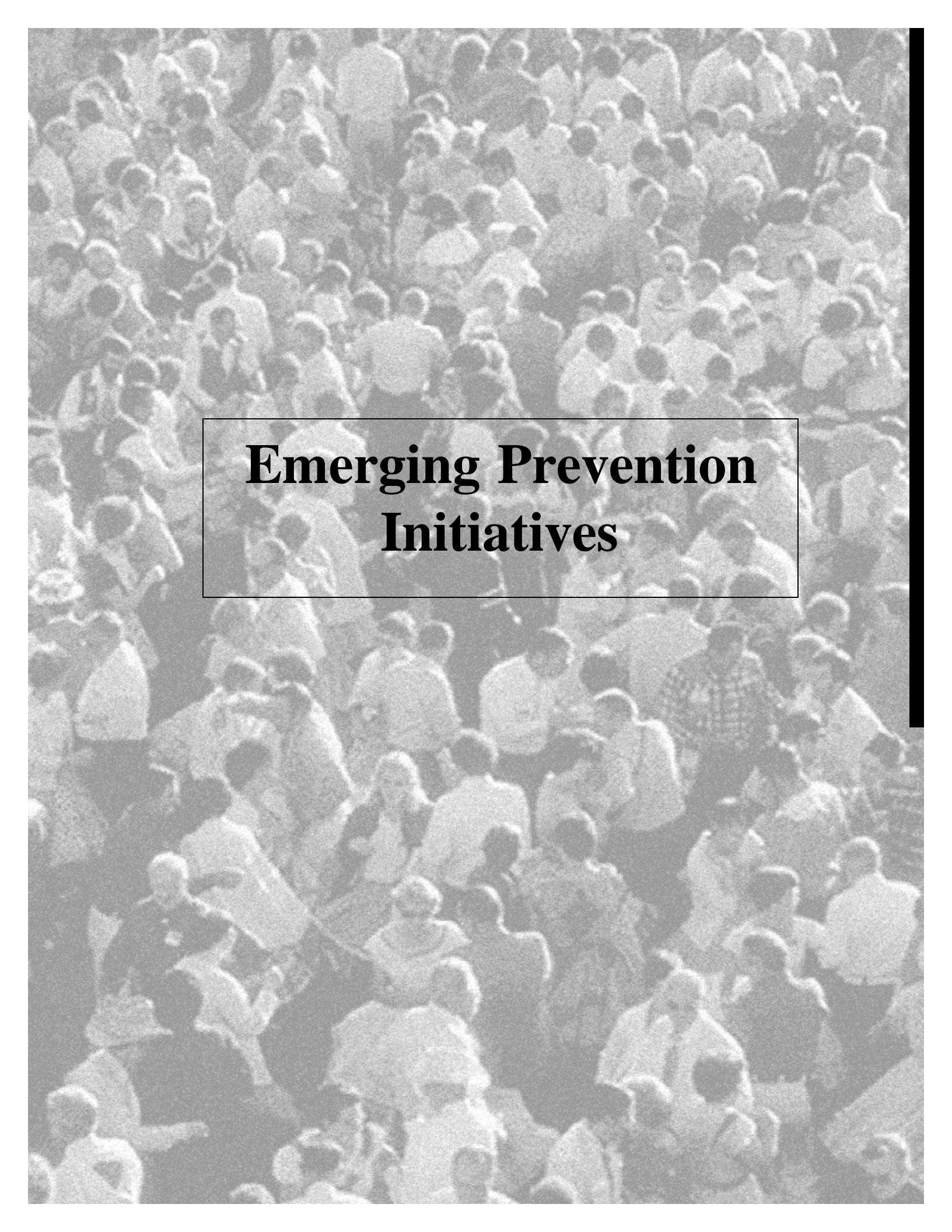
UNC Center for Health Promotion and Disease Prevention: 2.1

UNC Department of Exercise and Sport Science: 4.1, 4.2, 4.3, 4.4

UNC School of Public Health: 2.1, 2.2

UNC School of Public Health-Department of Health Behavior and Health Education: 3.1

\* P indicates Principal Agency



# **Emerging Prevention Initiatives**



## Chemoprevention

*Chemoprevention has been defined as the use of pharmacologic or natural agents that inhibit the development of invasive cancer either by blocking the DNA damage that initiates carcinogenesis or by arresting or reversing the progression of premalignant cells in which such damage has already occurred.<sup>1</sup>*

Pharmacologic chemopreventive approaches have possible uses for individuals who have tested positive for a genetic predisposition to cancer. However, as discussed below, there are risks that accompany use of these agents, and their efficacy is undergoing continued study. For individuals considered to be at normal risk for cancer, diets rich in fruits and vegetables and low in red meat consumption have shown promise as preventive approaches.<sup>2</sup> For a full discussion of dietary chemoprevention, please refer to the *Prevention-Diet* section.

### Pharmacologic Chemoprevention

Chemopreventive agents that have been shown to be effective in reducing cancer incidence include tamoxifen (for breast cancer), 13-cis-retinoic acid (for head and neck cancer), retinyl palmitate (for lung cancer), and an acyclic retinoid (for liver cancer).<sup>1</sup> Aspirin and other non-steroidal anti-inflammatory agents have been shown to reduce risk for colorectal cancer. Until recently, these agents had shown the greatest effectiveness in people at high risk for developing second primary tumors following treatment of an initial tumor (secondary prevention), while their effectiveness for primary prevention remained to be demonstrated.<sup>1</sup> However, data from the National Surgical Adjuvant Breast and Bowel Project (NSABP) Tamoxifen Prevention Trial (Fisher, Constantino, Wickerham, et al., 1998) showed that tamoxifen reduced the risk of invasive and noninvasive breast cancer by almost 50 percent among subjects in the trial, who were all at increased risk for breast cancer.<sup>3</sup> Two other trials, conducted in Italy (Veronesi, Maisonneuve, Costa, et al., 1998) and the United Kingdom (Powles, Eeles, Ashley, et al., 1998), did not find that tamoxifen reduced incidence of breast cancer.<sup>3</sup>

The potential risks and drawbacks of these

measures have been noted, such as an increased risk for endometrial cancer associated with tamoxifen. Other side effects of tamoxifen can include estrogen deficiency and, more rarely, vascular events.<sup>3</sup> Newer agents, such as raloxifene, do not pose an increased risk for endometrial cancer, but evidence of a protective benefit is more limited in the case of raloxifene than it is for tamoxifen, and it can cause some of the side effects that are associated with tamoxifen use.<sup>3</sup> A large clinical trial (Study of Tamoxifen and Raloxifene) is underway to ascertain whether raloxifene is effective in reducing breast cancer risk.<sup>3</sup> A benefit of both tamoxifen and raloxifene is decreased risk of osteoporotic fractures.

There is evidence from both animal models and human trials that aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) may protect against development of colorectal cancer. Of note is a 1991 study that prospectively investigated the effect of aspirin intake on colon cancer mortality rates.<sup>5</sup> After adjusting for dietary factors, obesity, physical activity, and family history, regular aspirin use at low doses was found to reduce the risk of fatal colon cancer.<sup>5</sup> A 1994 case-control study found that the risk of colorectal cancer was negatively related to aspirin use.<sup>6</sup> The possibility of gastrointestinal and renal side effects of NSAID use, especially in the elderly, was noted. It has been postulated that the mediating mechanism for the effect of NSAIDs on colon carcinogenesis is inhibition of prostaglandin synthesis.<sup>7</sup> Supporting this hypothesis, a 1998 study found that a specific prostaglandin inhibitor, celecoxib, inhibited both incidence and multiplicity of colon tumors.<sup>8</sup> There is evidence that a threshold level of aspirin intake exists in order for prostaglandins to be inhibited,<sup>8</sup> pointing to the need for further study of what the recommended dose should be.

## **Summary**

There are considerable restraints in proposing tamoxifen or raloxifene as cancer prevention agents from a public health viewpoint. Currently, the available evidence argues for advocating the use of these agents by physicians on an individual patient basis, primarily for women at substantial risk for breast cancer (projected risk of breast cancer equal to or greater than 1.66 over a five year period) rather than in normal-risk women. It is premature to recommend raloxifene for decreasing the risk of developing breast cancer outside a clinical trial setting. These recommendations are consistent with the American Society of Clinical Oncology's technology assessment on tamoxifen and raloxifene as breast cancer risk reduction strategies.<sup>9</sup>

Since significant side effects are associated with both tamoxifen and raloxifene, close medical supervision is required. It should be further noted that there is insufficient evidence to determine whether tamoxifen provides overall health benefit or increases breast cancer survival. It should be discussed as part of an informed decision-making process with careful considerations of risk, benefits and alternatives. Definitive public health recommendations for pharmacologic chemoprevention of both breast and colorectal cancer should be deferred pending the results of Phase 3 clinical trials.

The Prevention Subcommittee plans to monitor research developments in this important area as well as to gain an understanding of the perspective of North Carolinians regarding cancer chemoprevention. The Subcommittee will develop public health messages and programs as warranted by a review of the issues and evidence. The following objectives and strategies have been selected to accomplish those aims.

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## ***Chemoprevention Goals, Objectives, and Strategies***

### **Goal 1:**

**To critically review research findings and ethical issues related to chemoprevention of cancer and consider their applicability for development of public health messages and programs.**

#### **Objective 1**

To conduct a workshop that addresses for North Carolina the current status of knowledge and frequency of use of chemopreventive approaches for cancer and explores ethical, clinical, and other issues related to chemoprevention that need to be researched further. The workshop will be held in conjunction with topics on genetic testing and cancer presented by the Prevention and Care Subcommittees.

#### **Strategies**

1. Gather and review the position statements of national and state-level organizations.
2. Survey physicians regarding: (1) the frequency with which their patients are using chemopreventive approaches for cancer; and (2) their opinions of the advisability of chemopreventive approaches for cancer.
3. Conduct and identify existing findings from qualitative interviews with North Carolinians who have undergone genetic testing to ascertain whether they have used chemopreventive approaches for cancer.
4. Explore the potential for adding an item to the North Carolina Behavioral Risk Factor Surveillance System (BRFSS) that asks about attitudes toward chemoprevention of cancer.
5. Define goals and develop a plan for conducting a workshop that addresses North Carolina's specific needs.
6. Conduct the workshop.
7. Prepare and distribute a document summarizing the workshop.

#### **Objective 2**

Encourage participation in relevant chemoprevention studies (e.g. Study of Tamoxifen and Raloxifene (STAR), Selenium and Vitamin E Cancer Prevention Trial (SELECT), Adenomatous Polyp Prevention with Celecoxib (APC)).

#### **Strategies**

1. Identify centers within North Carolina that are participating in cancer chemoprevention studies (e.g. SELECT, Prostate Cancer Prevention Trial (PCPT)) and disseminate this information to physicians and organizations to alert men of these opportunities.
2. Distribute materials to SELECT clinical centers to facilitate recruitment to these studies.
3. Encourage the development and initiation of new chemoprevention studies.

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state (See *Coordination*).**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective followed by Strategy).

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention

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North Carolina Advisory Committee on Cancer Coordination and Control-Evaluation

Subcommittee: 1.4P

\* P indicates Principal Agency



## **Genetic Testing**

*The ability to identify genetic risk factors for particular cancer types has brought increasing attention to the clinical, ethical, and legal issues surrounding genetic testing. Evidence to date has identified a role for genetic mutations in cancers of the breast, ovary, and colon/rectum. Data regarding genetic mutations for other cancers is emerging.*

The contribution of genetic factors to population risk for cancer is thought to be relatively small when compared with behavioral and environmental factors. For example, in the case of breast cancer, 5-10% of cases are believed to be attributable to mutations in the BRCA1 and BRCA2 genes. Despite this relatively minor role of genetic factors in cancer risk at the population level, for individuals who carry the relevant genetic mutations, lifetime risk is high; lifetime risk of breast cancer is estimated at 85% by age 70 for those with the BRCA1 mutation, and breast cancer risk is similar for those who carry the BRCA2 mutation.<sup>1</sup> Cumulative risk of ovarian cancer for those with the BRCA1 mutation has been estimated to be 26% by age 70 for most mutation carriers; a small subset of carriers have been found to be at much greater risk, estimated at 85%.<sup>1</sup> Presence of the BRCA2 mutation confers a somewhat elevated cumulative risk for ovarian cancer, estimated to be 10% by age 70.<sup>1</sup>

Mutations in five genes (hMSH2, hMLH1, hMSH6, hPMS1, and hPMS2) cause hereditary nonpolyposis colorectal cancer, a type that has early onset and that increases risk for extracolonic cancers.<sup>2</sup> Mutations in the APC 11307K gene are associated with certain forms of familial colorectal cancer among Ashkenazic Jews.<sup>2</sup>

Increasing numbers of people are opting to undergo genetic testing to learn whether cancer-predisposing genetic mutations are present. A positive test for a cancer-predisposing genetic mutation brings with it decisions concerning whether to take preventive measures to lessen risk. The individual and his or her physician must carefully consider the evidence showing whether and to what extent available preventive measures are effective in preventing cancer. Such approaches include prophylactic mastectomy, prophylactic oophorectomy, and long-term

administration of chemopreventive agents such as tamoxifen or raloxifene.

### **Issues Surrounding Genetic Testing**

Expert task forces have pointed out the importance of genetic counseling for individuals considering genetic testing, including communication about the uncertainties in current estimates of risk for those found to be mutation carriers.<sup>1</sup> There is extensive evidence that the majority of people overestimate their personal risk for cancer and that this overestimation strongly influences decisions about genetic testing.<sup>3</sup> Current knowledge about the benefits and risks of options for surveillance and risk reduction (e.g. prophylactic mastectomy) should be discussed thoroughly during counseling.<sup>1</sup> Anxiety about cancer risk should be assessed and addressed.<sup>2</sup>

Genetic testing has several benefits for medical practice. It has been suggested that genetic testing is most useful when it can inform a clinical decision, such as whether to undergo prophylactic mastectomy.<sup>4</sup> An example of this benefit is evident in the case of a person with a strong family history of breast and ovarian cancer; genetic testing can assist her in pinpointing her levels of risk for each of these cancer types and, based on this information, whether to consider undergoing a surgical preventive procedure.<sup>4</sup> Genetic testing is also useful for identifying people who are most likely to benefit from earlier and more frequent screening; for example, the majority of those who undergo screening because of a slight family history of colorectal cancer are actually at average risk for developing the disease.<sup>4</sup> Testing for the MSH2 and MLH1 mutations would identify those among this group who are at high risk.<sup>2</sup> It should be noted, however, that the great majority of colorectal cancer

cases occur among average risk individuals.

On the other hand, genetic testing for cancer-predisposing mutations has several drawbacks that, according to many, are not fully understood by the public. Of primary concern is the interpretation of a positive or negative result.<sup>4</sup> In the case of breast cancer, the vast majority of women with some family history would test negative for the BRCA1 and BRCA2 mutations. However, these women could still be at elevated familial risk due to: 1) the failure of the test to detect the mutation (up to 30% of mutations may be missed by testing); or 2) the presence of a predisposing mutation in a gene that has not yet been identified.<sup>4</sup> They also may be at elevated risk due to environmental risk factors that affect multiple family members.<sup>4</sup> Thus it is important to recognize the false reassurance that can accompany genetic testing.<sup>3</sup> Such circumstances point to the necessity of developing sound informed consent procedures for genetic testing.<sup>4</sup>

Limitations of genetic testing are also considerable for those who test positive for a mutation. In some instances a variant in DNA sequence may not indicate a predisposing mutation.<sup>4</sup> A false positive result can have extremely detrimental consequences for those people who opt for a procedure such as oophorectomy and then learn this was unnecessary.<sup>5</sup> In addition, it has been noted that even when a known predisposing mutation is present that can effectively predict increased risk over a lifetime, the increased risk is lower in magnitude over the short term.<sup>4</sup> A third caveat is that the risk posed by the mutation is modified by numerous environmental and lifestyle factors as well as by other genes, making it impossible to quantify the elevated risk in any given individual.<sup>4</sup> Another limitation is the state of our knowledge about the role of genetic mutations in informing medical decision-making.

Finally, issues of privacy and of discrimination in insurance and employment are significant. Legislation varies across states, but national policy bodies have issued recommendations on how genetic testing results should be used in health insurance and employment contexts; their recommendations have strongly influenced state legislation.<sup>4</sup> For example, the National Institutes of Health-affiliated Task Force on Genetic Testing issued the following statement on Discrimination: "No individual should be subjected to unfair discrimination by a third party on the basis of having had a genetic test or receiving an abnormal genetic test result. Third parties include insurers,

employers, and educational and other institutions that routinely inquire about the health of applicants for services or positions."<sup>6</sup> The American Cancer Society has issued privacy and anti-discrimination recommendations consistent with the NIH-DOE Task Force on Genetic Testing. The American Cancer Society recommendations also express strong support for further studies to examine the ethical, legal, and social issues surrounding genetic testing and protection of individuals.<sup>7</sup>

North Carolina is among the small number of states that protect genetic information. Under North Carolina statutory law (G.S. 58-3-215 and G.S. 95-28), health insurers and employers cannot use genetic information when making coverage or employment decisions. Managed care organizations have begun implementing guidelines on genetic testing and counseling for their physicians and members.<sup>8</sup> The degree of protection from health insurance coverage and employment discrimination provided by the North Carolina statutes will become evident as legal cases are brought.

## **Research and Policy Statements**

Several national organizations and task forces are actively conducting research and issuing recommendations on genetic testing. The National Institutes of Health-Department of Energy Working Group on Ethical, Legal, and Social Implications of Human Genome Research created the Task Force on Genetic Testing to formulate recommendations and ensure the safety and effectiveness of genetic tests.<sup>6</sup> The Task Force states as its overarching goal "to recommend policies that will reduce the likelihood of damaging effects so the benefits of testing can be fully realized undiluted by harm."<sup>5</sup>

The American Society of Clinical Oncology issued a formal statement on genetic testing for cancer susceptibility on February 20, 1996. It states, "ASCO firmly believes that any physician who offers genetic testing should be aware of, and able to communicate, the benefits and limits of current testing procedures, and the range of prevention and treatment options available to patients and their families."<sup>9</sup> The statement endorses ten principles to guide clinical practice in genetic testing and counseling.

## **Preventive Options following a Positive Genetic Test**

For prophylactic mastectomy, there is considerable evidence that this procedure reduces breast cancer incidence. In one study, bilateral prophylactic mastectomy reduced risk by 90% among moderate- and high-risk women.<sup>10</sup> However, a risk remains following this measure; case reports have been cited showing breast cancer occurrence in residual glandular epithelium.<sup>10</sup> Reduction in risk for ovarian cancer following bilateral prophylactic oophorectomy has been estimated at 45%.<sup>11</sup> For a discussion of pharmacologic chemopreventive options, please refer to the *Chemoprevention* section. For a discussion of dietary chemoprevention, please refer to the *Diet* section.

### **Summary**

Genetic testing for cancer is a continually evolving area, with many complex implications for personal choice and professional practice. The predictive abilities of genetic tests for cancer and the risks and benefits of preventive procedures following a positive test will remain central questions. A full understanding of the issues involved and how these should translate into public health practices will require substantial research in the years to come. Decisions regarding whether to undergo genetic testing for a cancer predisposition should be made by careful and informed consultation between the individual and medical practitioners.

The Prevention Subcommittee plans to monitor research developments in this important area and to gain an understanding of the perspective of North Carolinians regarding genetic testing for cancer. The Subcommittee will develop public health messages and programs as warranted by a review of the issues and evidence. The following objectives and strategies have been selected to accomplish those aims.

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## ***Genetic Testing Goals, Objectives, and Strategies***

### **Goal 1:**

**To critically review research findings and ethical issues related to cancer-specific genetic testing and consider their applicability for development of public health messages and programs.**

#### **Objective 1**

To conduct a workshop that addresses for North Carolina the current status of cancer-specific genetic testing and explores ethical, clinical, and other issues related to genetic testing that need to be researched further. The workshop will be held in conjunction with topics on chemoprevention of cancer and with topics on genetics and cancer presented by the Care Subcommittee.

#### **Strategies**

1. Gather and review the position statements of national and state-level organizations.
2. Survey physicians regarding: (1) the frequency with which their patients are undergoing cancer-specific genetic testing; and (2) their opinions of the advisability of cancer-specific genetic testing.
3. Conduct qualitative interviews with North Carolinians who have undergone cancer-specific genetic testing to learn their perspective on the factors involved in their decision.
4. Coordinate with development of the State Genetics Plan.
5. Define goals and develop a plan for conducting a workshop that addresses North Carolina's specific needs.
6. Conduct the workshop.
7. Prepare and distribute a document summarizing the workshop.

### **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention Subcommittee: 1.1P\*,  
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\* P indicates Principal Agency



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*Screening is the detection of disease among people who do not have symptoms. Screening for cancer is considered effective if it meets several distinct criteria.*

First, it must demonstrate an ability to reduce cancer-related morbidity and mortality. Thus for a screening test to be effective, the specific cancer must be potentially curable if detected early and the test must be able to detect the cancer at an early stage when it can be treated with less intensity and at lower cost.<sup>1</sup> Second, the effectiveness of a screening test depends on its having high sensitivity and specificity; that is, people who have the disease must have a high likelihood of testing positive and people who do not have the disease must have a high probability of testing negative.<sup>2</sup> Third, screening tests must be affordable, not only so that they are accessible to individuals, but also so that the costs of screening entire populations do not outweigh the benefits.<sup>3</sup> Finally, cancer screening cannot be effective unless the tests are acceptable to and used by the population at risk and unless they are repeated at intervals appropriate to detect early cancer.<sup>4</sup>

Screening and early detection\* become particularly problematic when our ability to diagnose a disease outpaces our ability to treat it effectively. Patients may come to a clinic with some awareness of the benefits of screening tests, but they may know little about the potential risks or negative consequences of screening. Knowing that one has a disease before symptoms appear but when treatment may not be available may lead to emotional distress and needless suffering. Policymakers are wary of “creating disease in the absence of symptoms,” while practitioners find it difficult to explain to patients that screening is a two-edged sword that may bring with it as many questions as answers.<sup>5-6</sup>

An effective cancer-screening program has many dimensions. There are six components that must be addressed successfully for a program to have an impact on morbidity and mortality:

- public and patient education;
- provider referral;
- availability of services;
- access to services;

- quality assurance; and
- surveillance and evaluation of screening activities and outcomes.

Even when a screening test has been validated, it is rarely utilized to its capacity rapidly and by all vulnerable populations. This point is demonstrated in the text discussing each of the cancers that the Early Detection Subcommittee is focusing on. Several intervention approaches have been successful for increasing cancer screening rates. These include telephone and mailed reminders from providers, multimedia educational interventions, financial incentives, and peer counseling, which all have been shown to increase mammography use.<sup>9-23</sup> Provider interventions that have been shown to enhance mammography use include physician reminder systems, chart audit with feedback, and physician education.<sup>24-35</sup>

**Screening and early detection become particularly problematic when our ability to diagnose a disease outpaces our ability to treat it effectively.**

Over the past five years, the Early Detection Subcommittee has reviewed both data and the literature on screening for four cancers- breast, cervical, colorectal, and prostate; for three of them screening tests appear to be efficacious in reducing deaths. For cervical cancer, the benefits of screening are well documented.<sup>36</sup> There is evidence that regular screening for colorectal cancer is associated with a decrease in mortality, and in the past few years there is increasing agreement about how often screening should occur.<sup>37-39</sup> The advantages of mammography screening for breast cancer in women aged 50 to 74 are also well-documented. Screening for women in their forties and over age 70 has been controversial but is gaining more support.<sup>40-42</sup> For prostate cancer, solid evidence does not yet exist from randomized, controlled trials that screening results in decreased mortality.<sup>43</sup> The Subcommittee therefore does not recommend a public health screening initiative for prostate cancer at this time; rather, we propose goals and objectives that address \*In this section, “screening” and “early detection” are used interchangeably; they refer to non-symptom-prompted testing.

the need for public and professional education to promote informed decision-making about testing. The Subcommittee has also begun to focus on a review of screening recommendations for other cancers, specifically ovarian, testicular, skin, oral and endometrial cancers. The Subcommittee does not recommend screening for these cancers, as no evidence exists from randomized controlled trials that screening reduces mortality for each of these cancers. Our focus, though, is on educating the public and provider about risk factors, approaches for people at high risk, and how to assess screening options.

Screening for cancer is a moving target, in that the state of knowledge about different kinds of cancer is continually evolving. Moreover, new tests sometimes supplant older ones. When discussing screening recommendations, the Subcommittee has cited recommendations and guidelines from the National Cancer Institute, American Cancer Society, the U.S. Preventive Services Task Force, and other authoritative organizations. Where these groups agree on screening recommendations, the Subcommittee has set target goals for increasing the use of screening tests in the five years of this Plan. While 100 percent is the ideal goal for types of screening tests that have been proven effective, the Subcommittee has set goals that can be attained by the year 2006; after that time, the Plan will be evaluated and the target goals might be adjusted. Finally, any discussion of screening refers to the general population; persons at high risk for certain cancer have special needs. Screening tests and schedules for high risk persons should be determined through discussions between physicians and patients.

Nationally, and in North Carolina, African-Americans are more likely to develop cancer and to die from cancer than persons of any other racial and ethnic group.<sup>44</sup> In addition, while cancer incidence rates have decreased among whites, Hispanics and American Indians, these rates have remained the same among African-Americans and Asian/Pacific Islanders.<sup>44</sup> The cancers that the Early Detection Subcommittee has focused on, breast, cervical, colorectal, and prostate, have similar patterns. For breast cancer, African-American women have lower incidence rates than white women, but higher mortality rates. Both African-American women and men have higher colorectal cancer incidence and mortality rates than any other ethnic group. African-American men have the highest incidence and mortality rates for prostate cancer. Although cervical cancer incidence and mortality rates

are generally low, African-American women have higher incidence rates and mortality rates than white women. As with the rates of disease incidence and mortality, rates of utilization of recommended screening tests are lower among certain sub-groups of the population (e.g. low-income persons and persons without health insurance).<sup>45-47</sup> The elderly also are less likely to receive appropriate screening tests.<sup>46,48,49</sup>

The rapid, almost constant evolution of knowledge about cancer and its screening is especially evident in the field of genetics. As genetic susceptibilities are discovered and simple tests are designed to screen for susceptibility in large populations, questions of how to test, who to test, and the consequences of testing—especially discrimination—arise. In 1997, the Advisory Committee on Cancer Coordination and Control secured passage of statutes that prohibit discrimination in health insurance (G.S. 58-3-215) and employment (G.S. 95-28) based on genetic information.

Issues surrounding genetic testing will continue to face the Subcommittee and the State over the next several years. All North Carolinians must receive information about genetic advances, facts about how to assess one's own genetic history (only 5 to 10 percent of cancers are hereditary), and access to high risk clinics, if appropriate. No testing should be conducted without a meaningful process of informed consent.

Over the last five years, the Early Detection Subcommittee of the Advisory Committee on Cancer Coordination and Control and its partners have implemented a broad spectrum of initiatives to address early detection of breast, cervical, colorectal, and prostate cancer in North Carolina. Some highlights of accomplishments in these areas include:

- partnership with the Wal-Mart Corporation to promote breast cancer screening and awareness to shoppers in stores throughout the state;
- an annual Breast Cancer Awareness Month “kickoff” held in October at the State Capitol, which attracts media attention to breast cancer issues;
- the State Laboratory of Public Health’s adoption of the new thin layer preparation technique (*ThinPrep*) for the evaluation of Pap tests;
- revision of the manual, “Pap Smear Screening - A Guideline for Local Health Departments,” through a cooperative venture between the North Carolina Breast and Cervical Cancer Control Program and the Women’s Health Section of the

North Carolina Division of Public Health;

- completion of a survey of physicians and mid-level practitioners to gain an understanding of current colorectal cancer screening practices in North Carolina, which will inform future efforts to increase colorectal cancer screening;
- development and implementation of a flexible sigmoidoscopy training program for primary care providers and mid-level practitioners;
- implementation of a statewide print media campaign to promote awareness of colorectal cancer; development of a brochure presenting colorectal cancer data and screening guidelines, and distribution of the brochure to over 21,000 physicians, physician assistants, and family nurse practitioners in the State;
- development of a prostate cancer screening recommendation, issued in the summer of 2000; and
- development of educational materials concerning issues of prostate cancer screening and treatment, with a particular emphasis on developing materials for African-American men.

The Early Detection Subcommittee's goals and objectives for breast, cervical, and colorectal cancers were selected in order to reduce the burden of morbidity and mortality for the people of North Carolina. For this second *North Carolina Cancer Control Plan*, initiatives for five additional cancers will be undertaken by the Early Detection Subcommittee: endometrial cancer, oral cancer, ovarian cancer, skin cancer, and testicular cancer. The goals and objectives for these five cancers and for prostate cancer reflect the need for further discussion and recommendation as knowledge about these diseases accrues. The Subcommittee will revisit the issues surrounding screening for prostate and other cancers in the coming years. Efforts to alleviate racial, ethnic, socioeconomic, and age-related disparities in screening, and in the factors that influence screening, will remain central to the mission of the Early Detection Subcommittee.

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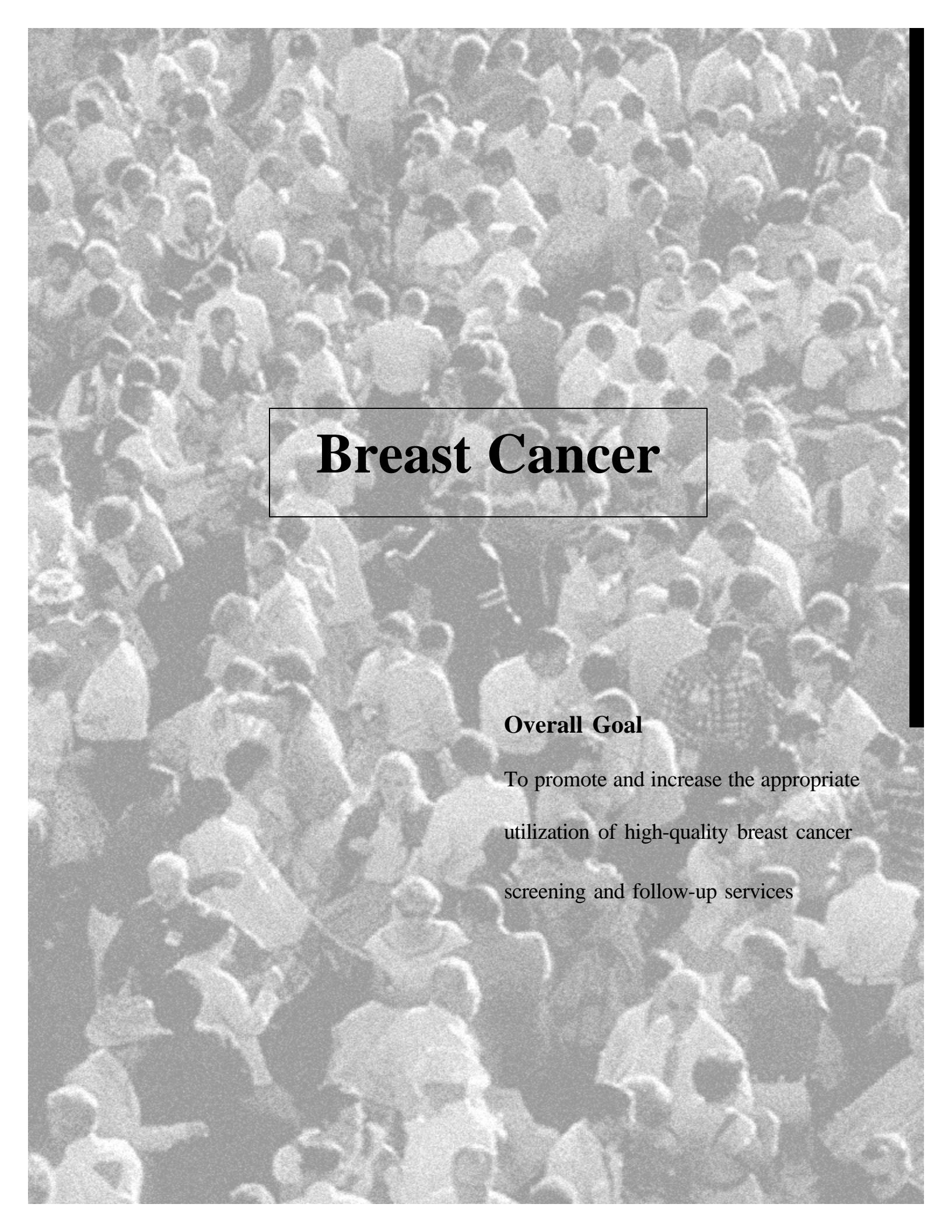
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# Breast Cancer

## Overall Goal

To promote and increase the appropriate utilization of high-quality breast cancer screening and follow-up services



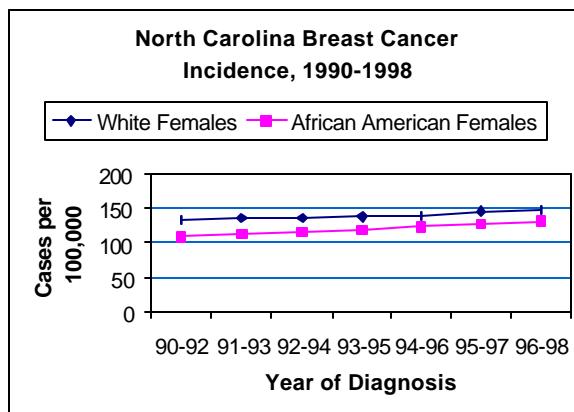
*Each year in North Carolina, approximately 5,700 women are diagnosed with breast cancer and 1,300 die from this cancer.<sup>1</sup> Nationally, the incidence of breast cancer has increased over the past twenty years. This observation is due in part to more women undergoing screening examinations, although screening alone does not seem to explain the entire increase.<sup>2</sup>*

Statistics from the National Cancer Institute's Surveillance, Epidemiology, & End Results Program (SEER) based on data available from 1990-1997 are as follows. Per 100,000 women in the United States, 109.7 are diagnosed with breast cancer each year (incidence rate) and 25.6 die from the disease (mortality rate). There are differences in these rates among women of different races. For example, per 100,000 women, breast cancer incidence rates are 114 for Whites, 100 for African-Americans, and 69 for Hispanics.

Despite little change in incidence rates nationally since 1990, there have been encouraging decreases in breast cancer mortality. However, these reductions have also varied by race. Even though Whites are more likely than African-Americans to develop breast cancer (114 v. 100 per 100,000), African-Americans are more likely to die from the disease (31 v. 25 Whites per 100,000). Breast cancer mortality has decreased among all three races but the reductions have been significant only among Whites and Hispanics. The decrease in breast cancer death among African-Americans has been quite small. These disparities have been explained, at least in part, by differences in breast cancer screening (see *Screening* section, below).

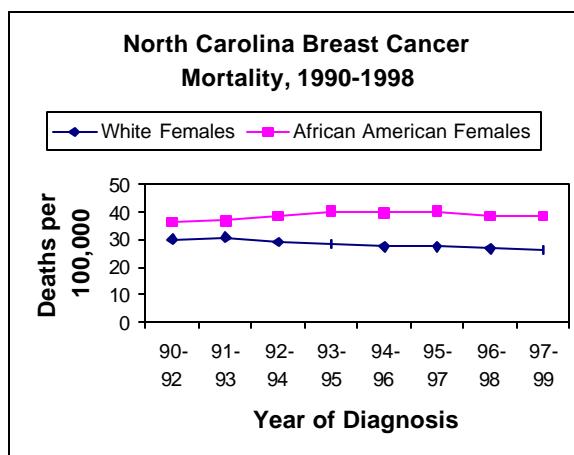
In North Carolina, breast cancer incidence rose between 1990 and 1998 for both White women and African-American women (*Figure 1*). The rate of increase in incidence was approximately the same in both groups. However, as shown in *Figure 2*, there has been a widening disparity in breast cancer mortality between White women and African American women. While the mortality rate for White women fell from 29.9 per 100,000 population in 1990 to 26.6 per 100,000 population in 1998, for African American women during the same period mortality rose from 36.3 per 100,000 population to 38.7 per 100,000 population.

Figure 1



Source: North Carolina Central Cancer Registry

Figure 2



Source: North Carolina Central Cancer Registry

## Risk Factors for Breast Cancer

Age is the most important risk factor for breast cancer. The risk of being diagnosed with invasive breast cancer increases by more than 15-fold between 30 and 70 years of age.<sup>3</sup> Over 78 percent of breast cancer occurs in women over 50 years old; over 50 percent occurs in women over 60. Two other important risk factors are a family history of breast cancer and a personal history of breast cancer.<sup>4</sup>

Secondary risk factors for breast cancer include delivery of a first child after age 30, never having given birth, history of endometrial or colon cancer, early menarche, obesity in post-menopausal women, alcohol use, and late menopause. Fat consumption, oral contraceptive use, hormone replacement therapy, and cigarette smoking are other possible, but not proven, risk factors.

In terms of primary prevention, tamoxifen, a selective estrogen-receptor modulator, has been shown to reduce breast cancer incidence among women at elevated breast cancer risk<sup>5</sup> and a large primary prevention trial is now underway to compare the efficacy of a similar drug – raloxifene – with tamoxifen.<sup>6</sup> These drugs are not without side effects; currently, there are few evidence-based methods of weighing risks and benefits to support women's decisions regarding use of these chemopreventive agents.

The American Society of Clinical Oncology conducted a technology assessment of tamoxifen and raloxifene and concluded that for women with a defined five-year projected risk of breast cancer equal to or greater than 1.66%, tamoxifen (20 mg/day for up to five years) may be offered to reduce their risk.<sup>7</sup> The conclusions are based on single-agent use of the drugs. The assessment states that it is premature to recommend raloxifene for reducing breast cancer risk outside of a clinical trial setting.<sup>7</sup> For additional discussion of tamoxifen and raloxifene, please refer to the *Chemoprevention* section. Another prevention strategy used by some high risk women is prophylactic mastectomy.<sup>8</sup> While this is a very severe method to prevent this cancer, women who are at extremely high levels of risk and suffer from both physical and emotional problems from this risk profile may choose this option.<sup>8</sup>

## Genetic Testing for Breast Cancer Susceptibility

Genetic testing for breast/ovarian cancer susceptibility is relatively new. BRCA1 was identified in 1994<sup>9</sup> and BRCA2 in 1995.<sup>10</sup> A positive result on a mutation test indicates enhanced breast and ovarian cancer risk – either higher risk of an initial cancer (for unaffected women) or a recurrence or second primary cancer (for women already affected by cancer). Women with BRCA1 or BRCA2 mutations have approximately a 33-50% risk of developing breast cancer by age 50.<sup>11,12</sup> By age 70, a mutation carrier's risk of developing breast cancer is 56-87%,<sup>12,13</sup> and her ovarian cancer risk is 28-44%.<sup>14</sup> However, whether or how much a mutation carrier's inherited risk can be lowered through surgery, chemoprevention, and/or behavior changes is still unclear and is being investigated.<sup>8,15-18</sup> (For additional discussion, please refer also to *Prevention-Genetic Testing* and *Prevention-Chemoprevention*).

**Until breast cancer can be prevented, the only way to reduce its mortality will continue to be through early detection and timely treatment.**

## Screening

Until breast cancer can be prevented, the only way to reduce its mortality will continue to be through early detection and timely treatment. Assuring that all women receive appropriate screening and necessary follow-up is a complex undertaking that requires a multifaceted, comprehensive plan. Such an approach involves three major components: screening, follow-up, and quality assurance. Regular mammography screening facilitates early-stage diagnosis which, in turn, contributes to mortality reduction. Indeed, almost 97% of women diagnosed with localized-stage breast cancer realize a 5-year survival, whereas those with distant disease have only a 20% chance of surviving five years.<sup>19</sup>

## Mammography

The potential for mammography to decrease mortality through early detection has been demonstrated through breast cancer screening studies conducted over the last 30 years. Eight major randomized controlled trials have been conducted for breast cancer screening, collectively including more than 500,000 women.<sup>20-31</sup> Together, these trials provide strong support for mortality decreases of up to 30% in women 50 and over who are appropriately screened.

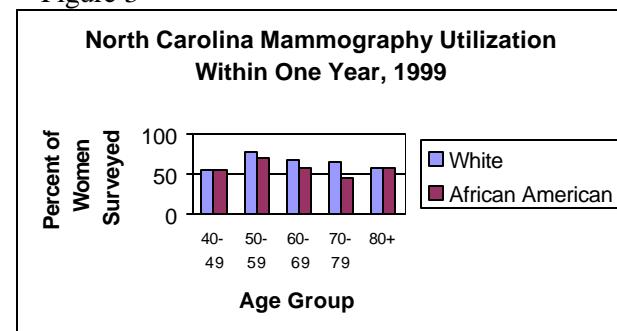
Until recently, mammography benefits for women ages 40 to 50 were not as clear as those for older women. However, in 1997, the American Cancer Society (ACS) and the National Cancer Institute (NCI) came together with new data<sup>32</sup> and jointly recommended annual screening for asymptomatic women beginning at age 40. While the joint American Cancer Society/National Cancer Institute recommendation did not specify screening frequency, the official recommendation of the American Cancer Society issued earlier in 1997 jointly with the American College of Radiology specified annual screening for asymptomatic women aged 40 and older.<sup>32</sup> The National Cancer Institute based its position regarding screening frequency on the guidelines of the presidentially appointed National Cancer Advisory Board, which concluded from its review of the scientific evidence that a recommended screening interval of one to two years for women in their forties was warranted.<sup>32</sup>

A 1997 meta-analysis of randomized controlled trials showed a statistically significant mortality reduction for women aged 40-49 (at entry) who received regular screening mammography.<sup>33</sup> One drawback of screening for women in this age group is the high rate of false-positives.<sup>34,3</sup> Risk for a false-positive mammogram result decreases with increasing age.<sup>35</sup> Some research has shown breast density, rather than age, to be the relevant factor in risk for false-positives. In a 1999 study, women with extremely dense breast tissue were almost two times more likely to have a false-positive mammogram than were women with fatty breast tissue. This effect persisted after controlling for age.<sup>36</sup> Because false-positive results can lead to overdiagnosis, unnecessary follow-up procedures, and associated psychological distress, it is particularly important for younger women to balance the potential benefits of mammography against its potential harms and costs.<sup>3</sup>

The American Cancer Society recommends annual screening of women ages 40 to 75. The National Cancer Institute recommends mammography with or without clinical breast examination for women ages 40 to 69 and states that screening may or may not be helpful for women ages 70 and older.<sup>116</sup> Despite the support of screening by these organizations, adherence to screening recommendations is still poor. The most recent national data from the Behavioral Risk Factor Surveillance System (BRFSS) show that 29% of women ages 40 or older have not had a mammogram in the last two years (CDC data, 2000) and 44% report no mammogram in the last 12 months. It is ironic that, as risk increases with age, mammography use declines.<sup>37</sup> Groups that have been found in some research to be less likely to receive regular screening include older women, minorities (especially Hispanic women), low income women, and women with fewer years of education.<sup>39</sup>

Cost is a significant factor in why some women do not receive regular screening.<sup>39</sup> A physician recommendation is another major factor in why women receive mammograms,<sup>40</sup> as is a woman's understanding of the need for a mamogram.<sup>41</sup> In North Carolina, 1999 data from the Behavioral Risk Factor Survey show that 23% of women aged 40 and older have not had a mammogram in the last two years and 33% of women aged 40 and older report no mammogram in the last twelve months. Figure 3 shows reported utilization of mammography within the previous twelve months. As can be seen, mammography utilization is lower among older women in North Carolina.

Figure 3



Source: Behavioral Risk Factor Survey, Centers for Disease Control and Prevention

As discussed earlier, late-stage diagnosis and death from breast cancer are more likely in African-American than White women. Differences in stage at diagnosis between African-American and White women have been related, at least in part, to differential rates of mammography use.<sup>42</sup> During the past decade, the national gap in screening mammography use by race has narrowed. In the early-to-mid 1990s, mammography remained under-used among minorities and women with lower incomes and education levels<sup>43,44</sup> – even among those receiving physician recommendations for mammography.<sup>45</sup> According to current national figures from the CDC, there is no longer a gap between proportions of African-American and White women who have *ever* had at least one mammogram.<sup>46</sup> However, during the late 1990s in North Carolina African-American women were still consistently less likely than White women to report having ever had a mammogram or to report having had a mammogram in the last year. The differences for this period are not statistically significant in all cases. 1999 data show that 82% of African-American women aged 40 and older in North Carolina reported having ever had a mammogram, versus 88% for White women.<sup>47</sup> Also in 1999, 57% of African-American women aged 40 and older in North Carolina reported having had a mammogram within the previous year, versus 65% for White women.<sup>47</sup> Our challenge now is to facilitate the routine repeat screening that leads to mortality reduction.

### Clinical Breast Examination

The recommendations of professional organizations differ with regard to whether clinical breast examination (CBE) should be performed as an adjunct to mammography. Whereas there is consensus about the importance of regular mammography, either alone or in combination with CBE, no professional organization recommends CBE alone. The U.S. Preventive Services Task Force, Department of Health and Human Services reports that there is insufficient evidence that CBE adds benefit to mammography or that it is a satisfactory substitute for CBE.<sup>48</sup> The National Cancer Institute supports screening that includes both mammography and CBE. The American Cancer Society recommends a clinical breast examination every three years for women between the ages of 20 and 39 and every year after that.<sup>49</sup>

The most recent national data from the

Behavioral Risk Factor Surveillance System show that 76% of women aged 40 and older reported that they had had an age-appropriate clinical breast examination (CBE).<sup>50</sup> In North Carolina, the proportion of women reporting that they had had an age-appropriate clinical breast examination in 1999 was the same as the national figure (76%); 45% of women aged 40 and older in North Carolina reported that they had had an annual CBE and mammogram (within guidelines).<sup>47</sup> Women who are older, poorer, and less educated are less likely to be screened regularly with CBE, as are African American and Hispanic women.<sup>51</sup> Lack of health insurance and lack of physician recommendation have been identified as additional barriers to clinical breast examination.<sup>51,52</sup>

### Breast Self-Examination

Regular breast self-examination (BSE) is a procedure that seems to be inexpensive and readily available to women; the American Cancer Society has recommended it for women ages 20 and older.<sup>53</sup> Other groups differ; for instance, the U.S. Preventive Services Task Force does not recommend that physicians encourage women to perform breast self-examination, although they also do not recommend that physicians cease encouraging women to do so.<sup>48</sup> For breast self-examinations to be effective in detecting early lumps, women need to be explicitly trained in lump detection skills; even with such training, however, the impact of breast self-examination is unproven.<sup>54</sup> Some large-scale studies that have been conducted have not shown a mortality benefit. Little new research in BSE has been recently funded. The practice of breast self-exam, however, may help a woman be more conscious of her breast health and therefore encourage her to utilize regular mammography and clinical breast examination.

### Public Education

Many studies have been conducted to identify both the barriers to screening and the interventions needed to overcome these barriers. As discussed earlier, cost,<sup>39</sup> physician recommendation,<sup>40</sup> and women's perceptions of the need for a mammogram<sup>55</sup> are three important factors in receiving screening. A survey of underserved women in six sites across the nation found reasons for not receiving screening to be similar to reasons stated by all women: lack of knowledge regarding screening and who needs to be

screened, lack of recommendation by a health professional, and no time.<sup>56</sup> This suggests that many interventions will work across population groups. However, there are particular barriers that have been found more prevalent among some cultural groups. For example, studies of African-American women have identified misconceptions about breast cancer risk that might undermine the perceived benefits of screening.<sup>57</sup> Many older women underestimate their true risk for the disease, particularly if they do not have a family history of breast cancer or do not understand that risk increases with age.

Barriers to receiving a clinical breast examination are similar to those for mammography, although rates of such examinations are somewhat higher than mammography.<sup>47</sup> Older, poorer, less educated working women, and women with less knowledge of breast cancer risk factors and screening guidelines, are all less likely to have a clinical breast examination, as are those with little contact with health-care providers.<sup>58,59</sup> Overall, research indicates that factors related to socioeconomic status are predictors of not receiving screening for breast cancer. Inaccurate beliefs about the disease also contribute to low screening rates.

Efforts to educate women about the need for breast cancer screening have varied in their ability to overcome these barriers and increase screening rates. Some successful attempts to persuade women of the necessity of screening mammograms have used nurse practitioners, videotapes, and in-person counseling delivered by nurses or peers, mailings, and telephone counseling.<sup>60-68</sup> Some have used a social networks,<sup>69-71</sup> community or health-care systems approach<sup>72,73</sup> rather than focusing exclusively on individuals. Interventions that are culturally sensitive, tailor information to specific needs of recipients, and work through various channels, including the overall health-care system, have been particularly successful.

Educational campaigns must be targeted to the appropriate audience, whether physicians or women. Some studies have suggested expending more effort in targeting health education campaigns to older women because this is the group with the greatest potential gain from breast cancer screening.<sup>74</sup> Others propose that health-care providers remind women of the need for mammograms during routine office visits

and that employers be encouraged to offer mammographic screening at the work site or provide compensated time for screening offsite.<sup>75</sup> In North Carolina, several studies have identified and tested ways to improve mammography use among minority and underserved populations. Interventions using a lay health educator approach have been implemented in eastern North Carolina for African-American women.<sup>70</sup> A project using both out-reach and in-reach strategies was found to be effective in increasing screening in low income housing communities in Winston-Salem and Greensboro.<sup>115</sup> Currently, an intervention employing an individualized counseling program delivered by lay health educators is being tested among low income women in Robeson County.

In an intervention with older, urban, minority women, use of an existing informal network, education sessions, and participant-planned follow-up activities increased knowledge as well as percentages of participants reporting that a friend had spoken with them about mammography

.<sup>76</sup> Data for older, urban women at various stages of mammography adoption indicate that mammography interventions for women contemplating mammography (thinking about having a mammogram in the next six months) should aim to reduce barriers and fears in addition to encouraging provider recommendation, whereas an explanation of the necessity for screening should be the intervention focus for women who are precontemplators (not thinking about having a mammogram within six months).<sup>57</sup>

Interventions should focus not only on improving one-time screening but also on improving repeat adherence (regular repeat screening in accordance with the National Cancer Institute's screening mammography recommendations). Recent research found that "off-schedule" women (women screened at least once and non-adherent with recommended screening intervals) had greater knowledge and were more positive about mammography than women who had never been screened, but their measures on these indicators were lower than "on-schedule" women.<sup>77</sup> The authors conclude that brief interventions from health care providers emphasizing the importance of repeat screening should be delivered to off-schedule women. Findings from a recent study suggest that, compared

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to usual care, tailored telephone counseling may be superior to tailored print communications for changing women currently off-schedule to on-schedule mammography.<sup>78</sup>

## Provider Referral and Promotion

Women report that the most important reason they have had a mammogram was a physician's recommendation.<sup>79</sup> In a recent study, women who named their physician as an important source of information on health and prevention were more likely to have had a recent mammogram.<sup>80</sup> In the 1990 National Health Interview Survey, however, over 30 percent of women reported that their physician had not advised them to have a screening mammogram.<sup>81</sup> Physician recommendation and mammography use have been found to decline as women's age increases<sup>82-84</sup> and to increase with higher income, education, and insurance.<sup>82</sup> Surveys of physicians show that the barriers to their recommending mammography include its cost, their belief that the examination is unnecessary, and concerns about radiation exposure.<sup>85</sup> A 1995 survey of physicians in North Carolina found that the most important physician barriers are lack of time, patient reluctance, and other health priorities with patients.<sup>40</sup>

Factors such as physicians' gender, specialty, practice setting, and year of medical school graduation influence the rate at which they refer women for mammography. For example, studies have shown that primary care practitioners and obstetrician/gynecologists are more likely to perform mammograms than other physician types.<sup>86</sup> Female gender and higher general prevention knowledge to be associated with higher mammography referral rates.<sup>87</sup>

Intervention programs need to be developed and/or disseminated that target physicians with the greatest deficiencies in breast cancer screening performance and knowledge, including older physicians in primary care settings and medical specialists.<sup>88</sup> Older women are those most in need of screening, and are also most likely to have chronic disorders that require them to be under the care of specialists. It is thus extremely important that these specialists recommend screening to age-appropriate patients. Recently developed models suggest that interventions designed with a dual focus on encouraging women to request screening and on ensuring appropriate physician recommendation

will be more effective than interventions targeting only one of these variables.<sup>89</sup>

As knowledge, attitude, and cost barriers fall, organizational barriers, chiefly found in primary care office environments, will probably assume a dominant role in determining how many eligible women receive mammography on a regular basis.<sup>90</sup> Factors of the practice environment that have been shown to correlate positively with mammography referral rates include lower patient volume and lower shared primary care.<sup>87</sup> A survey of managed care organization directors found that important organizational barriers to provision of mammography services were the inability of this service to achieve short-term cost savings for the managed care organization, high disenrollment rates, and conflicting recommendations regarding the effectiveness of mammography.<sup>91</sup> Research is underway to test the effectiveness of interventions that employ office systems to improve breast cancer screening rates.<sup>92</sup>

## Access

Cost has been identified as possibly the principal barrier to breast cancer screening.<sup>39</sup> In North Carolina, screening mammography is covered by state-regulated insurance policies and is also available to women whose family income is at or below 200 percent of poverty through the North Carolina Breast and Cervical Cancer Control Program (NC BCCCP). In some instances, a sliding fee scale may apply between 100-200% of poverty for this federally funded program. Currently, approximately 3.7% of eligible women are screened (approximately 10,000 women per year). The current screening rate for the NC BCCCP is lower than in previous years due to recent restrictions in eligibility. Medicare Part B coverage of breast and cervical screening removed women 65 years of age and older from North Carolina BCCCP eligibility. The primary target population for BCCCP is women 50-64 years of age.

Other important access barriers include lack of time, especially for women who work full-time, inconvenience of the times during which screenings are offered, and living more than 45 minutes from a screening site.<sup>75,93</sup> To increase screening rates, mammography needs to be available at low or no cost to women and mammography clinics need to be located in accessible areas. Data are mixed on the utilization of non-traditional work hours for screening.

Worksite-based interventions that remove common barriers to mammography (e.g. cost, convenience, accessibility) have been successful in improving utilization.<sup>94</sup> Among older, inner-city women, interventions that include scheduling of a next-day, no-cost appointment have been found effective in increasing mammography rates.<sup>79</sup> Use of networks of community-based nonprofit organizations to provide outreach, education, and mammography referral to low-income and other medically underserved women has also been effective in improving mammography screening.<sup>96</sup>

## Follow-Up of Abnormal Screening Results

For screening to result in a reduction in breast cancer mortality, all abnormalities must be appropriately followed up. As screening rates increase, the number of abnormalities will also increase. Delays in diagnosing breast cancer are a major reason for malpractice claims and result in the most costly awards.<sup>97</sup> There is strong medical evidence that delays in diagnosing cancer, and thus initiating treatment, lower the chance of survival.

The components of appropriate follow-up care depend on the results of both the clinical breast examination and the mammogram. Follow-up of breast abnormalities may include a diagnostic (as opposed to a screening) mammogram, fine needle aspiration, core biopsy, x-ray localization, ultrasound, and surgical removal of the lump or cyst. The diagnostic procedures have sensitivities for detecting breast cancer that vary from 60 to 95 percent.<sup>97-99</sup> Timely follow-up demands considerable coordination among primary care physicians, obstetrician-gynecologists, radiologists, surgeons, public health nurses, social workers, health educators, and physician office support staff.

For a number of reasons, follow-up for evaluation and treatment often is not completed. In a study of 10,434 mammograms conducted between 1995 and 1997, 44% of women with abnormal mammograms had no further follow-up.<sup>100</sup> Rates of non-compliance differ dramatically depending on the medical setting and the socioeconomic status and ethnicity of women. Factors associated with inadequate follow-up include rural residence and low income.<sup>101,102</sup> Lack of understanding by the patient about the next steps often contributes to incomplete follow-up, as

does inconsistent sharing of information among providers about tests that are required. Other follow-up issues include accessibility to professionals who can perform the procedures, the training level of professionals conducting the tests, quality equipment to perform procedures, as well as staff to interpret findings. Women also report that lack of communication that follow-up was necessary, cost of lost wages and medical care, systems factors, and fear are barriers.<sup>103</sup> Developing strategies to address barriers to follow-up is essential to increasing survival from this disease.

## Patient Education

Abnormal screening tests sometimes have negative psychosocial consequences and may result in failure to comply with further screening tests and treatment. Women who have abnormalities found on a screening mammogram often suffer from anxiety, depression, and fear of cancer, even if cancer is not ultimately diagnosed.<sup>104,105</sup> Psycho-educational interventions tailored to the unique needs of these women may reduce distress and promote continued adherence to follow-up recommendations.<sup>106</sup> Data from a North Carolina study, however, indicate that a false positive result does not appear to decrease the rates of further regular screening.<sup>107-109</sup>

The process of motivating women to return for follow-up begins with communicating the abnormal test result.<sup>104</sup> Such communications should balance needed information about the suspicion of breast cancer with reassurance about the relationship between early detection and cure.<sup>58</sup> The method of informing patients is also an important component of notification; proven strategies should be used to minimize patients' stress while optimizing their potential to follow through with recommendations.

## Provider Referral and Promotion

Compliance with follow-up appears to increase when the wait for a follow-up appointment is fifteen days or less, thus minimizing patient distress, and when instructions for follow-up are clear and understandable to the patient.<sup>103,104,110</sup> Because the follow-up procedures for breast abnormalities require an array of professionals, a woman is unlikely to receiving continuing care from the same practitioner at the same site. Rather, she is likely to encounter different

specialists at different sites, such as community health centers, health maintenance organizations, local health departments, and primary care and specialists' offices. Well-designed systems to assure adequate responses to abnormal tests would decrease the number of patients lost to follow-up and would likely increase survival. Such systems should foster communication across different specialties and make adequate provision for informing women of the next steps they must take to obtain adequate care.

Physician recommendations are critical to motivating women to return for appropriate follow-up.<sup>104</sup> An office systematic tracking or reminder system is essential for following women with abnormal results and for being able to assess compliance rates within a practice. Additional barriers to follow-up, as reported by women who have had abnormal mammograms, include provider insensitivity and clinic waiting time.<sup>104</sup>

## Access

Breast cancer diagnostic procedures are expensive and a particular problem for those who are uninsured or under-insured. Some public facilities in North Carolina provide diagnostic tests to indigent women. The North Carolina Breast and Cervical Cancer Control Program (NC BCCCCP) provides payment for a limited number of diagnostic services related to screening for eligible women. Yet, many other women do not meet the income requirements to become eligible for the program and, thus, may have difficulty affording diagnostic care.

Diagnostic procedures often demand the expertise of specialized practitioners who may not be readily available in rural regions of the state. Thus, transportation may be a barrier. Making these procedures more accessible to women with breast abnormalities discovered during screening must be a primary goal in providing comprehensive follow-up care.

## Quality Assurance for Breast Cancer Screening and Follow-Up

### Screening

Mammography with or without a clinical breast examination is the only screening technology clearly linked to reductions in breast cancer mortality. The

screening must be of high quality if it is to be effective. Several interrelated factors are critical to quality: professionals who are well trained to perform clinical breast examinations and to refer women appropriately for mammography; proper interpretation of the images; accurate and prompt reporting of the interpretation to both the clinician and the patient; and having definitive outcome data provided to the diagnostician to assess the accuracy of the tests. It is also vital for mammography equipment to be properly maintained by qualified personnel with a quality assurance program in place.<sup>111</sup>

Recent developments in mammography technology hold promise for improving breast cancer detection. Digital mammography may allow reduced false positives without a concomitant reduction in sensitivity.<sup>112</sup> This technology will soon be the subject of a large National Cancer Institute-sponsored screening trial.<sup>113</sup> Other technologies, such as Sestamibi scintigraphy and magnetic resonance imaging, hold promise for improved distinction between benign and malignant breast lesions.<sup>114</sup>

### Follow-up

The components of quality assurance for follow-up include:

- providing well-trained professionals to conduct the procedures;
- developing clear protocols for when and what procedures are to be used; and
- promoting communication among the professionals performing the diagnostic procedures so that care is coordinated for each patient.

A final concern is evaluation of follow-up issues. Data are available from several sources that provide statewide screening rates. Very little is known about follow-up rates after an abnormal mammogram. Such data are essential to a successful intervention whose ultimate goal is to decrease breast cancer mortality.

### Summary

A broad spectrum of programs are currently underway in North Carolina to address many of the issues that relate to breast cancer screening, follow-up, and quality assurance. Most studies to date have

recruited women who have had prior mammograms; a need and challenge for future intervention research will be to reach women who have not adopted mammography, many of whom have immigrated to the United States, are older, have lower levels of education, or are not regular users of the health care system.<sup>117</sup> Several new data sources are being developed and are proposed that will improve the ability to monitor the impact of these activities. The challenge is to coordinate these activities in a comprehensive manner, so that their results will favorably affect early detection options for women. Given our knowledge of how successful breast cancer screening can be, and what we know about the problems women in North Carolina have with the disease, the objectives that follow have been selected as goals for addressing early detection of breast cancer in North Carolina.

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## **Breast Cancer Goals, Objectives, and Strategies**

### **Goal 1:**

**To promote and increase the appropriate utilization of high-quality breast cancer screening and follow-up services.**

#### **Targets for Screening Rates by 2006\***

1. To decrease from 13% to 5% the proportion of women > 40 who have never had a mammogram.
2. To increase from 47% to 62% the proportion of women who have had an age-appropriate mammogram.
3. To increase from 76% to 81% the proportion of women who have had an age-appropriate clinical breast exam (CBE).
4. To increase from 45% to 53% the proportion of women who have had an annual clinical breast exam (CBE) and mammogram (within guidelines).

**Note:** During the next five years, efforts to improve screening rates for age-appropriate mammograms among African American, low- education, and low-income women will receive priority attention, since screening rates among these groups currently are lower than those for other populations.

\* Baseline screening rates obtained from the Behavioral Risk Factor Surveillance System, 1999.

#### **Targets for Follow-up Care by 2006\***

To increase appropriate and timely follow-up of women who receive abnormal mammograms and/or abnormal clinical breast examinations to 90 percent.

*\* Currently, there are limited data on follow-up care. Baseline data will be developed so as to quantify and measure this goal in the evaluation of this Plan.*

#### **Targets for Quality Assurance of Breast Cancer Screening and Follow-up by 2006\***

To assure that 99 percent of mammograms are satisfactory.

To establish a data system and evaluation plan to monitor the progress made towards achieving the quality assurance objectives.

*\* Currently there are limited data on the follow-up rates of abnormalities. Baseline data will be developed in the evaluation of this Plan.*

**On the following pages,**

**\*\*indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

## **Public Education for Breast Cancer Screening**

### **Objective 1**

To increase knowledge and improve attitudes of all women with regard to the importance of breast cancer screening and specifically among minorities and the underserved.\*\*

#### **Strategies**

1. Identify appropriate educational materials and programs to use in reaching all women, including those at highest risk for not receiving screening. \*\*
2. Gather and review existing educational materials developed by medical schools and schools of public health from funded research projects that have been proven effective in improving screening.
3. Disseminate the above materials to mammography facilities, physician offices, and health departments, as appropriate.
4. Provide promotional materials appropriate for high-risk groups, including African-American, low-income, and low-education women, to all providers who care for these high-risk groups. \*\*
5. Provide educational and promotional materials regarding breast cancer and breast cancer screening to appropriate local and statewide community organizations.
6. Develop media campaigns promoting appropriate breast cancer screening.

### **Objective 2**

To develop alliances with private businesses for the purpose of disseminating information on breast cancer screening and breast health education to the general public and specifically to minorities and the underserved.

#### **Strategies**

1. Identify businesses for partnerships, obtain agreements for alliances, and distribute public education materials through two additional North Carolina-based organizations (see also Cervical Section Objective 2, Strategy 1).

### **Objective 3**

To promote outreach activities within communities across the state and specifically among minorities and the underserved to raise awareness about breast cancer screening and breast health education. \*\*

#### **Strategies**

1. Develop appropriate training sessions for public health staff and other health professionals to attend.
2. Provide training to health educators and other public health department staff and health professionals on specific skills for outreach.
3. Work with community-based organizations and agencies to promote awareness and use of breast cancer screening.

## **Provider Referral/Promotion for Breast Cancer Screening**

### **Objective 4**

To increase the proportion of primary care providers who recommend regular mammograms to their eligible patients.

#### **Strategies**

1. Provide information annually to primary care providers about screening guidelines and current reimbursement rates for these exams.
2. Distribute to primary care providers materials for informing women of the need to screen and the importance of their role in recommending screening to women.

### **Objective 5**

To assure that all specialists (e.g. cardiologists, endocrinologists) who provide care to older women recommend age-appropriate breast cancer screening to at least 90 percent of their eligible patients. \*\*

#### **Strategies**

1. Distribute new screening guidelines and information to appropriate specialists about strategies for informing women about the need for screening, as needed.

## **Access to Services for Breast Cancer Screening**

### **Objective 6**

To reduce barriers to and the disparity of clinical breast exam and mammography among women. \*\*

#### **Strategies**

1. Monitor and distribute information on North Carolina legislation that requires insurance coverage for regular screening mammography of age-appropriate women. \*\*
2. Increase mammography rates for women who are un- or under-insured by expanding the proportion of providers in the North Carolina Comprehensive Breast and Cervical Cancer Control Program. \*\*
3. Promote age-appropriate screening at work sites across the state.
4. Determine the proportion of sites using expanded clinic hours among all providers of mammography. \*\*
5. Promote the use of community-based transportation services. \*\*

## **Client Education for Follow-up Care**

### **Objective 7**

To educate women about their risk of breast cancer and the need to return routinely on a regular basis for appropriate rescreening and/or diagnostic testing.

### **Strategies**

1. Identify or develop brochures, videos, and other media materials with tailored messages for women with screening mammogram abnormalities to explain in detail diagnostic care options and agencies providing care and other information.

## **Provider Referral and Promotion for Follow-up Care**

### **Objective 8**

To disseminate and recommend standardized clinical guidelines for providing follow-up care of each type of mammography result.

### **Strategies**

1. Update and disseminate clinical guidelines and information to all clinicians performing diagnostic tests for breast cancer.
2. Promote the use of reminder or tracking systems to determine the highest quality follow-up of women with abnormal results and assure prompt reminders for annual exams.
3. Encourage all referral sources (i.e., surgeons, etc.) to establish a monitoring system with the referring clinician with regular feedback on the status of follow-up for their client.
4. Identify available tracking and reminder systems to determine the highest quality packages.
5. Conduct a targeted campaign to encourage providers to adopt a selected system and educate them of the need to provide this service to patients.

## **Access to Follow-up Care**

### **Objective 9**

To provide adequate resources to enable all women in need of diagnostic follow-up to receive care in a timely manner.

### **Strategies**

1. Inform providers across the state of the resources available through the North Carolina Cancer Control Program for women at or below 115% of poverty. \*\*
2. Maintain referral resources at diverse geographic locations to provide comprehensive information on diagnostic and treatment services to women with breast abnormalities. \*\*

### **Objective 10**

To increase the knowledge of providers on appropriate methods for conducting clinical breast examinations and for properly instructing patients on how to perform thorough breast self-examinations.

### **Strategies**

1. Provide continuing education and updated guidelines to physicians, public health nurses, and other providers to upgrade their skills in conducting clinical breast examinations.
2. Provide continuing education for breast self-examination instruction for public health nurses and other health professionals.

## **Objective 11**

To provide ongoing training to radiology technologists and radiologists to improve skills in obtaining and accurately interpreting mammogram results.

### **Strategies**

1. Develop and provide continuing education to practitioners for obtaining and interpreting mammography.

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy).

American Cancer Society: 1.1P\*, 1.3P, 1.5P, 2.1P, 3.1P, 3.3P, 4.1P, 4.2, 6.3P, 6.5P, 8.2

American College of Radiology-North Carolina Chapter: 6.2, 7.2

American College of Surgeons: 5.1, 7.2

Breast Cancer Coalition of North Carolina: 5.1, 6.1, 6.4, 9.2

Brody School of Medicine at East Carolina University: 1.2, 8.2, 8.5

Cancer Information Service: 1.1, 1.3, 1.4, 1.5, 3.1, 3.2, 3.3P, 4.2, 7.2, 8.2, 8.5, 9.1, 9.2

Center for Corporate Health: 6.3

Duke University School of Medicine: 1.2, 8.2, 8.5

Mobile Health Outreach, Inc.: 1.1, 11.1, 7.2P, 8.2, 8.3, 8.5

North Carolina Academy of Family Physicians: 1.3, 1.4, 4.1P, 4.2P, 7.1, 8.2, 8.4, 10.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.2P, 3.3, 4.2, 6.1P, 6.4P, 7.2P, 8.2P, 8.3, 10.2

North Carolina Cancer Control Program: 9.1P, 9.2P

North Carolina Comprehensive Breast and Cervical Cancer Control Program: 1.5P, 3.1P, 3.2P, 4.1P, 5.1P,  
6.2P, 7.2P, 8.1P, 9.1P, 10.1P, 11.1P

North Carolina Council for Women: 1.5P

North Carolina Division of Aging: 1.1, 1.2, 1.3, 1.5P

North Carolina Division of Radiation Protection: 1.3, 11.1P

North Carolina Hospital Association: 6.4

North Carolina Medical Society: 3.3, 4.2P, 5.1P, 6.4, 7.1P, 8.1, 8.3, 8.4P, 8.5P

North Carolina Nurses Association: 1.1P, 1.4, 10.1, 10.2

North Carolina Office of Citizen Services-Care Line: 6.5, 9.2

North Carolina Office of Healthy Carolinians: 1.3, 1.4, 1.5, 3.3, 6.3

North Carolina Office of Public Health Nursing: 3.1, 3.2, 10.1, 10.2P

North Carolina Primary Health Care Association: 1.4, 1.5, 3.3, 4.1

Planned Parenthood: 1.4P, 1.5P, 3.2P, 5.P1, 6.4P

UNC School of Medicine: 1.2, 8.2, 8.5

UNC School of Medicine-Department of Radiology: 11.1P

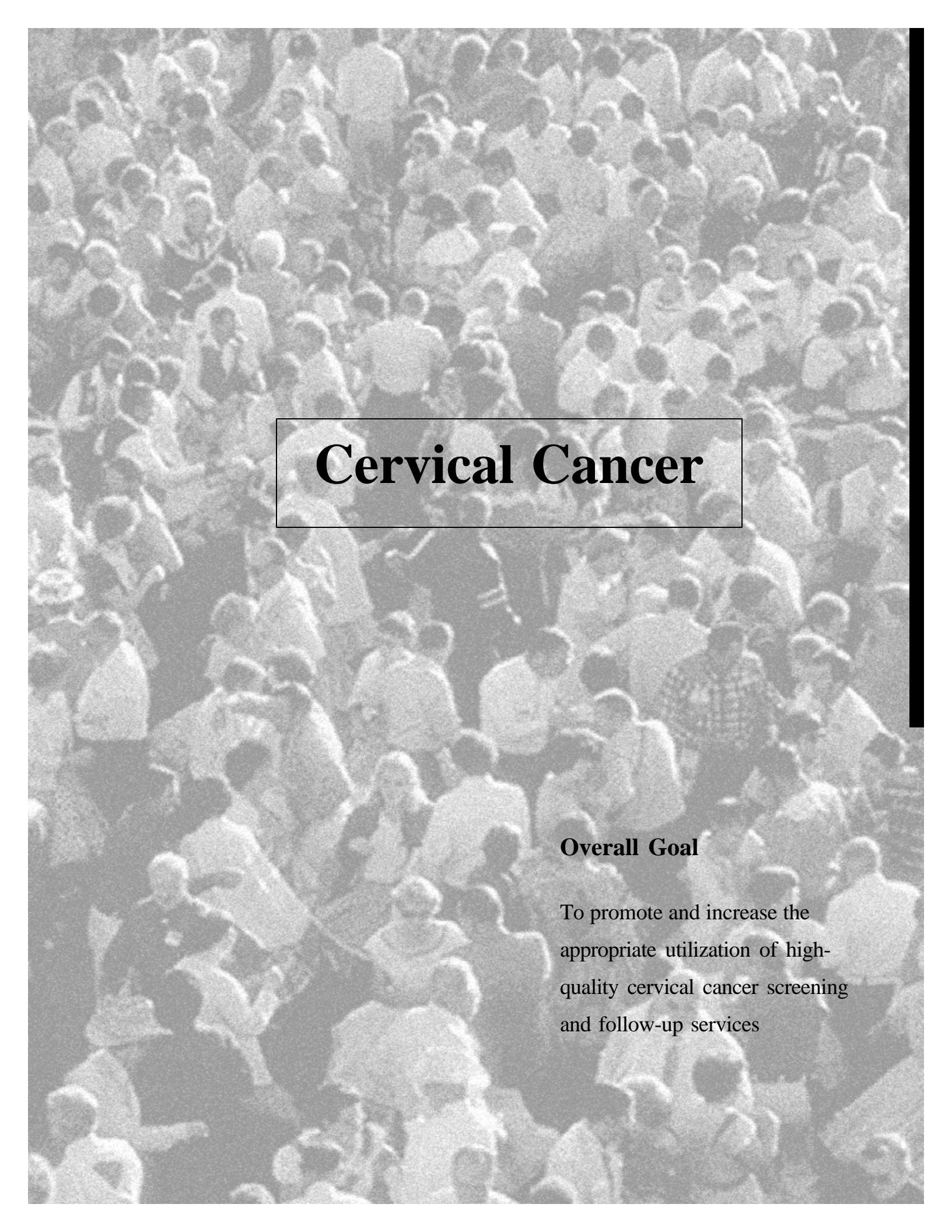
UNC School of Public Health: 1.2, 3.2

Wake Forest University School of Medicine: 1.2, 8.2, 8.5

Wake Forest University School of Medicine-Department of Public Health Sciences-Cancer Education and  
Prevention Center: 7.1P, 7.2P

\* P indicates Principal Agency





# Cervical Cancer

## Overall Goal

To promote and increase the appropriate utilization of high-quality cervical cancer screening and follow-up services

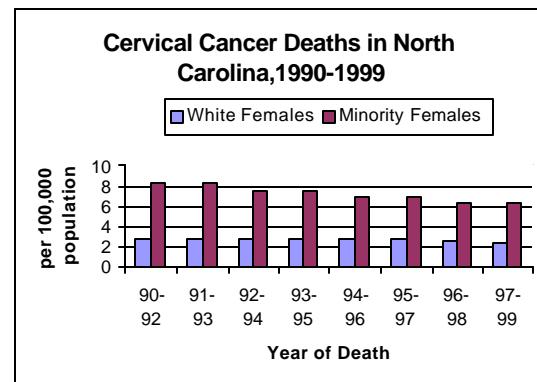


*“Cervical Cancer is a preventable and curable disease. The technology for detecting this disease and treating it is available.”<sup>1</sup> North Carolina has a long history of implementing cervical cancer control programs. However, there is still much work to be done. With the number of successful programs that have been identified in recent years, it is clear that further efforts can be made in reducing morbidity and mortality from this disease.*

In the first half of this century, cervical cancer was a major cause of cancer deaths among women. However, deaths from this disease were reduced dramatically with the advent and use of a screening test to detect cervical cancer in its early, most treatable stages. The main test used to screen for cervical cancer is the Pap smear, developed by George Papanicolaou in the 1930s and introduced for widespread screening in the 1940s.<sup>2</sup> The Pap smear, or Pap test, examines cells collected from the cervix and vagina. It can show the presence of infectious agents, inflammation, low grade abnormalities, pre-cancerous lesions, or cancer. Before cancer cells are found on the cervix, the tissues of the cervix undergo changes known as dysplasia, in which abnormal cells begin to appear. These cells are usually found with a Pap test. If treatment is not provided at an early stage of development, cancer cells begin to grow and spread more deeply into the cervix and to surrounding areas.

With the development of screening programs utilizing the Pap test, the cervical cancer mortality rate began falling dramatically beginning in approximately 1970, as shown by studies in the United States, Iceland, Nordic countries, Germany, Scotland, and Canada.<sup>2</sup> This reduction in mortality has not been observed in populations where screening is not prevalent.<sup>3</sup> The Pap test is perhaps the most effective cancer screening test we have, yet screening programs have not eradicated this cancer completely in any population.<sup>3</sup> Reasons for this failure have focused on either lack of regular screening or inadequate follow-up and treatment of pre-cancerous changes found during routine screening.<sup>4,5</sup> Abnormalities associated with Human Papilloma Virus (HPV) infection are the most troublesome in terms of failure to screen and treat appropriately.<sup>6,7,8</sup> The focus needs to be on continued research on and awareness of these factors.

Figure 1



Source: North Carolina Central Cancer Registry

As shown in *Figure 1*, cervical cancer remains a problem in North Carolina. Projections for the year 2000 show an estimated 395 new cases of invasive cervical cancer in North Carolina and an estimated 155 deaths.<sup>9</sup> This is especially tragic since most deaths are completely preventable. A majority of cervical cancer deaths are likely to occur in women over the age of 40.<sup>10</sup> North Carolina data further indicate a differing pattern of disease across racial and ethnic groups. African American women had a higher overall cervical cancer mortality rate than white women throughout the 1990s.<sup>9</sup>

Stage, which indicates the degree of spread of the disease at diagnosis, and race are important predictors of survival. Survival rates are improved when the disease is detected at an earlier stage. However, even at the same stage at diagnosis, nationally African American women have a poorer prognosis than do white women. Research shows that even though the proportions of African American and white women with distant (or invasive) disease at diagnosis are similar, African American women are more likely to die from the disease. A number

of reasons are thought to be involved, such as differences in adherence to screening, follow-up, and treatment.<sup>11</sup>

There are many factors that heighten the risk of cervical cancer, such as early age at first intercourse, multiple sex partners, smoking, and exposure to the Human Papilloma Virus. Long time use of oral contraceptives may also be a risk factor. However, given the availability of early detection and treatment procedures for cervical cancer, major risk factors for death are lack of appropriate screening and lack of prompt follow-up for abnormalities. These issues and references to several data sources and studies in North Carolina are discussed in the following sections.

## Screening

With regular Pap smear screening and appropriate follow-up care, invasive, or advanced, cervical cancer is usually preventable. Guidelines for cervical cancer screening endorsed in 1987 by the American Cancer Society, the National Cancer Institute, and American College of Obstetrics and Gynecology recommend an annual Pap smear with a pelvic examination for women who are, or have been, sexually active or who are 18 years or older. After three or more consecutive normal annual examinations, the Pap smear may be performed less frequently at the discretion of the physician.<sup>11</sup>

Although the screening rates for women reported in various national studies are generally high, they vary across different subgroups of the population. Women at the highest risk for cervical cancer are least likely to utilize screening.<sup>12</sup> National data from the 1999 Behavioral Risk Factor Surveillance Survey (BRFSS) indicate that 69 percent of all women aged 18 and over reported having had a Pap test within the previous year; 85 percent reported having had one within the previous three years.<sup>13</sup> Reported rates for having had a Pap test within the past three years are lower for Hispanic women (84.6%) than for White women (85.6%) or African American women (89.8%) women.<sup>13</sup> The proportion of women who report having had a Pap test within the past three years begins to decline after age 50; rates are 88% for women 18-49, but 86.4% for women 50-69, 81.8% for women 60-64, and only 72.2% for women aged 65 or older.

In North Carolina, data from the Behavioral Risk Factor Surveillance Survey (BRFSS) indicate that in 1999, 72 percent of all women aged eighteen and over reported having had a Pap test in the previous year; 91 percent of all women aged 18 and over reported having had one in the previous three years.<sup>13</sup> Reported rates were 90.4% for White women, 93.0% for African American women, 90.6% for Hispanic women, and 85.9% for women of other races/ethnicities. As with national rates, utilization is lower after age 50, as follows: approximately 94% of women aged 18-49 reported that they had had a Pap test in the previous three years, while the reported rates were 88.1% for women 50-69, 75.5% for women 60-64, and 78.6% for women aged 65 and older.<sup>13</sup> Both regional and national studies consistently indicate that higher education and income are associated with higher screening rates.<sup>14,15</sup> This finding may persist even for women with health insurance.

**Because barriers  
to screening differ  
across  
subpopulations,  
different  
strategies are  
needed to increase  
the utilization of  
screening.**

## Public Education

There are numerous reasons why women do not have Pap tests. These reasons vary across subpopulations. Lack of knowledge about cervical cancer and the need for regular screening, fear of finding cancer, and embarrassment about screening are negatively associated with screening.<sup>16,17</sup> Women who seem to be most likely to underutilize services are low income, older, from rural or non metropolitan areas, those who smoke, do not exercise, or are not getting regular health care.<sup>18</sup>

Because barriers to screening differ across subpopulations, different strategies are needed to increase the utilization of screening. Some of the barriers to screening can be reduced through implementing public education strategies to increase knowledge and change attitudes of women most in need of regular screening. Some public education programs to increase utilization of Pap test screening have been shown to be effective. For example, the Forsyth County Cancer Screening (FoCaS) Project resulted in a three-fold increase in the rate of regular Pap smear utilization among low income, minority women in the intervention group.<sup>19</sup> These strategies, however, are costly and not easily assumed by public health or voluntary agencies that operate on limited, fixed budgets. In addition, as the proportion of women

receiving Pap tests within guidelines approaches 90-95%, efforts are needed to reach the most recalcitrant women. These strategies and resources are the most difficult to obtain and maintain over time.

The choice of an educational strategy should be based on an understanding of the specific audience's knowledge, attitudes, beliefs, and behaviors.<sup>18</sup> Proven strategies for increasing Pap test utilization include clarifying the need for the Pap test and the risk of cervical cancer and developing lay health advisor programs that address Pap tests as part of educational efforts.<sup>19</sup>

## Provider Referral and Promotion

A physician recommendation is a very strong motivator for getting a Pap test.<sup>20</sup> A recent study of national trends in the use of preventive health care showed that most women who did not receive a Pap test did have recent contact with a physician.<sup>11</sup> These findings suggest that, although women are visiting physicians and are accessible to receiving medical advice, recommendations are not provided consistently. A 1992 North Carolina study of women diagnosed with invasive cervical cancer found that nearly 50 percent of these patients had no Pap test in the five years preceding their diagnosis. However, 83 percent of these women had used the health care system during this time period.<sup>21</sup> A literature review identified reasons why primary care providers do not adhere to cervical cancer screening guidelines. Reasons include provider characteristics, such as knowledge of the guidelines, specialty, gender, time constraints, forgetfulness, and inconvenience; patient characteristics, such as age and perceived refusal; and provider constraints such as lack of supplies and the cost of the test.<sup>11</sup>

In addition, it appears that there are important differences in screening rates among provider specialties. Women receiving care from nurses or from obstetricians/gynecologists are most likely to report having had a recent Pap test. Those receiving care from an internist are least likely to report being screened. If a woman is being seen regularly for more acute, life-threatening care such as blood pressure or diabetes checks, her provider may also be less likely to recommend a Pap test because of the added inconvenience to the patient and lack of time during the clinic visit to do a Pap test.<sup>22</sup> Many interventions have been found to be successful in increasing

screening rates among women receiving medical care. These include opportunistic screening (recommending Pap test screening when a woman is in an emergency room, provider's office, or hospital) or prompts, such as stickers on patient charts.<sup>23</sup> Studies have been done of invitation and recall systems and identified specific factors that appear to increase rates of utilization. These include, for example, clearly explaining the benefits of screening and using personal contact with health care staff to allay anxiety.<sup>12</sup>

## Access

The Pap test is performed by a wide range of health professionals, obstetrician / gynecologists, family physicians, internists, nurse practitioners, physicians assistants, certified nurse midwives, and nurses working in hospitals, clinics, offices, and industrial settings in private and public sectors.<sup>22</sup> Access issues include not only the number and type of providers available to women in each region of the state but also the cost of screening, insurance or other coverage, distance to a screening site, hours of service, and patient knowledge of the health care system. Lack of child care or transportation have also been shown to be major barriers to obtaining access.

The cost of screening can significantly influence utilization. Pap test cost varies according to the practice providing the care. Laboratory charge for a Pap smear (conventional smear technique) is approximately \$14.00. Laboratory charge for a monolayer *ThinPrep* technique is approximately \$28-30.<sup>34</sup> When institution charges and physician fees are included, however, the cost is considerably higher. Various national and state programs and policies have eased cost barriers. In 1990, Medicare coverage was expanded to include screening every three years. Legislation was passed in North Carolina requiring state regulated insurers to include screening. In North Carolina, Pap tests are provided at local health departments through the Breast and Cervical Cancer Control Program and Family Planning Services, free of charge to women or on a sliding fee scale, depending on the woman's income level. However, for women with no sick leave to visit a clinic during working hours, for those with no transportation, or for those who do not feel welcomed, access is still a major issue.

## **Quality Assurance for Cervical Cancer Screening**

### ***Accuracy of the Test***

As described earlier, a 1992 North Carolina study found that 50% of women diagnosed with invasive cervical cancer had not had a Pap test in the preceding five years.<sup>21</sup> This finding is generally offered to direct attention to screening rates. It is, however, important to question the history of the other 50% - the women who did have a Pap test. It is widely accepted that the natural history of this disease spans an interval of greater than five years. One must then examine the causes for failure to detect or failure to act upon significant abnormalities that presumably should be present on those early smears. There are two categories to consider. In the first category are the Pap tests that have no abnormal cells, even when intensely scrutinized in retrospect by multiple individuals. These Pap tests are truly negative. Many, or most, of these patients have or should have abnormal cells; however, the abnormal cells did not appear on the slide, usually due to inadequate sampling.

The second category includes those Pap tests that actually do have abnormal cells, but these cells have escaped detection. Some are missed, for no obvious reason, by the cytotechnologist. Most, however, are found to occur in smears that for many reasons are considered suboptimal (e.g., improper collecting technique, improper preparation and fixation, too much blood, or obscuring inflammation). These Pap tests are generally reported "normal" but a qualifier is added to acknowledge interpretive "limitations."

A separate group of Pap tests to consider are reported ASCUS (atypical, unknown significance). These are the Pap tests that have abnormal cells but neither the cytotechnologist nor the pathologist can categorize the abnormality with certainty.

Women who have tests in either of these latter two categories (test quality limitation and atypical unknown significance) must have their Pap tests repeated.<sup>35</sup> When working with a patient population where compliance and follow-up is a problem, it is desirable to keep repeat tests to a minimum. These two categories, when combined, can easily include 25-

30% of all Pap tests when the traditional smear technique is utilized. Therefore, it is important to understand that out of the 50% of invasive cervical cancer patients having had Pap tests in the preceding five years, a significant number of those patients had smears that, under usual circumstances, should have been repeated but were not.

Any screening program that focuses solely on "percent population reached" is concentrating efforts on only half of the problem. The other arm of that program must emphasize accuracy in diagnosis. The abnormal cells must be collected in the first place, it must be possible to examine them without the compromising factors that limit proper screening, and any abnormality should be characterized on the initial test, with a minimum of repeat tests required.

It is for these reasons that the North Carolina State Laboratory of Public Health is using the new methods of collection, preparation, and examination that are part of the *ThinPrep* monolayer Pap test. The *ThinPrep* Pap test technology yields a single layer of well-preserved cells on the test slide. Improved smear quality results in fewer Pap tests needing to be repeated and an increased detection of abnormalities.<sup>24-26,36-38</sup> The Cancer Cytology Branch of the State Laboratory of Public Health (SLPH) participated in the early clinical trials. Results at the State Laboratory of Public Health were similar to those at other clinical trial sites. Pap smear quality was significantly improved and there was increase in the detection of abnormalities.<sup>27</sup>

In May 1996, the FDA approved the *ThinPrep* Pap test for use in gynecological cytology. The FDA labeled the *ThinPrep* Pap System as "significantly more effective than the conventional Pap smear for the detection of Low Grade Squamous Intraepithelial (LSIL) and more severe lesions in a variety of patient populations. Specimen quality with the *ThinPrep* 2000 System is significantly improved over that of conventional Pap smear preparation in a variety of populations."<sup>28</sup> In August 1999, the Cancer Cytology Branch of the State Laboratory of Public Health began a transition to use of the *ThinPrep* technology. Since July 1, 2000, the State Laboratory of Public Health Cancer Cytology Branch has been employing *ThinPrep* technology for 100% of its testing.

The increased detection of precancerous lesions made possible by the use of *ThinPrep* is clearly

beneficial on its own. The fact that this technology lessens the need for repeat tests for a population that is less available to follow-up makes it an even greater achievement.

### **System Factors**

The second area of quality assurance for cervical cancer screening is in the laboratory. There must be an accurate and timely reading of the smear, including a clear report of results to the provider. After collection, the Pap test sample is sent with a clinical requisition form to the laboratory for interpretation. The quality of the reading of the smear is primarily dependent upon the level of expertise of those interpreting the slide. Cytotechnologists are in high demand and short supply and, because of salary competition, the workforce is quite mobile. Any shortages are likely to impact negatively the turn around time for receiving Pap test results and possibly overburden staff that are present.

## **Follow-up of Abnormal Screening Results**

For screening to be effective in reducing cervical cancer death rates, appropriate follow-up of all detected abnormalities must be available and utilized. Follow-up varies according to the results of the screening Pap smear. For less serious results, treatment for an infection and a subsequent repeat Pap smear are often sufficient to assure that there are no malignant cells present.<sup>29</sup> However, for any Pap test results indicating a precancerous lesion or suspicion of cancer, evaluation of the patient via colposcopy is recommended.<sup>30</sup> If cells do not appear normal when using a colposcope (i.e., a special device used for viewing the cervix), a sample of the cervical tissue (or biopsy) is taken and examined under a microscope.<sup>29</sup> From this analysis, the stage of the disease can be determined and appropriate treatment recommended.

It has been estimated that 40 percent or more of women with abnormal Pap smears fail to comply with follow-up recommendations.<sup>31</sup> Appropriate follow-up and treatment may not occur because of issues of patient education and understanding, provider promotion, access, or cost. Each of these factors has serious implications for the prevention of cervical cancer deaths.

## **Patient Education**

Abnormal test results often have negative psychological consequences and, unless addressed, may result in failure to comply with both treatment and future screening tests. Special intervention procedures, which use phone calls or in-person visits to find and remind women to return for follow-up, have obtained compliance rates of 33 to 95 percent.<sup>32</sup> Barriers, such as cost of the follow-up treatment, beliefs about cancer, lack of trust in the medical system, lack of access to transportation, and staff attitudes at health care facilities, all contribute to patients reactions to an abnormal test result and influence whether follow-up recommendations will be followed.<sup>33</sup>

There is strong evidence that women experience significant anxiety and stress when they are informed of abnormal results.<sup>32</sup> These reactions can often be mediated by the method and manner of notification. Upon receipt of the results from the laboratory, the provider has the responsibility of informing the patient. The usual methods of notification are in writing, over the telephone, or in person. Written forms, usually letters or postcards, may not be understandable to the patient because of the reading level of the message or because of terminology that is foreign or not clearly defined.<sup>32</sup> Telephone counseling is more costly, but could be used in explaining serious cases and might reduce the chance of severe psychological reactions to the test results. Whatever method is chosen, an important factor in the communication process is the patient as the receiver of the communications. Consideration should be given to developing and using strategies to communicate with patients with varying demographic characteristics, such as years of education and literacy. The communication provided could greatly affect the psychosocial impact on the woman of hearing the results and her willingness to seek additional care.

## **Provider Referral and Promotion**

The primary issue related to provider referral for follow-up care of abnormal Pap smear results is a clear and standardized protocol for when women should and should not be referred for additional diagnostic work. For example, having a standard practice for when coloscopies are to be provided will help to increase the number of appropriate referrals and reduce the number of unnecessary biopsies.

As previously mentioned, an important factor to consider is the mechanism for informing patients of their test results to assure that they clearly understand the next steps to be taken and the reasons. Although health care providers are the focal point for appropriate follow-up, many settings do not utilize regular tracking or reminder systems to systematically motivate women to return for follow-up. Such systems can be used to identify and monitor compliance among women with abnormal Pap tests. Other strategies that providers can use to help improve the notification process and reduce the negative psychosocial effects of abnormal Pap tests include: reduction of the time until the referral appointment, provision of clear instructions for follow-up recommendations, discussing the test results with patients orally, and reducing barriers to adherence within the medical system.<sup>32</sup>

## Access

Cost is a major issue in obtaining appropriate follow-up of an abnormal Pap test. The high cost of colposcopy, and of colposcopy with biopsy, can be a major barrier to obtaining adequate and timely follow-up care. In North Carolina, the North Carolina Cancer Control Program provides payment for care for women with low incomes. However, for underinsured or working poor populations across the state, cost remains a primary barrier to obtaining necessary care.

An additional barrier to access is the number of providers who are trained to perform diagnostic procedures. Often, these providers are located within large, urban areas and are not easily accessible to women living in rural communities. One solution is to make available more qualified providers; mid-level practitioners can and should be certified to perform colposcopy. The North Carolina Comprehensive Breast and Cervical Cancer Control Program has provided training and equipment to local health departments to help address this problem. Some progress has been made, but this remains a need in North Carolina. Consultations with knowledgeable practitioners need to be available for providers who are less experienced in providing this care. Other concerns regarding access to follow-up care are very similar to those for access to screening: they include lack of transportation or child care and offering clinic hours during non-traditional working hours.

## Quality Assurance for Follow-up of Abnormal Screening Results

The first major concern for quality assurance of follow-up for abnormal Pap test results is the training of those performing colposcopies. Gynecologists are specially trained to perform colposcopies with biopsies. Other specialists may also have limited expertise in performing this procedure. As previously mentioned, midlevel practitioners (i.e., nurse practitioners, physician assistants, etc.) can be trained to perform this procedure and thereby increase availability of services. Their expertise must be maintained by continued assessment either through continuing education courses or preceptor review. Preceptorships should be made readily available for trained practitioners to allow them to improve their expertise in identifying cancer or precancerous lesions. In addition, rigorous and standardized evaluation of all practitioners should be a part of any quality assurance program.

The second area of concern for quality assurance of follow-up for abnormal Pap test results is the standardization of care for various abnormalities. This is very difficult to achieve, since it would by necessity require standardization of examination and detection. Because there are varying degrees of expertise in what is actually a very difficult microscopic procedure, there will always be varying degrees of confidence that clinicians will place in the results from different laboratories. There has been a recent trend, not without controversy, to follow mild abnormalities with Pap smears alone. This clinical approach clearly requires that the Pap diagnosis be correct and underscores the advantages of the *ThinPrep* technology discussed earlier. Some physicians instead recommend that the Pap test should be replaced by colposcopy for routine follow-up. There is considerable controversy over whether this is a realistic, cost effective method of managing mild or borderline abnormalities, which are both numerous and, usually, harmless. Instead, there are numerically more significant high-grade abnormalities that present themselves first through an ASCUS (unknown significance) *ThinPrep* smear than as low-grade dysplasia *ThinPrep* smears. There is a certain logic and an emerging advocacy for devoting those colposcopy resources to ASCUS patients. Whether or not this is cost effective is primarily determined by the ASCUS rate of a given pathology

laboratory. To focus those resources most narrowly and effectively, it is recommended by some to test those ASCUS *ThinPreps* for the presence of Human Papilloma Virus (HPV), reserving colposcopy for those patients who test positive for the viruses known to cause cervical cancer. A major randomized, study has shown that HPV testing is highly sensitive in identifying which abnormalities detected with a Pap test require immediate attention.<sup>39,40</sup>

## **Summary**

North Carolina has a long history of cervical cancer control programs. One of the first screening programs in the country was started by Dr. John Kernodle at Duke University in the 1940s. More recently, the work of the North Carolina Cervical Cancer Task Force has been instrumental, as has that of the North Carolina Advisory Committee on Cancer Coordination and Control, in encouraging the legislature to pass a bill changing the type of Pap testing to utilize the liquid based *ThinPrep* technology rather than the conventional Pap smear. However, there is still much work to be done. With the number of successful strategies that have been identified in recent years, it is clear that further efforts can be made in reducing morbidity and mortality from this disease. Given our knowledge of successful cervical cancer screening programs, and ongoing problems North Carolina women experience with this disease, the following objectives have been selected as goals for the state in increasing early detection of cervical cancer.

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## ***Cervical Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To promote and increase the appropriate utilization of high quality cervical cancer screening and follow-up services.**

#### **Targets for Screening Rates by 2006\*:**

1. To increase the proportion of women age 18 and older with a uterine cervix who have ever received a Pap test from 94 percent to at least 98 percent.
2. To increase from 87% to 94% the proportion of women age 18 and older with a uterine cervix who have received a Pap test in the past 3 years.

**Note:** During the next five years, efforts to improve rates of Pap tests among low-education, low-income, and age 40+ women will receive priority attention, since screening rates among these groups (for a Pap test within the past 3 years) currently are lower than those for other populations.

\* Baseline screening rates obtained from Behavioral Risk Factor Surveillance System, 1999

#### **Targets for Follow-up Care by 2006\***

To increase appropriate and timely follow-up of women who receive abnormal Pap test results.

\*Currently there are limited data on follow-up care. Baseline data will be developed so as to quantify and measure this goal in the evaluation of this Plan.

#### **Targets for Quality Assurance of Cervical Cancer Screening and Follow-up by 2006\***

To assure that 80 percent of Pap tests are adequate and satisfactory by the Year 2001.

\*Currently there are limited data on the rates of satisfactory tests. Baseline data will be developed in the evaluation of this Plan.

**On the following pages,**

**\*\* indicates objectives and strategies that are focused on racial, socioeconomic, educational, or age-related disparities.**

## **Public Education for Cervical Cancer Screening**

### **Objective 1**

To increase knowledge and improve attitudes related to cervical cancer screening among all women.

#### **Strategies**

1. Identify appropriate educational materials and programs for reaching all women, including groups at highest risk for developing cervical cancer and/or lack of regular screening. \*\*
2. Develop media campaigns about the need to obtain regular cervical cancer screening.

### **Objective 2**

To develop alliances with businesses for the purpose of disseminating information on cervical cancer screening to the public.

#### **Strategies**

1. Identify appropriate businesses for alliances, obtain agreements and distribute public education materials through at least two additional North Carolina-based organizations (see also Breast Section Objective 2, Strategy 1).

### **Objective 3**

To promote outreach activities within communities to raise awareness about cervical cancer screening.

#### **Strategies**

1. Develop training sessions for public health and other health professionals on conducting outreach activities.
2. Provide training and materials to public health and other health professional staff on specific skills for outreach.

## **Provider Referral and Promotion for Cervical Cancer Screening**

### **Objective 4**

To assure that primary care providers recommend Pap tests to at least 95% of their eligible patients.

#### **Strategies**

1. Provide information to all primary care providers about screening guidelines.
2. Distribute materials to primary care providers for informing women of the need for screening and the importance of their role in recommending screening to women.
3. Gather and review existing educational materials developed by medical schools and Schools of Public Health from funded research projects that have been proven effective in improving screening and distribute materials to facilities that perform Pap tests (e.g. physician offices, Local health departments, and other providers).

4. Identify or develop and distribute educational and promotional materials regarding Pap test screening to physician offices, other providers, and appropriate local and statewide community organizations.

### **Objective 5**

To assure that specialists (e.g. cardiologists, endocrinologists) who provide ongoing care to older women recommend Pap tests to at least 90% of their eligible patients.\*\*

#### **Strategies**

1. Distribute up-to-date screening guidelines and information to appropriate specialists about strategies for informing women about the need for screening, as needed.

## **Access to Services for Cervical Cancer Screening**

### **Objective 6**

To reduce barriers to and the disparity of Pap test screening among women. \*\*

#### **Strategies**

1. Monitor and distribute information on applicable legislation, including Medicare legislation, Medicaid legislation, and North Carolina legislation (G.S. 58-51-57) that requires and/or permits insurance coverage for Pap test screening. \*\*
2. Facilitate access to providers who offer Pap tests at low or no cost to women who are un- or under-insured.  
\*\*\*
3. Promote Pap test screening at work sites across the state. \*\*
4. Determine the proportion of sites using expanded clinic hours for primary care providers. \*\*
5. Promote the use of community-based transportation services. \*\*
6. Assess the desirability and feasibility of training nurses working in community health centers and in private providers' offices to perform Pap tests.

## **Client Education for Follow-up Care**

### **Objective 7**

To educate women about their risk of cervical cancer and the need to return for appropriate rescreening or diagnostic tests.

#### **Strategies**

1. Promote notification to women (within two weeks of receipt of results) about their Pap test results in a form comprehensible at the fifth grade literacy level. \*\*
2. Disseminate educational materials to providers of Pap test screening in print and video form that explain Pap test results at the fifth grade literacy level. Develop new materials if necessary. \*\*

3. Disseminate brochures, videos, and other media materials with appropriate messages to explain in detail diagnostic care options and list agencies providing care and other information for women with an abnormal Pap test. Develop new materials if necessary.

## **Provider Referral and Promotion for Follow-up**

### **Objective 8**

To promote standardized clinical guidelines for providing follow-up care for each level of Pap test result (using Bethesda System to define levels of results).

#### **Strategies**

1. Disseminate clinical guidelines for follow-up to all clinicians who collect Pap tests.
2. Provide continuing education to providers on follow-up care and diagnostic tests.
3. Expand a previously completed study on system barriers to continued follow-up care (Paskett, Phillips, and Miller, 1995). Pilot study will examine the effectiveness of designating one coordinator in every clinic that provides Pap tests who is responsible for managing follow-up care.
4. Promote the use of reminder and tracking systems to inform women of their need for follow-up and/or rescreening.

## **Access to Follow-up Care**

### **Objective 9**

To provide adequate resources to enable all women in need of diagnostic services to receive care in a timely manner.

#### **Strategies**

1. Inform providers across the state of the resources available through the North Carolina Cancer Control Program for women at or below 115% of poverty. \*\*
2. Monitor the proportion of trained cytotechnologists in the state to assess person power and explore initiatives to address shortages.
3. Provide resources and technical support to encourage participation of cytotechnologists in existing continuing education programs (e.g. teleconferences).

### **Objective 10**

To increase the knowledge of providers concerning appropriate methods for the collection of Pap tests.

#### **Strategies**

1. Provide continuing education to clinicians to upgrade their skills in obtaining adequate Pap tests, including the use of newer, proven collection methods.
2. Implement new and effective technologies (e.g. ThinPrep) for collecting and interpreting cellular changes on Pap tests.
3. Assess the penetration of new detection methods within the state.

## **Objective 11**

To increase accurate and comprehensive sharing of information among providers involved in the care of women with abnormal Pap tests.

### **Strategies**

1. Examine the feasibility of encouraging private laboratories in North Carolina to provide clinicians with consistent feedback on the quality of their Pap tests and the adequacy of information provided with the sample.

## **Objective 12**

To improve the quality of follow-up care provided to women with abnormal Pap test results.

### **Strategies**

1. Provide continuing education to providers on conducting diagnostic tests.

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective followed by Strategy).

Allied Health Council of North Carolina: 9.2P\*

American Cancer Society: 1.1P, 1.2, 3.2P, 4.1P, 4.2, 4.3, 4.4, 5.1P, 6.3P, 6.5P, 7.2P, 7.3P

American Social Health Association: 1.1, 3.2

Brody School of Medicine at East Carolina University: 3.1P, 3.2P, 4.3

Center for Corporate Health: 2.1P, 6.3

Duke University School of Medicine: 3.1P, 3.2P, 4.3

North Carolina Academy of Family Physicians: 1.2, 4.1, 4.2, 5.1, 7.1, 8.1, 8.2, 8.3, 10.1, 12.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
3.1P, 4.2, 4.3P, 6.1P, 6.4P, 6.6P, 7.3P, 8.3P, 10.2P, 10.3P, 11.1P

North Carolina Cancer Control Program: 7.3P, 9.1P, 12.1P

North Carolina Comprehensive Breast and Cervical Cancer Control Program: 1.2P, 3.1P, 3.2P, 4.1P, 4.4P,  
5.1P, 6.2P, 6.3P, 9.1, 7.1P, 7.2P, 7.3, 8.1P, 8.3P, 9.1P, 9.3P, 10.1

North Carolina Medical Society: 4.2, 4.4P, 5.1P, 6.4, 7.1P, 8.1P, 8.2, 8.3P, 11.1P

North Carolina Nurses Association: 4.1P, 4.2, 6.6P, 8.1, 12.1

North Carolina Office of Healthy Carolinians: 2.1P, 4.4, 6.3

North Carolina Office of Public Health Nursing: 8.2, 10.1P

North Carolina Primary Health Care Association: 6.6, 7.2, 8.4

North Carolina State Laboratory of Public Health: 8.1P, 9.3, 10.2, 10.3P, 11.1

North Carolina Women's and Children's Health Section-Women's Health Branch: 3.1, 3.2, 6.2, 7.1, 8.1P,

Planned Parenthood: 1.1P, 3.1P, 5.1P, 6.2P, 7.2, 7.3P, 8.1P, 8.3P, 12.1P

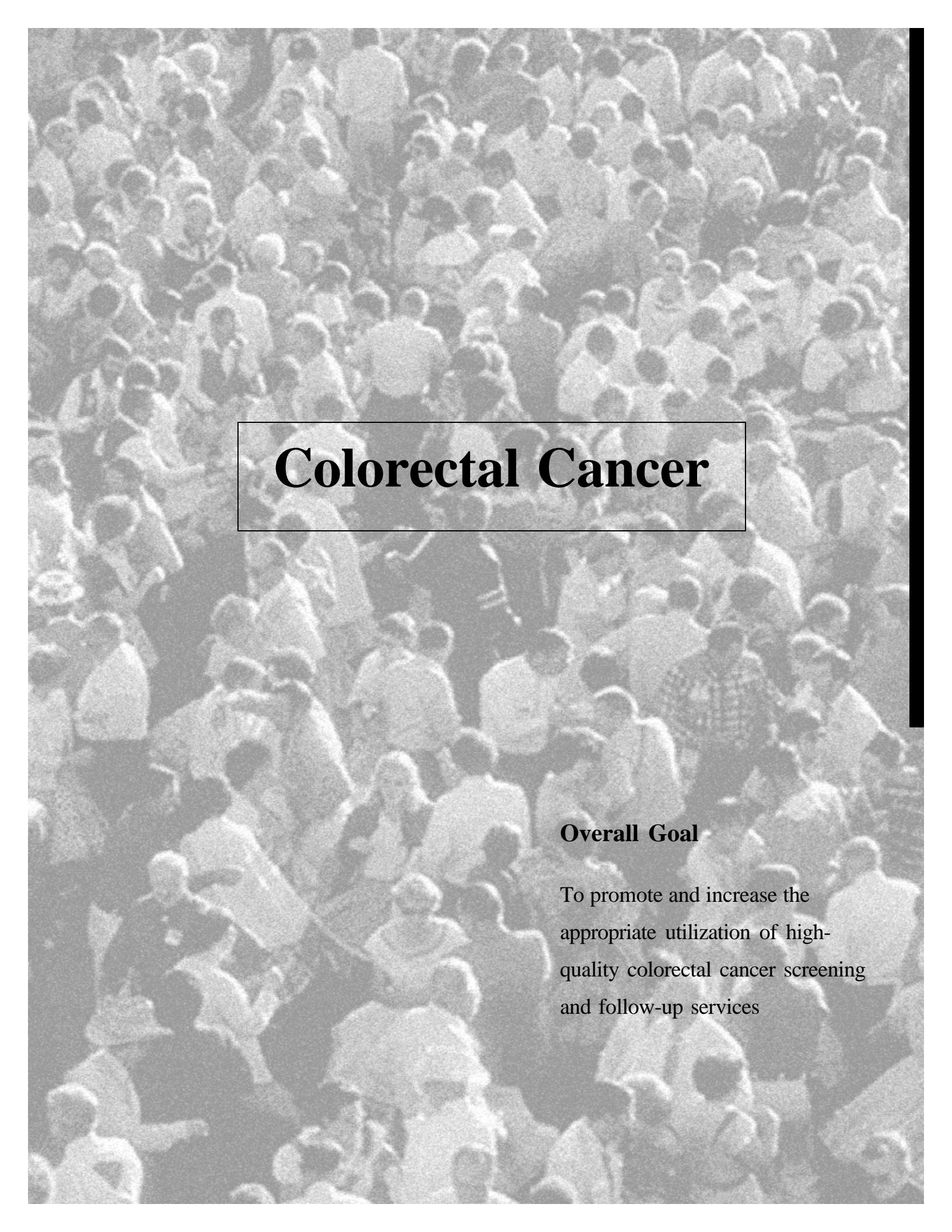
UNC School of Medicine: 3.1P, 3.2P, 4.3

Wake Forest University School of Medicine: 3.1P, 3.2P, 4.3

Wake Forest University School of Medicine-Cancer Education and Prevention Center: 1.1P, 7.2P, 7.3P, 8.3P,  
8.4P

\* P indicates Principal Agency





# **Colorectal Cancer**

## **Overall Goal**

To promote and increase the appropriate utilization of high-quality colorectal cancer screening and follow-up services

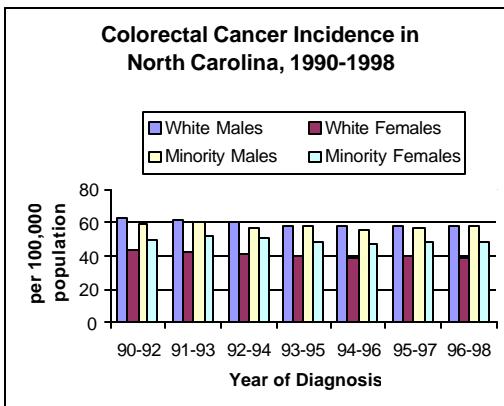


*Colorectal cancer is the second leading cause of cancer death in the United States, with approximately 56,000 deaths and 130,000 new cases expected in 2000.<sup>1</sup>*

Although the incidence of disease appears to be decreasing over the past 25 years, a 50-year-old person today has a 5 percent lifetime risk of being diagnosed with colorectal cancer and a 2.5 percent chance of dying from it.<sup>2</sup> Men have a somewhat higher incidence and mortality from colorectal cancer than women.<sup>1</sup> Colorectal incidence and mortality increase with increasing age.<sup>1</sup>

In North Carolina, 3,696 persons were diagnosed with colorectal cancer in 1998.<sup>3</sup> Projections indicate that an estimated 4,415 North Carolinians will be newly diagnosed with colorectal cancer in the year 2001 and an estimated 1,795 North Carolinians will die from the disease.<sup>3</sup> As can be seen in *Figure 1*, the age-adjusted incidence of colorectal cancer is higher for men than for women. African American women are at higher risk of developing colorectal cancer than White women. Colorectal cancer mortality is highest for African-American men and lowest for White women. African-American women have a substantially higher risk of colorectal cancer death than White women; in fact, their death rate is even higher than that for White men, despite the lower incidence of disease for women.<sup>3</sup>

Figure 1



Source: North Carolina Central Cancer Registry

## Risk Factors

Risk factors for colorectal cancer include a family history of the disease, a history of large (greater than one centimeter) adenomatous colon polyps, a history of inflammatory bowel disease such as ulcerative colitis and Crohn's colitis, and perhaps high dietary intake of red meat and dietary animal fat and low levels of physical activity.<sup>4</sup> Persons consuming diets high in fruits, vegetables, and fiber may have lower risk for colorectal cancer.<sup>4</sup> About 15-20 percent of all persons who develop colorectal cancer have a family history of the disease in a first-degree relative.<sup>4</sup> People with a first degree relative with colorectal cancer have a two-to three-fold greater risk than persons with no family history; that risk is increased further if the relative with colorectal cancer was younger than 55 at the time of diagnosis or if multiple family members are affected.<sup>5</sup> However, 75% of colorectal cancers arise in patients with no special risk factors for the disease.<sup>2</sup>

## Background

Although colorectal cancer continues to be an important cause of cancer incidence and mortality, its biological behavior presents an opportunity to substantially reduce its burden on health through screening and early detection. Most (but not all) colorectal cancers appear to develop slowly from adenomatous polyps over a period of 10 to 15 years.<sup>6</sup> The slow and orderly growth of adenomatous polyps provides a long period during which they can be detected and removed before they become malignant. Even if cancer develops, 5-year survival in the localized stages approaches 90%. Unfortunately, 5-year survival with metastatic disease is 10% or less despite best current therapy. Currently in North Carolina, in the absence of widespread screening, only 34.6 of colorectal cancers are detected in the curable

early stages.<sup>7</sup> Because of the slow typical development of colorectal cancer, its long and treatable pre-cancerous detectable phase, and the large difference in survival between local and metastatic disease, colorectal cancer is a good candidate for screening.

## Screening in asymptomatic average risk adults

Several screening strategies have been considered for preventing and reducing the morbidity and mortality from colorectal cancer in asymptomatic average risk adults over the age of 50: annual fecal occult blood testing (FOBT), sigmoidoscopy every 5 – 10 years (SIG), a combination of FOBT annually and SIG every 5 – 10 years, double contrast barium enema every 5 – 10 years, or colonoscopy every 10 years.<sup>5</sup> Each of these strategies and the supporting evidence for their effectiveness in detecting cancers early and reducing mortality are discussed below.

Persons at increased risk, including those with a personal history of adenomatous polyps or colorectal cancer, a family history of one or more first-degree relatives who have had colorectal cancer (especially when occurring before age 55), or those who have inflammatory bowel disease should be screened more aggressively (see screening high risk patients below). Patients with symptoms possibly suggestive of colorectal cancer, including (but not limited to) rectal bleeding, change in bowel habits, or otherwise unexplained weight loss, require a diagnostic work-up from their provider rather than screening.

### Fecal occult blood testing

Fecal occult blood testing involves checking three individual consecutive stool samples for evidence of microscopic amounts of blood. The FOBT can be rehydrated with the addition of a small amount of water before processing or can be developed unrehydrated. Screening with the FOBT has been shown to reduce colorectal cancer mortality in three large population-based trials of annual or biennial testing.<sup>8</sup> The Minnesota study of annual screening using mostly rehydrated FOBT cards found a 33 percent reduction in colorectal cancer mortality.<sup>9</sup> Two European trials tested biennial unrehydrated FOBT and found 15-18% mortality reductions over 8-10 years.<sup>10,11</sup> A recent supplemental publication from the Minnesota trial with 18 year follow-up found that biennial screening had a

similar reduction (21%) in mortality as the European trials.<sup>12</sup> Although the reduction in colorectal cancer mortality was larger in the Minnesota trial, the use of rehydration increased the number of false positive tests and subsequent follow-up exams: over 30% of participants had to undergo colonoscopy over the 13 year trial, compared with 5% in the European trials.

Currently, FOBT is the only screening test proven to reduce colorectal cancer mortality in a randomized trial. Nevertheless, it is an indirect test that detects blood in the stool rather than colorectal cancer itself. The ability of a single FOB “test” to detect cancer (sensitivity) is less than ideal (30-40% for unrehydrated cards) and it is ineffective in detecting polyps (5-10%).<sup>13</sup> Its specificity (the ability to produce a negative test when there is no disease present) has been estimated to be 90% for rehydrated testing and 96-98% for unrehydrated testing. Because colorectal cancer is uncommon and the specificity of the test is low, the positive predictive value for cancer is also low (2-10%).<sup>8</sup>

Despite its imperfect test characteristics, FOBT has been found to be effective and cost-effective in every major analysis of colorectal cancer screening, perhaps because the initial test is relatively inexpensive and free of harm and because annual testing presents many opportunities for detection. To be most effective, FOBT screening requires ongoing adherence, which may be difficult to achieve.

### Sigmoidoscopy

Sigmoidoscopy is a screening procedure that examines the lower colon using a lighted flexible tube. No trials of sigmoidoscopy screening have been completed, although two are underway currently.<sup>14,15</sup> However, two well-conducted case-control studies have found that periodic sigmoidoscopy, as infrequently as every five to ten years, can reduce by 70 percent the mortality from colorectal cancer within reach of the sigmoidoscope.<sup>16,17</sup> Sigmoidoscopy can detect and allow removal of pre-cancerous polyps, possibly preventing the development of cancer as well. The current 60cm flexible sigmoidoscope can visualize the lower third of the colon and will detect approximately 65% of patients with adenomas. Specificity for polyps and cancer is high, particularly if biopsy is performed on the initial exam. Complication rates are low and the procedure can be performed effectively in physicians’ offices that have

received sufficient training and invested in the required infrastructure for performing the test.

## Combination of FOBT and sigmoidoscopy

The combination of annual FOBT and every five year sigmoidoscopy is theoretically more effective than either test alone in reducing disease incidence and mortality, though there are no data from randomized clinical trials to determine the magnitude of this effect. The adverse effects are a combination of the adverse effects of each test alone. If a strategy of using both tests is chosen, the FOBT should be performed first, since a positive test will be followed by a full colonoscopy rather than flexible sigmoidoscopy.<sup>2</sup>

## Double-contrast barium enema

Barium enema has not been evaluated directly as a colorectal cancer screening test. It has the advantage of visualizing the entire colon. Older studies, many of which have important methodological flaws, suggest that its sensitivity for large polyps and cancers is 50-80% and its specificity to be 80-90%.<sup>2,18</sup> Recently published data from the National Polyp Study using appropriate methodology found that sensitivity for large polyps was 48% (95% CI 24%-67%) in a population undergoing surveillance after polypectomy.<sup>19</sup> The exam requires referral to a radiologist, and examiner skill and experience is important for optimizing test accuracy. However, these new data suggest that sensitivity may be lower than previously estimated: further research is needed.

## Colonoscopy

Screening colonoscopy has also not been evaluated in a randomized trial, but offers several potential advantages as a screening test. Because it visualizes the entire colon and allows detection and immediate removal of polyps, even relatively infrequent colonoscopy (every ten years) has the potential to reduce disease incidence and mortality. Its main drawbacks are its higher risk of complications (bowel perforation and bleeding), the somewhat more extensive preparation and recovery time required, and its cost. On the other hand, the need for fewer tests and the use of sedation during testing make it potentially attractive. Models have found colonoscopy to be comparable to the combination of FOBT and

sigmoidoscopy or the use of barium enema with respect to effectiveness and cost-effectiveness.<sup>13</sup>

## Screening high-risk patients

Patients at increased risk because of a family history of colorectal cancer in a single first-degree relative after age 60 can undergo usual screening. Those with multiple affected family members or in whom cancer developed at a young age should begin screening earlier (10 years prior to the earliest diagnosis of cancer in a family member or age 40, whichever comes first) with colonoscopy. Genetic testing may also be offered to patients suspected of having a genetic colorectal cancer syndrome (e.g. hereditary non-polyposis colon cancer or familial adenomatous polyposis), though its exact role in management remains somewhat unclear at this time. Patients with inflammatory bowel disease also require more aggressive screening.<sup>20</sup>

## Current Utilization

National, population-based data from the Behavioral Risk Factor Surveillance Study (BRFSS) in 1999 found that 44% of adults over 50 reported having been screened either with FOBT within the past year or with sigmoidoscopy/colonoscopy within the past five years. In North Carolina, the 1999 BRFSS found that 45% of adults over 50 reported having been screened either with FOBT within the past year or with sigmoidoscopy/colonoscopy within the past 5 years. Use of these screening methods was similar between men and women and between different racial groups.

In 1994, data from North Carolina primary care practices, 32% of adults over 50 completed FOBT within one year and 11% completed sigmoidoscopy or colonoscopy within 3 years.<sup>21</sup> In studies where patients were asked by their providers to return fecal occult blood test cards, compliance rates have been reported as high as 51 to 88 percent in primary care settings.<sup>22</sup> Compliance is highest in programs where primary care physicians recommended the test as part of a regular annual exam. Rates of acceptance for sigmoidoscopy screening have been variable with lower figures 5-10% from mass invitations and higher ones (30-60%) when direct invitations are provided, particularly to persons considered to be at high risk.<sup>23</sup>

## **Barriers to Screening**

Available data indicate that low screening rates are due to physician, patient, and health care delivery system factors.

### **Patient factors**

The largest barrier to screening for colorectal cancer is a lack of awareness that one is at risk despite the absence of symptoms and a lack of awareness of the availability of effective means for prevention and early detection. With respect to FOBT, surveys have found that practical reasons such as being "too busy" were most frequently cited as barriers.<sup>23</sup> The lack of having any health problem compelling the subject to be tested (i.e. a lack of understanding of "screening") was also commonly reported. Some patients reported that the test seemed unpleasant or embarrassing or that they didn't want to know if they had a problem. Subjects who have not had sigmoidoscopy have cited the absence of health problems or symptoms, practical reasons, and worry about pain and discomfort as the most common reasons for not being tested.<sup>23</sup> Colonoscopy and barium enema have not been studied sufficiently to determine barriers to screening.

### **Physician factors**

The most common reason cited by physicians for not performing FOBT is forgetfulness, an issue that is related to absence of office systems (see below).<sup>24</sup> Research indicates physician reluctance to recommend sigmoidoscopy screening is due to disagreement with the guidelines, cost to the patient, and inconvenience.<sup>24</sup> In a North Carolina survey, physicians also cited a concern about lack of training to do sigmoidoscopy.<sup>25</sup> Sigmoidoscopy is time consuming and is perceived as embarrassing and painful for patients. Physicians also report that patient lack of interest and fear of a cancer diagnosis inhibit screening with sigmoidoscopy.<sup>26,27</sup> However, one study that examined patient attitudes and compliance with sigmoidoscopy screening found that although patients reported high anxiety about the test, 75 percent complied with a recommendation from their physician to have the test and found the procedure to be less embarrassing and less painful than expected.<sup>27</sup> There are data showing that the majority of patients who undergo sigmoidoscopy would do it again if asked by

their physician.<sup>21</sup>

Research indicates that the most important motivator for undergoing screening is a recommendation by a primary care physician.<sup>23</sup> Though most physicians agree with screening guidelines for early detection of cancer, many do not follow through in their practices. Data from Prescribe for Health, a 1997 survey of practicing primary care physicians in North Carolina, found that over 80% of physicians considered flexible sigmoidoscopy effective and approximately 65% considered screening with flexible sigmoidoscopy part of their practice policy for preventive care. However, only about 5% of patients had documentation of completing a sigmoidoscopy within the past three years.<sup>21</sup> Since approximately 85 percent of all adults visit a physician at least once every two years, a major increase in screening could be predicted if physicians recommended screening regularly to all age-and risk-factor appropriate patients.

### **Systems issues**

System issues at the level of individual practices and health plans are important barriers to screening. The absence of preventive care tracking and reminder systems, especially for frequent testing like FOBT, makes screening difficult to sustain. Coverage for colorectal cancer screening differs from plan to plan and even within plans. Providers may react to uncertainty and confusion about whether a given screening test is covered by simply not raising the issue of screening. Hopefully, recent changes in Medicare that added coverage for colorectal cancer screening in average risk adults with FOBT, sigmoidoscopy, barium enema, and more recently colonoscopy will help to increase the uniformity of coverage. Providers may worry that patients who are referred to other physicians for screening will be lost from their practices and hence not refer them. Finally, lack of access to trained providers (both in total numbers and in geographic distribution) makes increasing the number of patients screened potentially difficult.

## **Strategies to increase colon cancer screening**

### **Patient Interventions**

Improving the use of colorectal cancer screening will require interventions directed to patients, providers, and office systems. Public awareness of the risk of colorectal cancer, the benefits of screening, and the need to ask one's health care provider for screening should be increased through broad public awareness campaigns (e.g. TV and radio) and more targeted interventions. Targeted interventions should be carried out through physicians' offices and through organizations and workplaces with large numbers of at-risk adults. Specific interventions should also be directed towards those at high risk, such as people with family histories of colorectal cancer. Special efforts should also be directed to reducing racial disparities in disease outcome among African-Americans, especially women, who have suffered disproportionately from colorectal cancer in North Carolina. An important means to increasing screening is to improve communication between providers and patients. Patient-directed decision aids can be used to improve communication and screening.<sup>28</sup>

### **Provider Interventions**

Medical practitioners should be aware of which screening procedures are effective and how to perform them or order them through referral to an appropriate provider. Knowledge alone, however, is insufficient. Studies of physician behavior change (not limited to colorectal cancer screening) have found that reminder systems, audit with feedback (where providers receive their screening rates and are asked to evaluate them as a tool to improvement), and small group educational sessions ("academic detailing") led by a local opinion leader are effective in changing physician behavior but that traditional continuing education and mass mailings are not.<sup>29</sup> A recent systematic review found that reminder systems increased FOBT completion rates by an average of 14%.<sup>29</sup> Previous training and the ability to perform sigmoidoscopy are associated with higher rates of sigmoidoscopic screening.<sup>23</sup>

Physicians appear to respond to patient cues to perform colorectal cancer screening, so interventions directed towards improving patient communication about colorectal cancer screening may also be an effective way to change physician behavior.<sup>28</sup>

### **Systems interventions**

In addition to implementing office level changes such as computerized reminders, screening could be enhanced by standardizing coverage for different forms of screening and by reducing co-payments required for screening tests.<sup>30</sup> Interventions to reach underserved populations, including promoting screening through churches, may also be effective in increasing screening and reducing disease burden.<sup>31</sup>

In Singapore, up to 50% of patients suffer from recurrence of colorectal cancer after surgery.<sup>32</sup> The CARES (Cancer Recurrence Support) System has been developed to predict the recurrence of colorectal cancer using a combination of Case-Based Reasoning (CBR), data mining, and natural language processing.<sup>32</sup> The system makes comparisons of patient cases and generates inferences to identify high-risk groups.<sup>32</sup>

**The challenge for  
the next five  
years is to  
increase the  
performance of  
colorectal cancer  
screening.**

### **Emerging screening tests and future research needs**

Researchers continue to search for more effective ways to screen for colorectal cancer. Recent developments include virtual colonoscopy, a method of using spiral computerized tomography (CT) scanning to create an image of the colon,<sup>33</sup> and initial testing of a stool assay that looks for DNA abnormalities.<sup>34</sup> Current data are insufficient to estimate how effective these new technologies will be in actually reducing colon cancer mortality. Further research is also required to better understand long-term adherence to testing and real-world rates of complications with colonoscopy.

### **Summary**

Given our understanding of the biological features and epidemiology of colorectal cancers and the evidence that screening reduces colorectal cancer

mortality, the challenge for the next five years is to increase the performance of colorectal cancer screening. Direct and indirect evidence from trials, observational studies, and cost-effectiveness analyses suggest that several different means of screening are effective in reducing disease incidence and mortality. They have also been shown repeatedly to be cost-effective compared with other commonly used screening tests such as mammography or Pap smears. Rather than attempting to designate a single preferred method of screening, it is recommended that efforts first be focused on increasing the proportion of average risk North Carolinians over age 50 that are screened regularly by any appropriate method: FOBT yearly, sigmoidoscopy every five years, the combination of FOBT and sigmoidoscopy, barium enema every five years, or colonoscopy every ten years.

The challenge in the first years of the 21<sup>st</sup> century will be to address the patient, provider, and systems level barriers to screening in order to increase the proportion of patients screened and reduce the extensive morbidity and mortality from colorectal cancer, including the troubling racial disparities in outcomes. The next section outlines specific objectives and strategies to address issues of colorectal cancer control. These objectives and strategies can be seen as a list of recommendations that have been developed by a group of cancer researchers, physicians, health educators, survivors, and advocates. The objectives and strategies listed are to be viewed as steps toward achieving the goal of promoting, increasing, and optimizing the appropriate use of high-quality colorectal cancer screening and follow-up services.

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## ***Colorectal Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To promote and increase the appropriate use of high-quality colorectal cancer screening and follow-up services.**

#### **Targets for Change by 2006\***

1. To decrease from 37% to 20% the proportion of people who have never had a Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, or a colonoscopy since their fiftieth birthday.
2. To increase from 30% to 60% the proportion of people age 50 and older who have had a Fecal Occult Blood Test (FOBT) in the past year.
3. To increase from 31% to 50% the proportion of people who have had a flexible sigmoidoscopy or a colonoscopy in the past 5 years.
4. To increase from 16% to 30% the proportion of people who are within recommended screening guidelines. Recommended guidelines are defined as people age 50 and older who have had a Fecal Occult Blood Test (FOBT) in the past year and a flexible sigmoidoscopy or a colonoscopy in the past five years.
5. To decrease to 20% the proportion of underserved who have never had a Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, or colonoscopy since their fiftieth birthday.
6. To increase to 10% above baseline the proportion of all providers who regularly offer appropriate colorectal cancer screening services to their eligible patients.

Current baseline screening rates are as follows:\*

Men: 40%

Women: 34%

African Americans: 44%

Low education (<9<sup>th</sup> grade): 49%

Low income (<\$15,000): 45%

**Note:** During the next five years, efforts to improve screening rates among African-Americans, low education, and low income persons will receive priority attention, since rates for never having had an FOBT, flexible sigmoidoscopy, or colonoscopy currently are higher than those for other populations.

\*Baseline screening rates obtained from the Behavioral Risk Factor Surveillance System, 1999.

**On the following pages,**

**\*\* indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

## **Facilitation of Screening**

### **Provider Factors**

#### **Objective 1**

To increase the proportion of providers who regularly offer appropriate colorectal cancer screening services to their eligible patients.

#### **Strategies**

1. Develop and implement educational workshops led by “champion” physicians to overcome barriers to successful implementation and provide continued support for appropriate colorectal cancer screening services.
2. Develop regional colorectal cancer screening referral list.
3. Communicate with universities to train future providers and teachers of providers to perform colorectal cancer screening to assure sufficient proportion of providers trained to perform screening tests, particularly flexible sigmoidoscopy.
4. Evaluate and disseminate available colorectal cancer screening tracking systems. If none are available, facilitate the development of a tracking system that runs on a personal computer and/or paper tracking system and disseminate it to providers throughout the state.

### **Access Factors**

#### **Objective 2**

To reduce access barriers to colorectal cancer screening for all men and women 50 years or older plus those deemed at high risk as defined by Medicare.

#### **Strategies**

1. Assure insurance coverage for colorectal cancer screening that meets or exceeds the level provided by Medicare for all adults 50 years or older plus those deemed to be at high risk as defined by Medicare. Assure this coverage through legislation if necessary.
2. Promote access to some form of colorectal cancer screening, such as Fecal Occult Blood Test (FOBT), through local health departments. (Please note link to objective 4, strategy 2.) \*\*
3. Using geographic mapping technology, conduct an assessment of available and necessary capacity for colorectal cancer screening.
4. Work with health insurance organizations to clarify levels of coverage for appropriate colorectal cancer screening.

## **Public Education for Colorectal Cancer Screening**

#### **Objective 3**

To increase public awareness about risk for colorectal cancer, the benefits of colorectal cancer screening, and the availability of effective means of prevention and early detection.

### **Strategies**

1. Assess current colorectal cancer screening practices in North Carolina.
2. Make available through the public health departments learner-appropriate educational materials to inform those 50 years and older of the prevalence and risk of colorectal cancer and available screening techniques. \*\*
3. Make available through the Internet learner-appropriate educational materials to inform those 50 years and older of the prevalence and risk of colorectal cancer and available screening techniques. \*\*
4. Provide learner-appropriate educational materials to primary care providers to disseminate to patients concerning the need for screening for colorectal cancer. \*\*
5. Promote colorectal cancer awareness month through local media, community organizations, and work sites.

## **Access to Follow-up Care**

### **Objective 4**

To promote financial support for those individuals who receive positive test results and are in need of further diagnostic services or treatment.

### **Strategies**

1. Encourage the acquisition of financial support for follow-up care for those who are at or below 200% of poverty level and who have no other coverage. \*\*
2. Assure access to follow-up care for those with positive results detected through local health department colorectal cancer screening (Please note link to objective 2, strategy 2).
3. Collect data that monitors follow-up care to be used in assessing appropriateness of care (Please note link to objective 2, strategy 2.). \*\*

### **Objective 5**

Reduce racial disparities in colorectal cancer incidence and mortality. \*\*

### **Strategies**

1. Identify existing or facilitate additional research with African –American adults over age 50 to identify barriers to early detection. \*\*
2. Identify, or develop, and test culturally appropriate educational materials for Objective 3 and facilitate dissemination of the materials in communities, work sites, and organizations with significant African–American populations. \*\*
3. Conduct exploratory research with Hispanic, Native American, and other minority populations to assess cultural beliefs and barriers to colorectal cancer screening. \*\*

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

American Cancer Society: 1.2, 2.1P\*, 3.2, 3.3, 3.4, 3.5, 4.1, 5.1, 5.2, 5.3

Brody School of Medicine at East Carolina University: 5.1, 5.3

Cancer Information Service: 1.2, 1.3, 3.2, 3.3, 3.4, 5.2

Colon Cancer Alliance: 1.3, 2.1, 3.5P, 4.1

Duke University School of Medicine: 5.1, 5.3

El Pueblo: 5.3

Medical Review of North Carolina: 3.1

North Carolina Academy of Family Physicians: 1.1P, 3.4

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.1, 2.4P, 3.2P, 3.3P, 3.4P, 4.3P, 5.1P, 5.2P, 5.3P

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee-Colorectal Cancer Workgroup: 1.4P, 2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Legislation and Education Subcommittee: 2.2P, 4.1P

North Carolina Cancer Control Program: 2.2, 4.1P, 4.2P

North Carolina Medical Society: 1.2, 1.3P, 3.4

North Carolina Office of Minority Health: 5.2, 5.3

North Carolina Primary Health Care Association: 1.3

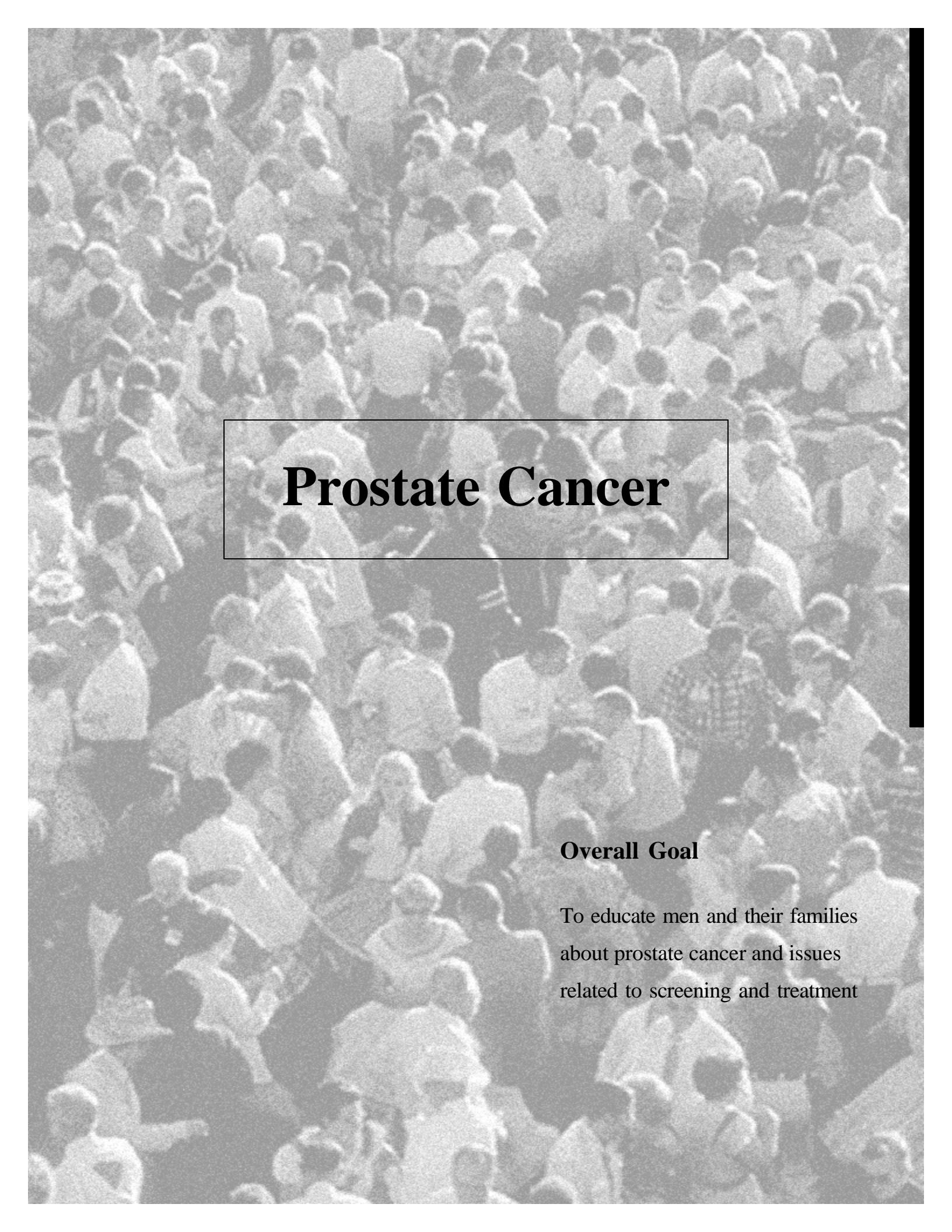
UNC School of Medicine: 5.1, 5.3

UNC School of Public Health: 2.3, 5.1, 5.3

Wake Forest University School of Medicine: 2.3, 5.1, 5.3

\* P indicates Principal Agency





# **Prostate Cancer**

## **Overall Goal**

To educate men and their families  
about prostate cancer and issues  
related to screening and treatment

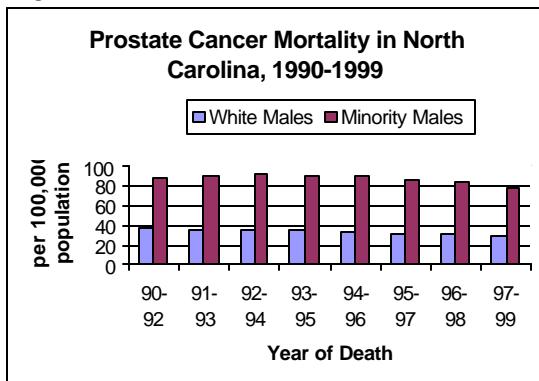


*Whether to recommend screening for prostate cancer among asymptomatic men is a difficult public health issue. The prevention of mortality and morbidity from this disease through screening and early detection is controversial, and there is currently no consensus among major medical and health organizations in the United States about recommendations for screening.*

Prostate cancer is the second leading cause of cancer death for men both nationally and in North Carolina.<sup>1,2</sup> In North Carolina, projections for the year 2001 show an estimated 5,990 new cases of prostate cancer and an estimated 1,030 deaths from the disease.<sup>2</sup>

Nationwide, the incidence of prostate cancer rose dramatically in the late 1980's and early 1990's, a trend that was attributed largely to the widespread adoption of the prostate specific antigen (PSA) test as a screening modality.<sup>3,4</sup> This trend was accompanied by a concomitant increase in earlier-staged cancers and a decrease in later-staged disease.<sup>5,6,7</sup> In addition, a decrease in prostate cancer mortality also has been observed since 1992. While these data appear to support the role of early detection (via PSA testing and digital rectal exam) in reducing prostate cancer mortality, it is still too early to truly determine if this is the case, or if other factors, such as lead time bias, attribution bias, improved treatment, a change in the natural history of the disease, overdiagnosis, or chance alone may be responsible.<sup>4,5,8</sup> More time and further study is needed before this determination can be made.

Figure 1.



Source: North Carolina Central Cancer Registry

African American men develop the disease at a rate higher than any other ethnic group in the world. They currently experience over twice the mortality rate of white Americans.<sup>9,10</sup> In North Carolina, this mortality rate is more than two and a half times greater than that for white men (*Figure 1*).<sup>1,11</sup> In fact, African American men in North Carolina have the highest prostate cancer mortality rate of any state in the nation. This mortality differential is largely due to the fact that African Americans in North Carolina have later stage disease at the time of diagnosis.<sup>12</sup> Even when diagnosed at the same stage, however, national survival rates of African Americans are lower than those of white men.<sup>9,10</sup> This suggests that there is something different about African American men that affects their survival, such as differences in the quality or type of treatment or genetic, lifestyle, or environmental factors that affect their response to treatment.

Hormonal, nutritional, genetic, and socioeconomic status factors have all been implicated as possible reasons for the racial disparity.<sup>9,10</sup> Rural residency may also play a role. Research indicates that rural residents, particularly African Americans, are twice as likely to have more advanced cancer at the time of diagnosis.<sup>12</sup> North Carolina has both a large rural population and a relatively high proportion of African Americans, highlighting a major public health problem in the state for which there is no clear solution at this time.

### Disease Characteristics

Researchers have postulated that there are actually three forms of prostate cancer: one that is latent, one that is moderately progressive and one that is rapidly progressive and very malignant.<sup>13,14</sup> Most prostate cancers are slow-growing and often do not cause symptoms for many years. Studies at autopsy

indicate that 30 to 50 percent of all men over the age of 50 have prostatic carcinoma, but the vast majority of men will not be diagnosed and will experience no significant effects from their disease.<sup>13</sup> However, about 9.5 percent of men will have a clinical diagnosis and, of these, about 20 to 25 percent will die of their disease.<sup>14</sup> Approximately 3 percent of the total population of men in the U.S. will die of prostate cancer.<sup>14</sup> More men die *with* prostate cancer than *of* it.

Currently, little is known about the factors that cause the majority of prostate cancers to remain latent while others develop rapidly and spread beyond the prostate by the time of diagnosis.<sup>15</sup> For most cancers detected clinically, there is no way to predict with certainty which will progress rapidly, leading to morbidity and mortality, and which will grow slowly and cause no symptoms within a man's lifetime.<sup>16</sup> The key issue, and a source of controversy, is how to reliably distinguish between tumors with different growth rates. Among those whose health will be affected, the tumors of a third will have already metastasized by the time of detection while the tumors of two thirds will be amenable to treatment.<sup>17</sup>

## Risk

Prostate cancer risk increases with age; the median age at diagnosis is 72.<sup>4</sup> New cases are relatively few among men younger than 50.<sup>4</sup> Thus, as the population ages, more men are at risk for developing prostate cancer. African American race incurs a higher risk, as does a family history of prostate cancer. There is a two- to four-fold increased risk among men with one first-degree relative with prostate cancer.<sup>18,19</sup> It is unclear whether familial risk is due to environmental or genetic influences. Saturated fat consumption has been associated with a small increase in risk of prostate cancer.<sup>13,20</sup> One study found that differences in saturated fat intake account for only up to 10 percent of the African-American increase in prostate cancer, suggesting that other factors are largely responsible for increased risk.<sup>21</sup>

## Screening

Early detection and screening procedures and

guidelines rely on digital rectal examinations and the prostate specific antigen (PSA) serum test. The PSA test, as originally devised, lacked specificity in differentiating the presence of malignant from benign growths (benign prostatic hypertrophy). Other tests used in combination with PSA, such as percent free PSA may improve specificity; however, this is still problematic. The promotion and availability of the tests have led to large numbers of American men being screened. The steep increase in new cases and in the numbers of men being treated for prostate cancer is at least partly a result of increased detection.<sup>3-8,23</sup>

**Currently, little is known about the factors that cause the majority of prostate cancers to remain latent while others develop rapidly and spread beyond the prostate by the time of diagnosis.**

Experts who advocate screening for prostate cancer usually agree that it should be done for men without symptoms who are at least 50 years old. Some experts recommend that African American men and those with a family history of the disease be screened beginning at age 40. However, it is not clear that screening men at higher risk at an earlier age will make screening more effective.<sup>23,24</sup> Because most prostate cancers are slow growing, it is commonly recommended that screening be discontinued for men with less than a ten-year life expectancy. In addition, neither the

PSA test, nor any current test, can distinguish between cancers that are latent and those that are not. This suggests that men whose disease might be minimally progressive may undergo both emotional distress and overly aggressive therapy.

The ability of the PSA test to detect prostate cancer at an early stage has raised hopes of reductions in mortality. A combination of the digital rectal examination and PSA (with ultrasound-guided biopsy for those needing follow-up) detects more cancers and increases the rate of detection of localized cancers.<sup>25,26</sup> However, a demonstration that early detection results in a mortality reduction awaits the completion of an ongoing randomized, controlled trial of screening, the National Institutes of Health Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial. This trial, designed to assess the effect of screening on mortality, has enrolled 75,565 men. Results will be available sometime after the study ends in 2015. Other trials, such as the European Randomized Study of Screening for Prostate Cancer (ERSPC)<sup>27</sup> being conducted in seven study centers, also are underway to demonstrate

whether early detection will result in a decrease in prostate cancer mortality.

Currently, the American Urological Association recommends screening for the early detection of prostate cancer, while the U.S. Preventive Services Task Force does not, citing lack of evidence from controlled studies. The National Cancer Institute does not have a recommendation either for or against prostate cancer screening. In contrast, the American Cancer Society recommends that physicians offer PSA and Digital Rectal Exam (DRE) screening to all men over 50 who have at least a 10 year life expectancy and to offer these tests at age 45 to men who are at high risk (e.g. strong family history (two or more affected first-degree relatives); African American men). These groups agree that research has yet to definitively support that PSA testing reduces mortality from prostate cancer. These differences in recommendations reflect different approaches regarding whether clinical medicine and public policy should encourage the use of potentially beneficial but unproven cancer prevention strategies before controlled studies establish their efficacy.<sup>28</sup>

A final screening issue is its potential effect on other health services. Resources and energy to screen for prostate cancer may come at the expense of other screening tests whose benefit has been more clearly demonstrated. For North Carolina, an extrapolation from national data indicates that it would cost over 35 million dollars annually to screen men aged 50 and over every year.<sup>29-31</sup> This may be worthwhile if it were known that screening greatly reduces mortality from prostate cancer, but the answer to this question awaits additional data.<sup>30</sup>

## Treatment Issues

Currently, the treatment of prostate cancer is a matter of controversy with virtually no professional agreement on a single course of treatment. The areas of greatest controversy and concern are the side effects of treatment, such as impotence and incontinence, or lack of treatment and the question of whether and for whom treatments are effective or necessary.

## Public Education

Current guidelines for screening differ greatly

among both voluntary and professional groups. This causes considerable confusion among the public. Hospitals, urologists, and prostate cancer awareness programs offer free prostate cancer screening. Local medical news coverage expresses concern over side effects of treatment while highlighting the availability of screening programs. A study of over 1,400 men attending screening clinics in the southeastern United States suggests that media coverage is one of the primary reasons that men seek screening.<sup>32</sup>

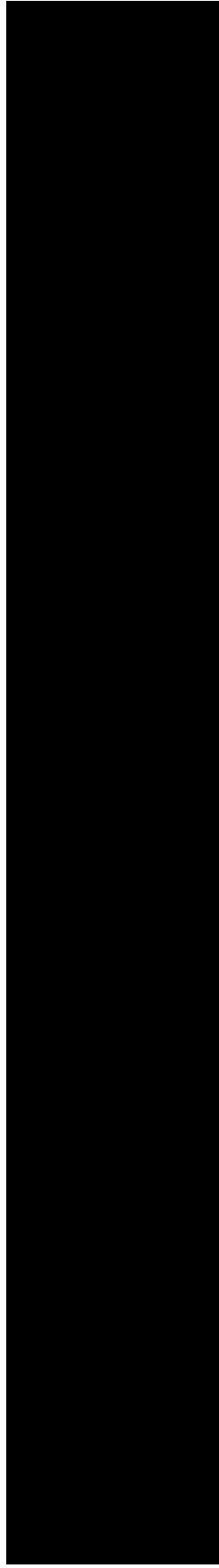
Once a consensus on the appropriateness of prostate cancer screening is achieved, we should provide comprehensive and straightforward information on that consensus position to all men and health care providers in North Carolina. In the meantime, we should provide clear, updated, and appropriate information on screening to allow men to make informed decisions concerning screening with their physicians. It is especially important for this public health initiative to provide culturally-based information specific for African-American men in North Carolina, because of the known increase in risk of being diagnosed with prostate cancer, of being diagnosed at a later stage, and of dying from this disease.

## Information Specific to North Carolina

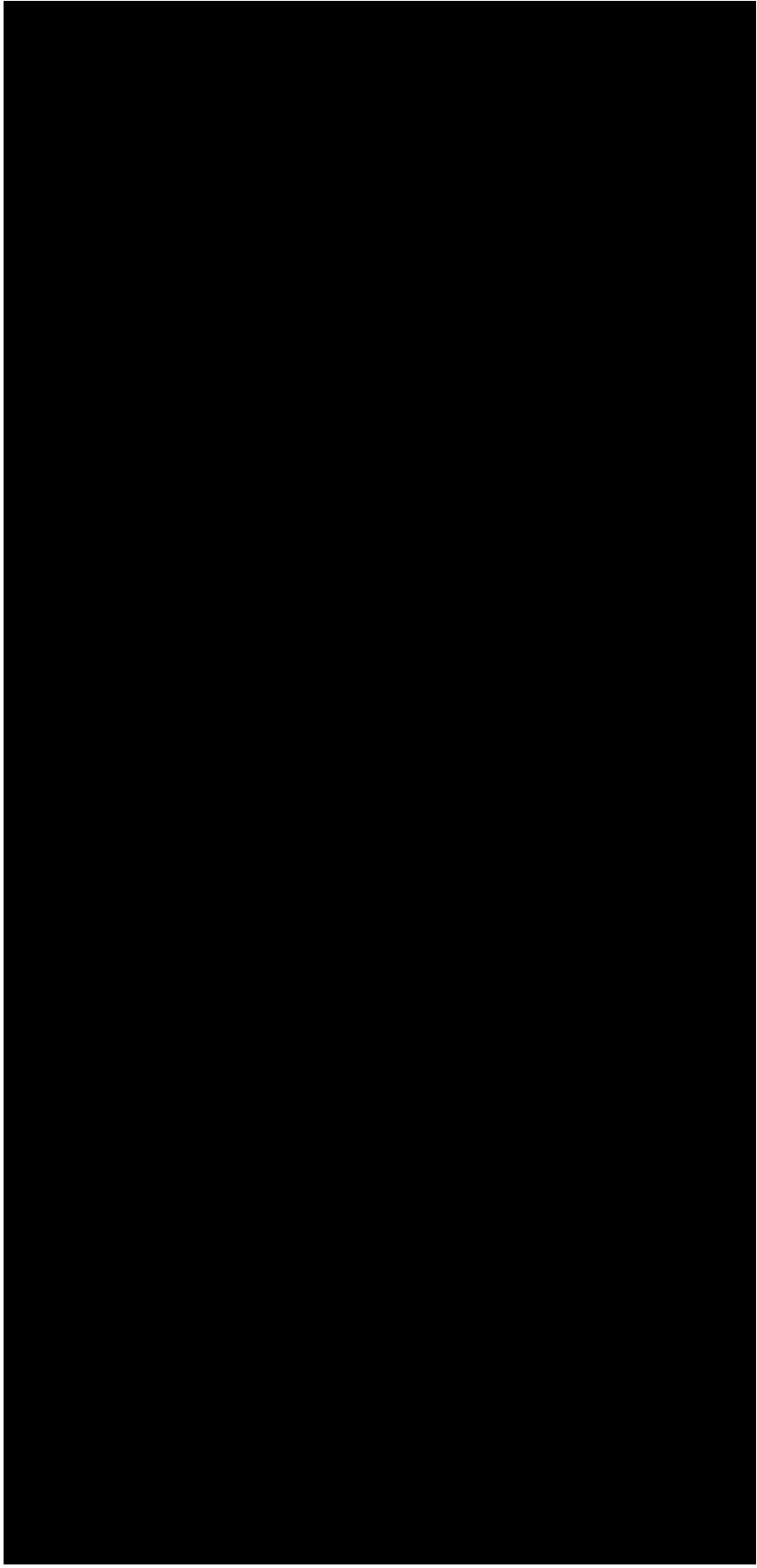
While the effectiveness of screening and treatment is being assessed in national studies, and comprehensive information about the benefits and potential risks of screening and treatment is provided to the public, it also is important that we develop a more thorough understanding of the issues regarding screening, access, and treatment that are specific to North Carolina (*Table 1*). A major focus of these efforts should include identifying environmental, lifestyle, and behavioral factors that increase for developing prostate cancer. North Carolina is in a unique position to investigate prostate cancer risk factors because of our high prostate cancer incidence and mortality, high proportion of rural residents, and relatively large African-American population.<sup>33</sup>

**Table 1.** Prostate Cancer Research in North Carolina <sup>34</sup>

**I. DATABASE ASSESSMENT AND DEVELOPMENT (cont.)**

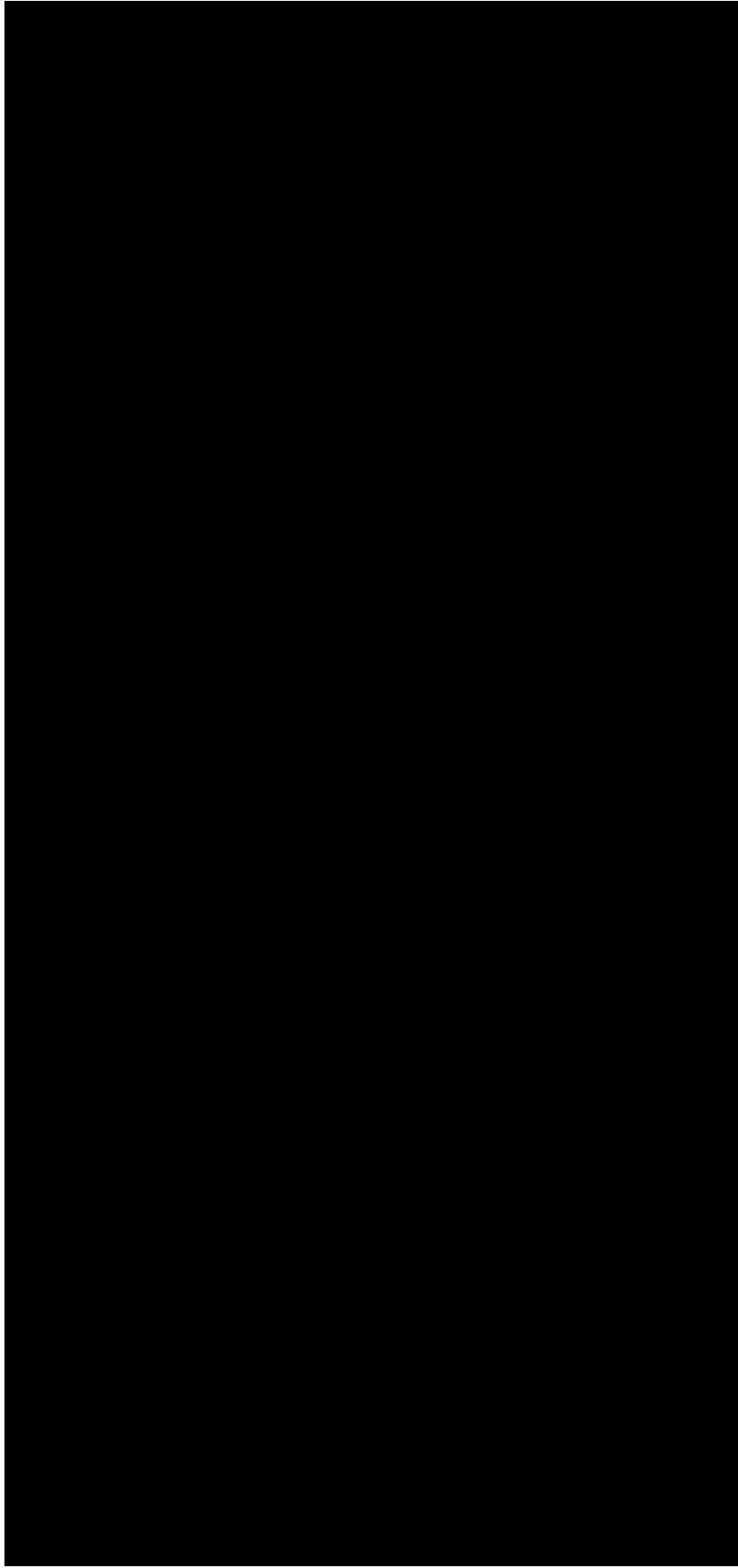


**II. PREVENTION AND TREATMENT**



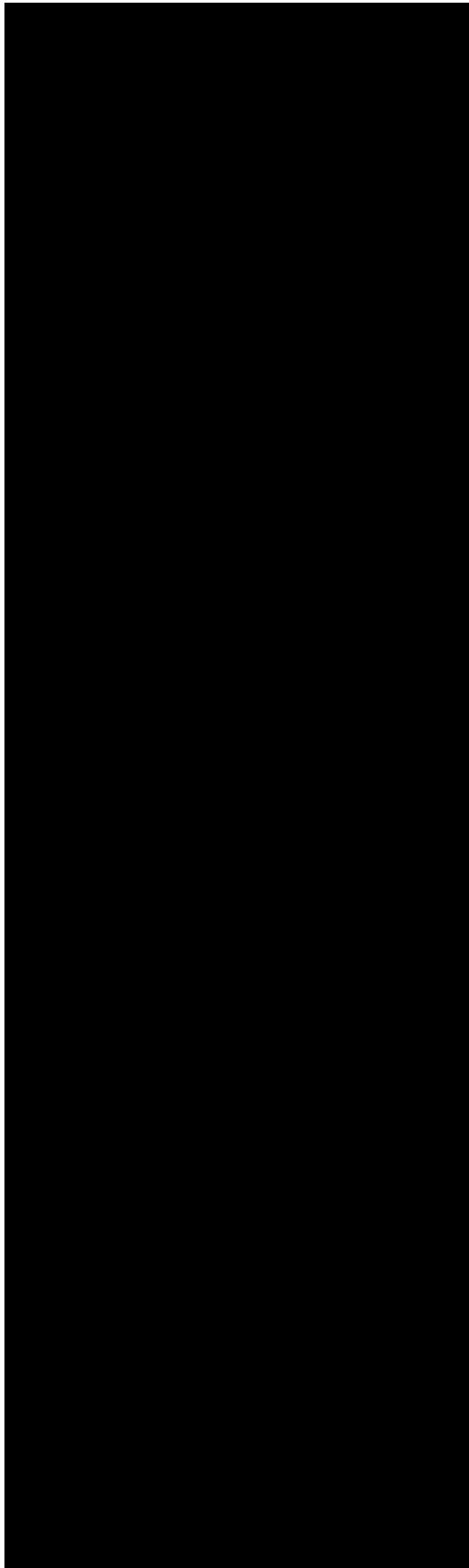


#### **IV. OTHER PERTINENT RESEARCH**



**IV. OTHER PERTINENT RESEARCH (cont.)**

**IV. OTHER PERTINENT RESEARCH (cont.)**



## **Summary**

Prostate cancer is an important health problem for men in North Carolina. It is especially challenging because of the large, “at-risk” population who live in the state and because of the controversy surrounding how best to manage the disease. As with all screening tests, the test’s effectiveness in reducing mortality must be demonstrated with data from a randomized controlled trial. In addition, the treatment and subsequent side effects of treatment must be judged to be “worth” the likelihood of not dying of the cancer. Until randomized controlled trials provide data on mortality with prostate cancer screening, this risk/benefit ratio cannot be determined. Incontinence (urinary and fecal) and impotence are major side effects of treatment for many men.<sup>43-45</sup> Thus, men need to be informed of the unknown risks and benefits of screening before receiving testing.

For this reason, our committee is dedicated to providing physicians and the public with information about prostate cancer. In addition, we are supportive of further research into preventing prostate cancer as evidenced by our objectives and strategies.

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## *Prostate Cancer Goals, Objectives, and Strategies*

### **Goal 1:**

**To educate men and their families about prostate cancer and issues related to screening and treatment.**

#### **Targets for Change by 2006:**

1. Increase the percentage of men aged 40 and older who have discussed prostate cancer screening with their doctor in the last year overall from 40% to 60%. For African-American men, increase this percentage from 35% to 60%.
2. Monitor the percentages of all men and of African-American men who have had digital rectal exam (DRE) and prostate-specific antigen (PSA) testing in the past year. At the present time, no targets have been set for screening. If the evidence regarding screening changes between 2001 and 2006, targets will be set.

#### **On the following pages,**

**\*\* indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

### **Objective 1**

To inform men about their personal risk for developing prostate cancer. Specific emphasis will be placed on men at high risk (African-American men and those with a family history of the disease). \*\*

#### **Strategies**

1. Identify, or develop, and distribute pamphlets in physician waiting rooms, health departments, and other provider sites.
2. Use the *North Carolina Medical Journal* with tear-out educational materials as a vehicle to provide copy-ready materials to primary care physicians for distribution to patients.
3. Plan a public education campaign that utilizes high-profile men of different ethnicities to increase awareness about the need to be informed about prostate cancer.\*\*
4. Encourage men, especially African-American men, to participate in Prostate Cancer Awareness Week activities (free Prostate Specific Antigen tests and Digital Rectal Exams). \*\*
5. Utilize community health outreach organizations to communicate information to men about their personal risk for prostate cancer to men and to refer for free Prostate Specific Antigen tests and Digital Rectal Exams where appropriate and desired. \*\*
6. Implement and deliver interventions to physicians' offices that are proven to effectively communicate accurate information to men and their families about screening and treatment options.

## **Objective 2**

To encourage timely and appropriate follow up of abnormal Prostate Specific Antigen (PSA) test results. If results are abnormal, men should be apprised of their treatment options.

### **Strategies**

1. Provide materials to providers to assist them with educating men and their families about their treatment options.
2. Facilitate rapid dissemination of information about new treatment options and the effects of treatments to physicians.
3. Provide tear-out sheets in the *North Carolina Medical Journal* to facilitate dialogue between men and their primary care physician.

## **Objective 3**

To provide suggestions to providers on how to communicate with patients and their families about their risk for developing prostate cancer.

### **Strategies**

1. Participate in annual statewide physician meetings to include talks and displays on prostate cancer.
2. Provide tear-out sheets in the *North Carolina Medical Journal* to facilitate dialogue between men and their primary care physician.
3. Add information to medical school curricula to train students in how to discuss prostate cancer with patients and their families.

## **Objective 4**

To encourage men to participate in efforts aimed at prostate cancer prevention.

### **Strategies**

1. Identify centers within North Carolina that are participating in prostate cancer chemoprevention studies (SELECT, PCPT) and disseminate this information to physicians and organizations to alert men of these opportunities.
2. Distribute materials to SELECT clinical centers to facilitate recruitment to these studies.
3. Test strategies to encourage African-American men to join these studies.
4. Encourage the development and initiation of new chemoprevention studies.

## **Objective 5**

To continue monitoring the evidence for or against prostate cancer screening and modify recommendations and targets as appropriate.

## **Strategies**

1. Gather and review studies on the efficacy of prostate cancer screening.
2. Present annual updates on information gathered to the Early Detection Subcommittee.

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

American Cancer Society: 1.1, 1.3P\*, 2.1P, 1.4, 1.5, 2.1, 2.2

Brody School of Medicine at East Carolina University: 1.1, 1.5, 3.3, 4.4

Cancer Information Service: 1.1, 1.3, 1.5, 2.1, 2.2, 4.1, 4.2

Comprehensive Cancer Center of Wake Forest University: 4.4

Duke Comprehensive Cancer Center: 4.4

Duke University School of Medicine: 1.1, 1.5, 4.4

North Carolina Academy of Family Physicians: 1.2, 3.1, 3.2

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee: 1.1P, 1.2P, 1.3P, 1.5P, 2.1P, 2.2P, 2.3P, 3.1P, 3.2P, 4.1, 4.2P, 4.4P

North Carolina Advisory Committee on Cancer Coordination and Control-Prevention Subcommittee: 4.2P, 4.4P

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee-  
Prostate Cancer Workgroup: 5.1P, 5.2P

North Carolina Cancer Control Program: 1.3

North Carolina Division of Aging: 1.3

North Carolina Medical Society: 1.2, 2.1, 2.2, 2.3, 3.1, 3.2, 4.1

North Carolina Office of Healthy Carolinians: 1.5

North Carolina Primary Health Care Association: 1.2, 3.1, 3.2

UNC Lineberger Comprehensive Cancer Center: 4.4

UNC Lineberger Comprehensive Cancer Center-Patient and Family Resource Center: 1.1, 1.3, 2.1

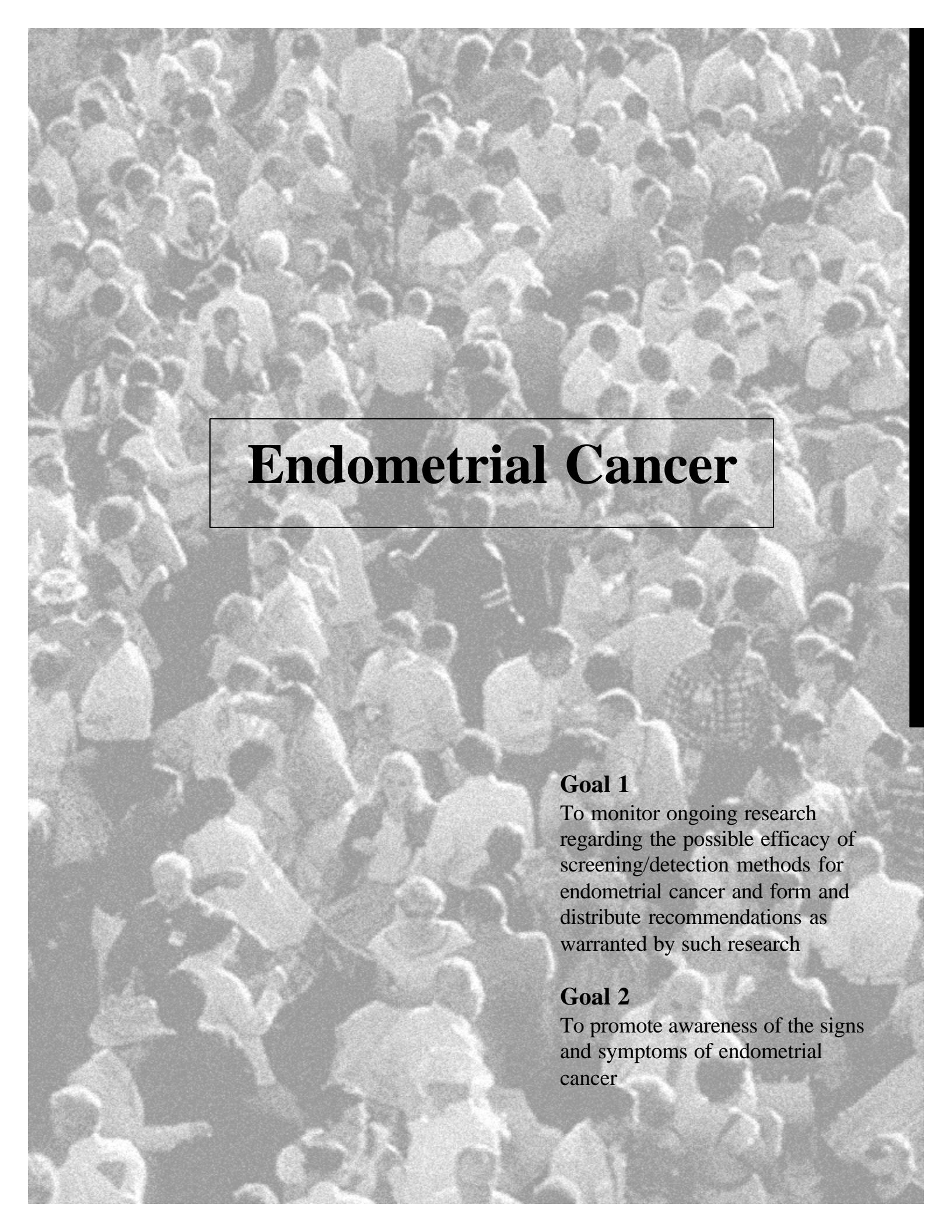
UNC School of Medicine: 1.1, 1.5, 4.4

Us Too International: 1.1, 1.3, 1.4, 2.1

Wake Forest University School of Medicine: 1.1, 1.5, 3.3, 4.4

\* P indicates Principal Agency



A grayscale microscopic image showing clusters of cells, likely endometrial tissue. Some cells appear larger and more irregular than others, suggesting a potential for cancerous changes.

# Endometrial Cancer

## Goal 1

To monitor ongoing research regarding the possible efficacy of screening/detection methods for endometrial cancer and form and distribute recommendations as warranted by such research

## Goal 2

To promote awareness of the signs and symptoms of endometrial cancer



*Endometrial cancer (cancer of the inner lining of the uterus, also called uterine cancer) is now the most frequently diagnosed gynecological malignancy in the United States, following the significant decline in the numbers of patients with cervical cancer.*

Overall, about 6% of all new cancers diagnosed in women originate within the uterus; however, only 2% of cancer deaths will be related to uterine malignancy.<sup>1</sup> The peak incidence is between age 58 and 60 years.

Since the 1970s, the incidence of endometrial cancer has been decreasing in the United States. Incidence has decreased from a high of 33 per 100,000 women to a present low of approximately 20 per 100,000 women. During this period, there has been no change in the risk factors for endometrial cancer and, unfortunately, no significant improvement in survival.<sup>2</sup>

It is estimated that about 36,100 women in the United States will be diagnosed with endometrial cancer in the year 2000 and 6,500 women will die of the disease.<sup>3</sup> In North Carolina, 807 women were diagnosed with endometrial cancer in 1998 and 191 women died of the disease.<sup>4</sup> Projections for the year 2000 indicate that an estimated 1,110 women in North Carolina would be diagnosed with endometrial cancer and an estimated 185 women would die of the disease.<sup>4</sup>

In the United States, risk for endometrial cancer among African-Americans appears to be similar to that among Caucasians for more virulent endometrial cancers; however, the risk among African-Americans is lower than that of Caucasians for less virulent, hormone-related endometrial cancers.<sup>5</sup> It has been suggested that the increased incidence of low-grade endometrial cancers may be due to socioeconomic factors or other factors that have not yet been identified.<sup>5</sup> Risk for mixed mesodermal tumors of the uterus is higher among African-Americans.<sup>6</sup> There are also racial differences regarding the stage at the time of diagnosis. Most of the cases in the Caucasian

population (75%) are diagnosed while still confined to the uterus while the figures are different for African-American women- localized cancer is present at the time of diagnosis in only 51%.<sup>1</sup> African-Americans tend to have cancers of poor differentiation or high risk tissue types, which tend to be diagnosed in advanced stages.<sup>7</sup> The incidence of endometrial cancer is lower among Native Americans, although there are considerable geographic differences. Endometrial cancer is the fifth most frequently diagnosed type of cancer among Native American women and Hispanic women, but ranks fourth among Caucasians.<sup>8</sup>

There are three types of endometrial cancer. The endometrioid type is seen in 90% of the cases and is caused mainly by unopposed estrogen exposure. In the second type, the cancer grows from the surface epithelium and is often associated with a very thin endometrium. These cancers, which are mainly of papillary serous type, appear very similar to ovarian cancer and have a poor outcome due to early spread of disease.<sup>9</sup> A third type of endometrial cancer, mixed mesodermal tumors of the uterus, is characterized by a combination of different malignant tissues. The prognosis for the mixed mesodermal type is worse than that for the endometrioid type.

In some reports using comprehensive staging and aggressive therapy, the overall survival for stage 1 endometrial cancer (cancer confined to the uterus) is over 90%. Good outcomes can also be achieved in more advanced stages, such as 95% survival in patients with stage 2 endometrial cancer (cancer confined to uterus and cervix)<sup>10</sup> and 81% survival in patients with stage 3C (cancer spread outside the uterus) endometrial cancer with lymph node metastasis.<sup>11</sup> These staging and

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treatment options should be available to all women in the United States.

Although the survival after treatment for endometrial cancer is quite good in many patients, there is room for improvement. Between 1989 and 1995, 96% of Caucasian women with localized endometrial cancer survived but only 80% of African-American women did. The figures for regional disease are 67% vs. 41%, respectively, and for distant metastasis, the figures are 28% vs. 12%.<sup>1</sup> These outcomes mainly seem to be due to poorer prognostic factors among African-Americans with endometrial cancer. In addition, some reports also detect a significant difference regarding adequacy and aggressiveness of treatment.<sup>12</sup> If treatment results are adjusted for stage and tumor type, race does not appear to influence survival.<sup>12</sup> This statement has been disputed, however.<sup>13</sup> Much research is still needed to separate lifestyle-related and socioeconomic factors from the questionable influence of race. The overall cancer survival rates are lower in Hispanics and Native Americans when compared to the Caucasian population.<sup>14</sup>

## Risk Factors for Endometrial Cancer

Most of the risk factors for endometrial cancer are related to the hormonal environment. The risk factors for premenopausal endometrial cancer are early age of menarche, episodes of irregular or absent uterine bleeding, no pregnancies, obesity, and inactivity. Risk factors for postmenopausal endometrial cancer include exposure to unopposed estrogen through production in fatty tissue or medication (e.g. tamoxifen), obesity, diabetes later in life, and hypertension. “Unopposed estrogen” refers to estrogen whose effect on the uterus is not counteracted by progesterone. These four features relate to the most frequent type of endometrial cancer, the endometrioid type.<sup>15</sup>

All factors that lead to an unopposed estrogen effect increase the risk of endometrial cancer. This can occur in several ways. Estrogen can be produced endogenously, for example, through conversion of androstenedione in the fatty tissue, through anovulation or polycystic ovarian disease, or through a hormone producing ovarian tumor such as a granulose cell tumor. Polycystic ovarian disease as well as irregular and infrequent menstruation are the most important endometrial cancer risk factors for young women, even

in the fourth decade of life. Exogenous hormones likewise can increase the risk of endometrial cancer. Initially, hormonal replacement therapy was given using estrogen alone, and an increased incidence of endometrial cancer was seen in the mid-1970s. The addition of progesterone reduces this risk. Evaluating patients who participate in a prepaid health plan, it was noted that there was a significant decrease in the incidence of endometrial cancer after increasing use of progesterone with estrogen in hormone replacement regimens.<sup>16</sup> A 1995 meta-analysis showed that there was a substantial increase in risk for endometrial cancer with long duration of unopposed estrogen use, and the increased risk persists for several years after discontinuation of estrogen use.<sup>17</sup> The meta-analysis also showed that there was a statistically nonsignificant elevation in mortality risk for users of unopposed estrogen.<sup>17</sup>

Medication with tamoxifen, which is frequently used for the treatment and most recently also for the prevention of breast cancer, may increase the risk of endometrial cancer. However, regarding the extent, there are different reports in the literature and most studies are significantly flawed.<sup>18</sup> The data from the NSABP 14 trial<sup>19</sup> as well as the NSABP1 trial<sup>20</sup> reveal only a slightly higher risk of endometrial cancer. A cancer registry study from Sweden did not identify a significant rise in the incidence of endometrial between the years of 1958-1993 in breast cancer patients, in spite of widespread use of tamoxifen during the later years.<sup>21</sup> Endometrial polyps develop more frequently during medication with tamoxifen, and in some reports the incidence of malignant polyps is also increased.<sup>22</sup> A mutation in the pTEN gene has been implicated in this form.<sup>23</sup> Variants of the estrogen receptor gene may be associated with an altered risk of endometrial cancer.<sup>24</sup> Mutations in the P53 gene are frequent in the second type of endometrial cancer.<sup>8</sup> Risk factors for the third type of endometrial cancer, mixed mesodermal tumors of the uterus, are the same as those for the endometrioid type.

Family history is a minor risk factor for endometrial cancer. The risk in a woman is significantly increased if her mother developed the disease at an early age. In many of these families there is also an increased risk for other malignancies, mainly colorectal, so that an association with the hereditary nonpolyposis colorectal carcinoma syndrome is possible.<sup>25</sup>

High consumption of fatty foods may increase

the risk of endometrial cancer, as observed in studies from Hawaii. On the other hand, high intake of vegetables, fruit, soy and plant estrogen may decrease the risk of endometrial cancer.<sup>26</sup> This effect, however, is evident mainly in women who were never pregnant or never used a post-estrogen treatment, however, so it seems that this is a minor influence. These differences in food intake may account for some of the racial imbalance regarding the risk for endometrial cancer.

Other gynecologic risk factors are also related to effects of the endocrine system. A higher number of pregnancies and especially a pregnancy later in life can significantly reduce the risk of endometrial cancer.<sup>27</sup> A multinational report noted a significant decreased risk of endometrial cancer for women on combination oral contraceptives, especially on preparations with a high progesterone content.<sup>28</sup> This has been confirmed in several other studies, and a long-term protective effect has been observed.<sup>29</sup> Other contraceptive devices have less influence. Regarding the IUD, two case-control studies showed conflicting data regarding whether its use influences risk.<sup>30,31</sup>

Smoking decreases the risk of endometrial cancer through its influence on the blood hormone concentration.<sup>32,33</sup> There are conflicting data regarding the importance of exercise. Finally, a definite relation of endometrial cancer risk to alcohol intake could not be noted in a case control study from the United States.<sup>34</sup>

## Symptoms of Endometrial Cancer

Most endometrial cancers cause symptoms such as irregular cycles or persistent menometorrhagia (prolonged and irregular uterine bleeding) in the premenopausal patient, postmenopausal bleeding or brownish discharge. Only 5% of the endometrial cancers are detected while still asymptomatic. Symptoms of advanced disease include pain and signs of abdominal or systemic spread. Eighty-seven percent of all endometrioid lesions are diagnosed at stage 1 or 2, whereas only 62% of all papillary serous lesions and 74% of all clear cell lesions are diagnosed at stage 1 or 2.<sup>35</sup>

## Evaluation of the Endometrium

The best noninvasive method for evaluation of the endometrium is the transvaginal ultrasound with measurement of the endometrial thickness. If the endometrium is less than 4 to 5 mm in thickness, the risk of endometrial hyperplasia or malignancy is minimal. The average thickness of an endometrial cancer is 18 mm. Other indications of malignancy seen with this diagnostic exam are fluid collection within the cavity, irregular lining, or abnormalities of the ovaries. The exam, however, is not yet accurate enough to replace the endometrial biopsy.<sup>36</sup> MRI is as effective,<sup>37-39</sup> but CT scan is not as good for evaluation of the endometrium. Both tests are adequate to screen for metastatic disease in the rare patient who will not undergo surgery.

Endometrial cytology has not been shown to be an effective screening tool as it is not sensitive enough for the diagnosis of precancerous lesions. In endometrial cancer, the architectural pattern of the lesion is very important and a cytological sample is not sufficiently accurate. Although the Pap smear is not a screening tool for endometrial cancer, it can aide in the diagnosis. If a postmenopausal woman is noted to have normal endometrial cells on Pap smear, her risk of endometrial pathology including hyperplasia and malignancy is substantial. If the endometrial cells appear abnormal, the risk of further problems is as high as 50%.<sup>40</sup> In Iceland, attending a screening visit with Pap smears and gynecological exam increased the yearly diagnosis of endometrial cancer and overall survival. This improvement is attributable mainly to discussion of early symptoms and further evaluation at time of the screening visits rather than to the evaluation of the Pap smear.<sup>41</sup>

The endometrial biopsy is the mainstay for the diagnosis of endometrial cancer. In the vast majority of patients, it is easy to perform in the office with mild to moderate discomfort. A variety of different instruments are available, mainly relying on suction or brushing to obtain a tissue specimen. The accuracy approaches 95%. A Dilatation and Curettage (D&C) should be performed if there are discrepant results regarding ultrasound and biopsy or if an examination under anesthesia will prove to be of further benefit. Hysteroscopy allows for visualization of the endometrium, which unfortunately is not a very accurate assessment. The main benefit is the directed biopsy of a localized lesion, which makes hysteroscopy

a more accurate test; the probability that the hysteroscopy will show a negative result when no cancer is present (negative predictive value) is higher than that of a D&C. It should be noted that, during hysteroscopy, the inside of the uterus needs to be distended to allow for examination. As a result, there is a possibility that cancer cells could be pushed through the tubes into the abdomen. This has been shown in several studies. However, it is not clear whether this is of prognostic importance.<sup>42</sup>

## **Screening for Endometrial Cancer**

Screening of the general population for endometrial cancer is not cost effective for the following reasons: 1) early symptoms and frequent early diagnosis with good treatment results already occur; 2) lower prevalence of the disease when compared to other malignancies that are screened for currently (5 per 1,000 asymptomatic women above age 45); 3) difficult accessibility of precursor lesions; 4) suboptimal sensitivity and specificity of noninvasive screening tests (ultrasound); 5) the necessity of an invasive procedure in order to obtain a histologic sample, causing discomfort; and 6) the higher cost of screening tests.

Even for women at increased risk, it is not clear whether screening is, overall, beneficial. There are no data to prove the efficacy in patients with morbid obesity or diabetes, but in these patients screening could be considered. The progesterone challenge test has been advocated to identify patients at very high risk for hyperplasia or malignancy. If bleeding occurs after medication with progesterone for 10 days in postmenopausal women, histologic evaluation of the endometrium is recommended.<sup>43</sup> The negative predictive value approaches 100% in several small studies. Even in patients taking tamoxifen, a definite benefit of routine screening has not been seen. In this patient population, ultrasound is not an effective evaluation technique as endometrial thickness is mainly related to the duration of tamoxifen therapy. If a thickness above 5 mm is regarded abnormal, a D&C still reveals atrophy in about 49% of the patients.<sup>44</sup> Therefore surveillance should include close attention to early symptoms and yearly pelvic exams with Pap smear.

There is no evidence that screening biopsies prior to estrogen replacement therapy or hysterectomy are worthwhile in asymptomatic patients; however,

even minor symptoms should be evaluated. In the postmenopausal patient with a uterus taking estrogen replacement therapy, every effort should be made to add progesterone to the regimen. If that is not possible, screening with ultrasound and endometrial biopsy every six to twelve months is imperative. For the same reason, premenopausal patients with infrequent menstruation need to receive regular treatment with progestational agents to prevent endometrial thickening. If that is not possible, endometrial biopsies are necessary. As a rule, endometrial biopsy should be done on all patients with irregular uterine bleeding, age 35 or older. It may be necessary even in younger patients if they present with symptoms and have risk factors.

## **Reducing the Risk for Endometrial Cancer**

Many of the risk factors leading to endometrial cancer are amenable to prevention. In premenopausal women it is important to treat episodes of oligomenorrhea (irregular or rare periods) with regular progesterone medication. The beneficial effect of combination oral contraceptive should be explained to all women to alleviate the fear that hormones cause cancer. The dietary risk factors, but also obesity and lack of exercise, are reduced by acceptance of a healthy lifestyle. In postmenopausal patients, estrogen-only replacement therapy should be avoided. Progesterone medication should be of adequate dosage and duration, at least 12 days per month.

## **Patient Education**

The first step in improving the outcome for patients with endometrial cancer is adequate patient education that stresses the importance of immediate evaluation of all episodes of postmenopausal bleeding or persistent irregular cycles in the premenopausal woman. Elderly women often do not see a gynecologist on a regular basis and are embarrassed to talk about vaginal bleeding. The primary care provider, who sees these women more frequently for the treatment of age-related medical problems, has a great opportunity to ask about symptoms and to discuss early warning signs and risk factors. A short gynecologic history not only improves detection of endometrial cancer, but also cervical and vaginal cancer. This opportunity is often missed. Raising

awareness of the problem by instructing peer groups and social leaders in the community is another option. In several programs, social support interventions have been more successful than purely educational programs. Social networks have been shown to exert a positive influence on cancer screening behavior.<sup>45</sup> In addition, other health care providers such as community nurses or church nurses should be involved in the educational process. These interventions may reduce barriers to early evaluation such as anxiety, lack of communication skills and lack of knowledge.

### **Provider Education**

As stated earlier, the primary care provider has the best opportunity to instruct women regarding warning signs and risk factors and to ask about early symptoms. The primary care provider prescribing estrogen replacement therapy has to be informed about the importance of including progesterone in adequate doses and duration. Lastly, all physicians should take endometrial cancer seriously. Although the outcome is often good, there is room for improvement. Many patients with endometrial cancer are not staged appropriately and do not receive optimal therapy. Adequate surgery and staging biopsies are important to plan postoperative therapy. If these resources are not available in the community, referral should be considered. After adequate staging, further postoperative therapy often is not necessary, but if needed it can be tailored to the individual situation of the patient. Unnecessary therapy leading to patient discomfort, long term complications, and increased cost can be avoided, whereas patients with high risk lesions receive aggressive therapy leading to improved results.

### **Access to Care**

All women should be assured that diagnosis and treatment is available, even in the absence of insurance, and information regarding support services should be disseminated. Transportation to a clinic for screening and treatment often is a significant problem. In addition, a fatalistic attitude often reduces utilization of available services. Third, all women should be knowledgeable about the preventable risk factors of endometrial cancer, mainly unopposed estrogen medication, oligomenorrhea, and obesity. In this respect it is important to emphasize the protective

effect of oral contraceptives.

### **Summary**

Endometrial cancer is the most frequently diagnosed gynecological malignancy in the United States, with a good prognosis in many cases. There is still room for improvement, especially with regard to treatment results in minority populations and adequacy of staging. Universal screening at this point is not cost effective, but efforts should be concentrated on patient education regarding risk factors, warning signs and early symptoms as well as access to health care. All health care providers should be well informed about appropriate estrogen replacement regimens.

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## ***Endometrial Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To monitor ongoing research regarding the possible efficacy of screening/detection methods for endometrial cancer and form and distribute recommendations as warranted by such research. Monitoring of research and formulation of recommendations will focus on general-risk populations and on high-risk populations.**

#### **Objective 1**

To report every six months to the Early Detection Subcommittee on the status of research and screening recommendations for endometrial cancer.

#### **Strategies**

1. Gather and review studies of the methods and efficacy of endometrial cancer screening
2. Monitor the position statements of national and state-level organizations.

### **Goal 2:**

**To promote awareness of the signs and symptoms of endometrial cancer.**

#### **Objective 1**

To obtain information for developing awareness initiatives.

#### **Strategies**

1. Work with agencies to obtain appropriate awareness and education materials.
2. Work with universities to obtain appropriate awareness and education materials.

#### **Objective 2**

To link with ongoing events to promote awareness of the signs and symptoms of endometrial cancer.

#### **Strategies**

1. Distribute awareness and education materials at health fairs and other public events.

### **Goal 3:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

Brody School of Medicine at East Carolina University: 2.1.2

Cancer Information Service: 2.1.1

Duke University School of Medicine: 2.1.2

North Carolina Academy of Family Physicians: 1.1.1, 1.1.2

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.1.1P\*, 1.1.2P, 2.1.1P, 2.1.2P, 2.2.1P

North Carolina Cancer Control Program: 2.1.1, 2.2.1

North Carolina Council for Women: 2.2.1

North Carolina Medical Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Nurses Association: 2.1.1, 2.2.1

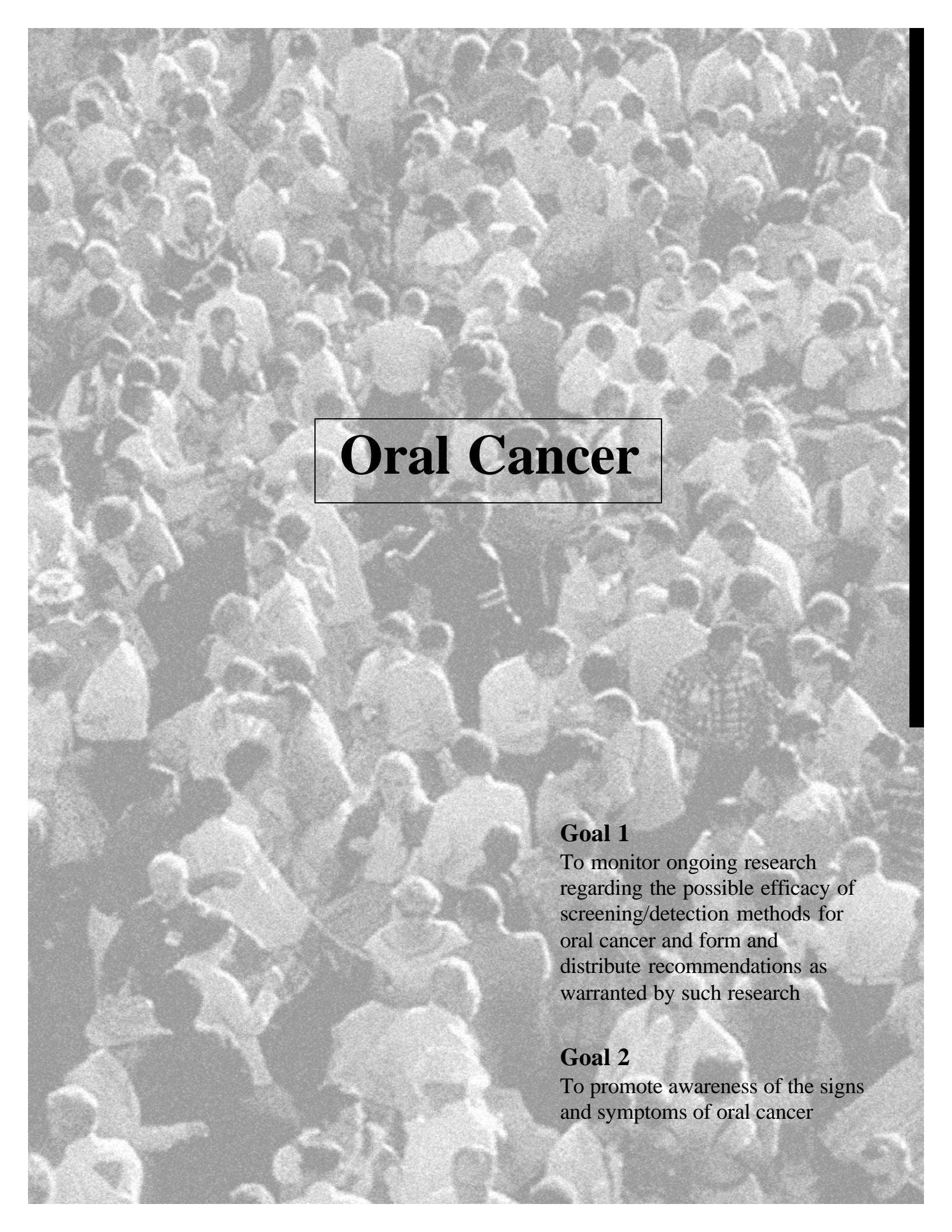
North Carolina Women's and Children's Health Section-Women's Health Branch: 2.1.1, 2.2.1

UNC School of Medicine: 2.1.2

UNC School of Public Health-Department of Health Behavior and Health Education: 2.1.2

Wake Forest University School of Medicine: 2.1.2

\* P indicates Principal Agency

A high-magnification black and white micrograph showing a dense layer of squamous cell carcinoma cells. The cells are polygonal with visible nuclei and some cellular differentiation. A prominent feature is a large, irregularly shaped cell in the center-right, which appears to be a tumor giant cell, characterized by its large size and multiple nuclei.

# Oral Cancer

## Goal 1

To monitor ongoing research regarding the possible efficacy of screening/detection methods for oral cancer and form and distribute recommendations as warranted by such research

## Goal 2

To promote awareness of the signs and symptoms of oral cancer



*Each year approximately 30,000 new cases of oral and pharyngeal cancer occur in the United States, and 8,000 people die from this disease.<sup>1</sup> Oral and pharyngeal cancer is responsible for more new cancer cases and more cancer deaths than cancers of the cervix, stomach, pancreas, kidney and leukemia combined.<sup>1</sup>*

Oral cancer includes cancers of the lips, tongue, floor of mouth, palate, gingiva and alveolar mucosa, buccal mucosa and oropharynx. In North Carolina, oral cancer is the 8<sup>th</sup> most common cancer, the 4<sup>th</sup> most common among minority males, and the 5<sup>th</sup> most common among all males.<sup>2</sup> Between 1993 and 1997, the average oral cancer mortality rate for North Carolina was 2.9/100,000 population, ranking North Carolina 13<sup>th</sup> in the nation for oral cancer mortality, and representing an 11.5% excess in the state's oral cancer death rate compared to the national rate.<sup>3</sup> Reflecting national trends, oral cancer in North Carolina occurs 3 times more commonly among men than among women, and twice as commonly among minorities as among whites.<sup>2</sup> The average age at diagnosis of oral cancer is 60 years.<sup>3</sup>

Despite recent advances in surgery, radiation, and chemotherapy, only about half of all persons diagnosed with oral cancer survive five years, with whites (five-year survival=56%) faring better than African Americans (five-year survival=34%).<sup>3</sup> Although the survival rates for many other cancers (e.g., breast, colorectal) have improved over the past two decades, the five-year survival rates for oral cancer have hardly changed. In fact, oral cancer five-year survival rates among minorities have declined since the mid-1970's.<sup>3</sup> While detecting oral cancer at an early stage improves survival, over 50% of all patients with oral cancer present with regional or distant spread, and 80% of African Americans present at these late stages.<sup>3</sup>

## Risk Factors

About three quarters of oral cancers are

attributed to tobacco use, either smoked or smokeless.<sup>4</sup> North Carolina has one of the highest rates of smokeless tobacco use in the country, particularly among minorities, and the highest rate of female smokeless tobacco use.<sup>5</sup> Using tobacco in combination with excess alcohol consumption greatly increases the risk of developing oral cancer.<sup>6</sup> Other risk factors for oral cancer include older age, occupational exposures, sun exposure (for lip cancer), and the presence of oral leukoplakia or erythroplasia, which are premalignant oral lesions. In addition, HIV-positive individuals are at increased risk for intraoral Kaposi's sarcoma and non-Hodgkin's lymphoma.<sup>6</sup>

## Screening

Although there is good evidence that persons with early stage oral cancer have improved survival, no randomized controlled trial has evaluated the efficacy of screening in improving oral cancer mortality. In addition, neither the abbreviated oral physical exam typical of most patient-physician encounters, nor the more extended, detailed oral exam advocated by oral cancer authorities has been evaluated for sensitivity, specificity and positive predictive value as a screening test for oral cancer.<sup>6</sup>

Nationally, 15% of adults reported having ever had an oral cancer examination.<sup>7</sup> Of these, 48% (7.2% of the adult population) had the exam in the past year, and 31% (4.65% of the adult population) had the exam within the past 1 to 3 years. Respondents who were white, above the poverty level, had greater than high school educational attainment and had more knowledge regarding oral cancer risk factors were

likely to have had an oral cancer exam.

Despite the paucity of data demonstrating the efficacy of screening in improving oral cancer mortality, the Oral Cancer Working Group of the Centers for Disease Control and Prevention recommends that state and national efforts to reduce oral cancer morbidity and mortality should focus on primary prevention and early detection.<sup>4</sup> Since older individuals (who are at greatest risk for developing oral cancer) are more likely to visit their physicians than their dentists in any given year,<sup>6</sup> primary care physicians must assume more of a role in counseling their patients regarding tobacco and alcohol cessation, in examining the oral cavity for suspicious lesions, and in referring patients to appropriate specialists for management.<sup>4</sup>

Given the strong link between tobacco and alcohol use and oral cancer, screening might be focused among patients who use these substances, with particular attention paid to minorities.<sup>6</sup> This is especially important in North Carolina where high rates of smokeless tobacco use and oral cancer mortality coexist among minority groups.<sup>5</sup> Statewide efforts to prevent and control oral cancer should also include public health campaigns to raise public awareness of oral cancer and its link to tobacco use and heavy alcohol consumption; continuing education for health-care professionals on the prevention and multidisciplinary management of oral cancer; and organizational approaches to reducing oral cancer such as developing collaborative arrangements between private and public sectors that have an interest in oral cancer control.<sup>4</sup>

## **Summary**

The Early Detection Subcommittee plans to monitor research developments related to screening for oral cancer and will form recommendations as warranted by a review of the evidence. The Subcommittee also places high priority on promoting awareness of the signs and symptoms of oral cancer. The following objectives and strategies have been selected to accomplish those aims.

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## ***Oral Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To monitor ongoing research regarding the possible efficacy of screening/detection methods for oral cancer and form and distribute recommendations as warranted by such research. Monitoring of research and formulation of recommendations will focus on general-risk populations and on high-risk populations.**

#### **Objective 1**

To report every six months to the Early Detection Subcommittee on the status of research and screening recommendations for oral cancer.

#### **Strategies**

1. Gather and review studies on the efficacy of oral cancer screening.
2. Monitor the position statements of national and state-level organizations.

### **Goal 2:**

**To promote awareness of the signs and symptoms of oral cancer.**

#### **Objective 1**

To obtain information for developing awareness initiatives.

#### **Strategies**

1. Work with agencies to obtain appropriate awareness and education materials.
2. Work with universities to obtain the appropriate awareness and education materials.

#### **Objective 2**

To link with ongoing events to promote awareness of the signs and symptoms of oral cancer.

#### **Strategies**

1. Distribute awareness and education materials at health fairs and other public events.

### **Goal 3:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

Cancer Information Service: 2.1.1, 2.1.2

North Carolina Academy of Family Physicians: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.1.1P\*, 1.1.2P, 2.1.1P, 2.1.2P, 2.2.1P

North Carolina Cancer Control Program: 1.1.2

North Carolina Health Promotion and Disease Prevention Section-Tobacco Prevention and Control Branch:  
2.2.1, 2.1.1

North Carolina Medical Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

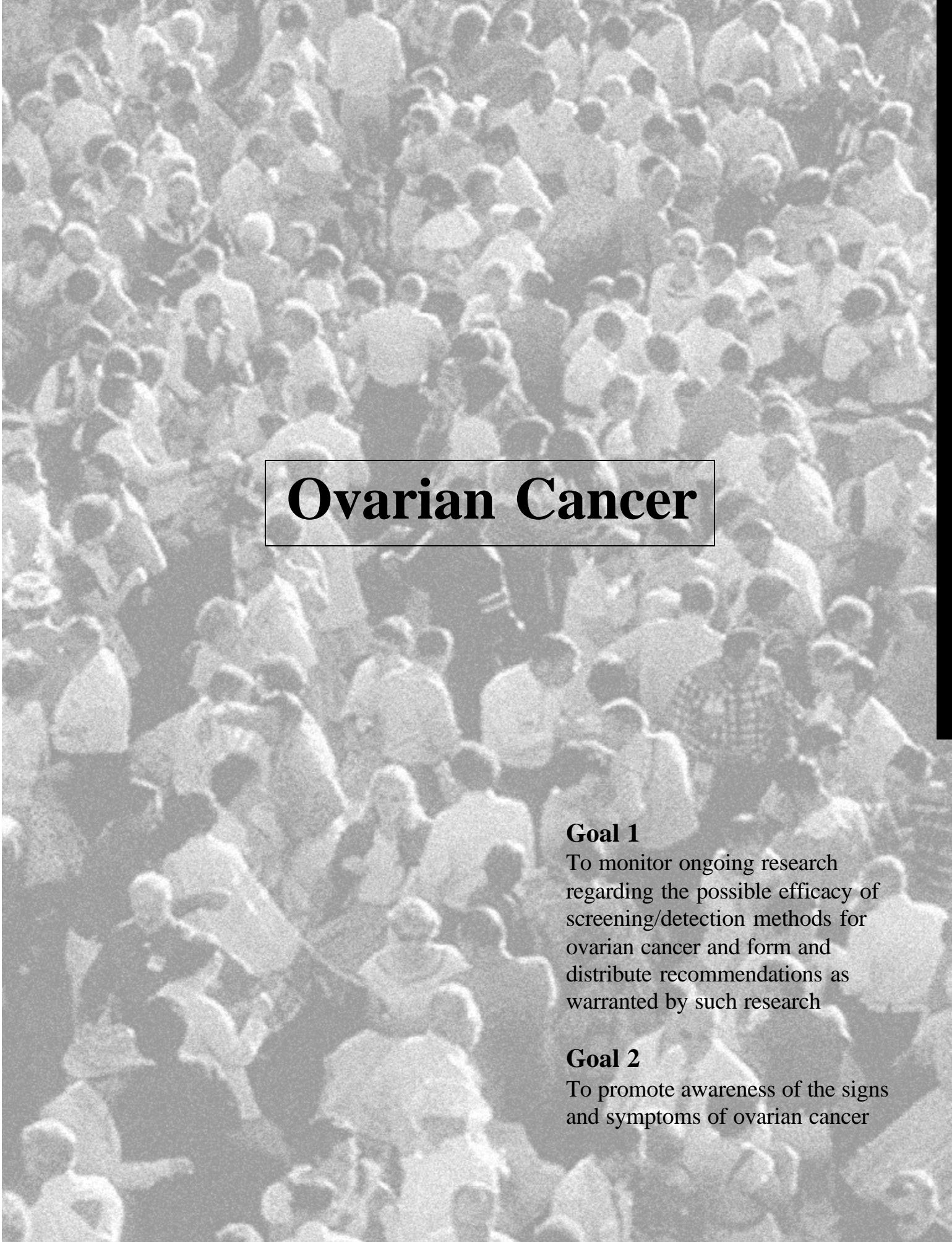
North Carolina Nurses Association: 2.1.1, 2.2.1

North Carolina Oral Health Section: 1.1.1, 1.1.2, 2.1.1, 2.2.1

UNC School of Public Health-Department of Health Behavior and Health Education: 2.1.2

\* P indicates Principal Agency



A high-magnification black and white micrograph showing a dense, irregular cluster of ovarian cancer cells. The cells are rounded with visible nuclei and some internal structures, creating a textured, cellular pattern.

# Ovarian Cancer

## Goal 1

To monitor ongoing research regarding the possible efficacy of screening/detection methods for ovarian cancer and form and distribute recommendations as warranted by such research

## Goal 2

To promote awareness of the signs and symptoms of ovarian cancer



*Ovarian cancer will strike an estimated 23,100 women in the United States in the year 2000 and will cause an estimated 14,000 deaths.<sup>1</sup> In North Carolina, projections for the year 2000 show an estimated 750 new cases of ovarian cancer and an estimated 390 deaths from the disease.<sup>2</sup>*

Ovarian cancer is the sixth most common cancer (other than skin cancer) in women and comprises about one-fourth of all gynecologic cancers, but causes more deaths than any cancer of the female reproductive system. It is the fifth-leading cause of cancer-related deaths for women in the United States.

Seventy-eight percent of ovarian cancer patients survive one year after diagnosis. The five-year survival rate of all stages is about 50%. If diagnosed and treated early, the rate is 95%, yet only about 25% of all cases are detected at the localized stage. Five-year survival rates for women with stage 3 or 4 disease are 30% and 19%.<sup>3</sup>

## Symptoms

Ovarian cancer is often without obvious signs or symptoms and thus 70% of women with ovarian carcinoma present with advanced disease. However, the majority of women with ovarian have at least one symptom,<sup>4</sup> and symptoms are most often the reason for the physician visit that leads to diagnosis. Possible symptoms have been categorized as abdominal (77%), gastrointestinal (70%), pain (58%), constitutional (50%), urinary (34%), and pelvic (26%).<sup>4</sup> Specifically, symptoms may include: persistent gas, nausea, or indigestion; increased frequency or urgency of urination (or in some women, difficulty urinating) in the absence of infection; irregular bowel activity (e.g., constipation or diarrhea); unexplained weight gain or loss, particularly weight gain in the abdominal region; pain during intercourse; pelvic or abdominal discomfort, such as heaviness, pressure or pain; bloating or feeling of fullness; abnormal menstrual or vaginal bleeding or discharge; loss of appetite; ongoing fatigue; distended or hard abdomen; palpable lump/mass in the abdomen; and backache.

Women with symptoms may delay seeking

medical care, thinking that the symptoms are due to aging, menopause, stress, or some other more common, less serious condition. Providers, as well, may not consider the possibility that symptoms may be attributable to ovarian cancer, leading to delayed diagnosis. Some studies<sup>4,5</sup> have found that patient-related or physician-related delay in diagnosis were associated with later stage disease and/or poorer survival, while other studies have not.<sup>6,7</sup>

## **Currently, there are no validated screening tests for ovarian cancer.**

## Risk Factors

Risk of ovarian cancer increases with age and over half of all cases occur in women over age 65. Ovarian cancer mainly affects white women. Other main risk factors for ovarian cancer include: a family history of ovarian or breast cancer, a personal history of breast or endometrial cancer, no or few pregnancies, and exposure to talc.<sup>8</sup> Various dietary factors, such as Vitamin D, are being examined as possible causes of ovarian cancer.<sup>9</sup>

With regard to family history, women who have a first-degree relative with ovarian cancer (mother or sister) represent a high risk group.<sup>8</sup> Data from seven case-control studies combined with data from the NCI's Surveillance, Epidemiology, and End Results (SEER) Program showed that women with a positive family history had a 9.4% lifetime risk of developing ovarian cancer.<sup>10</sup> This compared to a lifetime risk ranging from 0.6% to 3.5% for women who did not have a mother or sister with ovarian cancer; among these women, risk was greater for those who had had no pregnancies and had not used oral contraceptives.<sup>10</sup> In addition, being part of a family with certain hereditary syndromes predisposes women to ovarian cancer. Syndromes include ovarian, breast-ovarian, and Lynch 2 syndrome (HNPCC). Lynch 2 syndrome occurs when Lynch 1 syndrome (familial colon cancer)

is accompanied by familial breast, ovarian, endometrial, gastrointestinal and genitourinary cancer.

Prior use of oral contraceptives and parity (having been pregnant) have been found to be protective for ovarian cancer. According to Whittemore (1994),<sup>8</sup> two hypotheses have been postulated to explain the observed reduction in risk associated with pregnancy and oral contraceptive use. The first asserts that some sequelae of ovulation raise the risk of malignancy, and that pregnancies and oral contraceptive use are protective because they suppress ovulation. The second hypothesis posits that circulating levels of pituitary gonadotropins increase the risk of malignancy, and that pregnancies and oral contraceptives are protective because they suppress secretion of these hormones. Whittemore (1994) notes that there is evidence to support both hypotheses, as well as evidence that conflicts with them.

Other conditions associated with low parity that have been shown to alter ovarian cancer risk include infertility and hysterectomy.<sup>11</sup> Although infertility and inability to conceive have been reported to be associated with an increased risk of epithelial ovarian cancer, other studies have reported that a life-long irregular menstrual pattern is negatively associated with the risk of ovarian cancer, supporting the view that anovulation may be protective.<sup>12</sup> Whittemore et al. (1992b)<sup>13</sup> and Rossing et al. (1994)<sup>14</sup> reported data suggesting that there is an association between the use of fertility drugs and ovarian cancer that might explain the association with infertility. These studies suggest that ovulation induction and the hyperstimulatory effects of fertility medications on the ovary increase the risk of ovarian cancer.

Some investigators have suggested an alternative explanation for these findings and have proposed that the abnormal hormonal environment experienced by infertile women, rather than exposure to the drug, would explain this apparent association.<sup>11,15,16</sup> Data from case-control studies show that having had a tubal ligation or hysterectomy is associated with a small decrease in the risk of developing ovarian cancer.<sup>17,18</sup> An earlier menopause<sup>17</sup> or hormonal changes such as lower estradiol and progesterone levels resulting from tubal ligation or hysterectomy may explain these associations.<sup>11,17,18</sup>

## Screening

Currently, there are no validated screening tests

for ovarian cancer, although studies are underway to determine whether existing tests reduce mortality from this cancer.<sup>19</sup> Three modalities have been utilized to detect ovarian tumors: the pelvic examination, transvaginal ultrasound (TVUS),<sup>20</sup> and the CA-125 blood.<sup>21,22</sup> The transvaginal or transabdominal ultrasonography is being investigated as a primary screening mechanism.<sup>23</sup> Also being studied is a multimodal strategy using serum levels of CA125 tumor marker as the initial indicator and, if CA125 levels are elevated, transvaginal ultrasonography as the secondary testing mode.<sup>23</sup> Transvaginal ultrasonography provides higher quality images than transabdominal ultrasonography.<sup>24</sup>

To date, none of these tests has been demonstrated to reduce mortality from ovarian cancer.<sup>25</sup> The major problems with these methods are unacceptably high levels of either false negatives (pelvic exams) or false positives (TVUS and CA-125). The former leads to the failure to diagnose early stage tumors, while the latter leads to unnecessary follow-up tests (laparascopy) and worry/anxiety among women tested. A study currently being conducted in the United Kingdom will provide data from high-risk women who have been screened with various combinations of tests.<sup>23</sup>

In contrast to cervical cancer and breast cancer, there are no established precursor lesions for ovarian cancer and the incidence of ovarian cancer is rare compared to cancers for which screening is effective. Finally, there is evidence that invasive epithelial ovarian cancer may be so aggressive that prevention may be the best avenue to pursue.<sup>26</sup>

## Prevention

Prevention strategies for this cancer are few. As noted by Whittemore (1994), few of the risk factors for ovarian cancer are amenable to modification except oral contraceptive use and tubal ligation. It is important to highlight findings showing that use of oral contraceptives for at least four years may prevent more than half of all ovarian cancers.<sup>9</sup>

Some women with strong family histories of ovarian cancer (i.e., having a mother or sister with ovarian cancer) are choosing to receive prophylactic removal of their ovaries (oophorectomy).<sup>27</sup> While this procedure reduces a woman's risk of developing ovarian cancer, a small risk still exists. About 10% of ovarian cancer cases are thought to have a genetic basis.

Women with either genes BRCA1 or BRCA2 have a 15-30% lifetime risk of developing ovarian cancer.<sup>27</sup> These women, once identified, might be candidates for removal of their ovaries. Although it has been noted that current evidence does not warrant use of genetic testing for the BRCA1 and BRCA2 mutations as the principal method of predicting ovarian cancer,<sup>23</sup> the American College of Obstetricians and Gynecologists (ACOG) Committee on Genetics has stated that such testing might be beneficial for patients who have a strong family history of ovarian cancer or a family member with a BRCA.<sup>23</sup> However, there have been reports of ovarian-like peritoneal carcinomas among women who have had oophorectomies,<sup>28</sup> and loss of estrogen leading to osteoporosis is another possible complication.<sup>8</sup> A better understanding of genetic and environmental interactions that produce a cancer are needed.

## **Summary**

The most crucial need for controlling this cancer is effective prevention or early detection in high-risk women. The Early Detection Subcommittee plans to monitor developments in these important research realms and will form recommendations as warranted by a review of the evidence. The Subcommittee also places high priority on promoting awareness of the signs and symptoms of ovarian cancer. The following objectives and strategies have been selected to accomplish those aims.

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## ***Ovarian Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To monitor ongoing research regarding the possible efficacy of screening/detection methods for ovarian cancer and form and distribute recommendations as warranted by such research. Monitoring of research and formulation of recommendations will focus on general-risk populations and on high-risk populations.**

#### **Objective 1**

To report every six months to the Early Detection Subcommittee on the status of research and screening recommendations for ovarian cancer.

#### **Strategies**

1. Gather and review studies on the methods and efficacy of ovarian cancer screening.
2. Monitor the position statements of national and state-level organizations.

### **Goal 2:**

**To promote awareness of the signs and symptoms of ovarian cancer.**

#### **Objective 1**

To obtain information for developing awareness initiatives.

#### **Strategies**

1. Work with agencies to obtain appropriate awareness and education materials.
2. Work with universities to obtain appropriate awareness and education materials.

#### **Objective 2**

To link with ongoing events to promote awareness of the signs and symptoms of ovarian cancer.

#### **Strategies**

1. Distribute awareness and education materials at health fairs and other public events.

### **Goal 3:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See Coordination)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

Brody School of Medicine at East Carolina University: 2.1.2

Cancer Information Service: 2.1.1

National Ovarian Cancer Coalition: 2.2.1

North Carolina Academy of Family Physicians: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.1.1P\*, 1.1.2P, 2.1.2P, 2.1.1P, 2.2.1P

North Carolina Cancer Control Program: 2.1.1, 2.2.1

North Carolina Council for Women: 2.2.1

North Carolina Medical Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Nurses Association: 2.2.1

North Carolina Women's and Children's Health Section-Women's Health Branch: 1.1.2, 2.2.1

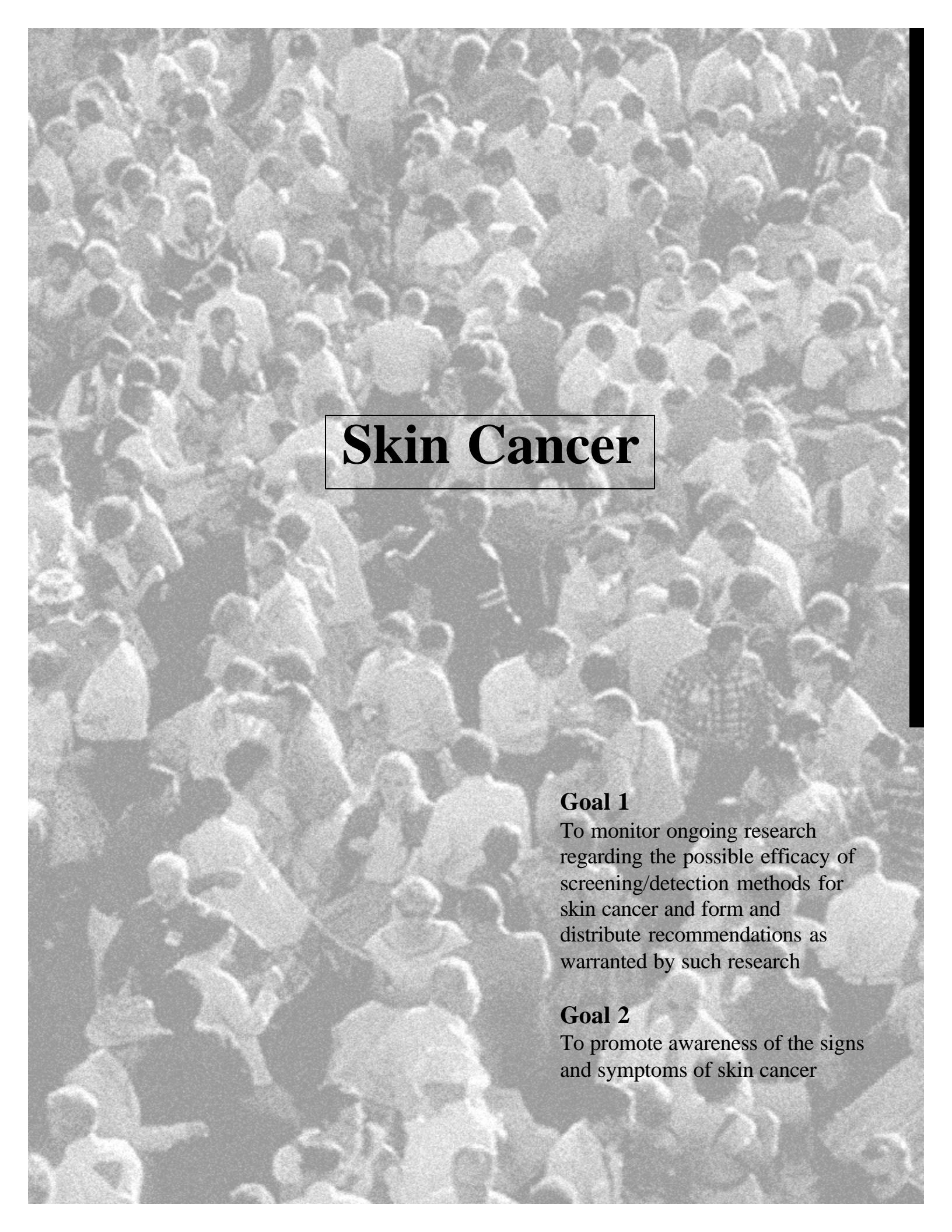
UNC School of Medicine: 2.1.2

UNC School of Public Health-Department of Health Behavior and Health Education: 2.1.2

Wake Forest University School of Medicine: 2.1.2

\* P indicates Principal Agency





# **Skin Cancer**

## **Goal 1**

To monitor ongoing research regarding the possible efficacy of screening/detection methods for skin cancer and form and distribute recommendations as warranted by such research

## **Goal 2**

To promote awareness of the signs and symptoms of skin cancer



*For a discussion of skin cancer prevention, please refer to the Prevention-Ultraviolet Radiation Protection section.*

*An estimated 48,000 cases of invasive malignant melanoma and 30,000 cases of melanoma *in-situ* will be diagnosed in the U.S. in the year 2000.<sup>1</sup> The number of newly diagnosed cases of malignant melanoma is increasing in Caucasian populations in the United States, and the rate of increase is greater than for any other form of cancer.<sup>2</sup>*

Malignant melanoma is the most deadly form of skin cancer. Melanomas are tumors that originate from pigment (melanin) - producing cells. When the tumor cells are confined to the upper layers of the skin, the melanomas are called *in-situ*. When the tumors grow beneath the skin, the melanomas are called invasive. An estimated 48,000 cases of invasive malignant melanoma and 30,000 cases of melanoma *in-situ* will be diagnosed in the U.S. in the year 2000.<sup>1</sup> The number of newly diagnosed cases of malignant melanoma is increasing in Caucasian populations in the United States, and the rate of increase is greater than for any other form of cancer.<sup>2</sup> In the 1930's, the lifetime risk of malignant melanoma was 1 in 1,500 in the U.S. The lifetime risk in the year 2000 is 1 in 74.<sup>1</sup> In the United States, about one fourth of melanoma patients are diagnosed before the age of forty.<sup>3</sup> Thus, the years of life lost from melanoma are higher than for most other forms of cancer.

The number of newly diagnosed cases of melanoma is lower among African Americans and Hispanics than among Caucasians. However, African Americans are often diagnosed with later stage malignant melanomas. A high proportion of melanomas in African Americans occur on the soles of the feet and have a poor prognosis.<sup>4</sup> It is also important to carefully examine the palms and nail beds of African Americans.

The age-adjusted incidence of malignant melanoma in the United States between 1990-95 was 12.2 per 100,000 persons per year.<sup>5</sup> The age-adjusted incidence of malignant melanoma in North Carolina

in the same period was 10.6 per 100,000 per year.<sup>6</sup> However, the number of new diagnoses is increasing steadily; in 1991, there were 786 persons newly diagnosed with malignant melanoma in North Carolina, while in 1997, the number of new diagnoses was 1,177. Projections for the year 2000 show an estimated 1,220 new cases of malignant melanoma and an estimated 225 deaths from the disease.<sup>6</sup> In North Carolina, 98% of cases are white, and 2% are other racial groups. Approximately half are male and half are female. Although most

cases are among those aged 50 and over, a significant proportion occur in persons aged 30 or younger (5%, or about 60 cases per year). North Carolina has one of the highest mortality rates for malignant melanoma in the nation, ranking second among females and third among males.<sup>7</sup>

### **North Carolina has one of the highest mortality rates for malignant melanoma in the nation.**

### **Risk Factors**

Risk factors for malignant melanoma have been studied predominantly among Caucasians. Factors that increase risk include a history of sunburn (especially during childhood), presence of multiple moles (as few as 20 moles increase risk), presence of moles with atypical features, history of melanoma in a first-degree relative, fair skin (blue/green eyes, blond or red hair, light complexion, and inability to tan), a history of non-melanoma skin cancers (such as basal cell and squamous cell carcinoma) and immune suppression.<sup>8</sup> Recent studies have shown that sunlight exposure increases the risk of malignant melanoma in African Americans.<sup>9</sup> Use of tanning beds has been linked to

increased risk of melanoma, especially among persons who are sensitive to sunlight.<sup>10</sup>

Currently, the best way to prevent malignant melanoma is sun protection: avoiding midday sun, regular use of physical barriers to the sun such as hats and other clothing as well as umbrellas and other forms of shade, and use of broad-spectrum sunscreen. It is not clear which types of sun protection are the most effective for lowering risk of melanoma; therefore, a combined approach is recommended.<sup>11</sup> Unfortunately, according to a recent survey, only one third of North Carolina beach goers report regular application of sunscreen or use of protective clothing at peak hours of sun exposure.<sup>12</sup>

## Early detection

Early detection is extremely important for malignant melanoma. The five-year survival for patients with melanomas thinner than 1 mm in depth is 94%, while the five-year survival is only 50% for patients diagnosed with melanomas greater than 3 mm in depth. Due to loss of growth control, melanomas often grow in an irregular manner. Using criteria known as the **ABCD** system, melanomas can often be recognized. These criteria for identifying melanomas are: Asymmetry, Border Irregularity, Color Variation (often shades of red, blue, brown or black), and Diameter (greater than 0.6 cm, the size of a pencil eraser). In addition, a change in a pre-existing mole or the development of a new mole should alert the individual to the possibility of melanoma. Melanomas can be flat or raised, and they are usually asymptomatic. Bleeding and ulceration are often signs of advanced disease.

Regular self-examination of the skin using a step-by-step procedure helps to identify melanomas when the lesions are thin and potentially curable.<sup>1,13</sup> A recent study suggested that skin self-examination lowered risk of melanoma,<sup>14</sup> but further research is needed. Melanomas are more common on sun-exposed areas of the skin, but they also occur on covered areas of the body (places that are not exposed to the sun). Melanomas often occur on areas of the body that are difficult to examine, including the scalp, the back and the back of the legs.

Skin examination by a physician helps to find melanoma at an earlier stage, especially for areas of the body that are difficult to examine. However, randomized, controlled clinical trials have not proven

that the death rate from melanoma is lowered due to regular skin examinations by a physician.<sup>15</sup> Therefore, experts do not agree on how often skin examinations should be performed.<sup>16</sup> Most experts agree that fair-skinned persons at high risk for melanoma (persons with a family or personal history of skin cancer, persons with multiple or atypical moles) should be examined by a physician or other trained observer every year beginning in childhood. Self-examination can supplement physician examination by identifying suspicious changes in between or in the absence of physician examination. Persons who know what skin changes to look for can identify what should or should not be followed up with professional medical attention.

Recommendations vary on skin examination for the general population. The American Cancer Society recommends that total skin examination by a physician be conducted every 3 years for persons aged 20-39 and annually after age 40. The American Academy of Dermatology recommends annual screening for all patients. The U.S. Preventive Services Task Force,<sup>17</sup> the Australian Cancer Society, and the International Union Against Cancer recommend regular screening only for high-risk persons. The American College of Preventive Medicine also recommends periodic skin examinations targeted at high-risk populations.<sup>13</sup> All experts agree that skin examination by a trained observer should be performed whenever a person notices a suspicious or changing mole on the skin. Skin examination takes only a few minutes, and it is safe and easily tolerated.

Unfortunately, the majority of adults in North Carolina do not undergo skin examinations by a physician or practice regular self-examination of the skin (North Carolina BRFSS, 1999). The most common reasons for failure to undergo regular skin examination include lack of knowledge about the importance of early detection of skin cancer (the ABCD rules), anxiety about skin cancer, and economic barriers to obtaining health care.<sup>16</sup> People in North Carolina are exposed to the sun through a variety of recreational and occupational activities. Therefore, skin examination is an important health behavior for North Carolina residents to learn and to discuss with their physicians.

## Summary

The Early Detection Subcommittee plans to monitor research developments related to screening

for malignant melanoma and will form recommendations as warranted by a review of the evidence. The Subcommittee also places high priority on promoting awareness of the signs and symptoms of malignant melanoma. The following objectives and strategies have been selected to accomplish those aims.

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## ***Skin Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To monitor ongoing research regarding the possible efficacy of screening/detection methods for skin cancer and form and distribute recommendations as warranted by such research. Monitoring of research and formulation of recommendations will focus on general-risk populations and on high-risk populations.**

#### **Objective 1**

To report every six months to the Early Detection Subcommittee on the status of research and screening recommendations for skin cancer.

#### **Strategies**

1. Gather and review studies on the methods and efficacy of skin cancer screening.
2. Monitor the position statements of national and state-level organizations.

### **Goal 2:**

**To promote awareness of the signs and symptoms of skin cancer.**

#### **Objective 1**

To obtain information for developing awareness initiatives.

#### **Strategies**

1. Work with agencies to obtain appropriate awareness and education materials.
2. Work with universities to obtain appropriate awareness and education materials.

#### **Objective 2**

To link with ongoing events to promote awareness of the signs and symptoms of skin cancer.

#### **Strategies**

1. Distribute awareness and education materials at health fairs and other public events.

### **Goal 3:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

American Cancer Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

Blue Ridge Cancer Coalition: 2.1.1

Cancer Information Service: 2.1.1

Center for Corporate Health: 2.1.1, 2.2.1

Eastern Carolina Cancer Coalition: 2.1.1

North Carolina Academy of Family Physicians: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection Subcommittee:  
1.1.1P\*, 1.1.2P, 2.1.1P, 2.1.2P, 2.2.1P

North Carolina Cancer Control Program: 1.1.1, 1.1.2

North Carolina Council for Women: 2.1.1

North Carolina Department of Public Instruction: 2.1.1

North Carolina Division of Child Development-Workforce Section: 2.1.1

North Carolina Division of Radiation Protection: 2.1.1

North Carolina Medical Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

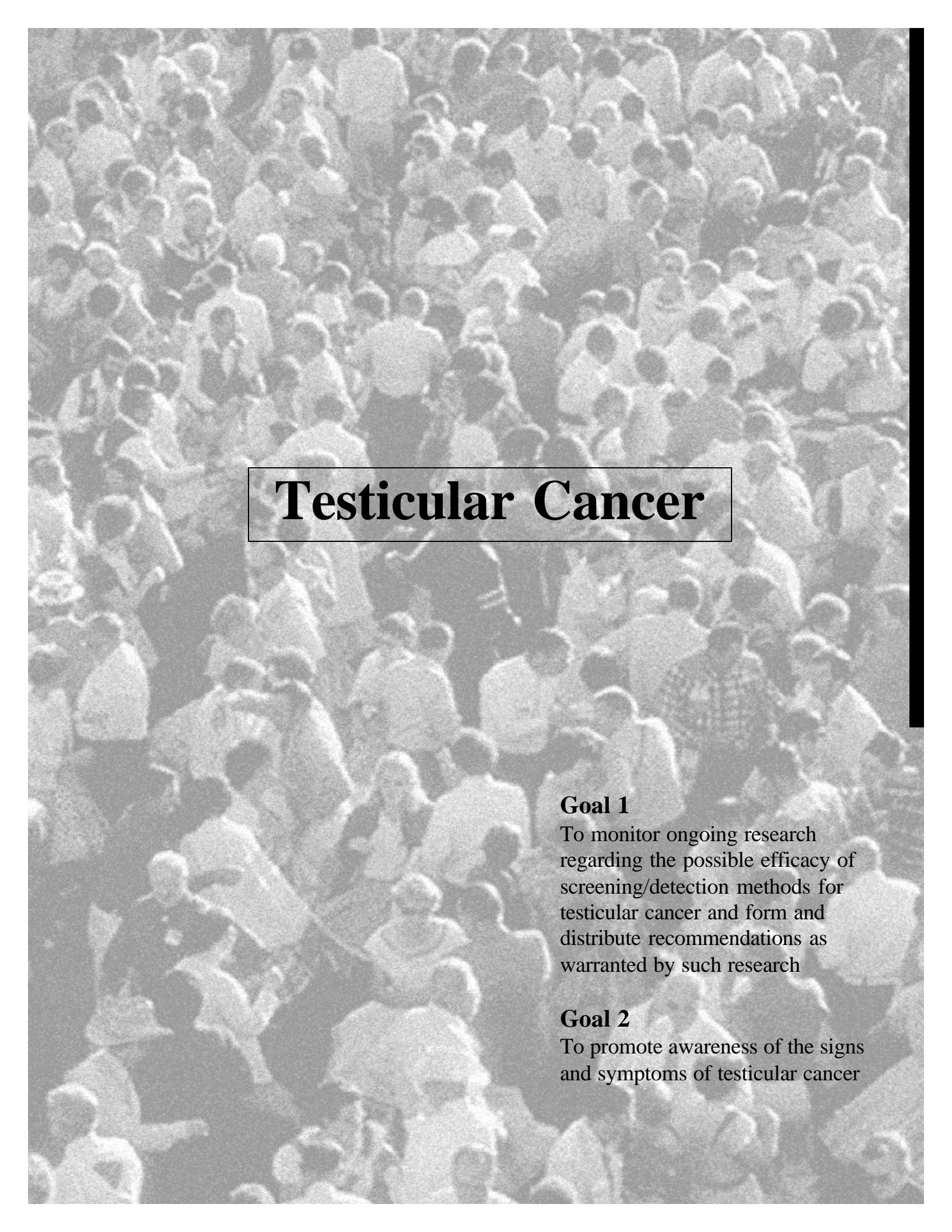
North Carolina Nurses Association: 2.1.1, 2.2.1

North Carolina Recreation and Parks Society, Inc.: 2.1.1, 2.2.1

UNC School of Public Health-Department of Health Behavior and Health Education: 2.1.2

\* P indicates Principal Agency





# **Testicular Cancer**

## **Goal 1**

To monitor ongoing research regarding the possible efficacy of screening/detection methods for testicular cancer and form and distribute recommendations as warranted by such research

## **Goal 2**

To promote awareness of the signs and symptoms of testicular cancer



*Early and accurate diagnosis of testicular cancer is of the utmost importance. Survival, despite improvements in the treatment of advanced disease, is still better for those diagnosed at an early stage.*

Testicular cancer is the most common form of cancer occurring in American men between the ages of 15 and 35. The peak incidence of testicular cancer is between the ages of 25 and 35, at 14/100,000 men.<sup>1</sup> Caucasians are at a higher risk for testicular cancer than other races; the incidence of testicular cancer in African-American men is less than one fifth that of white men.

Overall, testicular cancer is a relatively uncommon malignancy, with an annual incidence in the United States of 4/100,000 men. For the nation, in the year 2000 there will be an estimated 6,900 new cases of testicular cancer, and an estimated 300 deaths.<sup>2</sup> In North Carolina, projections for the year 2000 show an estimated 200 new cases of testicular cancer and an estimated 5 deaths.<sup>1</sup>

Testicular cancer has become one of the most curable solid malignancies. Prior to 1970, testicular cancer was associated with a survival rate of 64%. Currently, the survival rate of those patients diagnosed with testicular cancer, for all stages, is greater than 95%.<sup>4</sup> This dramatic improvement reflects improved diagnostic methods, tumor marker detection, chemotherapeutic regimens, and surgical techniques.<sup>5</sup>

## Screening

Early and accurate diagnosis of testicular cancer is of the utmost importance. Survival, despite improvements in the treatment of advanced disease, is still better for those diagnosed at an early stage.<sup>6</sup> The two principal screening techniques are physician palpation of the testes and self-examination of the testes by the patient. Reinforcing testicular self-exam can be performed by many types of health care professionals (e.g. nurses, nurse practitioners, etc.). Detection of a testicular mass constitutes a positive test.

Data are lacking on the sensitivity, specificity, or positive predictive value of testicular examination in asymptomatic persons, whether performed by

providers or by patients.<sup>7</sup> In addition, no studies have been conducted on whether screening for testicular cancer improves survival.<sup>7</sup> Therefore, the current recommendation of the U.S. Preventive Services Task Force is that there is insufficient evidence to recommend for or against routine screening of asymptomatic men for testicular cancer by physician examination or patient self-examination.<sup>7</sup>

Men with a history of undescended testes or testicular atrophy are at much greater risk for testicular cancer.<sup>7</sup> Data are lacking on whether screening in this population improves outcome.<sup>7</sup> The U.S. Preventive Services Task Force recommends that these high-risk men be informed of their increased risk of testicular cancer and counseled about the options for screening.<sup>7</sup>

There are still improvements that can be made in reducing the mortality of this disease. Unfortunately, delays in the diagnosis of testicular cancer are common and well documented. These delays are both patient- and physician-mediated. Patients with symptoms of testicular cancer, such as testicular swelling or testicular pain, may delay visiting the physician due to ignorance, embarrassment, fear of cancer, or fear of emasculation.<sup>8</sup> Several studies have hypothesized that a delay in presentation to a physician was also related, in part, to a lower socioeconomic status and a lower educational level.<sup>4,8</sup> Physicians' delay in the detection of malignancy most often results from the misdiagnosis of the testicular tumor as an infection, a reaction to trauma, a hydrocele, or a benign tumor.

Given the fact that patients diagnosed with localized disease have a survival rate greater than 98%, versus a survival rate of less than 75% for those diagnosed with distant disease, it is apparent that the delay in diagnosis must be reduced. Several recent studies have demonstrated that young men are generally unaware that they are at risk for testicular cancer. Simple educational material has been shown to be effective in increasing awareness of testicular cancer.<sup>8</sup> As well, physicians need to be reminded that

testicular masses should be viewed as malignant until proven otherwise. With such education of both patient and physician, there is a greater possibility of a cure for testicular cancer.

## **Summary**

The Early Detection Subcommittee plans to monitor research developments related to screening for testicular cancer and will form recommendations as warranted by future evidence. The Subcommittee also places high priority on promoting awareness of the signs and symptoms of testicular cancer. The following objectives and strategies have been selected to accomplish those aims.

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## ***Testicular Cancer Goals, Objectives, and Strategies***

### **Goal 1:**

**To monitor ongoing research regarding the possible efficacy of screening/detection methods for testicular cancer and form and distribute recommendations as warranted by such research. Monitoring of research and formulation of recommendations will focus on general-risk populations and on high-risk populations.**

#### **Objective 1**

To report every six months to the Early Detection Subcommittee on the status of research and screening recommendations for testicular cancer.

#### **Strategies**

1. Gather and review studies on the methods and efficacy of testicular cancer screening.
2. Monitor the position statements of national and state-level organizations.

### **Goal 2:**

**To promote awareness of the signs and symptoms of testicular cancer.**

#### **Objective 1**

To obtain information for developing awareness initiatives.

#### **Strategies**

1. Work with agencies to obtain appropriate awareness and education materials.
2. Work with universities to obtain appropriate awareness and education materials.

#### **Objective 2**

To link with ongoing events to promote awareness of the signs and symptoms of testicular cancer.

#### **Strategies**

1. Distribute awareness and education materials at health fairs and other public events.

### **Goal 3:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

Brody School of Medicine at East Carolina University: 2.1.2

North Carolina Academy of Family Physicians: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Early Detection  
Subcommittee: 1.1.1P\*, 1.1.2P, 2.1.1P, 2.1.2P, 2.2.1P

North Carolina Cancer Control Program: 1.1.2, 2.1.1, 2.2.1

North Carolina Medical Society: 1.1.1, 1.1.2, 2.1.1, 2.2.1

North Carolina Nurses Association: 2.1.1, 2.2.1

North Carolina Office of Minority Health: 2.1.1

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*Each year, over 32,000 North Carolinians are diagnosed with cancer. In 1997, an estimated 127,500 of the State's residents were under medical treatment for the disease.<sup>1</sup> The goal of cancer treatment is to cure the patient or control the progression of the disease while maintaining the highest quality of life possible.*

The National Cancer Institute has articulated the belief that cancer mortality can be significantly reduced through the widespread application of state-of-the-art treatments.<sup>2</sup> New cancer therapies have resulted in improved survival and even cure for many patients over the past several decades. State-of-the-art therapies include advances in bone marrow transplantation, brachytherapy, and cytoreductive techniques, as well as the development of multi-modality strategies, or combinations of surgical, radiation, and drug treatments. With the use of multi-modality strategies, both surgery and radiation therapy have become more directed and less disfiguring.

Other treatment advances include gene manipulation and development of new drugs that are injurious to cancer cells but preserve normal cells. New breakthroughs in gene therapy over the past ten years have led to over 400 approved gene therapy clinical trials in the U.S. Of these, 60% have been focused on cancer treatment. In addition, within the past decade, adjuvant therapy has been shown in clinical trials to substantially enhance survival prospects for children with solid tumors and women with breast cancer. Furthermore, National Cancer Institute studies comparing the mortality of cancer patients enrolled in clinical trial protocols to patients who were not enrolled have shown reduced mortality for clinical trial participants. Clinical trial designs have become more sophisticated so that trials can be stopped earlier and efficacious therapies diffused faster. These advances have contributed to enhanced survival, improved quality of life, increased compliance with prescribed treatments, and decreased morbidity for many cancer patients. The President's Cancer Panel has called for enhanced dissemination and adoption of interventions demonstrated to be efficacious in clinical trials.<sup>3</sup>

Cancer is a complex, chronic disease that often requires intensive use of health-care services and

technologies. Thus, the cancer patient may have multiple needs, including access to practitioners, facilities, and services that provide optimal care during treatment. To reduce the burden of cancer in North Carolina, care must be available, affordable, accessible, and state-of-the art. The mission of the Care Subcommittee is to determine the extent to which cancer patients in the State have access to appropriate care and to identify strategies to improve access to care where improvement is needed. Specifically, the

**Cancer is a complex,  
chronic disease that  
often requires  
intensive use of  
health-care services  
and technologies.**

Care Subcommittee evaluates issues related to the geographic distribution and availability of high-quality services, financial access, quality of care issues such as pain control, palliative care, and survivorship needs. Survivorship encompasses follow-up care, long-term side effects of cancer care such as fatigue and lymphedema, and the psychological and emotional impact of this disease on survivors and their families. The Subcommittee also assesses public and provider awareness of the needs of cancer patients. Finally, the Care Subcommittee monitors emerging research areas that impact cancer care, such as genetics and alternative and complementary medicine. The overall intent of the Subcommittee is to identify and address gaps that exist in the delivery of care and support services.

Evaluation of cancer care issues was greatly aided when, in 1995, the North Carolina General Assembly appropriated funds that expanded the data collection and reporting efforts of the Central Cancer Registry to include first course of treatment. This enhanced data collection has allowed patterns of care at the state level to be systematically studied. For example, preliminary work has shown North Carolina to have one of the lowest rates of lumpectomy with radiation therapy for treatment of early stage breast cancer in the nation. The expanded Central Cancer Registry data will allow this and other practice pattern issues, such as the treatment of colon cancer, to be

identified and compared to the accepted standard of care set forth by the National Cancer Institute. This data will greatly facilitate ascertainment of the extent to which cancer patients are receiving optimal care.

The recent addition of clinical trials data elements to the North Carolina Central Cancer Registry represents another important advancement in North Carolina's monitoring ability. The additional variables indicate whether patients were enrolled in NCI-approved clinical trial protocols. These data elements will allow State researchers and public health officials to determine the extent to which cancer patients are being enrolled in clinical trials, ascertain the characteristics of those patients, and monitor the impact of managed care and other delivery system changes on clinical trials. Currently, the completeness of the data is limited, as some smaller facilities are not aware of their patients' clinical trial involvement.

Since 1996, the Care Subcommittee of the Advisory Committee on Cancer Coordination and Control has taken steps to identify barriers to care through a comprehensive assessment of care issues and has initiated efforts to address these barriers. The Subcommittee has focused on four areas of concern identified in the *North Carolina Cancer Control Plan 1996-2001*.

- Financial Access to Care
- Access to Pain Control
- Education and Awareness of Care
- Geographic Availability of Care

The following is a brief summary of accomplishments over the past five years.

#### **Financial Access Efforts 1996-2001:**

To reduce barriers to care, it is necessary to address financial access to clinical trial protocols, allocation of North Carolina Cancer Control Program resources, and access to health insurance coverage for both patients and survivors for treatment and continuing care.

In 1997, the Subcommittee conducted a review of current health insurance legislation and insurance reform efforts to identify provisions that promote coverage of NCI-approved clinical trials and state-of-the-art therapy. The review revealed that legislative efforts range from a treatment to treatment approach to comprehensive approaches and that, although state efforts have proved to be helpful, it is Federal law,

including amendments to the Employee Retirement Income Security Act (ERISA), that will ensure coverage for clinical trials in all health insurance plans. In 2000, President Clinton announced that Medicare will revise its payment policy to reimburse the routine patient care costs of clinical trials. In addition, the order spearheads an educational campaign aimed at Medicare beneficiaries and providers and directs the U.S. Department of Health and Human Services to track Medicare clinical trials spending. However, this policy change removes only a portion of the barriers to participation. 63 percent of all cancer patients are older than 65, yet this group comprises just 33 percent of enrollees in cancer clinical trials.

In 1997, the Care Subcommittee conducted a study investigating the extent to which cancer patients are denied coverage of NCI-approved clinical trials by public or private insurers.<sup>4</sup> The study found that patients in managed care plans were less likely to be enrolled in clinical trials than patients with fee-for-service coverage, and that patients in managed care plans were no more likely to be enrolled than Medicare, Medicaid, self-pay, or other coverage patients. Patient refusal, a substantial reason for non-enrollment, pointed to the need for continued efforts to educate physicians and the public about the value of clinical trials.

A significant improvement in cancer patients' access to state-of-the-art care was achieved in 1999, when a bill introduced by Senator T.L. Odom became law in North Carolina (G.S. 135-40). The statute requires that the State Employees' and Teachers' Comprehensive Major Medical Plan provide coverage for patient costs incurred as a result of treatment provided in a clinical trial. The statute applies to clinical trials for all cancers and for life-threatening, degenerative or permanently disabling conditions. Despite these improvements in financial access to cancer care in North Carolina, more assistance will be required in the coming years, especially for low-income patients. In addition, all North Carolinians must be made aware of the financial assistance available to them.

#### **Pain Control Efforts 1996-2001:**

Fear of uncontrolled cancer pain is frequently cited as a barrier to the early diagnosis and treatment of cancer. Diagnosed cancer patients often are unaware that control of cancer pain is not only possible, but the right of every cancer patient. Health care providers

are frequently unaware of the most effective pain management techniques, and too often are unaware of the extent of their patients' pain. To promote awareness among patients, family members, and health-care professionals of effective management strategies for cancer pain, the Care Subcommittee supported the activities of the North Carolina Cancer Pain Initiative.

These efforts included:

- Production and distribution of over 3000 copies of a video on successful pain management, entitled "Living without Cancer Pain: A North Carolina Success Story"
- Review of the North Carolina statutes, rules and regulations by the Practice Board Review Committee, which found no significant statutory or regulatory barriers to pain management
- Coordination of focus groups to identify barriers to pain management for persons living with cancer pain
- Implementation of a survey of pain management barriers in home health and hospice groups
- Creation and production of an Annual Cancer Pain Control Awareness Week campaign with information kits containing posters, newspaper articles, public service announcements, videos, and brochures. The kits were distributed to hospitals, hospices, home health and CAP agencies and nursing homes.
- Receipt of 501(3)(C) status for the Cancer Pain Initiative
- Formation of the Pain Consultation Service
- Distribution of more than 6000 copies of the Agency for Health Care Policy and Research practice guidelines to hospitals, pharmacies, home health providers, hospices, private practice offices, radiation therapy facilities, and American Cancer Society offices throughout the state.

#### **Education and Awareness Efforts 1996-2001:**

In 1998, the Care Subcommittee conducted a needs assessment of health-care practitioners to assess awareness of telephone information services, clinical trials, support programs and transportation services. Based on the findings, recommendations were made to: publicize the 1-800-4-CANCER number; consider the Internet for clinical trial education; use personal testimony of a patient who had a successful experience with clinical trials, combined with statistics and information concerning the advances in medical

knowledge produced by clinical research; and appeal to altruism by emphasizing that patients will help themselves and others by participating in a clinical trial.

Focus groups were conducted with patients to determine their information needs and the results showed that patients move through stages in their readiness to process information and that it would be beneficial for providers and patients to take these stages into consideration when educating their patients.

In 1999, Dr. Roger Anderson of Wake Forest University conducted a survey to determine interests by primary care physicians in Continuing Medical Education on cancer topics. Findings indicated that there is a high demand for general topics such as cancer screening, updates on diagnostic skills, and high risk detection. Specific topics for which there was a high level of interest included patient and family support, pain management, treatment options, and genetic susceptibility.

In 1996 the Cancer Information Service had an "abandonment" rate of 30%, which was a barrier for North Carolinians seeking information from the 1-800-4-CANCER number. Since that time, upgrades provided to the Cancer Information Service in both telecommunications and computing equipment have enabled a reduction in the busy signal and an elimination of the abandonment rates, which currently is 0%. The service can now accommodate substantial promotion of the 1-800-4-CANCER number in North Carolina.

Since clinical trials are considered the primary means of identifying the most effective cancer treatments for the future, there is great interest in bringing about the positive community perspective on cancer clinical trials that is thought to be instrumental for increasing enrollment into trials. In 1999 and 2000, the Advisory Committee on Cancer Coordination Control, the National Cancer Institute, and the Cancer Information Service jointly conducted a statewide educational campaign focusing on the value of clinical trials in cancer prevention, early detection, and treatment. The goal of the educational workshops was to increase community awareness and knowledge of cancer clinical trials. Using materials provided by the National Cancer Institute, eleven train-the-trainer sessions have been conducted. The sessions were targeted toward community members who had organizational ties or who were visible in their respective communities. Nurses and local health

educators were also encouraged to attend. The workshops provided participants with a basic understanding of clinical trials and included information on how the trials are conducted, myths about clinical trials, the cancer research process, and “real life” challenges associated with clinical trials. The workshop also explored ideas about how to participate in clinical trials outreach and advocacy in local communities.

### **Geographic Availability and Access Efforts 1996-2001:**

In 1999, the Care Subcommittee partnered with East Carolina University to coordinate cancer services in the eastern part of North Carolina. The goal of the effort is to establish networks or linkages among rural providers and urban cancer centers so that optimal care is more accessible to rural cancer patients. The Eastern Carolina Cancer Coalition was formed to carry out this important initiative.

In 2000, the Care Subcommittee collected data from the statewide Care-Line directory of health-care services and the American Cancer Society to ascertain the geographic distribution of transportation services for North Carolinians with medical care needs. These services are provided by both public and private sources. A noteworthy improvement in availability of medical transportation services is the expansion of the American Cancer Society’s Road to Recovery program from 13 units in 1996 to 52 county-based units currently.

### **Summary**

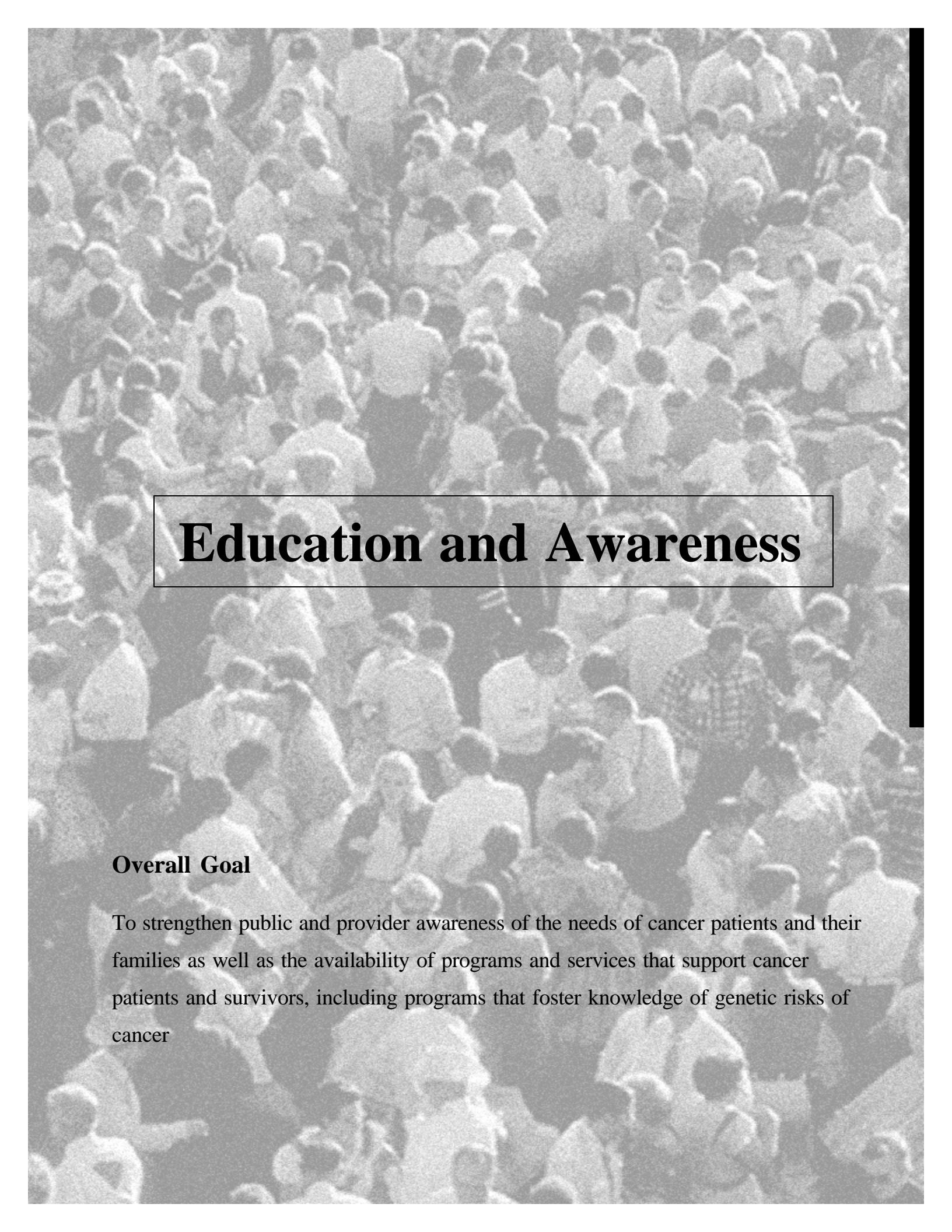
The Care initiatives implemented to fulfill the objectives and strategies specified in the *North Carolina Cancer Control Plan 1996-2001* centered on issues of financial access, access to pain control, geographic availability, and education and awareness. In addition to a continued focus in these four areas, this second edition of the *North Carolina Cancer Control Plan* adds genetics, alternative and complementary medicine, lymphedema, and survivorship as priorities for the Care Subcommittee’s efforts. Identifying and alleviating racial, ethnic and socioeconomic disparities in access to and quality of care is an important focus of the new Plan. The objectives and strategies outlined in the sections that follow have been formulated to address the current barriers to cancer care in the state, so that all North

Carolinians diagnosed with cancer have access to, and are aware of, treatment and support services.

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# **Education and Awareness**

## **Overall Goal**

To strengthen public and provider awareness of the needs of cancer patients and their families as well as the availability of programs and services that support cancer patients and survivors, including programs that foster knowledge of genetic risks of cancer



*Fifty years ago, only 20 percent of cancer patients lived five years after diagnosis. As of 1996, 60 percent survive their disease for five years or longer, according to the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) data. Thus, issues pertaining to cancer patient quality of life, rehabilitation, and preservation of function have become increasingly important to lessen the impact of this disease and save lives in North Carolina.*

Counseling, support groups, and techniques for symptom management all may influence the quality of life of the cancer survivor. Advances in the management of the disease have led to more favorable attitudes toward cancer and less fear of treatment for the disease among the public. Since the early 1970's, the National Cancer Institute has disseminated cancer information to the public and health-care providers through its Office of Cancer Communications. Based on the success of such programs as the Cancer Information Service, the Physician Data Query Database, and the Special Populations Networks to support outreach to the underserved, the National Cancer Institute has concluded that the public as well as health-care providers are accepting of this information. The American Cancer Society and community-based cancer programs also have been instrumental in increasing public and provider awareness of the disease. In evaluating public acceptance of the Cancer Information Service, the National Cancer Institute has documented an increased volume of calls as well as increasingly sophisticated questions, suggesting that the public has become more informed about cancer.<sup>1</sup> The National Cancer Institute has pointed to this growing acceptance and use of cancer information as indicative of a heightened "cancer consciousness" among the U.S. public.

The President's Cancer Panel has stated the high priority of enhancing education and awareness in the national cancer agenda. In its 1999 report, *The National Cancer Program: Assessing the Past, Charting the Future*,<sup>2</sup> the Panel outlined three key recommendations. The Panel is conducting a series of regional meetings to learn from communities about the cancer care delivery challenges they face and how

they are being addressed. The recommendations are:

(1) "Actions must be taken to remove barriers that prevent the benefits of research and quality cancer care from reaching all populations. Specifically:

- It is the responsibility of legislators and policymakers to enact laws and policies needed to ensure access to quality cancer care for all, including evidence-based interventions across the spectrum of cancer prevention and care, and participation in quality clinical trials.
- Mechanisms are needed to ensure that public and private health care payers have access to, understand, and accept sound scientific evidence concerning the benefit of cancer care interventions of all types, such that these services are incorporated into the standard of care for all.
- Both the public and health professionals must become more aware of the cancer problem and what we currently know about prevention and all aspects of care. This should be accomplished through culturally appropriate public education targeting children and adults, enhanced medical school curricula, and continuing medical education.

(2) Public pressure must be brought to bear in recruiting to the national cancer effort sectors that have not perceived themselves to have a role in the cancer problem; these sectors include agriculture, the media, the food industry, other industry, and trade; and

(3) The current and future cancer workforce—researchers and care givers of all types—requires greater training and expertise in prevention, rehabilitation, cancer control, communications, the use of new technologies, end of life care, and other areas.”

While North Carolina possesses elements of a sound infrastructure for disseminating cancer information, there is room for improvement. Certainly, efforts to raise public awareness must take into account the State’s changing demographics, including growing populations of Asian and Hispanic North Carolinians as well as a sizable segment of the population that is functionally illiterate. In 1999, the Care Subcommittee conducted a needs assessment of health-care practitioners to assess awareness of telephone information services, clinical trials, support programs and transportation services. The findings included recommendations to: publicize the 1-800-4-CANCER number; consider use of the Internet for clinical trials education; use personal testimony of a patient who had a successful experience with clinical trials combined with statistics and information concerning the advances in medical knowledge produced by clinical research; and appeal to altruism by emphasizing that patients will assist themselves and others by participating in a clinical trial.

Also in 1999, the Care Subcommittee conducted a series of focus groups with patients to determine their information needs. The results showed that patients move through stages in their readiness to process information and that it would be beneficial for providers and patients to take these stages into consideration when educating their patients. There were also special recommendations to aid in educating newly diagnosed patients.<sup>3</sup> The Care Subcommittee is investigating the feasibility of providing information cards listing toll-free cancer information telephone numbers and a summary of state health insurance protection mechanisms for consumers. The Subcommittee is also exploring the use of Internet home pages to provide a summary of current cancer control programs, services, and activities in the state.

In 1996, the Cancer Information Service had an “abandonment rate” of 30%, which was a barrier for North Carolinians seeking information from the 1-800-

4-CANCER number. Since that time, upgrades provided to the Cancer Information Service in both telecommunications and computing equipment have enabled a reduction in the busy signal and an elimination of the abandonment rate, which currently is 0%. The service can now accommodate substantial promotion of the 1-800-4-CANCER toll-free number in North Carolina. The Care Subcommittee is exploring the feasibility of a small study to track the resolution of financial assistance calls to both the Cancer Information Service and the American Cancer Society.

Since clinical trials are considered the primary means of identifying the most effective cancer treatments for the future, there is great interest in bringing about the positive community perspective on cancer clinical trials that is thought to be instrumental for increasing enrollment into trials.<sup>4</sup> In 1999 and 2000, the Advisory Committee on Cancer Coordination Control, the National Cancer Institute, and the Cancer Information Service jointly conducted a statewide educational campaign focusing on the value of clinical trials in cancer prevention, early detection, and treatment. The goal of the educational workshops was to increase community awareness and knowledge of cancer clinical trials. Using materials provided by the National Cancer Institute, eleven train-the-trainer sessions have been conducted. The sessions were targeted toward community members who had organizational ties or who were visible in their respective communities. Nurses and local health educators were also encouraged to attend. The workshops provided participants with a basic understanding of clinical trials and included information on how the trials are conducted, myths about clinical trials, the cancer research process, and “real life” challenges associated with clinical trials. The workshop also explored ideas about how to participate in clinical trials outreach and advocacy in local communities.

#### **Survey to Assess Demand for Continuing Education Programs on Cancer-Related Topics Among Primary Care Physicians**

Health-care practitioners, especially those in rural and underserved areas, need to be apprised of

current cancer therapies and resources, including information on where and how to obtain these resources for their patients. A survey completed in 1999 by Roger Anderson of Wake Forest University indicated that although there is less than 20% interest in continuing medical education for any one topic, there is a high demand for general topics such as cancer screening, updates on diagnostic skills, and high risk detection. Specific topics for which there was a high level of interest included patient and family support, pain management, treatment options, and genetic susceptibility.<sup>5</sup> Area Health Education Centers will be a part of a workgroup to provide these continuing education sessions. Following is a detailed description of the methods and findings of the study.

### Executive Summary

In May, 1999, The North Carolina Advisory Committee on Cancer Coordination and Control contracted with the Department of Public Health Sciences, Wake Forest University School of Medicine to conduct a survey of primary care physicians in North Carolina. The purpose was to assess physicians' perceived need for cancer care and treatment continuing medical education (CME) (Objective 3, Strategy 1 of the *North Carolina Cancer Control Plan 1996-2001*-Education and Awareness).

**Methods.** A 66-item needs assessment survey was developed by Drs. Anderson and Michielutte, researchers at the Wake Forest University School of Medicine. The survey measured interest in screening, diagnosis, treatment, follow-up care, and preferred method for receiving CME of cancer related topics.

From a list of primary care physicians shown on the North Carolina Physician Roster, grouped according to urban vs. non-urban area (using NC Data Center designations of metropolitan place names), a sample of 300 physicians per urban/non-urban grouping was selected. Each sample was mailed a questionnaire with a postage-paid return mailer. Follow-up of non-responders was conducted. From a sample of 539 physician a total of 231 surveys (43%) were completed and returned.

**Results.** The mean number of years in practice was 16.6 ( $\pm 16$ ) and mean age was 48.2 years ( $\pm 11$ ). Approximately 48 percent of respondents classified

themselves as family medicine, 27 percent as internal medicine, 20 percent as OB/GYN, and 4.5 percent as "other." A substantial proportion of practitioners, nearly 37 percent, had not attended any cancer-related CME sessions in the past two years, and only 22 percent had attended only one session. A total of 73.6% of the respondents had attended on average 1 or fewer cancer-related CME sessions per year.

Interest in participating in cancer-related CME topics was generally high, with 58 percent being 'very interested' in cancer screening topics, 53 percent 'very interested' in techniques to identify high risk prevention, approximately 33 percent 'very interested' in follow-up care (specifically side-effects from treatment), and 47 percent 'very interested' in a general update of diagnostic skills.

Item content with the highest interest or demand for Continuing Medical Education within major topic areas include:

Screening- general screening, breast, skin, cervical, ovarian and prostate.

Diagnosis- update of diagnostic techniques

Prevention - identify high risk groups, general topics, smoking cessation

Treatment - palliative care, pain management, general patient care/management

Follow-up - side effects, lymphedema, long-term follow-up.

Continuing Medical Education topics for which there was generally *low* enthusiasm, within major topic areas included:

Screening - flexible sigmoidoscopy, biopsy (punch, excise skin lesions, endometrial), colposcopy

Diagnosis - staging, study protocols, multidisciplinary teams

Follow-up care- therapist availability

There were few differences in CME interest and demand by practice location (urban/non-urban). Some differences in CME interest were noted by medical specialty type, however (*Table 13*). Family medicine

physicians had a statistically higher level of interest in screening, treatment and follow-up care than did OB/GYN practitioners and other specialists.

The preferred method of accessing a cancer-related CME was by in-person lecture (63 percent) rather than a video-conference format (6 percent), which was clearly not favored. Traditional Area Health Education Center (AHEC) lectures and presentation format was the most favored mode (37 percent). However, 23 percent reported a 'very favorable' attitude toward accessing a CME session over the Internet.

### **Conclusions:**

A significant proportion of primary care physicians reported not attending a cancer-related CME in the past 2 years. More than 50 percent had attended only 1 session in the past 2 years. Despite this general under-access of cancer-related CME information, there is a high level of demand for general CME topics related to cancer, with approximately 50 percent of respondents reporting being 'very interested'. One conclusion to draw from these results is that reasons for not attending a past cancer-related CME likely involve availability and convenience rather than perceived need or importance of the content area.

There was generally low CME interest for education on procedures such as biopsy, sigmoidoscopy, and staging, possibly because many primary care physicians do not perform these. An in-person lecture is the most preferred means to conduct a CME despite new, and perhaps lower cost alternatives (e.g., video-conferencing). However, nearly one-quarter of respondents viewed the Internet as a favorable mode to deliver cancer care education. Interest in CME topics varied somewhat by practice type. Most notably, follow-up care and prevention topics were in highest demand by family medicine.

Results of this survey are being used to develop a CME strategy, with a goal to develop an AHEC program for cancer-related topics. The breadth and scope depends largely on available resources to conduct the sessions, including a lecturer and funds for materials and advertising. A partnership with state-wide AHEC would bring experience with state-wide CME dissemination, administrative assistance in the preparation and distribution of brochures, processing charges and payments, and conducting a program evaluation. A working group has been convened to develop a CME strategy. Other strategies to explore

include Internet assisted-learning programs as an alternative offering wide access. However, issues of accrediting such a program must be resolved.

### **Summary**

Resources and support services for people diagnosed with cancer are strong and are growing in number. Increasingly, the needs of persons who have or have had cancer and the uniqueness of those needs at different stages of survivorship are being recognized and reflected in cancer support programs. It is vital that North Carolinians—patients, providers, and the public—be aware of this wealth of resources, which exist both within North Carolina and at the national level. Progress made in enhancing the awareness among any of these three communities is likely to have a beneficial effect on awareness among the others. The Care Subcommittee has identified the following objectives and strategies as approaches that will positively impact awareness of cancer resources and support services in North Carolina over the next five years.

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## The Role of Genetics in Cancer Care

*Many recent advances in cancer treatment can be attributed to both an improved knowledge of cancer pathogenesis and to technical breakthroughs in scientific disciplines that have recently become more closely integrated with cancer treatment.*

There have been major advances in the care of patients with cancer over the past two decades. Radiology can target tumors with focused beams that cause less damage to nearby healthy tissues, while increasing the treatment dose delivered directly to tumors that might have been inoperable in the past, including a subset of brain tumors. The newest hormone therapies available for prostate cancer promise improved efficacy and reduced side effects. Regardless of the modality, many recent advances in cancer treatment can be attributed to both an improved knowledge of cancer pathogenesis and to technical breakthroughs in scientific disciplines that have recently become more closely integrated with cancer treatment.

### **Historical connections between genetics and cancer care**

For decades, there have been evolving connections between genetics and cancer care. Geneticists and oncologists have worked together to provide preventative cancer care by identifying individuals at increased risk for malignancy. Cancer risk can be determined based on the diagnosis of an inherited medical condition or syndrome, such as the increased risk of leukemia in people who have Down syndrome.<sup>1</sup> More commonly, elevated cancer risk is based on the diagnosis of similar cancers in several family members. For example, the lifetime risk of prostate cancer for individuals who have two immediate family members affected with prostate cancer is increased five times above the general population.<sup>2</sup> The union of genetics, oncology, and epidemiology has been invaluable in advancing our ability to predict hereditary cancer risk. The recognition that some individuals are predisposed to

cancer offers opportunities to better understand the basic etiology of malignancy.

### **Developing connections between genetics and cancer care**

Within the past ten years, the role of genetics in cancer care and treatment has expanded beyond the recognition of individuals whose clinical diagnosis or family history identifies them as being at increased risk for malignancy. The new opportunities for geneticists to become involved in cancer care are largely due to a series of breakthroughs by molecular biologists. The discovery of genes that predispose to cancer, such as the breast cancer genes titled BRCA1 and BRCA2, is forging increasing ties between geneticists and oncologists. For patients who are at an increased risk of breast cancer based on their family history, BRCA gene testing provides additional cancer risk information that is specific to the patient. The results of BRCA gene testing allow more informed decision-making regarding cancer screening and treatment because a patient can know her own risk of developing breast cancer. For example, some patients may base their decision to pursue prophylactic mastectomy on the results of BRCA gene testing. Women who have inherited the common 185delAG mutation in the BRCA1 gene have almost a 90% lifetime risk to develop breast cancer, a significant increase when compared to the 11% risk among the general population.

### **The promise of gene therapy**

Despite the recent gene discoveries outlined above, and the development of clinical testing for cancer predisposition genes, genetics has remained an

adjunct contributor rather than a primary approach to clinical care and treatment of cancer patients. However, the role of genetics in the fight against cancer is poised to take on new roles in cancer care. With gene therapy, we are beginning to explore a new generation of cancer treatments. In ten years, there have been over 400 approved gene therapy clinical trials in the United States, involving more than 4000 participants.<sup>3</sup> These trials have sought new treatment alternatives for a variety of diseases. Of these trials, more than 60% have focused on cancer treatment. Gene therapy clinical trials have been conducted or are underway for cancers of the bladder, breast, colon, ovary, prostate, renal cell, glioblastoma multiforme, Hodgkin's and non-Hodgkin's lymphoma, melanoma, mesothelioma, neuroblastoma, non-small cell lung cancer, squamous cell carcinoma of the head and neck, acute myelogenous leukemia, and chronic myelogenous leukemia.<sup>3</sup>

### A sample of the current approaches to gene therapy

Tumor suppressor gene therapy is one type of gene therapy, which targets the uncontrolled cell growth that underlies some types of cancer.<sup>4</sup> An example of a tumor suppressor is the p53 gene. When p53 is active and working properly, it can prevent cancer by regulating normal cell growth. If a cell begins uncontrolled growth, p53 can also fight the progression of cancer by initiating the self-destruction (apoptosis) of such a cell. A malfunctioning p53 gene can allow unchecked cellular growth, resulting in cancer. Tumor suppressor gene therapy seeks to correct the uncontrolled growth of cancerous cells by adding new p53 genes to a cell to replace the function of faulty tumor suppressor genes.

Attempts to boost the body's immune response to tumors dates back nearly 100 years,<sup>5</sup> and now molecular biology offers selective harnessing of the immune system. With immunogene therapy, the body's infection fighting systems are directed to seek and destroy cancer cells.<sup>6</sup> For example, these therapies may introduce either cytokine genes or antigen genes to supplement the immune recognition and response of subtle cellular differences in cancer cells.<sup>7</sup> Active cytokine genes produce proteins called cytokines (such as interleukin-2), which stimulate the proliferation,

development, and activity of specific cells (such as T cells) that are critical in mounting a cancer sensitive immune response.<sup>8</sup> The targeted introduction of antigen genes into cancer cells aims to stimulate the production of antibodies which "flag" these cells as different, thus focusing the immune system on recognition of the cancer cells.<sup>6</sup> Study of immunogene therapy has not been limited to its use for the treatment of active malignancy; in a laboratory setting, cancer vaccines have been effective in preventing cancer in mouse models of aggressive cancer.<sup>4</sup>

An approach called Gene Directed Enzyme Prodrug Therapy (GDEPT), or "suicide gene therapy," sensitizes cancer cells to specific prodrugs. With this strategy, a specific suicide gene is selectively transferred into cancer cells. This is followed by administration of an inactive prodrug. Within the cancer cells, the activity of the suicide gene works to convert the prodrug into a drug that poisons the cell. There has been a great deal of research into the utility of suicide gene therapy for brain tumors, and recent gene discoveries may allow refined suicide gene approaches in the treatment of prostate cancer.<sup>7,9</sup>

### We have only reached the cusp of what is possible in cancer treatment.

### Summary and Future Directions

Despite the innovative techniques and remarkable progress that has been made in gene therapy research, we have only reached the cusp of what is possible in cancer treatment. Since the first attempt at gene therapy in 1990, there has been a recurrent pattern of encouraging laboratory results, followed ultimately by disappointing clinical trials. For the most part, gene therapy has been limited by the inability to introduce genes into the targeted cancer cells in such a way as to produce a measurable therapeutic response in the patient.<sup>10,11</sup> It appears that current efforts are focused on overcoming the technical barriers that have become apparent only after the initial generation of research.<sup>11,12</sup>

There are recent reports of two gene therapy trials that produced measurable clinical benefit in patients. The first study showed improvement in patients with hemophilia B, and the other demonstrated phenotype reversal in patients with X linked severe combined immune deficiency.<sup>13,14</sup> Although these trials were not directed at cancer treatment, gene therapy for cancer may benefit from these successes.

With modest sequential refinements in the current technology, the next decade of research should be an exciting time for gene therapy, and the role of genetics in cancer care can only be expected to grow in this environment.<sup>12</sup>

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## Alternative and Complementary Medicine

*A national telephone survey conducted in 1990 indicated that 34% of Americans made a total of 425 million visits to alternative medicine practitioners in 1990, surpassing the total number of visits to primary care physicians (388 million)<sup>1</sup>.*

Alternative and complementary medical approaches may be used for a variety of purposes: to heal and to prevent illness; to improve quality of life; or to maintain well-being. The field of alternative medicine has achieved tremendous growth and acceptance in recent years. A national telephone survey conducted in 1990 indicated that 34% of Americans made a total of 425 million visits to alternative medicine practitioners in 1990, surpassing the total number of visits to primary care physicians (388 million)<sup>1</sup>. Recent surveys have estimated that the percentage of cancer patients who use one or more complementary or alternative treatments as part of their treatment ranges from 37-69%.<sup>2,3</sup> The expansiveness of the subject is evident in the number of consumer publications currently being issued in this area. Following is a brief review of concepts and definitions from this field. This overview relies heavily on reviews by Cassileth (1999)<sup>4</sup> and Cassileth and Chapman (1984).<sup>5</sup>

“Alternative medicine” is an umbrella phrase used to describe a large collection of remedies or practices whose efficacy has not been demonstrated by scientific research. If their efficacy were supported by scientific research, these approaches would cease to be “alternative” and would become part of mainstream medicine.

It is important to distinguish “alternative medicine” from “complementary medicine,” with which it is often associated. “Alternative medicine” refers to products or therapeutic regimens used instead of mainstream cancer care. By contrast, “complementary medicine” refers to additional care, such as meditation or therapeutic massage, which may be thought of as supportive care that can be used in addition to mainstream care. “Integrative medicine” refers to care that combines elements of conventional and complementary medicine. Integrative medicine programs have been established at approximately twenty medical centers in the U.S. The National

Institute for Complementary and Alternative Medicine (formerly, Office of Alternative Medicine) is providing support to Integrative Medicine programs to teach physicians about complementary approaches.<sup>6</sup>

The field of alternative medicine is changing rapidly. From the 1940s through 1960s, pharmaceutical-like therapies were used widely. The most popular alternative therapies during this era included krebiozin, Koch’s glyoxylide (distilled water), Hoxsey’s plant tonics, and Laetrile (amygdalin). Today, popular interest in “natural” remedies has led to interest in a fundamentally different type of alternative medicine. The National Institute for Complementary and Alternative Medicine groups alternative medicine into seven categories (1) diet and nutrition; (2) mind-body techniques; (3) bioelectromagnetics; (4) alternative systems of medical practice (traditional remedies); (5) pharmacological and biological treatments; (6) manual healing methods; and (7) herbal medicine. Examples of these are given below.

### Diet and Nutrition

Dietary regimens are often key components of many alternative treatments. One of the most popular diet therapies in recent years is macrobiotics, which initially gained prominence in the 1960s. The macrobiotic diet excludes meat and promotes the consumption of soybeans. The diet derives 50-60% of its total calories from whole grains, 23-30% from vegetables, and the remainder from seaweed, beans, and soups. The macrobiotic diet is known to be deficient in B vitamins. It has not been demonstrated to be of use as an anti-cancer regimen.

### Mind-Body Techniques

A principal belief of many alternative therapies is that the mind has the ability to heal the body.

Meditation, biofeedback and yoga are examples of techniques that have entered mainstream medicine because of their demonstrated efficacy in stress reduction and in the control of some physiological reactions. The mind-body approach to cancer gained considerable attention with the publication of findings in 1989 suggesting that women with breast cancer who attended a weekly support group survived longer than women who did not.<sup>7</sup> Although few can doubt the many benefits of a positive attitude in general, the finding that this can have a beneficial effect on cancer survival has not been replicated by other studies.

### Bioelectromagnetics

It has been asserted that magnetic and electric fields play a role in curing disease. The 18<sup>th</sup> century Austrian physician, Anton Mesmer, who coined the term “animal magnetism,” and who was a forerunner of the field of hypnotism, is probably the most well-known proponent of this claim. In the present day, Wolfgang Ludwig in Germany and others contend that magnetic field energy can have a therapeutic effect on the growth of tumors. There is little published evidence to support this claim. Magnets have also been touted as therapy for a variety of musculoskeletal ailments. It should be noted that the claims regarding bioelectromagnetics are therapeutic; this field is not synonymous with the activities of researchers, primarily epidemiologists, who claim that magnetic fields (e.g., those surrounding electrical power lines) may cause cancer.

### Traditional and Folk Remedies

This group of therapies encompasses ancient systems of medicine from around the world. For example, Ayur Veda is a traditional healing system from India that is currently popular in the United States. This category also includes traditional Chinese medicine and its techniques (e.g., acupuncture, acupressure, qigong). Traditional Chinese medicine includes its own pharmacopoeia with specific cancer remedies.

### Pharmacologic and Biological Treatments

There are numerous alternative pharmacological therapies available. These include shark cartilage, immuno-augmentative therapy (IAT), and anti-idea

neoplastons. In 1992, William Lane popularized the idea that consumption of shark cartilage would protect against cancer. It has been asserted that shark cartilage works by inhibiting the formation of new blood vessels (angiogenesis), a mainstream medical concept, though it has not been scientifically demonstrated to do so. Human research on shark cartilage has stalled considerably, possibly because many of these products have been found to be contaminated. IAT is an alternative therapy based on the notion that cancer therapies should balance protein components in the blood. Scientific support for IAT is lacking. Antineoplastons are peptides purportedly identified from human urine and believed to have an anti-cancer effect. Although an example of success with antineoplaston therapy has been published in the mainstream literature,<sup>8</sup> it has not been replicated,<sup>9</sup> and the very existence of antineoplastons has been questioned.

### Manual Healing

Manual healing techniques are a heterogeneous group of procedures. They are united by the belief that each person has an energy field surrounding her/his own body. The therapies are presumed to work by strengthening and balancing this bio-field. One of the most popular of these theories is called therapeutic touch. Practitioners of therapeutic touch do not actually touch patients. Rather, they move their hands several inches over a patient’s body in order to remove “congestion” in the body’s electrical field.<sup>10</sup>

### Herbal Medicine

The field of herbal medicine is large, encompassing the pharmacopoeias of Chinese and other traditional medicines, as well as other practices. Essiac is a popular herbal medicine. It is a component of four herbs: burdock, Turkey rhubarb, sorrel, and slippery elm. Essiac has been shown not to have anti-cancer properties, and it is illegal to distribute essiac in the U.S., although it is available in Canada. Other popular herbal remedies for cancer include iscador, derived from the mistletoe tree. A potential problem with many herbal medicines is the presumption that because these drugs are natural, they are harmless. This is a dangerous misconception, as many “natural” products can have dangerous side effects.

## Perspectives of Persons Living with Cancer

It is important to recognize the widespread support for alternative and complementary approaches among people living with cancer. According to some people with cancer, the advantages of alternative approaches over traditional medicine include their broad emphasis on treating the entire person, goals centered on optimizing wellness and quality of life, and a philosophy oriented toward supporting the body rather than acting on or against it (personal communication, Anne Mader, Director, Cornucopia House, December 2000).

People with cancer also point to the trust, openness, and time for discussion that often characterize their relationships with practitioners of alternative medicine. Data from focus groups conducted in 1998 showed that some patients feel there is a gap in information from health care providers concerning alternative and complementary medicine. Patients noted a lack of knowledge among their health care providers about approaches such as hypnosis and acupuncture for pain control. Also cited was a reluctance on the part of health care providers to consider alternative and complementary options. Some focus group participants stated that, in the absence of information from providers, people with cancer often obtain information and assistance from other patients.<sup>11</sup>

## Summary

Alternative and complementary treatments have a long history of popularity among consumers. Despite the lack of controlled research on most of these “natural” modalities, many do have physiological effects, and they are being used by millions of Americans. Thus, both their potential for clinical effectiveness and their potential for adverse effects must continually be kept in mind by both patients and physicians. Individuals should inform their medical practitioners of any alternative regimens they may be following.

It is likely that new therapies in this area will continue to emerge. There will be an ongoing need for clinical trials to learn more about the potential efficacy of alternative and complementary approaches. Research on how these approaches are being used by consumers will also remain a high priority.

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## ***Education and Awareness Goals, Objectives, and Strategies***

### **Goal 1:**

**To strengthen public and provider awareness of the needs of cancer patients and their families as well as the availability of programs and services that support cancer patients and survivors, including programs that foster knowledge of genetic risks of cancer.**

#### **Target by 2006:**

North Carolinians will be aware of cancer information services, support programs, and care options. North Carolinians will also be aware of emerging cancer care options, including the risks and benefits of the use of alternative and complementary medicine.

**Data Sources:** Data will be collected on the use of available resources including clinical trials and support services. Data will reflect demographic information to determine whether efforts to increase awareness of available programs and services are reaching a diverse population including Hispanics, Asians and the functionally illiterate segment of North Carolina.

**Impact by 2006:** Awareness of the needs of cancer patients and of the availability of programs and services that support cancer patients and survivors will increase. The data collected above will be used to formulate specific targets.

#### **On the following pages,**

**\*\*indicates Objectives and Strategies that are focused on racial, socioeconomic, educational, or age-related disparities.**

### **Objective 1**

To increase the access and awareness of North Carolinians with cancer to quality cancer information services, including the Cancer Information Service (CIS), American Cancer Society (ACS), Physician Data Query (PDQ), and information services provided by North Carolina's comprehensive cancer centers.

#### **Strategies**

1. Determine a baseline in the number of telephone contacts to the Cancer Information Service (CIS) in 2000 and track the percentage increases in contacts in each of the next five years, adjusting for changes in state population growth, with a goal of increasing contacts by 10% by 2006. Population growth data will be obtained from the State Data Center.
2. Develop an education program for health care providers to include materials provided by the Cancer Information Service (CIS) and the American Cancer Society (ACS), and an information card that provides phone numbers, web sites and locations to access the Internet (libraries, cooperative extension centers, malls).

3. Assist the Cancer Information Service (CIS) and the American Cancer Society (ACS) with promotion of their 1-800-4-CANCER and 1-800-ACS-2345 telephone numbers by convening two working days annually to distribute posters, pamphlets, brochures and public service announcements (PSAs).

## **Objective 2**

To increase the use of the Internet to obtain information about cancer.

### **Strategies**

1. Develop the web page for the North Carolina Advisory Committee on Cancer Coordination and Control and the links to additional cancer information sites.
2. Conduct usability study for the web page and use findings to enhance the page's design.
3. Collect baseline data on the number of hits to the North Carolina Advisory Committee on Cancer Coordination and Control web page and hits to the existing links on the page.
4. Incorporate the web sites into existing media campaigns.
5. Partner with the National Black Leadership Initiative on Cancer (NBLIC), the Hispanic Initiative on Cancer (Redes N Action), and the Cancer Information Service (CIS) to publicize ways to access computers and the Internet.

## **Objective 3**

To educate the public and health care providers about the communication needs of cancer patients, families, and care givers at each stage of the disease process.

### **Strategies**

1. Develop a pamphlet and public service announcement (PSA) on the changing communication needs of cancer patients and their families and care givers.
2. Develop a workshop for health care professionals on the changing communication needs of cancer patients and their families and care givers. Offer two workshops each year to a variety of health care professionals, including physicians, nurses, chaplains, and social workers.
3. Offer educational workshops through existing support groups for people living with cancer and their families.

## **Objective 4**

To encourage the distribution of cancer information to patients, providers, and the public, with an emphasis on distributing the information to racial and ethnic groups more adversely affected by cancer, low literacy populations, and rural residents. The information will include availability of transportation services.\*\*

### **Strategies**

1. Utilize existing materials and develop informational cards, public service announcements (PSAs) and other promotional materials in Spanish.\*\*

2. Distribute information cards to agencies and organizations currently reaching the underserved, including community and migrant health centers, cooperative extension centers, and community-based organizations.\*\*

## **Objective 5**

To promote and provide targeted continuing education programs on cancer-related topics. Special emphasis will be placed on practitioners in rural and underserved areas.\*\*

### **Strategies**

1. Promote use of the Internet for health care practitioners and utilization of the NCI's 1-800-4-CANCER toll-free number and the American Cancer Society's 1-800-ACS-2345 toll-free number, with an emphasis on counties that do not have a teaching hospital.\*\*
2. Collect information on existing cancer-related Continuing Medical Education (CME) web-based trainings.
3. Distribute information on all existing web-based trainings related to cancer.
4. Develop web-based Continuing Medical Education courses (CMEs) based on the needs identified in the North Carolina Advisory Committee on Cancer Coordination and Control pilot CME survey study.
5. Collaborate with university-based medical schools and Area Health Education Centers (AHEC) to develop workshops and a speakers bureau for health care professionals on cancer related topics.

## **Objective 6**

To increase public and provider awareness of financial resources available in North Carolina.

### **Strategies**

1. Collect data on the existing financial resources that are available.
2. Develop informational resources related to financial resources and distribute to providers.

## **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See Coordination)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

American Cancer Society: 1.1P\*, 1.2P, 2.4P, 5.1P

Cancer Information Service: 1.1P, 1.2P, 1.3P, 2.4P, 2.6P, 3.2P, 4.1P, 4.2P, 5.1P

Colon Cancer Alliance: 3.2

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 2.1P, 2.2P, 2.3P, 2.5P, 2.6P, 3.1P, 3.2P, 3.3P, 4.2P, 5.2P, 5.3P, 5.4P, 5.5P, 6.1P, 6.2P

North Carolina Cancer Control Program: 6.1P, 6.2P

North Carolina Medical Society: 1.2, 5.1

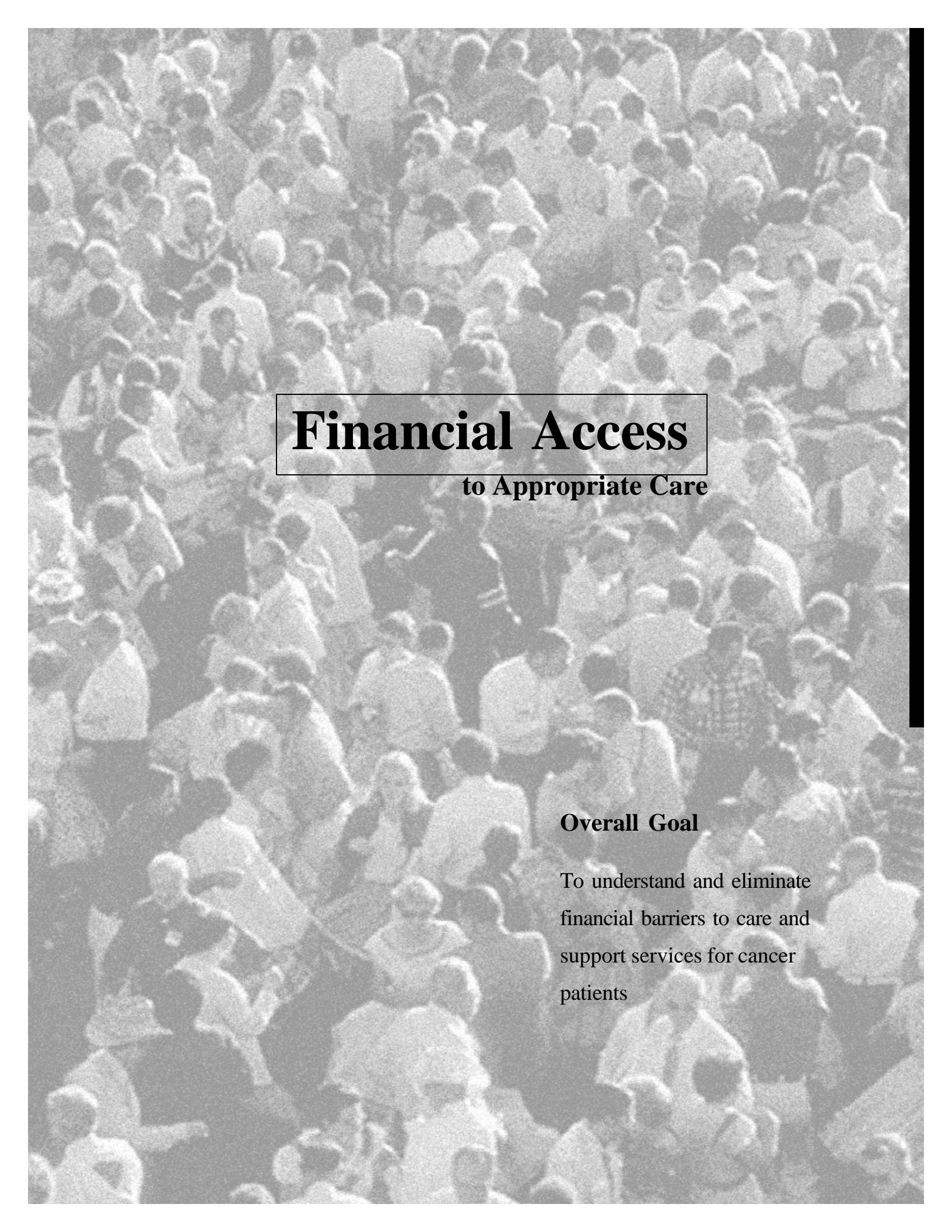
North Carolina Office of Minority Health: 4.2

North Carolina Office of Public Health Nursing: 5.2

North Carolina Primary Health Care Association: 5.1

UNC School of Public Health-Department of Health Behavior and Health Education: 1.2

\* P indicates Principal Agency



# **Financial Access**

**to Appropriate Care**

## **Overall Goal**

To understand and eliminate financial barriers to care and support services for cancer patients



*Each year, the estimated costs of cancer total \$107 billion nationally, with \$37 billion in direct medical costs, \$11 billion attributable to lost productivity of those unable to work because of their illness, and the remainder resulting from the lost productivity of those who die from the disease.<sup>1</sup> In North Carolina, it has been estimated that the cost of cancer is approximately \$2.9 billion per year: \$1.0 billion for medical care, \$362 million in lost productivity from those who become ill, and \$1.64 billion for future productivity losses from those who will die prematurely.<sup>2</sup>*

Cancer patients in North Carolina may be covered for health-care services under an individual health insurance plan, group health insurance plan (typically obtained through an employer), public program such as Medicaid, Medicare, or the State Cancer Control Program, or be uninsured. The coverage may be under a traditional indemnity plan (fee-for-service, or FFS), preferred provider organization (PPO), or more tightly controlled provider network such as a health maintenance organization (HMO). An estimated 64 percent of Americans under 65 years of age who have health insurance receive their coverage through their employer.<sup>3</sup> In North Carolina, employer-based health insurance can be grouped into three categories: 1) small-group policies (i.e., self-employed individuals or businesses with 49 or fewer employees); 2) large-group policies (i.e., businesses with 50 or more employees), and 3) Employee Retirement Income Security Act (ERISA) or self-funded plans.<sup>4</sup> Employers in the state are not required to offer health insurance as a benefit.

### **Employer-Based Health Insurance**

In the early 1990s, the North Carolina General Assembly began crafting laws that would aid small businesses in providing health insurance coverage to their employees. Insurance companies marketing policies to small businesses in the state are now required to offer a choice of at least two plans: small group “basic” and small group “standard.” They also are no longer allowed to exclude individuals deemed to be “high risk” from these two types of group policies or to refuse to offer a policy at all to a small business employing one or more high-risk individuals. Although an insurer may impose a waiting period before covering an employee’s pre-existing condition, this restriction cannot be reimposed if the employee moves to another group plan (i.e., portability of coverage). These reforms came about because of the discovery that nearly half

of all uninsured working adults in the state were employed by small businesses. In general, the cost of health insurance policies to small businesses can be prohibitively expensive, often 10 to 40 percent higher than the cost of a comparable policy written for a large employer. Small businesses are permitted to form alliances for purposes of purchasing health insurance at more favorable rates. The first such alliance became operational in mid-1995, and others are being planned. If a small business offers health insurance to its employees, it is required to offer the benefit to all permanent, full-time (i.e., 30 hours per week or more) workers.<sup>4</sup>

Large-group provisions are similar to those of small groups. If a large employer decides to offer health insurance as a benefit, it must offer the benefit to all permanent, full-time (i.e., 30 hours per week or more) employees. Insurers are prohibited from practicing medical underwriting: in other words, excluding an employee from coverage or charging the employee a higher premium because of current, past, or perceived health status. Insurers are allowed to deny reimbursement of treatment for a pre-existing condition for up to 12 months after the policy goes into effect. Unlike small-group plans, however, insurers are not required to meet “guaranteed issue” provisions in large-group plans;<sup>4</sup> “guaranteed renewal” provisions for all group products were mandated in legislation passed at the close of the 1995 session of the General Assembly.<sup>5</sup>

ERISA provisions prevent states from regulating employer-sponsored health plans. In an ERISA plan, the employer assumes responsibility for reimbursing the health-care bills of its employees. When the North Carolina General Assembly mandates coverage of particular services (e.g., mammograms), ERISA plans are excluded. ERISA plans may impose pre-existing condition waiting periods of any length; they may exclude coverage of particular conditions; they may set premiums at any level. The State cannot regulate

the extent of the cost-sharing burden an ERISA employer imposes on its employees. The only recourse for an individual who has been denied reimbursement or coverage under an ERISA plan is to file suit in federal court.<sup>4</sup>

## **Individual Health Insurance**

Individual health insurance plans are purchased by the individual or family and not through a group arrangement such as an employer. Individual plans may be more costly and offer less coverage than group plans. In North Carolina, insurers offering individual plans are permitted to practice medical underwriting, in which applicants are screened for their medical history and an individual with an unfavorable medical history may be refused a policy. Insurers are also allowed to issue an individual policy that covers everything except treatment of a specific condition such as cancer.<sup>4</sup> Legislation passed by the North Carolina General Assembly limits pre-existing condition exclusion periods to 12 months; previously, under an individual plan, insurers could refuse to reimburse treatment relating to a pre-existing condition for up to two years.<sup>5</sup>

## **Health Insurance and the Cancer Patient**

The State provides health insurance protection mechanisms for consumers. Several might be particularly beneficial to cancer patients: 1) the North Carolina Department of Insurance will investigate insurers that either fail to pay a claim or fail to pay in a timely manner; 2) insurers must allow a grace period for late payment of premiums; 3) insurers must give advance notification of policy termination (equal to one-fourth the number of months of continuous coverage); and 4) insurers must reimburse for the services of licensed non-physician health-care providers such as optometrists, podiatrists, dentists, chiropractors, psychologists, clinical social workers, and advanced practice nurses.

In addition, the State requires insurers that cover the cost of a drug used in treating one type of cancer to cover the cost of this drug in treating another type of cancer, provided that the drug has been approved by the federal Food and Drug Administration and

deemed efficacious in treating the other type of cancer by the American Medical Association Drug Evaluations, American Hospital Formulary Service Drug Information, or U.S. Pharmacopoeia Drug Information.<sup>4</sup>

Furthermore, North Carolina continues efforts to reduce the number of uninsured in the State.<sup>7</sup> The Insurance Reform Advisory Committee of the North Carolina Health Planning Commission proposed legislative changes to improve portability of coverage, decrease the duration of pre-existing condition exclusions, and mandate guaranteed issue and guaranteed renewal for all group plans, some of which

were passed into law by the North Carolina General Assembly in the 1990s.<sup>5,6</sup> In addition, the Children's Health Insurance Program (CHIP) was instituted in North Carolina in 1998. The program provides comprehensive health insurance coverage to uninsured low-income children who are residents of the state.

Nevertheless, cancer patients may experience considerable difficulty in obtaining or maintaining their health insurance coverage. Insurance policies may contain pre-existing condition clauses that preclude coverage of medical care relating to the residual effects of the cancer or its treatment.

When allowed, the practice of experience-rating may influence insurers to "screen out" or charge higher premiums to applicants with a history of cancer.<sup>8</sup> National efforts, such as the Health Insurance Portability and Accountability Act of 1996, have attempted to limit the loss of coverage due to pre-existing conditions or diagnoses due to health problems, such as cancer.<sup>9</sup> However, cancer survivors seeking new or continuing individual policies may be offered coverage at rates so high as to be unaffordable. One study conducted in North Carolina showed childhood cancer survivors to be 29 times more likely to be denied health insurance coverage than their siblings without cancer.<sup>10</sup>

Insurance reforms enacted by the North Carolina General Assembly have improved access to types of services health insurance for cancer survivors and other individuals with chronic diseases to some extent. Although North Carolina has not followed the example of 26 other states in establishing a state-operated risk pool for the purpose of providing health insurance

coverage to the medically uninsurable (ie., individuals who do not have health insurance coverage because of their medical histories),<sup>10</sup> the Blue Cross and Blue Shield Access Program is a private, voluntary effort serving the same purpose. Lack of portability across individual, group, ERISA, and public plans, which potentially exposed the cancer patient or survivor to lengthy pre-existing condition exclusion periods, was ameliorated through House Bill 230, Sec. 23A.1 (b), (c), (d), (e), (f), and (g).<sup>5</sup>

Despite these efforts, however, cancer patients in the state may encounter significant financial barriers to care, especially if they are unemployed, regularly work less than 30 hours per week, or have health insurance coverage with large deductibles, large co-payments, or treatment as well long-term benefit limits. The economic losses faced by cancer patients and their families are believed to be considerable, including diminished earnings, reduced life savings, and altered life goals, all of which are the result of patient and family efforts to finance the costs of cancer care.<sup>11</sup> Hewitt and Breen found that, in the longer term, cancer diagnosis and survivorship may impact future health and life insurance coverage or employment.<sup>12</sup> The rapid movement of many corporations and state governments toward managed care has raised questions about cancer patients' access to high-quality care.<sup>13</sup>

### **The Challenges of Managed Care and the Uninsured**

Managed care is an accelerating trend in health care delivery in the United States and North Carolina. In 1991, 47 percent of individuals who received their health insurance coverage through an employer were covered by managed care. By 1994, this figure had increased to 65 percent.<sup>14</sup> Although managed care market penetration in North Carolina lags the average for the nation managed care continues to establish a growing presence in the State, with an overall managed care penetration rate in NC of approximately 17.5% in 2000, compared with an estimated national rate of 65-70%.<sup>15-17</sup> The typical managed care plan places boundaries on how and from whom the patient may receive health services, as well as the types of services that may be provided in a given situation.<sup>18</sup> Medical

care is provided through a defined network of physicians and hospitals.<sup>19</sup> Patients attempting to obtain care outside of this defined network may be faced with substantial financial barriers.

At the same time that the proportion of the population enrolled in managed care has increased, the number and percentage of Americans and North Carolinians who lack any health insurance coverage also have risen steadily.<sup>20</sup> Despite well-publicized attempts by the Clinton administration and Congress to provide insurance coverage for more Americans, 1998 Census figures estimated 15% ( $\pm .6\%$ ) of North Carolinians (or more than 1.125 million residents) were without any insurance coverage.<sup>21</sup> These figures do not include the underinsured, those lacking enough insurance coverage to meet basic health care needs.

### **The uninsured cancer patient is more likely to experience delays in diagnosis and treatment as well as fragmented care.**

Minorities comprise a disproportionate and increasing share of the uninsured, the majority of whom are employed and poor.<sup>22</sup> The uninsured cancer patient is more likely to experience delays in diagnosis and treatment as well as fragmented care. Survival has been demonstrated to be worse for poor and uninsured cancer patients than for privately insured cancer patients.<sup>23</sup> The uninsured cancer patient also places an uncompensated care burden on health-care facilities. The typical high-cost uninsured patient has either heart disease or cancer, conditions that require sophisticated care over a long period of time, and presents at cancer diagnosis with more advanced disease.<sup>24,25</sup>

### **Government Programs**

Elderly, lower income, and disabled North Carolinians are covered under the Medicare and Medicaid programs. It is important to recognize, though, that Medicare does not provide full health-care coverage. In fact, Medicare has been estimated to cover less than 50 percent of a beneficiary's health-care costs, requiring many beneficiaries to seek supplemental coverage through Medicaid or "Medigap" policies.<sup>4</sup> Many cancer patients, however, neither have health insurance nor qualify for financial assistance under the Medicare and Medicaid programs. A national survey showed less than half of individuals living at or below the federal poverty level to be covered by Medicaid.<sup>26</sup>

Current Medicaid eligibility for disabled individuals who are not covered by Supplemental Security Income in North Carolina stands at 40 percent of the federal poverty level; for the Supplemental Security Income-covered disabled individual, current Medicaid eligibility approaches 70 percent of the federal poverty level. Major changes in the Medicare and Medicaid programs presently are being debated by the United States Congress. If enacted, their impact on access to care for cancer patients in the state will need to be monitored carefully. Increased enrollment of Medicare and Medicaid beneficiaries in managed care plans is a widely-anticipated change.

Recognizing the needs of indigent citizens diagnosed with or suspected to have cancer, North Carolina, in 1945, established the Cancer Control Program, which can provide coverage for up to 8 days of diagnostic services and 30 days of treatment services during each fiscal year. Approximately \$3 million is allocated to the Program each year to cover hospital, professional, and clinic fees.

To be eligible for the Cancer Control Program, one must be a North Carolina resident or migrant farmworker, have a gross family income at or below 115% of the federal poverty level and have been determined by a physician to have a 25 percent or better chance of five-year survival at the time of treatment. The income cut-off increased from 100% to 200% of poverty in 1995 but then dropped to the current 115% level in 1997 after a budget shortfall. A major concern is that these eligibility requirements limit access for many cancer patients. First, the Program does not cover palliative care, drugs for the patient's use outside of the treatment facility nor reimbursement for patient mileage to cancer centers. Second, the low financial criteria, which considers gross income during the twelve months prior to the treatment request and without any allowed deductions, essentially excludes previously working families for whom a diagnosis of cancer can mean loss of income and insurance coverage during the treatment phase. For some, it means that they delay or forgo treatment services. Ultimately, the state, in one form or another, bears this burden.

Third, a patient's physician must refer to the Program and work with the local health department to complete the required paperwork. The process

coupled with the low Medicaid reimbursement rate can be a deterrent for some physicians. Because patients must be referred to the program by their physicians, it is important that physicians throughout the State be apprised of current Cancer Control Program eligibility criteria.<sup>27</sup> Providers and communities throughout the state should be continuously informed about how to access coverage for eligible indigent patients with cancer.

For FY 2000, 460 providers delivered Cancer Control Program-sponsored diagnostic services to 1,507 North Carolina residents — 93% of whom were female, 66% were white, 44 % were age 21-34, 73%

had no third party coverage, and 54% had income below 85% of the federal poverty level — at an average cost of \$572.75.

**Recognizing the  
needs of indigent  
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Program.**

For FY 2000, 299 providers delivered CCP-sponsored treatment services to 549 North Carolina residents — 88% of whom were female; 42 % were age 21-34 (8%, <=20; 13%, 35-44; 16%, 45-54; 15%, 55-64; 6%, >65); 66% were white (29%, black, 5%, American Indian/Hispanic/Other); 66% had no third party coverage and 52% had income below 85% of the federal poverty level — at an average cost of \$2,062.51.

The breakdown by primary diagnoses were as follows: 78%-breast and cervical, 3%-colon, 1%-lung, 2%-prostate, 2%-skin and 14%-other.

\*These numbers are unduplicated counts for providers and residents. The Program serves the "poor" who have little or no resources for diagnostic and treatment services. Even though the Program income is set at 115% of poverty (\$19,608 for a family of 4), more than half of those are below 85% of the federal poverty level.

### **Access to Clinical Trials**

Clinical research in cancer involves testing protocols that compare the best available standard of care against new therapy in a clinical trial. Clinical trials are considered state-of-the-art care by the National Cancer Institute and clinical oncologists of all specialties. Tremendous advances in treating many cancers have resulted from this process. There is considerable concern, however, that inadequate support for clinical trials will impede progress in

treating cancer.<sup>28</sup> A critical issue involves refusal of insurance companies to reimburse cancer care that is based on clinical trial protocols. Peters and Rogers demonstrated the arbitrariness of decisions made by insurance companies in determining whether to cover women with advanced-stage breast cancer who were enrolled in clinical trials of bone marrow transplantation.<sup>29</sup> Bried and Sheffler reported that elderly cancer patients may have limited access to therapies because of coverage limits, particularly if the therapy is deemed "experimental."<sup>30</sup> Reluctance of insurers to reimburse care rendered as part of a chemoprevention trial for cancer survivors or individuals at high risk of developing cancer has been cited as a barrier to trial participation.<sup>28</sup> In addition, there is growing concern about the role of managed care in cancer treatment.

In managed care arrangements, care is financed on a capitation basis with a strong emphasis on keeping costs down; because of their complexity and resource intensity, clinical trials may be viewed by managed care firms as too expensive and therefore are not offered to patients as a treatment option.<sup>31</sup> A 1998 study by the Care Subcommittee found that patients covered by managed care were half as likely to be enrolled on clinical protocols as those with traditional fee-for-service coverage.<sup>32</sup> The National Cancer Institute notes that increased willingness on the part of third party payers to reimburse experimental therapies is essential to support clinical trials, which are widely believed to be the most effective means of assessing the effectiveness of new treatments.<sup>8</sup>

Several states, notably Maryland and Rhode Island, have been successful in granting wider coverage for cancer clinical trials. The Care Subcommittee has worked to ensure coverage for clinical trials for state employees covered by state plans. Despite these efforts, insurance coverage continues to be a problem. A 1999 report by the U.S. General Accounting Office found that most health insurers continued to exclude coverage for all clinical trials, although insurers claimed that case-by-case coverage was possible. Surveys of the GAO of 11 NCI-designated Cancer Centers found varied levels of success in working with insurers, with all experiencing at least some difficulties, including greater time spent with insurance issues. Anecdotal evidence suggested benefit in demonstrating

cost parity for those enrolled on clinical trials.<sup>33</sup> A study underway by the RAND Corporation in conjunction with NCI-funded cooperative groups (Cancer and Leukemia Group B, National Surgical Adjuvant Breast and Bowel Project, the Radiation Therapy Oncology Group, Gynecologic Oncology Group, the Southwest Oncology Group, the North Central Cancer Treatment Group, and the Eastern Cooperative Oncology Group) aims to compare treatment costs of patients enrolled on clinical trials compared to those receiving standard therapies.

### **In 1998, the Clinton administration announced new initiatives focused on eliminating health status and treatment disparities due to race and ethnicity.**

## **Health Care Disparities**

Recently, broader issues of health care disparities have been recognized. In 1998, the Clinton administration announced new initiatives focused on eliminating health status and treatment disparities due to race and ethnicity. In 1999, Surgeon General Dr. David Satcher announced Centers for Disease Control (CDC) coalitions in 18 states to work on issues related to health disparities. Government efforts culminated in the establishment of a Coordinating Center for Research on Health Disparities to target improvement in minority health. This Center will also work on a strategic plan for addressing issues related to health care disparities. Health care disparities related to race, ethnicity, sex, age, geographic area (e.g., region or inner city vs. rural), or socioeconomic status relate to all areas of the Cancer Control Plan. In the financial access arena, the Care Subcommittee will focus on the relationship of disparities to insurance coverage and access to cancer care and supportive services (cancer patients); and that between disparities and uncompensated care or undercompensated care (providers).

## **Other Issues**

Finally, financial worries are experienced by many cancer patients, even those covered by private or public insurance. In two studies in Pennsylvania, insurance and unmet financial needs ranked among the most significant concerns of cancer patients and their caregivers.<sup>34,35</sup> Cancer patients may experience difficulty in paying for expensive medication, equipment, and supplies not covered by third party

payers.<sup>36</sup> In addition, some physicians may be less likely to direct patients towards more expensive therapies if they are un- or underinsured. Unmet costs of cancer treatment affects both patients and providers. Studies by the Care Subcommittee and reports by physicians have indicated significant unmet costs, both in the gap between billed and reimbursed services, and that of provided compared to billed services. These studies have pointed out the great difficulty in assessing actual unmet costs.

## **Summary**

A substantial proportion of persons diagnosed with cancer face financial circumstances that limit or obstruct completely their ability to receive cancer care. Government programs and legislative mandates have been established to address some of the barriers to financial access to care, but great need remains. Causes of the problem are complex, and a full understanding of the factors involved is essential in order to effect an improvement. The Care Subcommittee has set forth the following objectives and strategies as the critical next steps in beginning to ensure financial access to care for all North Carolinians who are diagnosed with cancer.

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## ***Financial Access Goals, Objectives, and Strategies***

### **Goal 1:**

**To understand and eliminate financial barriers to care and support for cancer patients.**

#### **Target by 2006:**

Whether through private insurance, Medicare and Medicaid, or the Cancer Control Program, North Carolinians with cancer will have adequate financial access to care and support services.

**Data Sources:** Data from ongoing financial access studies and quantitative data on expenditures and the numbers served by the North Carolina Cancer Control Program will help determine the extent to which North Carolinians have adequate financial access to care and support services.

**Impact by 2006:** The proportion of North Carolinians who have adequate financial access to care and support services will increase. The data collected above will be used to formulate specific targets.

**On the following pages,**

**\*\*indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

### **Objective 1**

To minimize or eliminate financial barriers to appropriate clinical trial protocols as an essential means of advancing state-of-the-art therapy.\*\*

#### **Strategies**

1. Measure the number and percentage of insurance plans covering clinical trials, the extent of coverage for clinical trials vs. standard therapy, and the number of North Carolinians whose plans would cover clinical trials.\*\*

### **Objective 2**

To expand the availability and optimize the use of North Carolina Cancer Control Program resources.\*\*

#### **Strategies**

1. Measure the percentage change in awareness of and expanded support for the North Carolina Cancer Control Program among providers and patients, as evidenced by the change/increase in numbers of patients served as a result of an increase in the budget for the North Carolina Cancer Control Program or more inclusive standards for access to the program.\*\*

### **Objective 3**

To quantify and reduce the number of patients who have unmet financial needs (e.g. patient charges for medical, palliative, and supportive care not reimbursed by third party payers).\*\*

#### **Strategies**

1. Measure and quantify unmet needs, change in unmet needs (\$, %, or number of people with unmet needs), number of cancer patients and survivors with insurance/third party coverage, number or percentage of services/needs covered, number of patients/survivors with available health care coverage.\*\*
2. Monitor legislative developments regarding the Breast and Cervical Treatment Act which, if passed in North Carolina, will provide Medicaid funds for treatment of women who are screened and diagnosed through the North Carolina Comprehensive Breast and Cervical Cancer Control Program.

### **Objective 4**

To quantify the amount of uncompensated care provided by institutions and physicians and analyze the possible reasons for why this care is uncompensated.

#### **Strategies**

1. Quantify uncompensated care, change in uncompensated care (in terms of dollar amounts, percentages, or number of claims), number of institutions changing provided services or accepted patients due to uncompensated care.

### **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective followed by Strategy). All strategies are Goal 1.

Brody School of Medicine at East Carolina University: 1.1

Cancer Information Service: 1.1

Duke University Medical Center: 1.1

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 3.1P\*, 4.1P

North Carolina Cancer Control Program: 2.1P

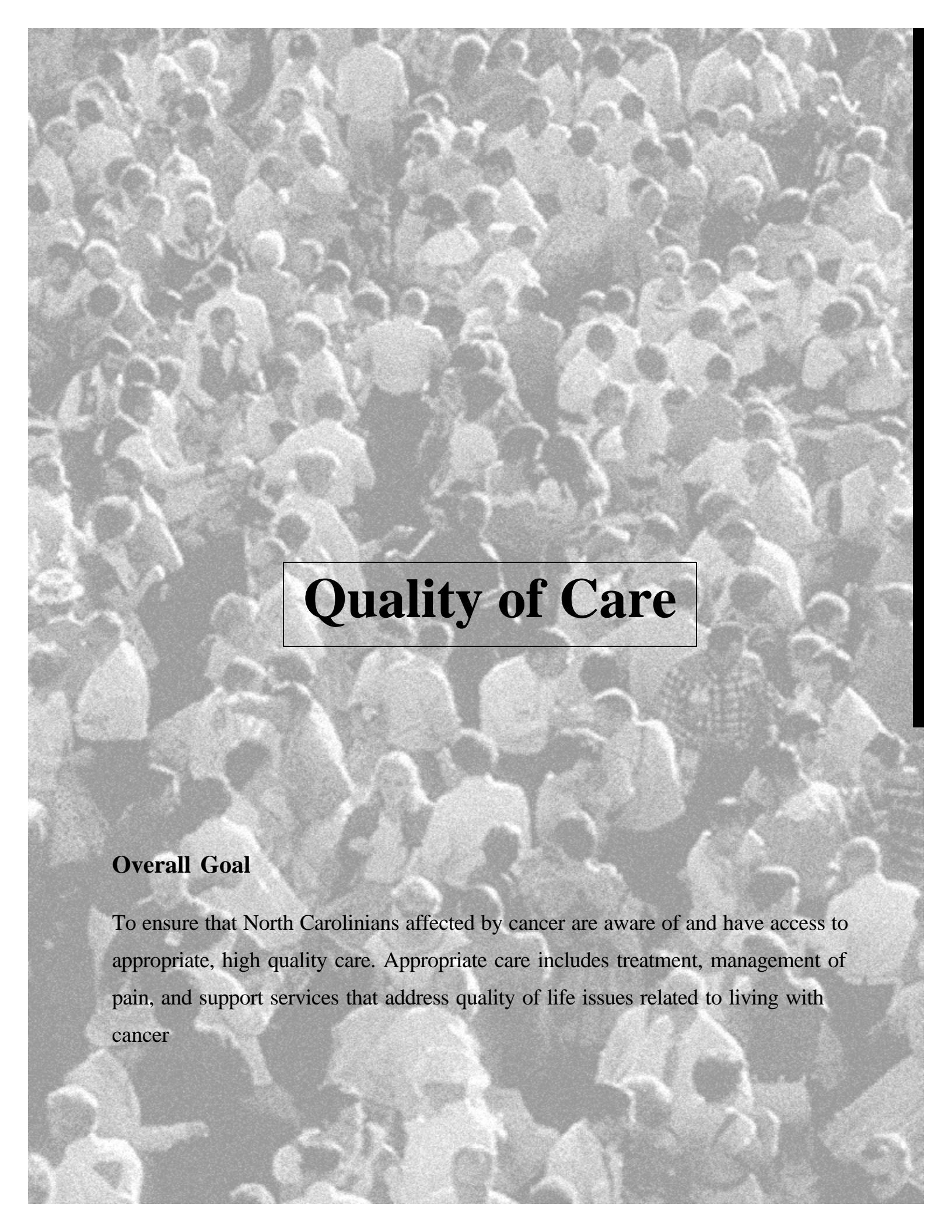
UNC School of Medicine: 1.1

UNC School of Public Health: 3.1

Wake Forest University School of Medicine: 1.1P

\* P indicates Principal Agency





# **Quality of Care**

## **Overall Goal**

To ensure that North Carolinians affected by cancer are aware of and have access to appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer



## **Appropriateness of Care**

*During the past five years, several national studies have established guidelines for state-of-the-art surgical<sup>1-2</sup> and medical care<sup>3-6</sup> for women with breast cancer and cervical cancer,<sup>7-8</sup> and for all people with colorectal cancer<sup>9-12</sup> or early stage lung cancer.<sup>13-14</sup>*

We now know that lumpectomy and radiotherapy offers benefit equivalent to mastectomy for primary treatment of many women with stage 1 or stage 2 breast cancer. There are also established guidelines for postoperative adjuvant chemotherapy or anti-estrogen hormonal therapy for many women with newly diagnosed breast cancer. Several studies have shown the benefit of adding chemotherapy to well-established radiotherapy protocols for women with cervical cancer.

Many patients with colorectal cancer are also candidates for postoperative radiotherapy or adjuvant chemotherapy, which has been found to decrease the chance of recurrent disease by 25%. For lung cancer patients, higher survival is observed for patients receiving cancer-directed treatment than those who are untreated.<sup>15</sup> Several studies have demonstrated that survival can be increased for patients with non-small cell lung cancer, which represent 75-80% of the lung cancer cases in the U.S.<sup>16</sup> In addition to being a growing focus for research, ensuring quality cancer care is featured in a 1999 report by the Institute of Medicine.<sup>17</sup>

### **Breast Cancer**

A recent national study examined the care of 144,759 women who underwent surgery for early-stage breast cancer.<sup>18</sup> The authors noted that breast-conserving surgery is being used more frequently in clinical practice. The authors also noted that breast-conserving surgery is a more complex treatment than mastectomy, by virtue of the separate incision required for axillary lymph-node dissection and the necessity for postoperative radiotherapy. The authors

hypothesized that this greater complexity would lead to decreased conformity with the recommended care. Results confirmed the hypothesis. The proportion of women receiving appropriate primary therapy (mastectomy or breast conserving surgery plus radiation) fell from 88% in 1983-89 to 78% by the end of 1995; the proportion of women receiving an inappropriate form of mastectomy remained stable, but the proportion of women receiving an inappropriate form of breast-conserving surgery (omission of radiotherapy, axillary node dissection, or both) increased from 10% in 1989 to 19% in 1995.

**Despite the higher survival that has been documented for patients receiving cancer-directed treatment for lung cancer compared with those who are untreated, a sizable and increasing proportion of patients in the U.S. receive no treatment.**

### **Cervical Cancer**

Due to the widespread use of the Pap smear as a screening tool in the United States, more patients are being diagnosed at earlier clinical stages of disease, resulting in an increased rate of survival. Despite this success, variations in treatment patterns do exist and have been indicated in several national studies. To date, there is no published research on whether the patterns of care seen for cervical cancer nationally also exist in North Carolina.

Standard treatments of cervical cancer include surgery, radiotherapy, chemotherapy, or some combination of the three depending on cancer stage, size, and co-morbidities. Younger women are significantly more likely than older women to be treated with surgery rather than with radiotherapy.<sup>19</sup> Among all women undergoing surgical treatment, the type of hysterectomy performed is appropriate in 80-96% of cases.<sup>20</sup> There is also a significant survival advantage among women with smaller cancers who undergo surgical treatment versus radiotherapy,

regardless of age. However, no survival advantage between the two treatment groups exists in women with larger cancer.<sup>19</sup> The combination of radiotherapy and chemotherapy in women not undergoing hysterectomies appears to be an increasingly acceptable form of treatment, increasing from about 7% in 1984 to 25% in 1990.<sup>21</sup> Although controversial, this adjuvant therapy has been reported to decrease the risk of death by 30-50%.<sup>22</sup>

Gynecologic oncologists now perform the majority of hysterectomies for cervical cancer, with general gynecologists playing a lesser role. In addition, these hysterectomies are rarely performed in the community hospital setting. One study reports that patients undergoing radiotherapy in a community hospital setting consistently receive lower doses of radiation than those treated at academic centers.<sup>23</sup>

Documented racial differences in patterns of admission and resource utilization for diagnostic and surgical therapeutic procedures have also been noted for cervical cancer. A recent report indicates that older, minority women are less likely than white women to have hysterectomies and more likely to be treated with less definitive procedures.<sup>24</sup>

## Colorectal Cancer

Variations in treatment patterns for colorectal cancer have been documented. Adjuvant therapy is less likely to be provided to rural residents in North and South Carolina.<sup>25</sup> Surveillance and monitoring for colorectal cancer patients after surgery varies by specialty of physician.<sup>26</sup> Variations in colorectal cancer outcomes have also been documented. Improved survival has been observed among surgeons with more experience and training.<sup>27-29</sup> The extent to which variations in treatment, and ultimately outcome, are influenced by patient characteristics (such as socio-economic status or acceptance of selected therapies) or medical system characteristics (such as provider skill and training) is unknown. Better knowledge about the patterns of care for colorectal cancer patients in North Carolina will allow us to identify appropriate strategies to improve care.

## Lung Cancer

Despite the higher survival that has been documented for patients receiving cancer-directed treatment for lung cancer compared with those who

are untreated, a sizable and increasing proportion (14% to 19% from 1985 to 1995) of patients in the U.S. receive no treatment.<sup>15</sup> Undertreatment, or suboptimal treatment of non-small cell lung cancer has been estimated to range from 34% among Stage 1 patients to 73% among Stage IV patients.<sup>16</sup> Whether a patient receives treatment for non-small cell lung cancer is associated with non-clinical demographic factors.<sup>30</sup> The percent of patients receiving no treatment increases with increasing age and decreases with higher incomes. Racial disparity in treatment has also been observed, with lowest non-treatment rates among non-hispanic whites compared to other races<sup>30</sup> and lower surgical rates among African Americans compared to whites.<sup>31</sup> In addition, a study in South Carolina found survival to be associated with specialty of surgeon, with thoracic surgeons achieving better outcomes than general surgeons.<sup>32</sup> Little is known about treatment patterns for lung cancer in North Carolina.

## Study of Appropriateness of Cancer Care in North Carolina

We do not yet know how well the medical and surgical practice guidelines for cancer have been disseminated throughout medical communities in North Carolina and whether citizens of North Carolina are in fact receiving state-of-the-art cancer care.

Between 2001 and 2006, the Care Subcommittee plans to analyze data reported to the North Carolina Central Cancer Registry with the aim of determining the initial care of cancer patients. The North Carolina Central Cancer Registry has complete statewide incidence reporting for recent years and our initial project will be to determine how complete our treatment data is for this group of patients by comparing the accuracy of the treatment data to Medicare billing data.

A study to be conducted by Dr. Roger Anderson of Wake Forest University, working in collaboration with the North Carolina Central Registry and Medical Review of North Carolina, will include an analysis of the 1998 data on all cases of stage 1-3 breast cancer and colorectal cancer diagnosed and treated in North Carolina. The study seeks to answer questions related to financial coverage of treatment and the quality of care provided. In particular, the study will link registry and claims data for the purposes of 1) assembling a more complete data set for cancer patterns of care than is currently available for North Carolina; and 2)

expanding the scope of the registry data by looking beyond the first course of treatment. Using published standards for cancer care developed by the National Cancer Institute and American Cancer Society, the data will be analyzed to determine overall proportions of patients whose data are consistent with standards of care in North Carolina, and whether this outcome varies by insurance status (Medicaid, Medicare, VHA). As part of the study, the data will be analyzed to answer the questions of the Appropriateness of Care Workgroup related to accuracy of treatment data and to provide a ‘snapshot’ of the patterns of care in North Carolina for breast and colorectal cancer. The analysis will examine the following variables: geographic patterns, race, age, provider type (teaching vs. non-teaching institution), and referral patterns.

The incompleteness of current data poses a major challenge to obtaining an accurate view of the patterns of cancer care in North Carolina. Many North Carolina citizens live in communities that may have only limited ability to report initial care to the North Carolina Central Cancer Registry. Following analysis of the treatment data for breast and colorectal cancer, the Care Subcommittee plans to continue to analyze patterns of care, including cervical and lung cancers.

## **Summary**

Widespread adoption of accepted treatment standards is an integral component of high-quality cancer care. Data on current patterns of care for breast, cervical, and colorectal cancers in North Carolina will provide critical information for ascertaining the extent to which North Carolinians are receiving state-of-the-art care. The objectives and strategies that appear on the following pages represent the Care Subcommittee’s priorities for assessing the quality of cancer care in the state.

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## ***Appropriateness of Care Goals, Objectives, and Strategies***

### **Goal 1 (Quality of Care):**

**To ensure that North Carolinians affected by cancer are aware of, and have access to, appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer.**

#### **Target for Appropriateness of Care by 2006:**

North Carolinians with cancer will have adequate access to optimal care.

**Data Sources:** The data collected in appropriateness of care studies will help determine whether optimal care is being provided and what percentage of patients are receiving optimal care.

**Impact by 2006:** The proportion of North Carolinians with adequate access to optimal care will increase. The data collected above will be used to formulate specific targets.

#### **On the following pages,**

**\*\*indicates objectives and strategies that are focused on racial, ethnic, socioeconomic, educational, or age-related disparities.**

### **Objective 1**

To determine what percentage of North Carolinians with colorectal, cervical and breast cancers are provided optimal treatment for these cancers based on the recognized best standard of care.

#### **Strategies**

1. Determine whether data from the North Carolina Central Cancer Registry, insurance claims data, and/or hospital discharge data could be used to analyze the type of cancer care being provided to North Carolinians.
2. Based on the results of the North Carolina Central Cancer Registry data study, develop studies to identify the type of care provided to patients, including primary treatment modalities and adjuvant therapy. These studies may include colorectal cancer, cervical cancer, and breast cancer.

### **Objective 2**

To determine the influence of cancer patients' geographic area of residence and economic status on their choice of treatment.\*\*

### **Strategies**

1. Using the data collected from each of the studies, analyze the data to identify patterns of care by geographic area of residence and payer source.

### **Objective 3**

To determine potential reasons for providing less than optimal care in North Carolina, based on the data analysis on standards of care.

### **Strategies**

1. Using the data collected, conduct a survey and/or focus groups to determine barriers to optimal care in North Carolina.

### **Objective 4**

To educate health care providers on the current patterns of care in North Carolina, as identified by Objective 2, Strategy 1.

### **Strategies**

1. Publicize results of above studies and promote discussion among health care providers of currently accepted standards of care for:
  - a. Primary management of breast cancer, including adjuvant therapy;
  - b. Combined modality therapy of rectal cancer (chemotherapy, radiotherapy and surgery);
  - c. Adjuvant therapy of colon cancer metastatic to regional lymph nodes provided at time of initial surgical removal of cancer; and
  - d. Combined modality therapy of advanced localized cervical cancer (chemotherapy and radiotherapy).

### **Goal 2:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

American Cancer Society, Southeast Division: 3.1P\*, 4.1

Association of North Carolina Cancer Registrars: 4.1

Colon Cancer Alliance: 4.1

Medical Review of North Carolina: 1.1, 1.2, 2.1

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 3.1P, 4.1P

North Carolina Central Cancer Registry: 1.1P, 1.2P, 2.1P

North Carolina Medical Society: 4.1

UNC Sheps Center for Health Services Research: 1.1, 1.2, 2.1, 3.1, 4.1

United Health Care: 4.1

Wake Forest University School of Medicine: 1.1, 1.2, 2.1

\* P indicates Principal Agency

## **Geographic Access to Appropriate Care**

*Geographic access involves a potential linkage between patient and health-care provider. Actual linkage is established when the patient seeks care from the provider. This linkage may weaken as distance and travel times increase.<sup>1</sup>*

Even when health-care services are geographically accessible, however, patients may not actually use them. Minorities and people of lower socioeconomic status often have reduced access to health-care services because of lack of insurance or lack of transportation, or due to cultural barriers. An individual's knowledge of and beliefs about what causes illness and how it can best be treated also influence whether and what type of care are sought.<sup>2</sup> Outreach by the provider is one approach for promoting the linkage between patient and provider.

Inadequate health-care access is cited as a contributing factor to the rise in cancer incidence and mortality nationally between 1973 and 1992. Cancer incidence decreased steadily between 1992 and 1996, while the overall increasing cancer mortality rate began to slow in the mid-1980s and reversed to a decline after 1991.<sup>3</sup> As noted by the National Cancer Advisory Board in its 1994 evaluation of the National Cancer Program, "researchers can develop new cancer treatments, but they cannot guarantee people's access to...these therapies."

North Carolina has the second-largest rural population of any state in the United States, with an estimated 2.5 million North Carolinians, or 33 percent of the State's population, living in areas designated as rural in 1998.<sup>4</sup> Moreover, fifty-seven of the State's 100 counties have been deemed in whole or in part Health Professional Shortage Areas (HPSAs).<sup>4</sup> 1994 data show that an estimated 15 percent of North Carolina's population live in communities that are medically underserved\*.<sup>5</sup>

\* Medically underserved is defined on the basis of characteristics related to inadequate access to primary care services: low income, lack of health insurance, elderly, poor health outcomes, and inadequate supply of primary care physicians.<sup>5</sup>

With a rank of One indicating highest underserved population as a percentage of total population, North Carolina ranked 40<sup>th</sup> in the nation in 1994.<sup>5</sup> Nationally, an estimated 17 percent live in communities that are medically underserved.<sup>5</sup>

Many rural hospitals are financially distressed, and public funding of health care in rural America tends to lag the average for the United States. As a result, rural providers may have reduced ability to adopt newer technologies and also may lack the resources necessary to ensure continuity of care.<sup>6</sup> Rural cancer

patients may be faced with the need to travel substantial distances in order to obtain treatment. Along with the time factor, this entails fuel and lodging costs as well as the need for someone to either accompany or transport them.<sup>7</sup> This increased travel time and cost can affect health care choices as patients weigh these factors against their need for care.<sup>8</sup>

A 1992 study showed that rural and minority North Carolina residents with cancer are diagnosed at later stages of disease than their urban or non-minority counterparts.<sup>9</sup> These findings support the work of Liff et al., which demonstrated substantial differences in stage at diagnosis for rural compared with urban cancer patients in Georgia.<sup>10</sup> One important reason for the urban-rural differential may be distance to health-care providers. Other factors are likely to be involved as well, including the greater poverty, lower incomes, lesser educational attainment, and reduced likelihood of health insurance coverage of rural residents. These problems may be especially acute for such special population groups as racial and ethnic minorities and the rural elderly.

There is some empirical evidence that geographic access to and utilization of health-care services significantly influence cancer outcomes. The findings of Howe et al. (1992) indicated that rural

patients were significantly less likely to have access to state-of-the-art breast cancer treatment than urban patients.<sup>11</sup> In addition, their findings suggested that urban-rural differences in state-of-the-art treatment may be related strongly to the differential in tumor staging, and that differential urban-rural access to state-of-the-art care contributes to the differential urban-rural rates in breast cancer case fatality.<sup>11</sup>

The Care Subcommittee has adopted the elements of comprehensive cancer treatment as defined in the 1992 Texas Cancer Control Plan.<sup>12</sup> These include: 1) hospitals with accredited cancer treatment programs; 2) radiation therapy facilities; 3) health-care specialists in cancer; 4) hospice programs; and 5) transportation and local housing services for cancer patients and their families. A sixth category, support and survivorship services, is another important focus of this Plan. The remainder of the section on geographic availability follows this structure.

With three National Cancer Institute-designated comprehensive cancer centers, North Carolina has a greater concentration of this unique resource than any state other than New York. Also, North Carolina's four medical schools are each affiliated with and support active, accredited oncology programs. In addition, the Southeast Cancer Control Consortium, a National Cancer Institute-sponsored Community Clinical Oncology Program organization, is based in Winston-Salem and affiliated with health-care providers in Winston-Salem, Charlotte, Asheville, Goldsboro, Raleigh, Greensboro, Hendersonville, Statesville, and Gastonia. The purpose of the Community Clinical Oncology Program is to make the latest National Cancer Institute-sponsored clinical trials available to patients and providers outside the traditional academic medical center setting, and the Southeast Cancer Control Consortium is one of the largest Community Clinical Oncology Programs in the country. Furthermore, there are ongoing efforts among some urban providers of cancer care to establish care networks or linkages with rural providers so that patients in rural areas are afforded the latest technologies and optimal care. The emerging technology of telemedicine is facilitating these efforts. It should be noted, however, that 15 North Carolina counties lack a hospital, and thus must "export" all

patients requiring inpatient care to counties with greater health-care resources.

Community hospitals with oncology programs can seek voluntary accreditation through the American College of Surgeons Commission on Cancer program. Accreditation categories include Teaching Hospital Cancer Program, Community Hospital Comprehensive Cancer Program, and Community Hospital Cancer Program. The Program stresses the resources and

processes a hospital-based oncology program should have in place in order to provide high-quality cancer care to patients.<sup>13</sup> 29 hospitals in North Carolina have achieved American College of Surgeons accreditation; three additional hospitals are pursuing accreditation. As of 2000, 56% of the State's population live in counties with an approved program, compared with 44% in 1996. Figures 1 and 2 show the distribution of approved and approval-pending

hospitals. The College recommends that any hospital that annually reports 200 cases or more to its tumor registry seek accreditation. By this criterion, there are 12 hospitals in the state that should initiate efforts at becoming accredited. Ten of these facilities report 500 cases or more to the Central Cancer Registry. Figure 3 shows the number of estimated annual cancer cases at hospital registries across the state.

For cancer patients who require radiation care, there are 83 licensed linear accelerators and 33 treatment simulators in sites across the state. In 1996, there were 62 licensed linear accelerators and 34 treatment simulators in 37 sites. Figures 4 and 5 show the statewide distribution of radiation therapy facilities with county-based population and cancer prevalence.

The National Cancer Institute Physician Data Query information system was accessed to obtain current distributions of oncology-related physicians in the state. Oncology-related physicians are defined as hematologists, oncologists, pediatric hematologist-oncologists, gynecologic oncologists, radiation oncologists, and surgical oncologists. As can be seen in Figures 6 and 7, a sizable number of counties in the state, many of which are in rural regions, do not have oncology specialists, according to National Cancer Institute data. As there does not appear to be a manpower standard specifying a recommended number of oncologists for a given population size,

**As of 2000, 56% of the State's population live in counties with an American College of Surgeons-approved oncology program, compared with 44% in 1996.**

whether North Carolina has an optimal number of oncologists cannot be determined.

Oncology nurses are also an important component of the State's health-care professionals specializing in the care of cancer patients. According to North Carolina Medical Board data, there are approximately 92,500 registered nurses in the state.<sup>14</sup> An estimated 900 of these nurses are members of the Oncology Nursing Society, which has chapters in Charlotte, the Piedmont area, the Raleigh-Durham-Chapel Hill ("Triangle") area, the Greenville area (Coastal chapter), and the Asheville area (Carolina Blue Ridge chapter). One-hundred seven North Carolina registered nurses have been designated Oncology Certified Nurses. These numbers suggest that there is a need for greater representation among North Carolina nurses in both the Oncology Nursing Society and the Oncology Nurse certification. Nationally, there are approximately 30,000 Oncology Nursing Society members.<sup>15</sup>

Hospice nurses may now be designated as Certified Hospice and Palliative Nurses through a national written exam. In North Carolina, there are 159 nurses who hold this designation, and more than 5,600 in the United States.<sup>16</sup>

Both hospice and home health services appear to be well-represented in the state, as shown in Figures 8 and 9. Home-based hospice care is available in all 100 of the state's counties. In addition, distinct hospice inpatient facilities or units are available in 47 counties and residential care facilities are available in 27 counties. There has been a dramatic increase in the availability of these services since 1996, when distinct hospice inpatient facilities were available in only five counties and residential care facilities were available in only three counties. Every county has at least one Medicare-certified, full-service home health agency, although not all are Medicare-certified.<sup>17</sup>

The statewide Care-Line directory of health-care services, operated by the North Carolina Department of Health and Human Services, was used to determine the location and distribution of transportation services for individuals with medical care needs. These services are provided by both public and private sources (Figure 10). The American Cancer Society's Road to Recovery patient transportation program has 52 county-based units in North Carolina. This program has been expanded significantly since 1995.

Finally, Figures 11-14 show the average annual

numbers of persons served by the North Carolina Cancer Control Program, by county. This program was established by the General Assembly in 1945 and has three components: (1) Diagnosis and Treatment; (2) Prevention, Education, and Early Detection; and (3) the North Carolina Central Cancer Registry. When the Cancer Control Program was established, its primary purpose was to provide financial assistance for medical care to eligible persons who had, or were suspected of having, cancer. This purpose continues today. Beginning in the 1950s, with the new technology of the Papanicolaou smear, the program was broadened to include early detection activities.

There are now over eight million cancer survivors nationwide.<sup>18</sup> As this figure increases due to

**There are now over eight million cancer survivors nationwide.** the use of early detection tests and improved treatments, more and more attention is focused on issues cancer survivors face. NCI has recently established an office of Cancer Survivorship to address the needs of this population, and numerous studies are underway to examine quality of life and long-term effects (late effects) of treatment. As these studies mature we will understand how to make survivorship a better experience.

It is important that support services be available and accessible for those living with cancer, whether the cancer has been recently diagnosed or treated many years earlier. As the concept of survivorship has evolved from one focusing primarily on clinical outcomes to one that includes long term quality of life, the need for expanded services for survivors is receiving increasing attention. These services include financial advice, information on managing chronic treatment-related symptoms, support groups for short- and long-term survivors, and wellness programs to maintain optimal overall health. While there are numerous hospital-based support groups for persons undergoing treatment, longer-term community-based support groups and opportunities for the financial and other services previously described are few, both nationally and within North Carolina.<sup>19</sup>

The Advisory Committee on Cancer Coordination and Control and its partners have implemented several initiatives during the last five years to improve geographic access to care and support services for people with cancer. These initiatives were outlined in the first edition of this Plan, the North Carolina Cancer Control Plan 1996-2001. These efforts

have included the establishment of a Regionalization Workgroup to address geographic access issues in the eastern region of North Carolina. An Eastern Regional Cancer Coalition has been formed to build networks or linkages among rural providers and urban cancer centers so that optimal care is more accessible to rural cancer patients. Efforts are also underway to increase the number of certified oncology nurses in North Carolina.

## **Summary**

As noted earlier, the geographic availability of many cancer care and support services has expanded substantially over the last five years. The Care Subcommittee will aim to achieve further increases in the geographic distribution and availability of these needed services by 2006.

# 2000 National Cancer Institute (NCI) and American College of Surgeons (ACOS) Accredited Cancer Centers and 2000 County Population

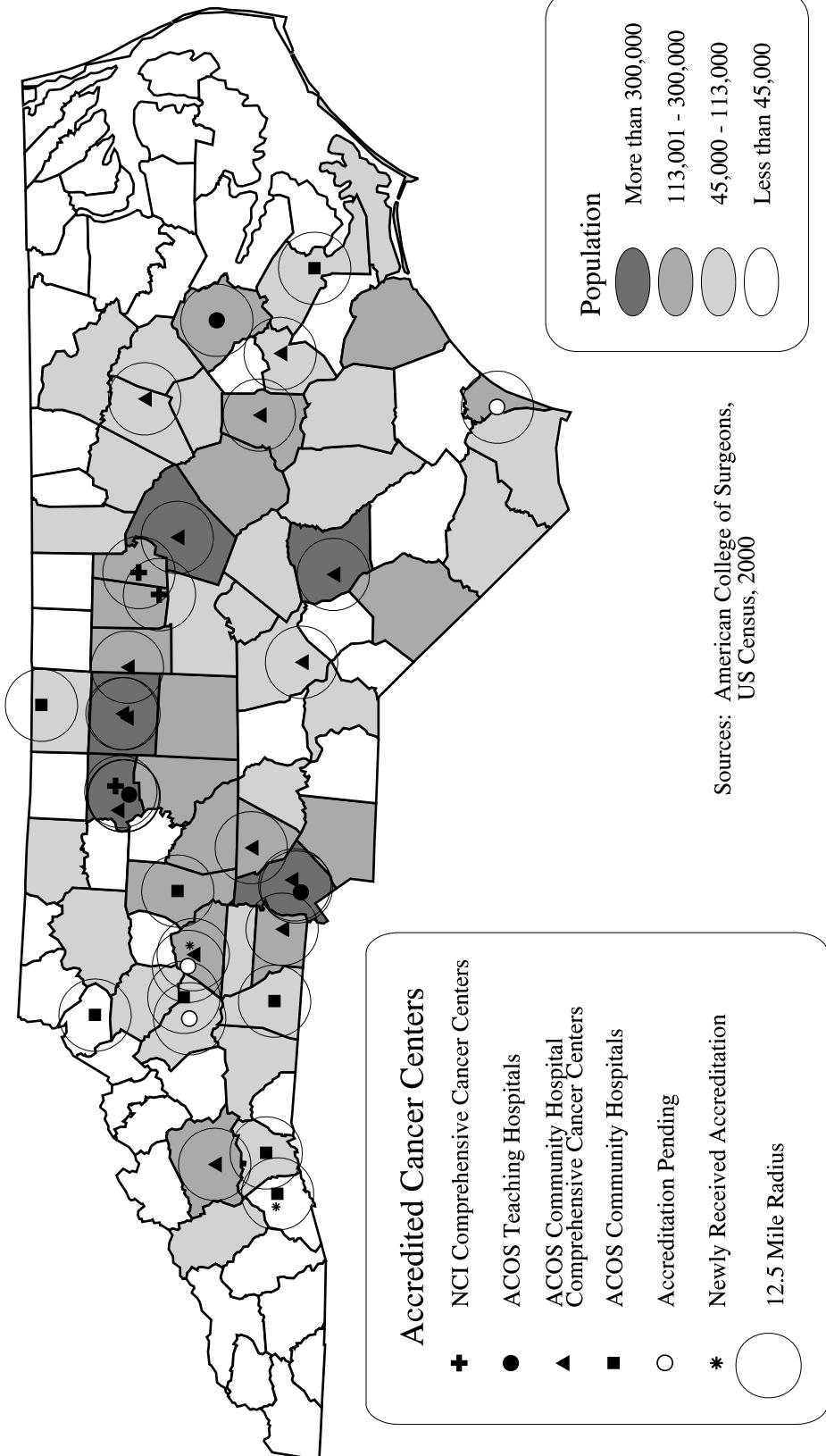


Figure 1

# 2000 National Cancer Institute (NCI) and American College of Surgeons (ACOS) Accredited Cancer Centers and 2001 Estimated Cancer Prevalence

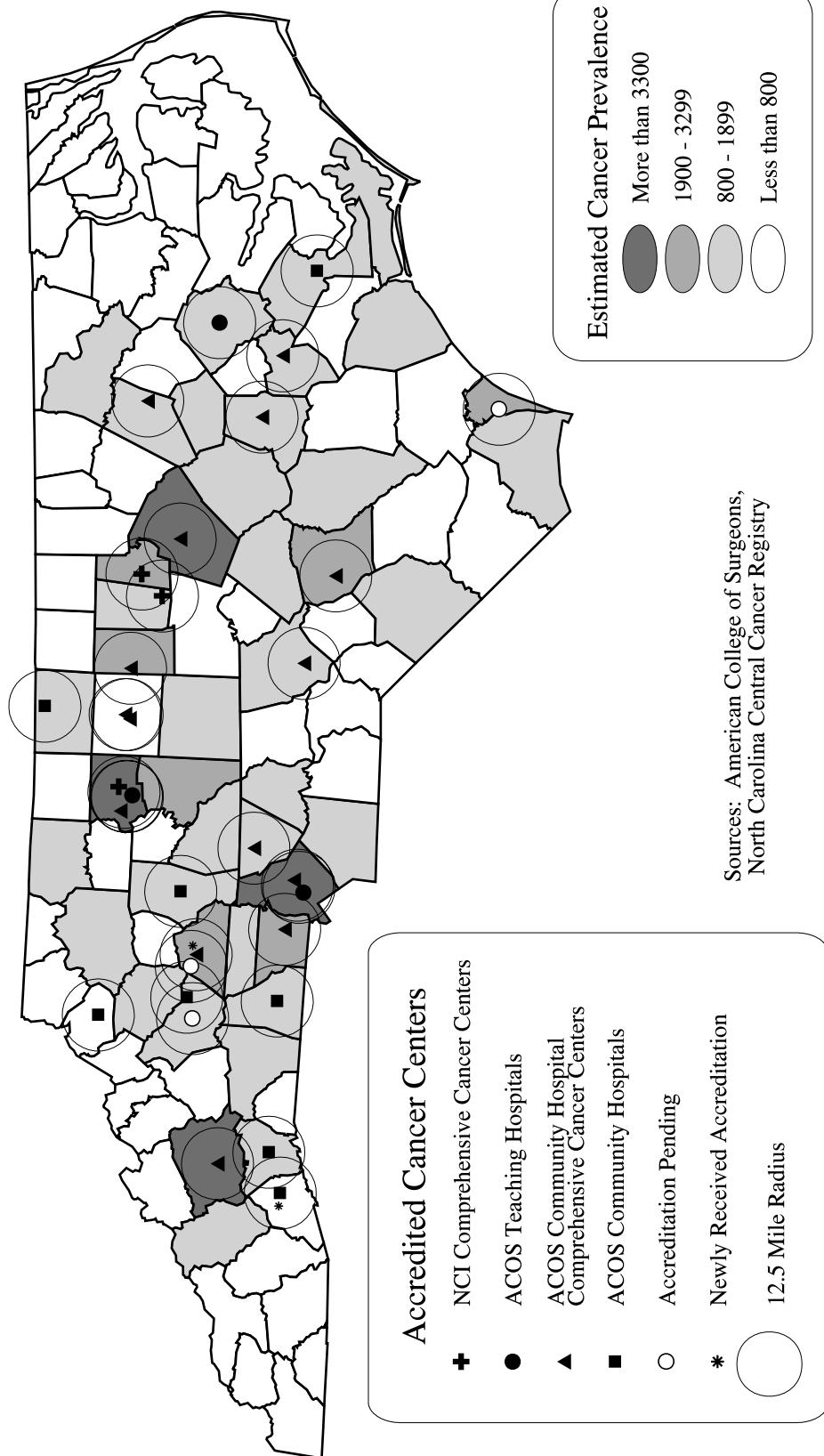


Figure 2

# 2000 Estimated Accessed Annual Cancer Cases of Hospital Tumor Registry System

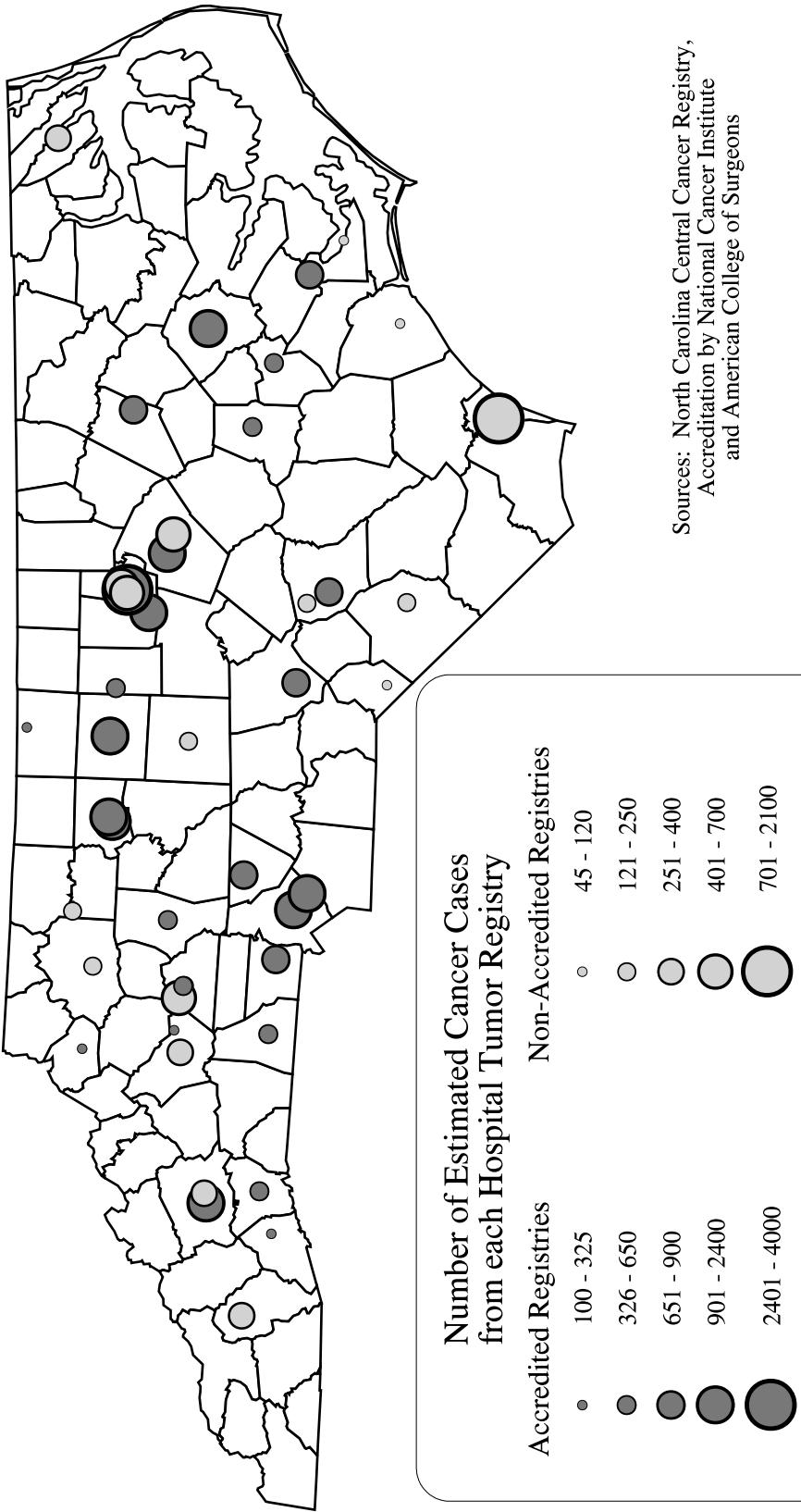
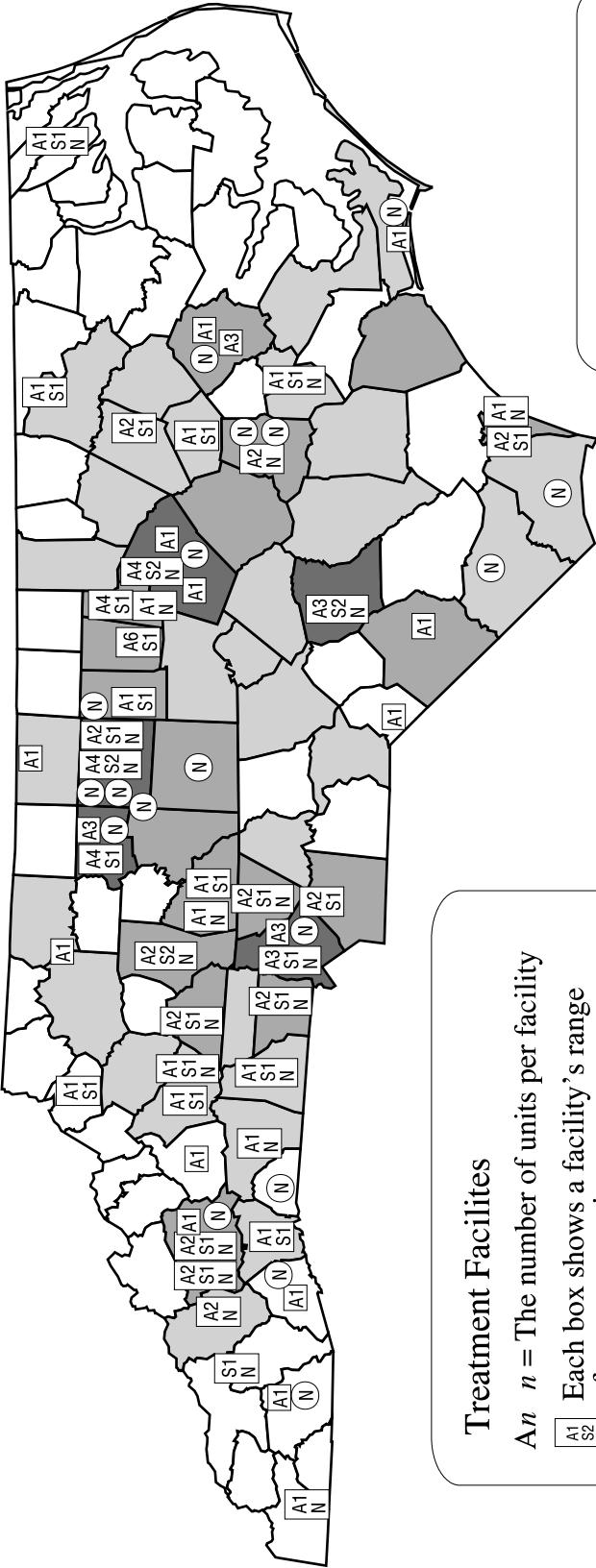


Figure 3

# 2000 Radiation Treatment Facilities and 2000 County Population



## Treatment Facilities

An n = The number of units per facility

Each box shows a facility's range of treatment options.

(N) Non-Accelerator Only

Treatment Options

A Accelerators

S Treatment Simulators

N Non-Accelerator Treatments

Sources: North Carolina Department of Environment and Natural Resources,  
Division of Radiation Protection,  
US Census, 2000

Figure 4

# 2000 Radiation Treatment Facilities and 2001 Estimated Cancer Prevalence

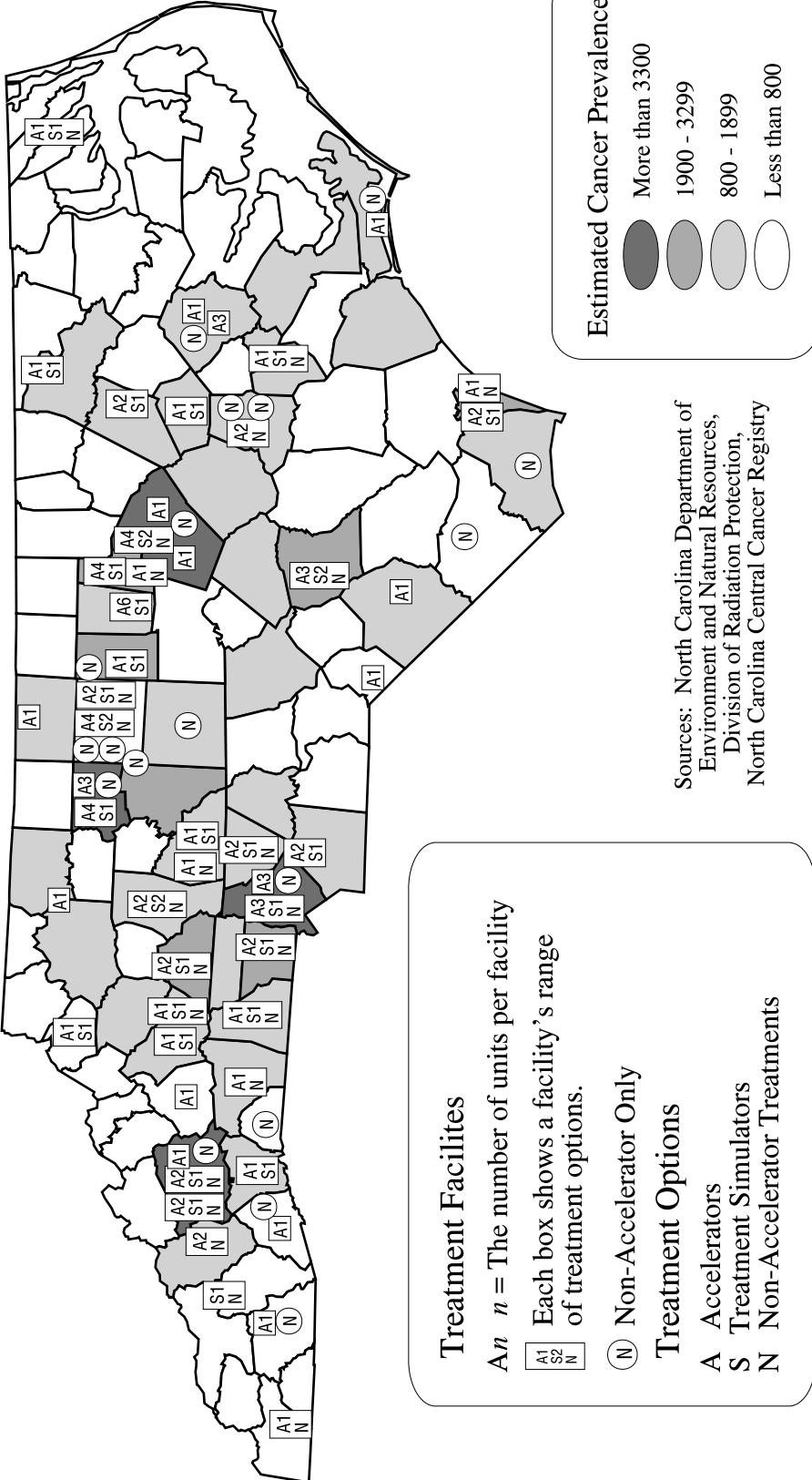


Figure 5

# 2000 NCI-Listed, Oncology-Related Specialists Among Active, Non-Federal, Non-Resident Physicians and 2000 County Population

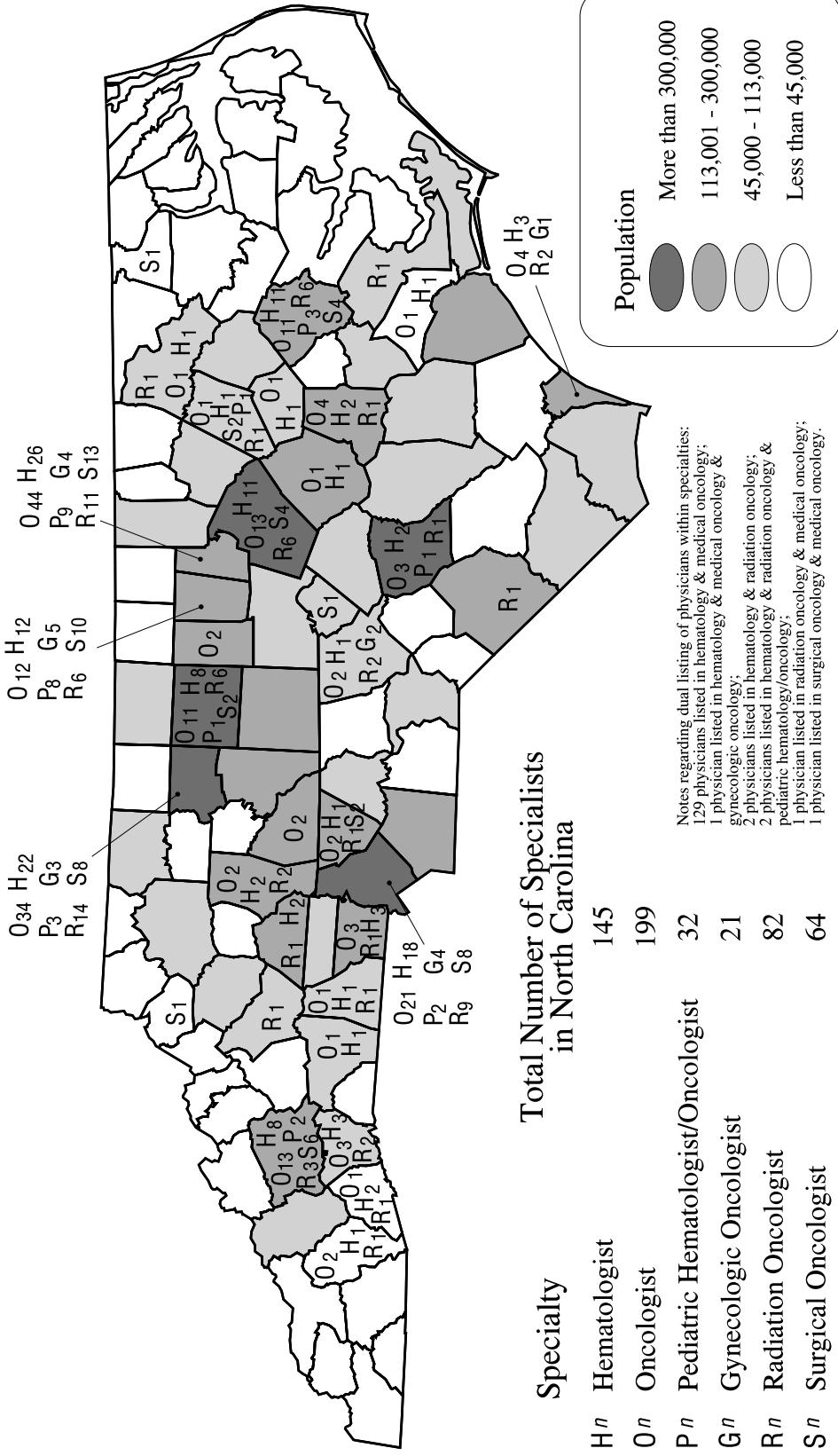
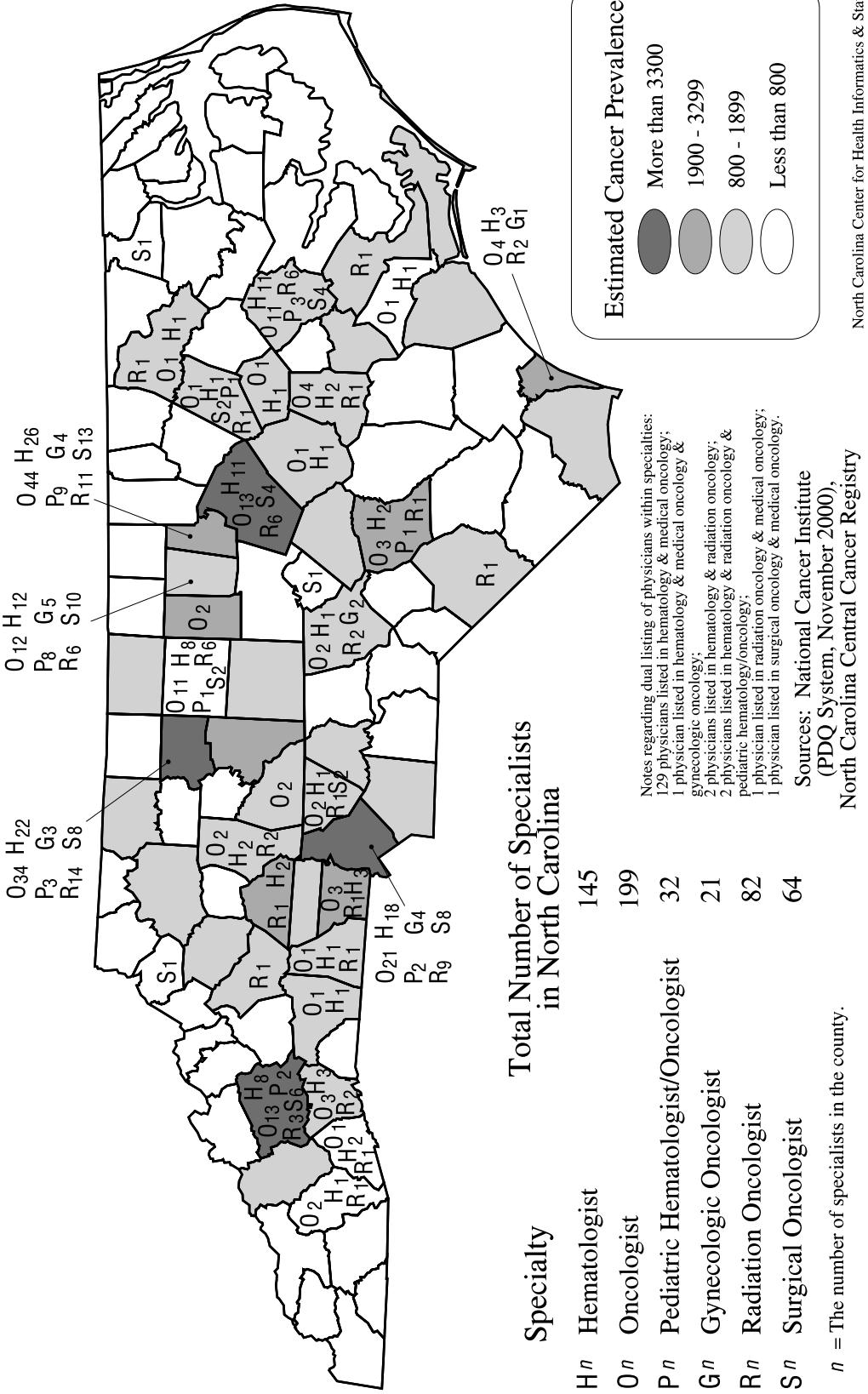


Figure 6

## 2000 NCI-Listed, Oncology-Related Specialties Among Active, Non-Federal, Non-Resident Physicians and 2001 Estimated Cancer Prevalence

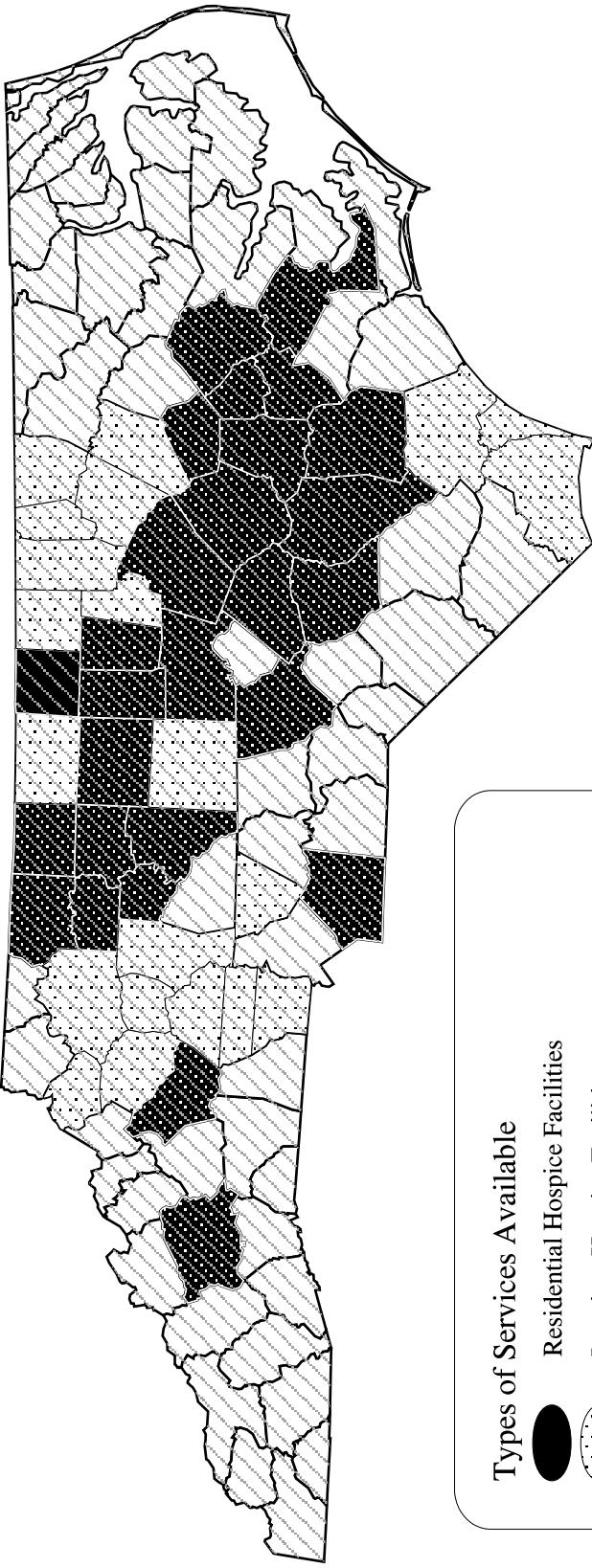


$n$  = The number of specialists in the county.

(IHQ System, November 2000), North Carolina Central Cancer Registry

*Figure 7*

# 2000 Hospice Services



Source: Hospice for the Carolinas, Inc.

Figure 8

# 2000 Home Health and Home Care Services

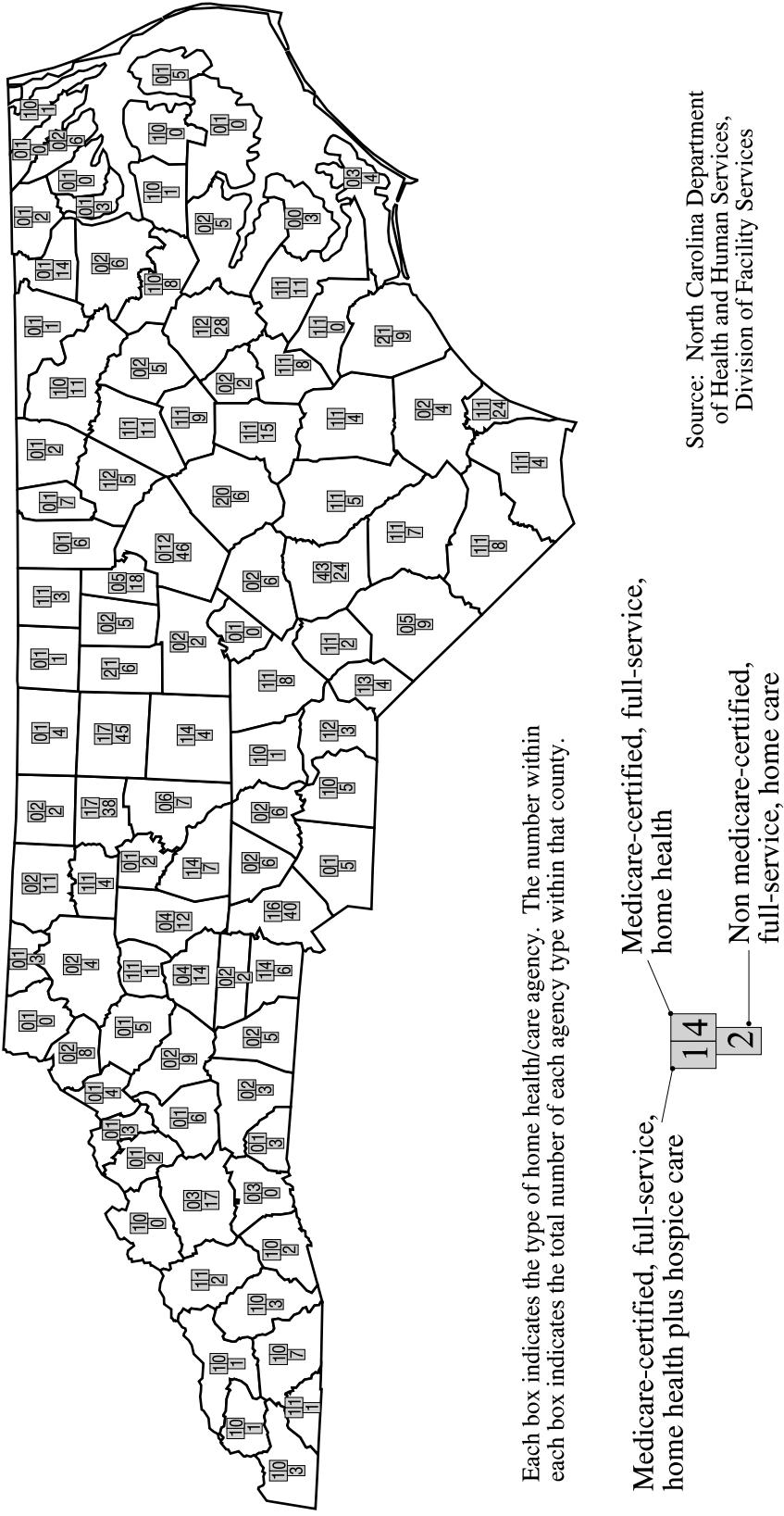
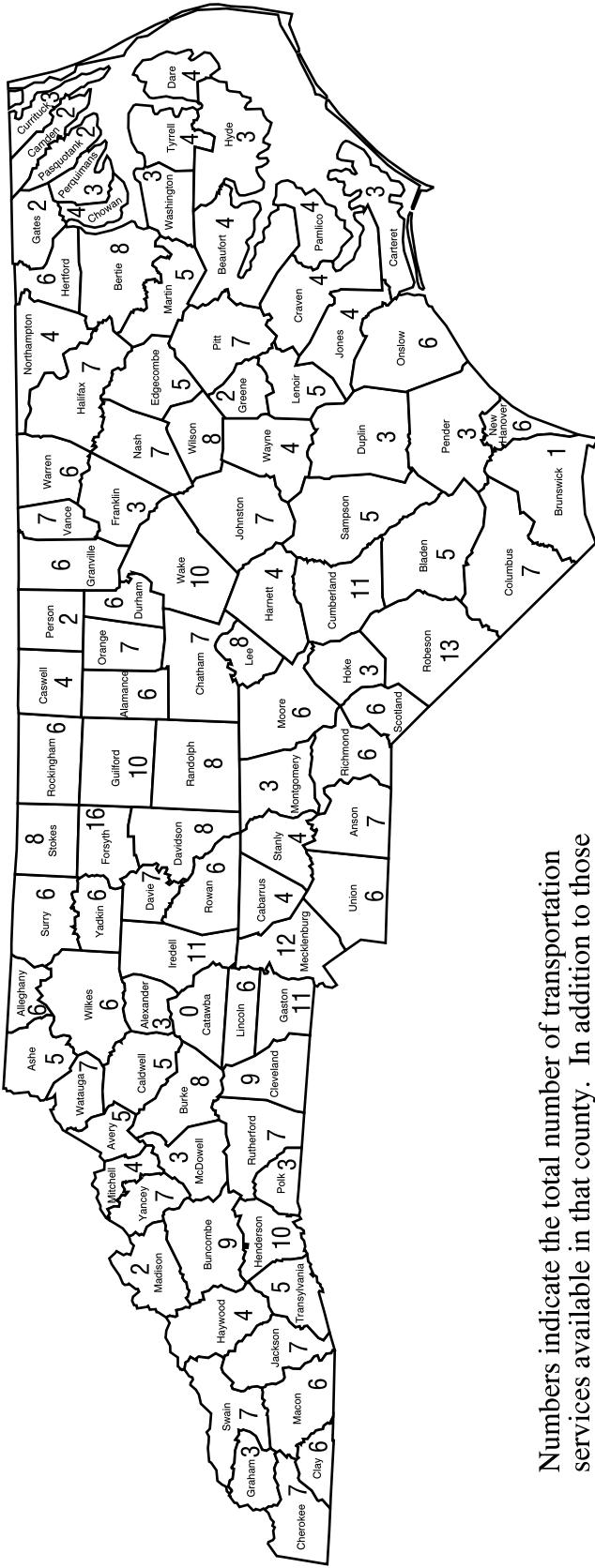


Figure 9

# 2000 Medical Transportation Services by County

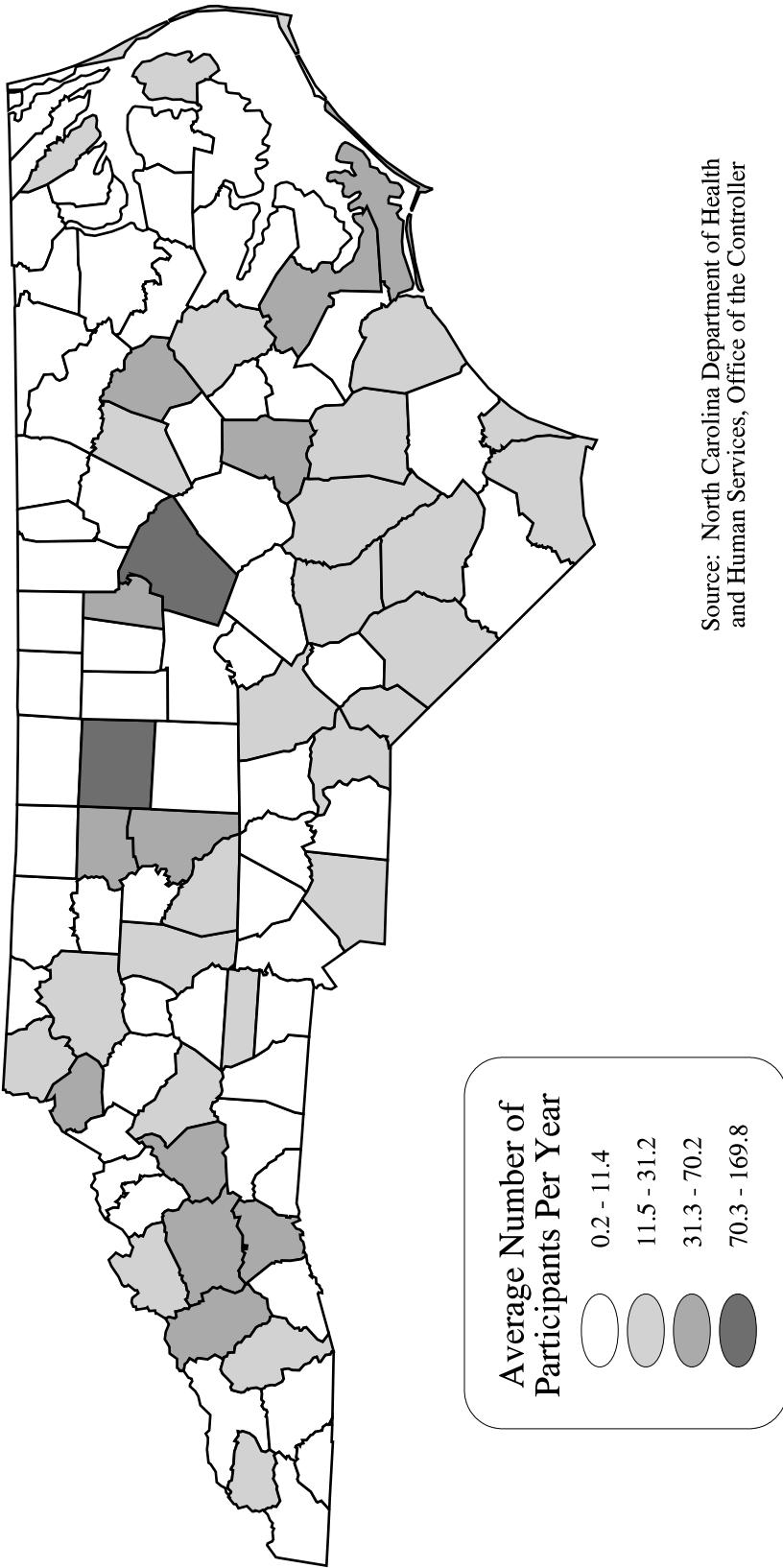


Numbers indicate the total number of transportation services available in that county. In addition to those services shown on the map, there are 23 agencies that provide transportation services statewide.

Source: North Carolina Department of Health and Human Services,  
Office of Citizen Services, Information and Referral Careline

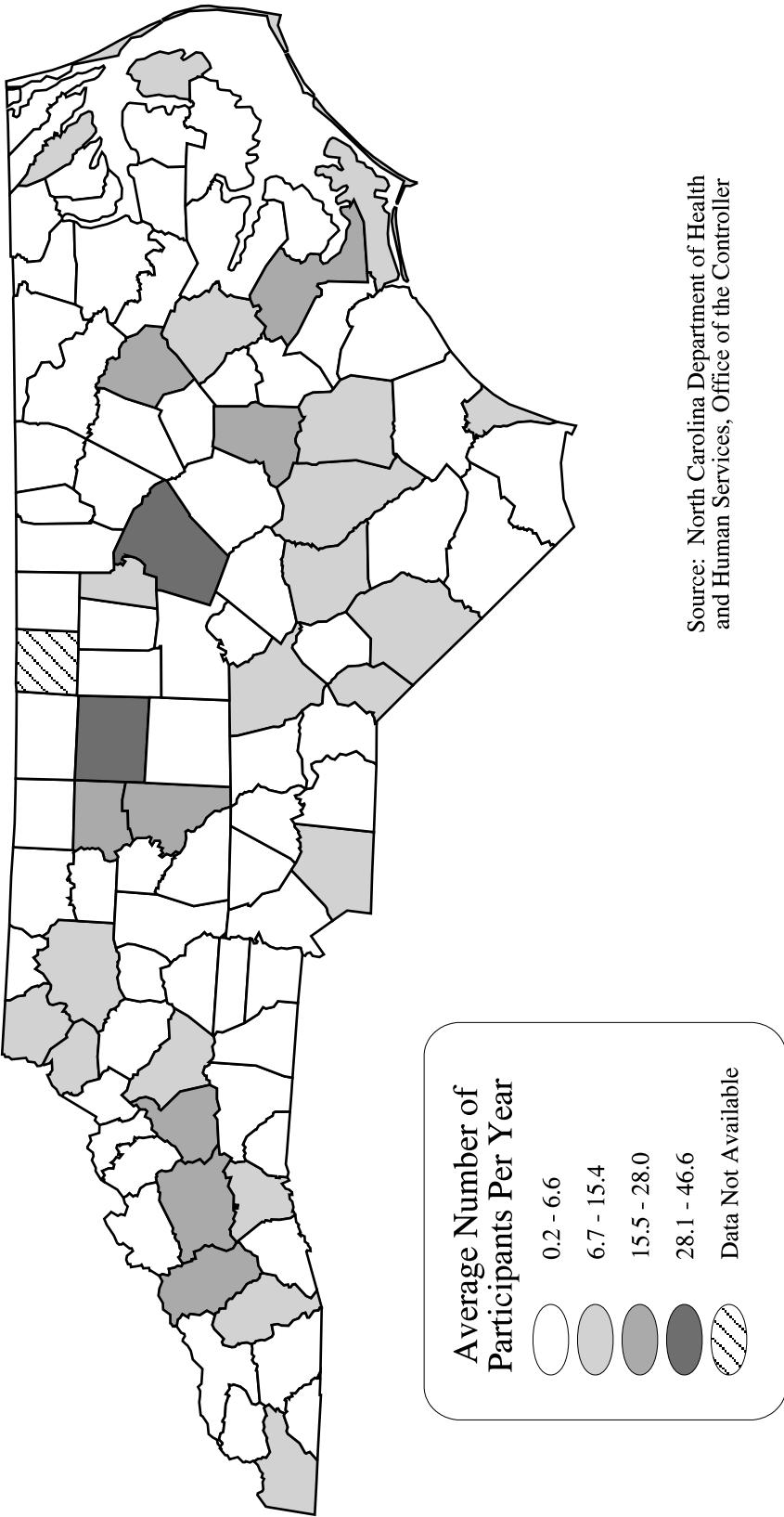
Figure 10

# 1996 - 2000 North Carolina Cancer Control Program Average Annual Number of Participants Served, Diagnostic Services



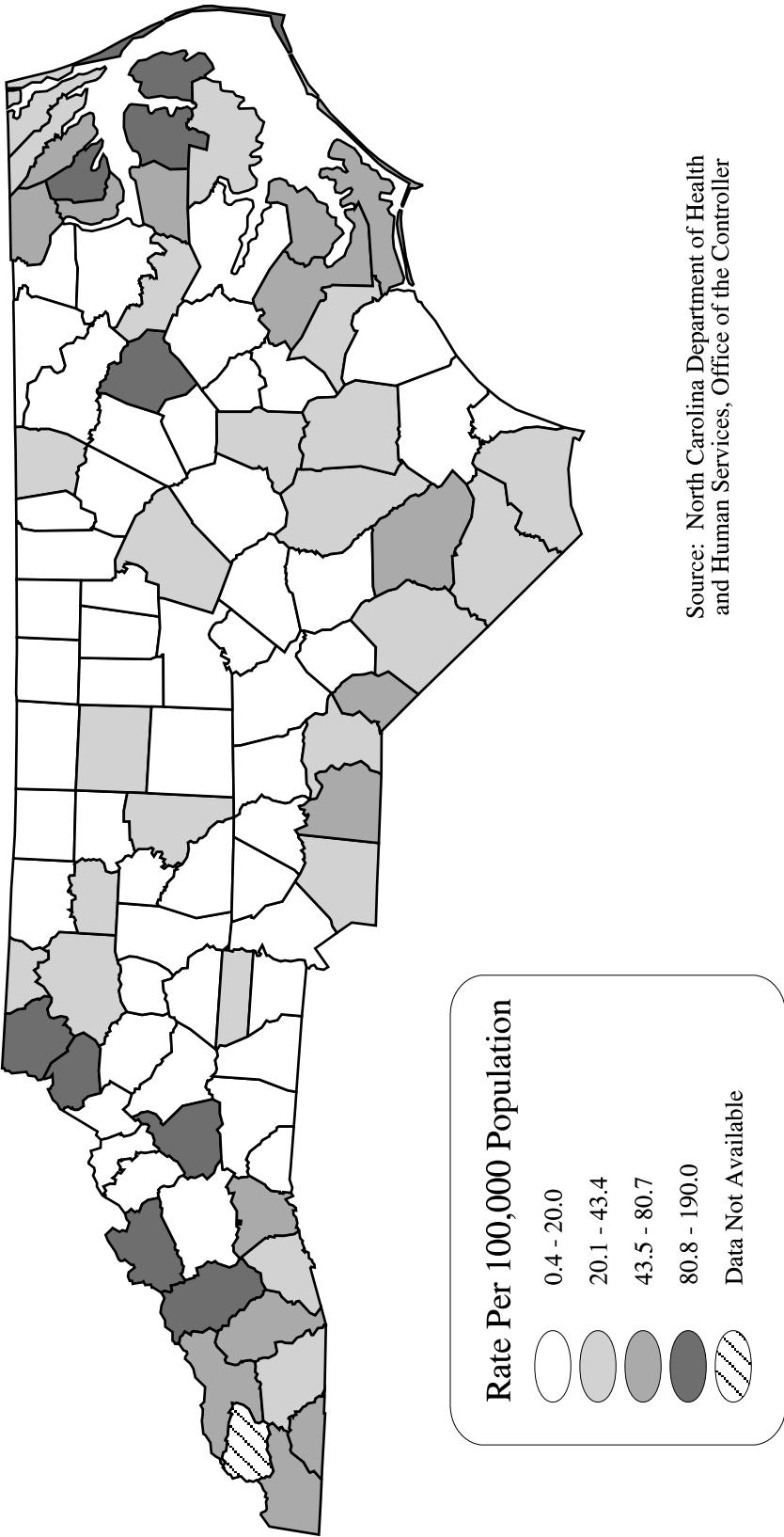
Source: North Carolina Department of Health and Human Services, Office of the Controller

# 1996 - 2000 North Carolina Cancer Control Program Average Annual Number of Participants Served, Treatment Services



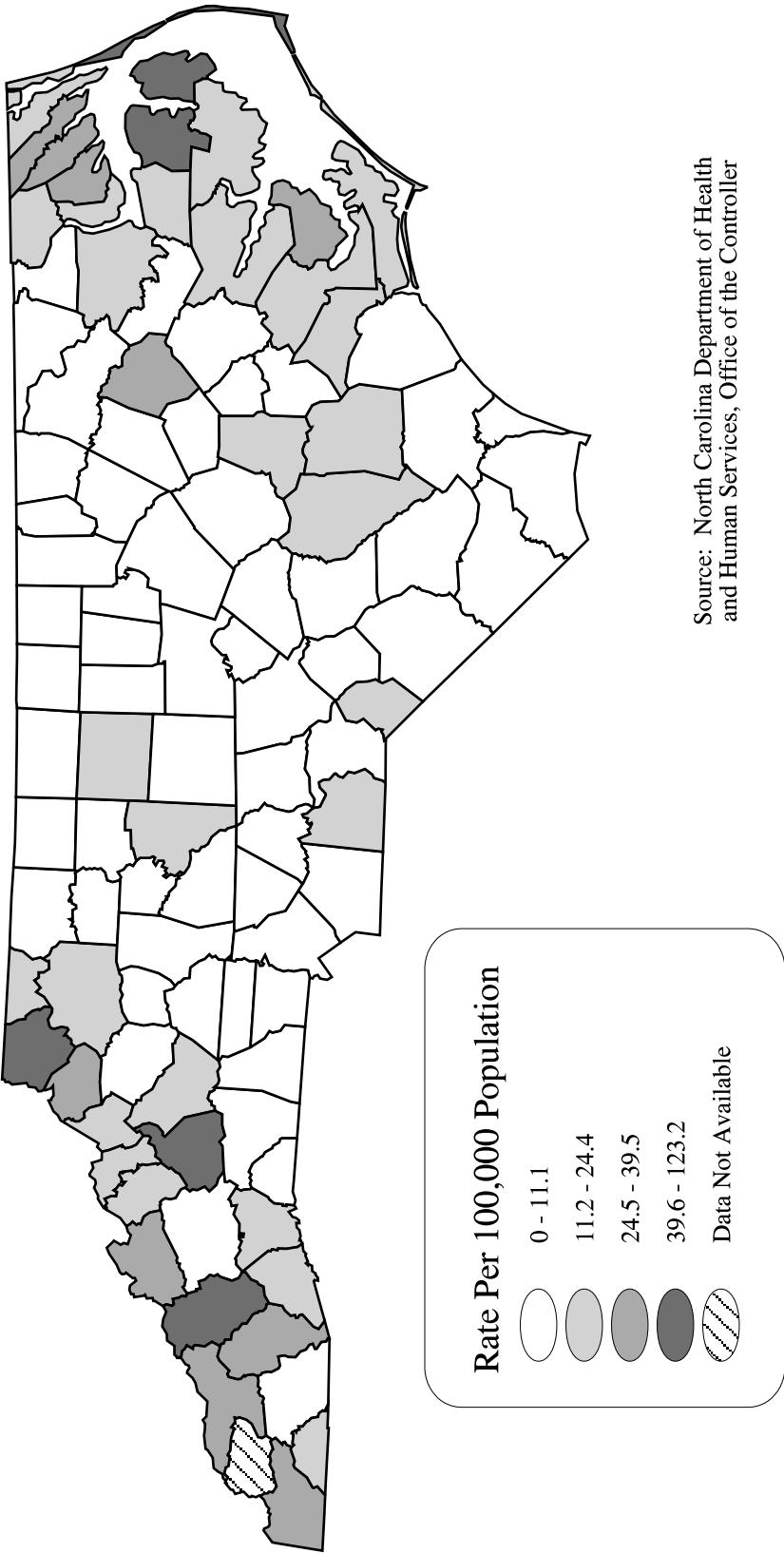
Source: North Carolina Department of Health and Human Services, Office of the Controller

# 1996 - 2000 North Carolina Cancer Control Program Rate of Participants Served, Diagnostic Services



Source: North Carolina Department of Health  
and Human Services, Office of the Controller

# 1996 - 2000 North Carolina Cancer Control Program Rate of Participants Served, Treatment Services



Source: North Carolina Department of Health and Human Services, Office of the Controller

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## *Geographic Access Goals, Objectives, and Strategies*

### **Goal 1 (Quality of Care):**

To ensure that North Carolinians affected by cancer are aware of, and have access to, appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer.

#### **Target by 2006:**

North Carolinians with cancer will have adequate geographic access to optimal care.

Data Sources: Data will be collected on the availability of cancer resources to assist counties.

Impact by 2006: The proportion of North Carolinians with adequate geographic access to optimal care will increase. The data collected above will be used to formulate specific targets.

### **Objective 1**

To increase the number of hospitals in North Carolina with cancer programs accredited by the American College of Surgeons-Commission on Cancer.

#### **Strategies**

1. Form a workgroup to develop strategies to identify existing barriers to increasing the number of hospitals to become accredited cancer centers. Report to the Care Subcommittee during 2002.
2. Based on the barriers identified in Strategy 1, implement a plan to increase the number of hospitals with accredited cancer programs.

### **Objective 2**

To increase the number of cases reported to the Central Cancer Registry by hospitals that do not have a registry.

#### **Strategies**

1. Identify hospitals without tumor registries, send a letter of support for reporting cases to the Central Cancer Registry, and provide a copy of the administrative rule.

### **Objective 3**

To increase the percentage of radiation therapy facilities offering low-cost transportation and housing services to patients.

#### **Strategies**

1. Identify existing barriers to provision of low-cost transportation and housing.

2. Based on the barriers identified, partner with groups across the state to discuss and plan how to eliminate these barriers.

#### **Objective 4**

To support efforts to establish linkages among rural providers and urban cancer centers so that optimal care is more accessible to rural cancer patients.

#### **Strategies**

1. Continue support of the Eastern Carolina Cancer Coalition and encourage collaborative efforts in the community to provide optimal care to rural cancer patients and identify and support regional efforts with similar goals across North Carolina.

#### **Objective 5**

To increase the number of oncology-certified nurses and the number of nurses in the state who hold membership in the Oncology Nursing Society.

#### **Strategies**

1. Meet with regional groups of the Oncology Nursing Society to identify and discuss ways to encourage nurses to seek oncology certification, Oncology Nursing Society membership and involvement.
2. Identify and approach organizations that might be willing to fund scholarships to support nurses in obtaining oncology certification. Possible funding sources include the North Carolina Advisory Committee on Cancer Coordination and Control, hospitals, and universities.

#### **Goal 2: To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective followed by Strategy).

American Cancer Society: 2.1, 3.1P, 3.2P

American College of Surgeons: 1.1, 1.2, 2.1

Association of North Carolina Cancer Registrars: 2.1P

Blue Ridge Cancer Coalition: 4.1

Eastern Carolina Cancer Coalition: 4.1

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 1.1P, 1.2P, 2.1, 3.2, 4.1P, 5.2, 5.2

North Carolina Central Cancer Registry: 2.1P

North Carolina Department of Health and Human Services-Office of Citizen Services Care Line: 3.1

## Cancer Pain Management

*Pain control continues to be a significant problem for many patients living with cancer despite increasing support for institutionalization of effective pain management services in all health care practice sites. Even though the pain associated with cancer can be managed effectively in most patients, cancer pain is often undertreated.*

Thirty percent of patients with cancer have pain at the time of diagnosis, and 65 to 85 percent have pain when their disease is advanced.<sup>1</sup> The panel that developed the Agency for Health Care Policy and Research practice guideline for management of cancer pain advocates prompt and aggressive treatment of cancer pain.<sup>2</sup> Cancer pain can be effectively treated in 85 to 95 percent of patients using an integrated program of medications, nerve blocks, radiation therapy, surgery, and cognitive/behavioral therapies<sup>1</sup>. Despite the existence of effective treatment options, the World Health Organization estimates that up to 70 percent of patients with cancer pain do not receive adequate relief.<sup>3</sup>

Unnecessary suffering, disability and reduced quality of life are well known consequences of unrelieved cancer pain. Recent studies show that additional consequences of unrelieved pain include impaired immune function, loss of appetite, sleeplessness, decreased bowel and pulmonary function, and anxiety and depression. These consequences lead to longer hospital stays, increased rates of re-hospitalization, increased outpatient visits and decreased function that frequently result in loss of income and insurance coverage.<sup>4</sup> Thus the costs of unrelieved pain bear a physical, emotional, social, and financial impact on the individual patient, the family and the economic and health care systems of our country.

### **North Carolina Initiatives to Address Pain Control Access Issues**

The Cancer Pain Advisory Committee (CPAC), a work group of the Care Subcommittee of the North Carolina Advisory Committee on Cancer Coordination

and Control, was convened in February 1998. CPAC was charged with the task of developing and implementing a plan of action to meet the Access to Pain Control Goals and Objectives outlined in the *North Carolina Cancer Control Plan 1996-2001*. Collaborative alliances were established with the North Carolina Cancer Pain Initiative (NCPI) and other interested parties to carry out the CPAC mission.

The Cancer Pain Advisory Committee and the North Carolina Pain Initiative conducted a series of surveys to identify the barriers to provision of optimal pain in North Carolina. In 1992, surveys of health-care practitioners in institutional settings identified the chief barriers as lack of knowledge about pain management, inadequate assessment of pain and conservative prescribing and administration patterns as the chief barriers to the provision of optimal pain management.

In 1998, a survey and focus groups were conducted in community settings with home health nurses, hospice nurses, and persons living with cancer. Nurses identified lack of education and experience in pain management, lack of physician support, lack of pain assessment skills on the part of health care providers and patients, and fear of regulatory boards as the main barriers to effective pain management. Persons living with cancer reported that the main barriers were fear of addiction and loss of control, belief that pain is an inevitable part of having cancer, lack of knowledge on the part of health care providers and patients, lack of time and reluctance to talk with health care providers about pain, and inability to obtain needed supplies and follow-up care in home community settings. Persons living with cancer also made it clear that the desire for relief of pain went well beyond control of personal discomfort to the need

to be able to care for and enjoy one's family, to return to work, and to pursue other life interests. Findings from the survey and focus groups are consistent with findings documented in current national and international literature.<sup>5,6,7,8</sup>

In order to examine whether there were any legally imposed impediments to the provision of effective pain management, CPAC recruited representatives from the North Carolina Boards of Medicine, Nursing, and Pharmacy to review existing practice acts, statutes and regulations. No significant statutory or regulatory barriers to successful pain management in North Carolina were found; however, problems of misconceptions, myths, and misinformation regarding cancer pain management were identified. David E. Joranson confirmed the findings of this group in his 1999 report evaluating pain management related statutes and regulations in seventeen states, including North Carolina.<sup>9</sup> The Practice Review Group was also asked to contribute to the formulation of a joint statement by the North Carolina Boards of Medicine, Nursing, and Pharmacy Practice. The statement, entitled "Joint Statement on Pain Management in End-of-Life Care," was issued in October 1999.

It became clear to CPAC and its partners that correction of the major impediments to effective pain management would require expanding knowledge and understanding of the topic among health care providers, patients and the general public. With the help of the Pain Initiative, the American Cancer Society, Area Health Education Centers, and the newly formed North Carolina End of Life Care Coalition, Cancer Pain Control Awareness Week was held in June 1999 and 2000. A variety of educational materials were produced for use during Pain Control Awareness Week activities: a video depicting six patients and three oncologists discussing how effective pain management could be achieved; presentation materials to be used with the video in group discussions; and a brochure entitled "Managing Pain When You Have Cancer." These items, along with the Agency for Health Care Policy and Research Clinical Practice Guideline for Management of Cancer Pain,<sup>2</sup> copies of the "Joint Statement on Pain Management in End-of-Life Care," and related American Cancer Society materials were distributed to 1200 health care providers and multiple

community agencies and groups in 1999 and to an additional 600 of these organizations in 2000. Newspaper advertisements on pain management were published across the state and a videoconference for health care providers on effective pain management were part of the Awareness Week activities for both years. Numerous organizations supported and participated in the Awareness Week campaigns, including professional and trade associations, health care and governmental agencies, and volunteer, civic and community groups.

In order to address more effectively the challenge of improving access to pain management, the North Carolina Cancer Pain Initiative drafted and approved by-laws that included provisions for employing staff, establishing regional affiliates, and making application for incorporation and non-profit status. The by-laws also included a provision to change the name of the North Carolina Cancer Pain Initiative to the "North Carolina Pain Initiative" to enable the organization to better address the needs of health care

**Resources to  
promote effective  
pain management  
have increased  
steadily over the  
last five years.**

agencies seeking to improve their pain management services. The Pain Initiative is taking the lead in developing an institutionally based consultation service to begin in February 2001. The service will receive support from CPAC, the North Carolina End-of- Life Care Coalition, American Cancer Society, and the American Alliance of State Cancer Pain Initiatives. The Pain Initiative also plans to become a clearinghouse of pertinent pain management information

such as that gathered in the 1999 Best Practices in Pain Management Survey administered by CPAC to hospitals, hospice and home health agencies across North Carolina.

Resources to promote effective pain management have increased steadily over the last five years. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has developed standards on assessment and management of pain that will be a mandatory part of the accreditation process effective January 1, 2001.<sup>10</sup> A survey of North Carolina institutions providing health-care-provider education is being developed by the North Carolina End-of-Life Care Coalition for completion in 2001. The survey will assess the institutions' curricula on end-of-life care, including pain management. Data from this survey will be used to identify the changes needed, and a plan

outlining the best approaches to effect the changes will be developed with input from all stakeholders.

The North Carolina End-of-Life Care Coalition has been institutionalized as part of The Carolinas Center for Hospice and End-of-Life Care. Knowledge about the effects of unrelieved pain on adults who are older, cognitively impaired, or at the end of life has increased.<sup>11,12</sup> There are also new research findings on managing pain in children.<sup>13</sup> Many new educational tools are available on the topic of effective pain management.<sup>14</sup> Ongoing research has yielded new pharmacologic and complementary pain control methods and a better understanding of the barriers to effective pain management.<sup>15</sup>

## **Summary**

North Carolina has a strong organizational and technological foundation for achieving effective cancer pain management for its citizens. The partners who are working together to promote access to effective pain management services have grown in both number and strength. While the growth of resources is exciting and encouraging, much work remains to be done. All practice sites need to have pain management policies, procedures, and standing orders, as well as a committee to ensure that effective pain management services are being provided. This structure is currently available in some agencies, such as larger hospitals and hospices. However, many small hospitals, home health agencies, nursing home, and local clinics need assistance and encouragement to incorporate the components of effective pain management into their daily practice.

The pain management content of the curricula of schools providing education for health care providers must be examined to identify missing elements and amended to include all components of effective pain management. Practicing clinicians need continuing education in effective pain management that is offered in multiple formats. Education of patients, families, and the general public about effective pain management is equally important. In summary, it is imperative that all available resources be effectively brought to bear to further increase knowledge and awareness of the components of effective pain management and to ensure access to effective pain management through all health care practice sites in North Carolina.

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## ***Cancer Pain Management Goals, Objectives, and Strategies***

### **Goal 1 (Quality of Care):**

**To ensure that North Carolinians affected by cancer are aware of and have access to appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that will address quality of life issues related to living with cancer.**

Target for Cancer Pain Management by 2006:

All North Carolinians living with cancer will receive state-of-the-art management of their cancer pain.

### **Objective 1**

To support the activities of the North Carolina Pain Initiative.

#### **Strategies**

1. Employ a full-time staff person and a part-time clerical person to build NCPI membership, assist with dissemination of pain control information, and promote community awareness and education regarding pain control issues.
2. Establish and promote a pain management consultation service to assist home health agencies, nursing homes, and small hospitals with assessing, improving and institutionalizing effective pain management services.
3. Establish a clearinghouse on best practices in pain management to be disseminated by web site, newsletter and use of toll free number.

### **Objective 2**

To promote awareness and adoption of current recommended standards of care for effective pain management.

#### **Strategies**

1. Disseminate copies of the recommended standards of care for effective pain management to hospitals, pharmacies, home health providers, hospices, nursing homes, private practice offices, radiation therapy facilities, and American Cancer Society offices throughout the state.

### **Objective 3**

To promote awareness of current recommended standards of care for effective pain management among patients, families, and the general public.

### **Strategies**

1. Disseminate copies of current recommended standards of care for effective pain management to patients, families and the general public. The information will be disseminated in multiple formats, to include: community group presentations of the pain management video, brochures/books on pain management, pain self assessment and guidance on talking with health care providers about pain, newspaper ads, public television presentation of the pain management video, and web sites.

### **Objective 4**

To encourage incorporation of cancer pain management issues within curricular for health-care professionals-in-training, particularly physicians, nurses, and pharmacists.

### **Strategies**

1. Distribute information on current recommended standards of care for effective pain management to individuals responsible for curriculum development at the state's medical, nursing and pharmacy schools, and assess use of this information.
2. Analyze data collected on the pain management portion of the 2001 survey of end-of-life care curricula of North Carolina institutions providing education for health care providers and use these data to inform and facilitate needed additions and changes to the pain management curricula of these schools.

### **Objective 5**

To promote awareness of cancer pain management issues among practicing health-care professionals, with a particular emphasis on community-based nurses, pharmacists and primary-care physicians.

### **Strategies**

1. Provide continuing education programs in multiple formats on management of cancer pain.
2. Provide information on cancer pain issues to the state's health care providers, especially practicing physicians, nurses, and pharmacists during the annual Pain Control Awareness Week and at other times during the year when indicated.

### **Goal 2 for Quality of Care:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of the strategies shown (listed as Objective followed by Strategy). All strategies are Goal 1.

American Cancer Society, Southeast Division: 1.1P\*, 1.2, 1.3, 2.1, 3.1, 5.2

Cancer Information Service: 1.3, 2.1, 3.1, 5.2

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 1.1P, 1.2, 1.3, 2.1, 3.1, 4.1P, 4.2, 5.1, 5.2

North Carolina Association for Home and Hospice Care: 2.1, 5.1

\*P indicates Principal Agency

North Carolina Medical Society: 5.1

North Carolina Nurses Association: 5.1

North Carolina Pain Initiative: 1.1P, 1.2P, 1.3P, 2.1P, 3.1P, 4.1, 4.2, 5.2P

The Carolinas Center for Hospice and End-of-Life Care: 1.1, 1.2, 2.1, 4.1, 4.2P, 5.1, 5.2



## Lymphedema

*Patients with cancer can develop lymphedema from surgical resection of lymphatic vessels and nodes, from radiation-induced fibrosis around these structures, and from obstruction of lymphatics and nodes by metastatic tumor.*

Lymphedema is defined as “an accumulation of lymphatic fluid in the interstitial tissue that causes swelling, most often in the arm(s) and/or leg(s), and occasionally in other parts of the body.” Lymphedema can develop when lymphatic vessels are missing or impaired (primary), or when lymph vessels are damaged or lymph nodes removed (secondary).<sup>1</sup> Patients with cancer can develop lymphedema from surgical resection of lymphatic vessels and nodes, from radiation-induced fibrosis around these structures, and from obstruction of lymphatics and nodes by metastatic tumor. Lymphedema causes concern to patients due to the perception that it inevitably leads to significant swelling, disfigurement and loss of mobility. It can be a constant reminder of the cancer diagnosis and, once present, requires 24-hour attention. It causes concern to health care professionals due to lack of knowledge about effective prevention and treatment interventions and the worry that the patient’s fear of potential side effects may delay diagnosis or treatment.

Following cancer treatment there may be an acute lymphedema, seen frequently after axillary treatment for breast cancer, that resolves in a few weeks. Having an episode of acute lymphedema post-operatively or during and shortly after radiation therapy does not increase the risk for chronic lymphedema.<sup>2</sup> The time period following completion of the cancer treatment and resolution of the acute lymphedema and prior to the onset of symptoms of chronic lymphedema is called the “latent phase.” During this phase, the limb appears normal but the function of the lymphatic system is compromised.

Many people who develop lymphedema recall a triggering event, which can be quite minor such as a mosquito bite, a minor injury or an airplane flight. Lymphedema then evolves through stages. The first stage is reversible; the edema resolves with elevation and is absent upon arising from sleep. The tissue is soft and maintains an indentation when the edematous

limb is pressed. If untreated, the first stage progresses to the second stage during which gravity no longer resolves the edema and decreased range of motion is reported.<sup>3</sup> A more severe third stage is called “elephantiasis”. The skin is thickened and mobility is significantly reduced. Lymphangiosarcoma (Stewart-Treves Syndrome) is a rare soft tissue sarcoma arising from chronically edematous extremities.<sup>4</sup>

### Incidence

Breast cancer has resulted in the largest number of people with cancer-related lymphedema. The incidence of lymphedema with other types of cancer is less well understood. Retrospective studies of the incidence of breast carcinoma-related lymphedema show a range of from 6% to 30%.<sup>5</sup> The largest retrospective study examined 5,868 cases of breast cancer in Germany going back to the 1950’s (included were 211 women with both breasts involved). The criterion for lymphedema was an increase in arm

**Table 1. Incidence of lymphedema following treatment for breast cancer: All with axillary lymph node dissection<sup>6</sup>**

Overall incidence	24.0%
Radical mastectomy and radiation	44.0%
Radical mastectomy without radiation	22.3%
Modified radical mastectomy and radiation	28.9%
Modified radical mastectomy without radiation	19.1%
Lumpectomy and radiation	10.1%
Lumpectomy alone	6.7%

circumference of at least 2 cm. This study showed a decline in lymphedema with more conservative surgical procedures and without radiation therapy, as shown in Table 1.<sup>6</sup>

These data are consistent with a study by Kissin in 1986 of 200 patients. The study showed the highest incidence of lymphedema in the group of patients who had undergone both axillary lymph node dissection and radiation therapy.<sup>2</sup>

The incidence and prevalence of lymphedema in the United States population and North Carolina are unknown. Applying Schunemann and Willich's (1997) findings of lymphedema incidence (*Table 1*) to 1997 breast cancer incidence data (by type of treatment received) for North Carolina,<sup>7</sup> one can estimate the numbers of cases of expected lymphedema based on the treatment received (*Table 2*).

Sentinel lymph node biopsy is a surgical procedure whereby the breast tumor is injected with a dye or radioactive protein, which facilitates lymphatic mapping. The advent of this technology is expected to significantly reduce the incidence of lymphedema.<sup>8,9</sup> It is hoped that promotion of cancer screening and early detection will also reduce the incidence of lymphedema as cancer is treated at an earlier stage.

## Prevention

The mainstay of lymphedema prevention remains early cancer detection. Fortunately, especially for breast and cervical cancer, screening has resulted in a shift in presentation toward an earlier stage, which permits less extensive treatment. Once cancer has been diagnosed, preventive strategies will help reduce the incidence of lymphedema. Persons at risk are advised to follow certain precautions, some of which are anecdotal. Other precautions have a sound scientific basis, but none has been validated by prospective studies.<sup>10</sup>

Expecting people to change their lifestyles to prevent lymphedema is a challenge for the physician, since it is uncertain whether lymphedema will develop and there is a shortage of scientific studies on the efficacy of preventive approaches. However, in the interest of informed consent and patient control over his or her own life choices, it is essential that options for lymphedema prevention be discussed with the patient (*Table 3*).<sup>11</sup> The recommendations are life long and include avoiding introducing anything past the barrier of the skin, since this may cause infection. Early treatment when signs of infection arise is essential. Consider having antibiotics on hand so that treatment

**Table 2. Expected numbers of cases of lymphedema following treatment for breast cancer:  
All with axillary lymph node dissection<sup>6</sup>**

Treatment Type	Incident Cases, Breast Cancer <sup>7</sup>	Lymphedema Incidence Rate <sup>6</sup>	Expected cases of Lymphedema
Radical Mastectomy and Radiation	3	44%	1
Radical Mastectomy without Radiation	34	22.3%	7
Modified Radical Mastectomy and Radiation	288	28.9%	83
Modified Radical Mastectomy without Radiation	2467	19.1%	471
Lumpectomy with lymph node dissection and Radiation	1016	10.1%	102
Lumpectomy with lymph node dissection without Radiation	546	6.7%	36
<b>Total</b>	<b>4354</b>	<b>16.1%</b>	<b>700</b>

can be started promptly. Simple precautions can be taken by wearing gloves when working outdoors and while washing dishes, in order to avoid irritation from hot water and detergents. Taking precautions against mosquito bites and inadvertent burns is advised. Cuticles should not be trimmed but rather pushed gently when getting a manicure.

Also to be avoided are constrictive clothing, jewelry, and shoulder bags on the involved limb. Signs are posted in hospitals to caution against blood draws, IV lines, and monitoring of blood pressure on the involved limb. Pink armbands are available to help remind medical personnel.<sup>12</sup> Due to the pathophysiology of lymphedema, during the latent phase a class 1 (20 - 30 mm Hg) compression garment is recommended during vigorous activities as well as during airline flight as the onset of lymphedema has been reported with more frequency in these situations.<sup>13</sup>

**Table 3. Essential Precautions for the At-Risk Extremity**

Avoid injury, infection and burns-treat with antibiotics at first sign of infection	1992 and 1995, lymphedema reduction following CDT averaged 63% for the arm and 69% for the leg. <sup>19</sup> In a 1998 study, the reductions following CDT averaged 59% for the arm and 68% for the leg. <sup>20</sup> Reductions in lymphedema following treatment with CDT have been shown to persist at 12 months <sup>16</sup> and 36 months. <sup>19</sup> Decreased incidence of infection following CDT has also been reported. <sup>21,22</sup>
Avoid constricting clothing, jewelry or accessories	
Avoid muscle strain - wear compression garments when exercising	
Avoid IVs, needle sticks and blood pressure monitoring of involved limb	
Elevate limb when possible	
Wear compression garments during airplane travel	

## Diagnosis

The diagnosis of lymphedema is most often based on the history and physical exam. There is usually no pain, but tightness and aching are common complaints. A sensation of fullness may be reported even before edema can be observed during physical examination. It is generally believed that ninety percent of the people with chronic lymphedema note the onset within the first three years after treatment. Lymphedema diagnosed 20 to 30 years after cancer treatment is unusual but reported. J.R. Casley- Smith reviews, in detail, methods of estimating extremity volumes from several circumference measurements, water displacement and a device using an infrared light to estimate volume. The circumference measurement is accurate, simple and cheap.<sup>14</sup> Measurements are made not only to assess the initial degree of

lymphedema but also to follow the response to therapy.

## Treatment

The most effective, non-invasive, safe and dependable treatment for lymphedema is termed "combined (sometimes complex or complete) decongestive therapy" or CDT.<sup>15,16</sup> CDT has two phases. Phase One, or the intensive phase, is done on a daily or twice daily basis for 1 to 4 weeks and involves a multifaceted approach: skin care; manual lymphatic drainage (MLD), a unique form of massage; multilayer bandaging with short stretch bandages; and specific exercises while wearing the bandages. Phase Two serves to maintain and maximize results achieved during Phase One. It includes skin care, low stretch support garments (20 to 50mmHg) during the day, bandaging at night, and exercises. Over time MLD helps to decrease the fibrosis and improve the quality of the skin and subcutaneous tissue.<sup>17,18</sup>

Treatment results with CDT have been

satisfactory.<sup>16,19</sup> In a study conducted between

1992 and 1995, lymphedema reduction following CDT averaged 63% for the arm and 69% for the leg.<sup>19</sup> In a 1998 study, the reductions following CDT averaged 59% for the arm and 68% for the leg.<sup>20</sup> Reductions in

lymphedema following treatment with CDT have been shown to persist at 12 months<sup>16</sup> and 36 months.<sup>19</sup> Decreased incidence of infection following CDT has also been reported.<sup>21,22</sup>

All patients have been shown to respond to CDT to some degree, but if the response is not as expected then the physician must consider whether the correct diagnosis was made and whether other concomitant diagnoses are left untreated (e.g. congestive heart failure, diabetes, deep vein thrombosis). Other factors to be considered as possible reasons for a reduced response include the technique of the therapist, poor compliance by the patient, and possible patient self-infliction.

Volumetrics is a tool that may be used to monitor response to treatment. Volumetrics are calculated to determine the volume of fluid difference between an affected extremity and a non-affected extremity. If both extremities are involved, then the volumetrics before

and after treatment are compared. Volumetrics are determined by taking circumferential measurements every four centimeters up the extremity and using these measurements in a mathematical formula that determines the volume differences.

## **Training and Certification**

CDT therapists have been trained in a variety of schools, all teaching a very similar technique. There is an effort underway to develop a national certification exam that will require a minimum of at least 80 hours of training. The certification will help patients and referring clinicians determine where best to seek treatment.

In North Carolina there are a growing number of treatment programs offering combined decongestive therapy. There are only a few physicians in North Carolina who have received training in the treatment of lymphedema with CDT.

## **Psychosocial and Financial Aspects**

Lymphedema can affect one's daily life, self image, and sexuality.<sup>21-23</sup> Programs that offer treatment for lymphedema are encouraged to incorporate a support network or support group to enable patients to discuss coping mechanisms and issues related to lymphedema.<sup>24</sup> The National Lymphedema Network ([www.lymphnet.org](http://www.lymphnet.org)) has provided resources for individuals with lymphedema and there are many chat rooms on the Web where information is exchanged.

The Women's Health and Cancer Rights Act of 1998 led to Medicare payments for the treatment of cancer related lymphedema. Most private insurers provide insurance reimbursement as well. There is a continual struggle for appropriate reimbursement given the time required per session and the need to treat at least daily for an adequate response.

## **Additional Resources and Future Directions**

Several important efforts have been undertaken to promote education about lymphedema and assistance for those who have the condition. Given the fact that breast cancer survivors make up a large fraction of those living after being treated for cancer, the American Cancer Society held an international lymphedema workshop on breast cancer treatment-related lymphedema in February 1998. The workshop

resulted in recommendations for research, clinical practice, public and professional education, and advocacy.<sup>25</sup> The National Lymphedema Network (NLN) has been working since 1988 to provide education and guidance to lymphedema patients, health care professionals and the general public. In addition, the NLN supports research into the causes and possible alternative treatments for lymphedema.<sup>1</sup>

In North Carolina, the Lymphedema Workgroup of the Care Subcommittee of the North Carolina Advisory Committee on Cancer Coordination and Control was formed in 1999 to help address the needs of both patients and providers who face this diagnosis. To these ends, the Lymphedema Workgroup has planned several important initiatives. For example, the Workgroup will provide continuing education programs. A traveling exhibit with information about lymphedema is available for display at medical conferences as well as conferences for the lay community. The exhibit also includes information about resources in North Carolina. A brochure for patients who have been treated for cancer is being distributed widely to hospitals and medical offices. A video about lymphedema prevention and treatment is being developed and will be available in 2001. Other efforts planned for the years 2001 through 2006 include: conducting surveys of hospitals and the public concerning treatment activities and knowledge; collecting baseline incidence and prevalence data for North Carolina; developing studies of treatment modalities, and distributing information on existing treatment and support services.

## **Summary**

There are many unmet needs for the patient with lymphedema. Lymphedema will be addressed more effectively once the medical and surgical community is better informed about its prevalence, prevention and treatment.

Research on the incidence, prevalence, prevention, and treatment outcomes for lymphedema is encouraged. Incidence and prevalence data would assist greatly in determining how to address the needs of North Carolinians who have lymphedema or are at risk for it. Again, the mainstay of lymphedema prevention remains early cancer detection.

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## ***Lymphedema Goals, Objectives, and Strategies***

### **Goal 1 (Quality of Care):**

**To ensure that North Carolinians affected by cancer are aware of and have access to appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer.**

#### **Target by 2006:**

Health care providers and patients who have been treated for cancer will be made aware of and have access to support services to prevent and manage the symptoms of lymphedema.

**Data Sources:** Data will be collected on the prevalence of lymphedema in North Carolina and on the availability of support services for this condition. Methods to measure awareness of support services will be explored.

**Impact by 2006:** The proportion of North Carolinians who are aware of support services to prevent and manage the symptoms of lymphedema will increase and the incidence of lymphedema will decrease. The data collected above will be used to formulate specific

### **Objective 1**

To collect baseline data to determine the incidence and prevalence of lymphedema in North Carolina over the five-year period from 2001-2006.

#### **Strategies**

1. Develop and conduct a study to identify persons with lymphedema.

### **Objective 2**

To develop and disseminate an inventory of organizations and groups that provide education and treatment of lymphedema in North Carolina.

#### **Strategies**

1. Develop and implement surveys for hospitals to determine the existence of any lymphedema treatment activities.

### **Objective 3**

To gather and review existing data on the causes of lymphedema.

### **Strategies**

1. Identify studies being developed and encourage survey questions that focus on determining the risk factors associated with lymphedema and questions that assess the impact of lymphedema on quality of life.

### **Objective 4**

To promote awareness of lymphedema management issues among practicing health care professionals, with an emphasis on identifying persons at risk for lymphedema and ways to prevent lymphedema.

### **Strategies**

1. Identify health care providers who would like more information on lymphedema and provide educational in-services on lymphedema treatment and prevention. Focus efforts on the accredited comprehensive community cancer centers in North Carolina.
2. Provide continuing education programs (CMEs) on lymphedema to cancer centers.
3. Provide at least six tours of a traveling exhibit to medical conferences.
4. Provide statewide distribution of lymphedema information, including availability of treatment services and certification programs for providers.

### **Objective 5**

To promote public awareness of lymphedema, with particular emphasis on persons with lymphedema and persons at risk for the condition.

### **Strategies**

1. Develop and display a traveling exhibit for the general public and cancer patients/survivors to raise awareness of lymphedema and its treatment. The exhibit will be used at health fairs and with patient advocacy groups.

### **Objective 6**

To promote the credentialing of lymphedema therapists.

### **Strategies**

1. Provide current information to Lymphedema therapists and physical therapists on the various therapies and how to obtain credentialing of these services.

### **Objective 7**

To increase physician awareness regarding appropriate candidates for lymph node dissection, sentinel lymph node biopsy and those for whom lymph node evaluation is not required.

### **Strategies**

1. Include information regarding appropriate candidates for lymph node dissection, sentinel lymph node biopsy and lymph node evaluation in the traveling exhibit and CME program.

## **Objective 8**

To encourage insurers to provide reimbursement for the treatment of lymphedema and the necessary durable medical equipment associated with treatment.

### **Strategies**

1. Provide insurers with the data collected on the incidence and prevalence of lymphedema.
2. Provide information to insurers on the standard of care for the treatment of lymphedema and associated benefits to persons with lymphedema.

### **Goal 2 for Quality of Care:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy). All strategies are Goal 1.

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 3.1P\*, 4.2P,  
4.3P, 5.1P, 5.2P, 6.1P, 7.1P, 8.1P, 9.1P, 9.2P

American College of Surgeons: 4.1P, 4.4P, 5.3P, 5.4P, 8.1

\* P indicates Principal Agency



## **Living with Cancer/Survivorship**

*It is estimated that more than 8.4 million Americans are living after being diagnosed with cancer.<sup>1</sup> There are approximately 95,000 North Carolinians living with cancer.<sup>2</sup> Fifty years ago, only 20 percent of cancer patients lived five years after diagnosis. Today, more than 60 percent survive their disease for five years or longer.<sup>1</sup> Thus, issues pertaining to cancer patient quality of life, rehabilitation, and preservation of function have become increasingly important.*

The National Coalition for Cancer Survivorship defines “survivorship” as beginning at diagnosis and continuing through the remainder of life.<sup>3</sup> The idea that cancer survival begins on the day of diagnosis is replacing the longstanding belief that survival only begins once a patient is in remission.<sup>4</sup> Survivorship is no longer equated with long-term survival or cure.<sup>5</sup>

Advances in diagnosis and treatment of cancer have led more people to look forward to longer, productive lives. Pediatric oncology has had great success and ranks among the most impressive in medical accomplishments. A disease that was uniformly fatal 40 years ago can now be cured with an overall success rate approaching 80%.<sup>6</sup> Advances in the management of the disease have led to more favorable attitudes toward cancer and less fear of the disease’s treatment among the public. The National Cancer Institute reports that respondents to surveys such as the 1987 National Health Interview Survey are more optimistic about the potential to treat cancer effectively than they have been in the past.<sup>3</sup>

In 1975, Dr. Giulio D’Angio expressed a need to offer lifelong support and wrote “...a parallel effort is required in oncology so that the children of today don’t become the chronically ill adults of tomorrow.”<sup>6</sup> This vision has become a reality today. There is a growing movement for cancer support as indicated in 1988 when A Cancer Survivors Bill of Rights was written by Natalie Davis Springarm and was published by the American Cancer Society.<sup>5</sup> The changing terminology from cancer victim to survivor shows that the cancer survivorship movement has made progress and it belies the still frequently held myth of cancer as a death sentence.<sup>5</sup> New efforts focusing on how to

reduce the long-term effects of therapy (late effects) are beginning. These efforts include the refinement of treatment protocols and the possibility that genetic research will yield future cures without late effects.<sup>6</sup>

### **Cancer Survivors’ Needs**

During the period of survivorship, individuals may be faced with physical, emotional, social, vocational, and financial challenges.<sup>3</sup> Physical disabilities due to either the cancer or its treatment may have a multi-system effect causing damage to heart, kidney, liver and central nervous systems. Examples of the late effects of surgery include functional changes and cosmetic deformities resulting from amputations, lymphedema resulting from lymphadenectomy, and intestinal obstructions from adhesions following abdominal surgery.<sup>7</sup>

**The idea that cancer survival begins on the day of diagnosis is replacing the longstanding belief that survival only begins once a patient is in remission.**

The specific challenges faced by cancer survivors may vary greatly depending on cancer type and treatment mode. Chemotherapy may cause late effects such as cataracts, pulmonary fibrosis (hardening of lung tissue), decreased liver function and impairment of central and peripheral nervous systems. Decreased renal function may occur and sometimes results in the need for kidney dialysis. The late effects of radiotherapy mostly involve the organs and tissues that are the target of treatment and may include atrophy, fibrosis and cosmetic deformities. It is often unclear who is monitoring these side effects - the oncologist or the primary care physician. The oncologist frequently does not follow a patient beyond the five years following treatment.<sup>7</sup>

Fatigue is another important concern of survivors. For example, one study showed that one-

half of a sample of Hodgkin's disease patients reported energy problems into their 9<sup>th</sup> year of follow-up.<sup>7</sup> Fatigue impacts quality of life for survivors, including their ability to manage their home, career and relationships.

Sexual problems are some of the most common long-term effects of cancer treatment.<sup>7</sup> Approximately 50% of breast and gynecological cancer survivors report experiencing profound sexual dysfunction and it is estimated that 70% of men with prostate cancer have sexual dysfunction.<sup>7</sup> The most common complaints are loss of sexual desire in both men and women, erectile dysfunction in men and dyspareunia (painful intercourse) in women.

Depression has also been reported, occurring in fewer numbers than other problems but persisting for as many as 8 years following diagnosis.<sup>7</sup> When treatment is finished, the survivor, family, friends and co-workers may expect a time of "life as usual" to return. Often, it is during this period that the survivor experiences feelings of anxiety and depression that were not felt during the time of mobilizing to get through the rigors of treatment. Without preparation, this can be a difficult stage in recovery.<sup>8</sup>

For survivors of childhood cancer, long-term effects may include impaired organ function and altered growth and development. Continuity of care and follow-up between childhood and adulthood is a frequent concern.<sup>9</sup>

Fears of losing insurance coverage or employment and the social stigma associated with having cancer may create an isolating lifestyle. In one study, vocational problems nearly doubled from the initial year after treatment to the ninth year after treatment.<sup>7</sup> Research has shown that approximately 90% of cancer survivors returning to the job market encounter discrimination when trying to find employment.<sup>4</sup>

## **Services to meet Survivors' Needs**

Counseling, support groups, and techniques for symptom management all may influence the quality of life of the cancer survivor.<sup>3</sup> Several public and private organizations have initiated efforts in recent years to voice the needs of survivors and provide resources and interventions to manage the short and

long-term effects of cancer and its treatment. Information to assist with numerous survivorship issues currently is available from national organizations such as the National Coalition for Cancer Survivorship, the American Cancer Society, and CancerCare. The National Cancer Institute (NCI) established the Office of Cancer Survivorship (OCS) in 1996 to support research of survivorship issues and education designed for professionals who deal with cancer patients and survivors.<sup>7</sup> Issues that merit focused research, according to the OCS, include long-term medical and psychological effects of treatment, discrimination in the workplace and economic issues, reproduction and fertility problems following treatment, and genetic and other factors that increase the risk of second cancers.<sup>10</sup> Such efforts are intended to fulfill the OCS mission to "enhance the quality and length of survival of all persons diagnosed with cancer and to minimize or stabilize adverse sequelae of cancer survivorship."<sup>11</sup>

**When treatment is finished, the survivor, family, friends and co-workers may expect a time of "life as usual" to return.**

During a conference held at NCI in March 1998, researchers highlighted the need for greater understanding of the long-term effects of cancer treatments. Current knowledge of late effects is limited, owing to the widespread protocol that discontinues follow-up care beyond the 5-year mark for tumor control. This 5-year mark does not adequately reflect the impact of therapy.<sup>7</sup> To increase the knowledge base, the conference participants encouraged systematic research. The participants also noted a need to make better use of cooperative groups and cancer registries to link them with primary treatment and subsequent outcomes. They recommended that survivor clinics be established and that registries be formed to facilitate the systematic assessment of physical late effects, using research funding.<sup>7</sup> It is critical that we understand the late effects so that that may be prevented in the future.

The majority of existing educational and psychosocial support services for survivors are offered in medical treatment settings. Support services offered in a community setting are fewer in number but growing.<sup>12</sup> The option to receive support services in a non-medical setting may have several benefits, including the ability to tailor information to individual learning styles and an emphasis that extends beyond symptom management to broader quality of life and

wellness goals.<sup>12</sup> In addition, some patients welcome the opportunity to meet in a setting that is free of reminders of their time in treatment.<sup>12</sup>

The importance of self-advocacy skills is frequently mentioned in discussions of cancer survivorship. The National Coalition for Cancer Survivorship offers self-advocacy training in audiotape, Internet, and interactive group formats. The training modules were developed based on the skills identified as essential in surveys of cancer survivors and oncology professionals: communication, information-seeking, problem-solving, decision-making, and negotiating.<sup>13</sup>

## **Summary**

The list of cancer survivorship concerns and needs is long. Resources are needed to better understand the issues and to provide tools to manage them. There is a continuing need for appropriations for cancer research.<sup>5</sup> It is also critical that we develop survivor clinics to provide a systematic assessment of physical long-term effects. We need to encourage the formation of survivor support networks throughout our state. These networks should offer subjects such as stress reduction, nutrition, employability, legal advocacy, information for follow-up after cancer treatment, and peer survivor support groups.<sup>4</sup> Such services would be consistent with the preferences of survivors, who in a 1994 survey expressed the opinion that physicians, other cancer survivors, nurses, family, and friends are all appropriate sources of assistance in coping with survivorship challenges.<sup>10</sup>

A critical task for cancer survivors is to regain a sense of control over their lives. The cancer experience challenges individuals to continue with personal growth, engage in medical consumerism, maximize choices, problem solve creatively, maintain a positive, hopeful outlook and advocate for self and others.<sup>5</sup> Cancer survivorship recognizes information as strength. Therefore we need to provide basic advocacy skills training that includes information-seeking skills, communication skills, problem-solving skills, and negotiation skills. Healthcare no longer considers passivity a desirable trait; a mutual participation model has emerged, whereby both patient and provider have input into healthcare decisions.<sup>5</sup>

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## ***Living with Cancer/Survivorship Goals, Objectives, and Strategies***

### **Goal 1 (Quality of Care):**

**To ensure that North Carolinians affected by cancer are aware of and have access to appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer.**

#### **Target for Change by 2006:**

North Carolinians and their health-care providers will be aware of and have access to support services to effectively manage issues related to living with cancer.

**Data Sources:** Data will be collected to identify the availability of continued support services following the treatment of cancer including the management of symptoms, financial assistance, psychological and social support and the needs of those diagnosed in childhood. Methods for measuring awareness of support services will be explored.

**Impact by 2006:** The proportion of North Carolinians who are aware of support services to effectively manage issues related to living with cancer will increase. The data collected above will be used to formulate specific targets.

### **Objective 1**

To identify and develop an inventory of the cancer support resources available within and outside North Carolina, including financial, legal, physical, social, emotional, psychological, and transportation resources.

#### **Strategies**

1. Develop a survey to identify the cancer support resources in North Carolina and distribute the survey to the accredited cancer programs in the state, the American Cancer Society, and county health departments and agencies that could provide information on existing resources.
2. Develop and disseminate a comprehensive list of all cancer support resources in North Carolina.

### **Objective 2**

To promote public awareness of available cancer support resources.

#### **Strategies**

1. Distribute the inventory of cancer support resources (see Objective 1) to the public via the Internet, brochures, and lists distributed to the organizations offering cancer support resources.

### **Objective 3**

To promote awareness among health care providers of available cancer support resources.

#### **Strategies**

1. Distribute the inventory of cancer support resources (see Objective 2) to health care providers using the Internet and brochures. Mail the inventory to oncologists and cancer programs in the state.

### **Objective 4**

To promote public awareness of the stages of cancer survivorship and the needs specific to each stage.

#### **Strategies**

1. Identify, or develop if needed, an informational brochure on the stages of cancer survivorship and distribute through the organizations offering cancer support resources.
2. Conduct media outreach to attain newspaper and television coverage of survivorship issues.

### **Objective 5**

To promote awareness among health care providers of the stages of cancer survivorship and the needs specific to each stage.

#### **Strategies**

1. Identify, or develop if needed, an informational brochure on the stages of cancer survivorship and distribute through the existing cancer programs.
2. Conduct media outreach to attain newspaper and television coverage of survivorship issues.

### **Goal 2 for Quality of Care:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of the strategies shown (listed as Objective, Strategy).

American Cancer Society: 1.1P\*, 1.2P, 2.1P, 3.1P, 4.1, 5.1

American College of Surgeons: 3.1, 4.1, 5.1

Cancer Information Service: 1.1P, 2.1P, 3.1P

National Cancer Institute-Office of Cancer Survivorship: 5.1

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 1.2, 3.1, 4.1P\*, 4.2P, 5.1P, 5.2P

North Carolina Department of Health and Human Services-Office of Citizen Services Care Line: 1.2P, 2.1

North Carolina Medical Society: 3.1, 4.1

\* P indicates Principal Agency

## **Childhood Survivorship**

*Of the approximately 300 children under 20 years of age who are found to have cancer in the state of North Carolina each year,<sup>1</sup> more than 70% can expect to be cured of their disease.<sup>2</sup>*

The number of disease-free years at which a patient is considered cured varies with the original diagnosis; late relapses are more common with some types of tumors than with others (personal communication, Dr. Julie Blatt, UNC Department of Pediatrics, February 2001). The prevalence of childhood cancer survivors among young adults (15 to 45 years of age) in the United States, currently estimated at 1 in 900 persons, is expected to increase to as many as 1 in 250 persons in the year 2010.<sup>2</sup> Whether or not these astonishing estimates are entirely accurate, they do reflect the undisputed progress made in pediatric oncology over the past few decades. They also underscore the need to screen survivors of childhood cancer for late effects (long-term effects) of cancer therapy, because almost half these survivors are likely to have or to develop disabilities that alter quality of life.<sup>3</sup> These may involve any organ system as well as non-medical issues.<sup>4</sup>

A nonexhaustive list of problems that may occur includes short stature, learning disabilities, infertility, heart failure, and second cancers. Problems with psychosocial adjustment (e.g., issues of marriage, education), and with insurance once these individuals are no longer covered by their parents' policies, are well described. Survivors of childhood cancers face psychosocial issues as they grow older that need to be addressed as issues particular to cancer survivorship, and not viewed solely within the etiological framework used to assess and address problems (e.g. anxiety, depression) in the general population (personal communication, Marc Huber, February 2001).

In North Carolina, several tertiary care centers see survivors of pediatric cancer in the setting of a dedicated late effects clinic. A growing number of transitional programs combine pediatric and medical

expertise. Diagnosis- and treatment-based algorithms for predicting long-term problems in individual patients have been published.<sup>5</sup> Particularly before the long-term survivor of childhood cancer 'graduates' to the care of a non-pediatric oncologist (either a medical oncologist, internist, pediatrician, family practitioner, nurse practitioner, or obstetrician-gynecologist), his or her treatment record and possible long-term problems should be reviewed with the family and, in the case of an adolescent, with the patient. Correspondence between pediatric oncologist and subsequent caretakers should address these same issues.

A typical interim history focuses both on medical problems and on problems of psychosocial readjustment, school and job performance, and insurance. A complete physical examination looking for late effects is routine. Recommendations for laboratory tests are individualized based on the patient's disease and therapeutic history. Because of the delayed onset or potentially progressive nature of some problems, evaluations often bear repetition yearly or every other year. In addition, the same preventive health considerations directed at the population at large are warranted at least to the same degree in the long-term survivors of childhood cancer. These include avoidance of smoking and excessive

alcohol consumption, monthly self-examination of breasts or testes, and other cancer-related screening checks.

Although long-term survivors of childhood cancer generally are thought to be cured of their primary malignancy, the possibility of late recurrences unfortunately needs to be kept in mind. The greatest cause of death beyond 5 years from diagnosis remains recurrent tumor. Therapeutic strategies change over time, so that surveillance for late effects is an evolving issue.

### **Survivors of childhood cancers face psychosocial issues as they grow older that need to be addressed as issues particular to cancer survivorship.**

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## ***Childhood Survivorship Goals, Objectives, and Strategies***

### **Goal 1 (Quality of Care):**

**To ensure that North Carolinians affected by cancer are aware of and have access to appropriate, high quality care. Appropriate care includes treatment, management of pain, and support services that address quality of life issues related to living with cancer.**

#### **Target by 2006:**

North Carolinians and their health-care providers will be aware of support services to effectively manage issues related to living with cancer.

**Data Sources:** Data will be collected to identify the availability of continued support services following the treatment of cancer including the management of symptoms, financial assistance, psychological and social support and the needs of those diagnosed in childhood. Methods for measuring awareness of support services will be explored.

**Impact by 2006:** The proportion of North Carolinians who are aware of support services to effectively manage issues related to living with cancer will increase. The data collected above will be used to formulate specific targets.

### **Objective 1**

To develop an inventory of the cancer support resources available within and outside North Carolina including financial, legal, physical, social, emotional, psychological, and transportation resources.

#### **Strategies**

1. Develop and implement a survey to assess the cancer support resources available in North Carolina, with special emphasis on survivors of childhood cancer.

### **Objective 2**

To promote awareness among health care providers of the unique needs of survivors of childhood cancers, including the need for continuity of care between the pediatric oncologists and subsequent health care providers.

#### **Strategies**

1. Identify, or develop if needed, a brochure addressing the needs of survivors of childhood cancers and distribute this information to primary care physicians in North Carolina.
2. Conduct media outreach to attain newspaper and television coverage of childhood survivorship issues.

### **Objective 3**

To increase the number of survivor groups across the state, with an emphasis on ensuring geographic availability.

#### **Strategies**

1. Identify existing support groups across the state and promote an increased focus among these groups on childhood cancer survivors and the unique survivorship issues involved.
2. Identify available resources at each of the accredited cancer centers to establish childhood survivor groups.

### **Goal 2 for Quality of Care:**

**To coordinate data collection and programmatic efforts with existing or ongoing studies and programs being implemented across the state. (See *Coordination*)**

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Objective, Strategy).

American Cancer Society: 3.1P\*

Cancer Information Service: 3.1P

North Carolina Advisory Committee on Cancer Coordination and Control-Care Subcommittee: 1.1P, 2.1P,  
2.2, 3.2P

\* P indicates Principal Agency

## **IV. Legislation and Education**

## **Subcommittee Members**

**Senator T.L. Fountain Odom**

Subcommittee Chair

**Representative Martha Alexander**

**Senator Robert C. Carpenter**

**Representative Zeno Edwards**

**Senator William N. Martin**

**Representative Thomas E. Wright**

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*North Carolina has one of the oldest and best-structured cancer control programs in the nation. This includes a formal Cancer Control Program as well as other legislative initiatives focused on reducing the burden of cancer in the state.*

## **North Carolina Cancer Control Program**

Recognizing the needs of indigent citizens diagnosed with or suspected to have cancer, the General Assembly established the Cancer Control Program in 1945. Legislation governing this Program is listed in *Table 1*. The Cancer Control Program is mandated to “establish and administer a program for the prevention and detection of cancer and for the care and treatment of persons with cancer.” To carry out this mandate, there are three components of the Cancer Control Program: (1) Diagnosis and Treatment; (2) Prevention, Education, and Early Detection; and (3) the North Carolina Central Cancer Registry.

When the Cancer Control Program was established, its primary purpose was to provide financial assistance for medical care to eligible persons who had, or were suspected of having, cancer. This purpose continues today. Beginning in the 1950s, with the new technology of the Papanicolaou smear, the program was broadened to include early detection activities.

**Diagnosis and Treatment:** The Cancer Control Program provides coverage for up to 8 days of diagnostic services and 30 days of treatment services during each fiscal year. Approximately \$3 million is allocated to the Program each year to cover hospital, professional, and clinic fees.

To be eligible for diagnostic services under the Cancer Control Program, the person’s condition must be strongly suspicious of cancer or cervical dysplasia (abnormal Pap smears of certain types). For treatment services, the person must have a confirmed cancer and have been determined by a physician to have a 25 percent or better chance of five-year survival of the cancer or cervical dysplasia at the time of treatment. Also, one must be a North Carolina resident or migrant farmworker and have a gross family income at or below 115% of the federal poverty level. The income cut-off increased from 100% to 200% of poverty in 1995 but

then dropped to the current 115% level in 1997 after a budget shortfall.

A major concern is that the preceding eligibility requirements limit access for many cancer patients. First, the Program does not cover palliative care, drugs for the patient’s use outside of the treatment facility, or reimbursement for patient mileage to cancer centers. Second, the low financial criteria, which consider gross income during the twelve months prior to the treatment request and without any allowed deductions, essentially excludes previously working families for whom a diagnosis of cancer can mean loss of income and insurance coverage during the treatment phase. For some, it means a delay or forgoing of treatment services. Ultimately, the state, in one form or another, bears this burden. Third, a patient’s physician must refer to the Program and work with the local health department to complete the required paperwork. The process coupled with the low Medicaid reimbursement rate can be a deterrent for some physicians. Because patients must be referred to the program by their physicians, it is important that physicians throughout the state be apprised of current Cancer Control Program eligibility criteria.<sup>1</sup> Providers and communities throughout the state should be continuously informed about how to access coverage for eligible indigent patients with cancer.

For FY 2000, 460 providers delivered Cancer Control Program-sponsored diagnostic services to 1,507 North Carolina residents — 93% of whom were female, 66% were white, 44 % were age 21-34, 73% had no third party coverage, and 54% had income below 85% of the federal poverty level – at an average cost of \$572.75.

For FY 2000, 299 providers delivered Cancer Control Program-sponsored treatment services to 549 North Carolina residents — 88% of whom were female; 42 % were age 21-34 (8%, age 20 or younger; 13%, age 35-44; 16%, age 45-54; 15%, age 55-64; 6%, age 65 or older); 66% were white; 29% were African American, 5% were American Indian, Hispanic, or of

other descent; 66% had no third party coverage and 52% had income below 85% of the federal poverty level — at an average cost of \$2,062.51. The breakdown by primary diagnoses were as follows: 78%-breast and cervical, 3%-colon, 1%-lung, 2%-prostate, 2%-skin and 14%-other.

An additional 1,004 North Carolina residents received services for cervical dysplasia during FY 2000. The Cancer Control Program has provided funds to outpatient cervical dysplasia clinics throughout the state since 1976. State expenditures for the Cancer Control Program between 1987 and 1999 are shown in *Table 2*.

\*These numbers are unduplicated counts for providers and residents. The Program serves the “poor” who have few or no resources for diagnostic and treatment services. Even though the Program income is set at 115% of poverty (\$19,608 for a family of 4), more than half of those are below 85% of the federal poverty level.

**Prevention, Education, and Early Detection:** Prevention and Education- The Cancer Control Program is involved in informing and educating patients, the public, and health professionals about how to reduce the risks of cancer. The Program develops and provides materials, technical assistance and consultation to local health departments, and to the extent possible, to other public and private providers. The Cancer Information Service (National Cancer Institute) and the American Cancer Society, among others, are key partners in cancer control educational efforts.

Local Health Department Screening Services- The nature and scope of screening for cancer in health departments are locally determined. State funding for these services is often supplemented by local funds. Historically, the major cancer prevention and early detection activities in the local public health department setting have been directed at cervical and breast cancer, relying on the Pap smear, clinical breast examination, and breast self-examination. Screening for additional cancers (e.g., skin, colorectal, prostate, testicular, mouth and throat) is provided in some local health departments. Within many health departments, clients are informed and educated about personal behaviors associated with a high risk of developing cancer and assisted to change or modify those behaviors.

**North Carolina Central Cancer Registry:** The operation of a statewide cancer registry has been statutorily mandated since 1945 (see *Table 1*). This registry collects, analyzes, and disseminates information on incidence, mortality, demographics, treatment and follow-up data for all cancer cases in North Carolina. A key activity of the Central Cancer Registry is collaboration with and support of cancer research within the state.

## Additional Cancer Control Legislation

In addition to the Cancer Control Program Legislation, there is other legislation specifically supporting cancer control efforts (*Table 3*). Among these are several laws focused on third party insurance coverage of cancer screening tests and treatment. As early detection and effective treatment modalities have advanced, North Carolina lawmakers have kept pace with statutes that facilitate access to these services and technologies for all citizens.

State programs such as Children’s Special Health Services and Oral Health include cancer as a focus. The State Laboratory of Public Health reads and interprets over 155,000 Pap tests annually from local health departments. Women’s Preventative Health Services, housed in the Women’s Preventive Health Unit, Women and Children’s Health Section, Division of Public Health screens over 131,000 women annually for cervical and breast cancer primarily through local health departments. This Program is funded by local, federal and state dollars. The Tobacco Prevention and Control Branch within the Division of Public Health targets lung and oral cancer incidence through a diverse array of initiatives that promote smoke-free environments and tobacco-free lifestyles.

The early 1990s was an exciting and fruitful time for cancer control. A prime example is evident in the work of Life Savers, a coalition of concerned women representing a wide spectrum of organizations from across North Carolina. It was the aim of Life Savers to pass legislation requiring all insurers regulated by the state to cover mammography and Pap smears. This legislation was signed into law in 1991 (*Table 3*). The success of this effort reflected the long-time strength of resources for cancer control in North Carolina and demonstrated the remarkable public health advances that can be achieved by people who care about cancer issues.

## **North Carolina Advisory Committee on Cancer Coordination and Control**

Reflecting the multitude of efforts in cancer control and the work of Dr. John Kernodle, in September 1992 Senator George Daniel and the late Representative Nick Jeralds requested that the General Assembly establish a study commission on cancer. Within a year, the study commission proposed the establishment of a statewide cancer coordinating and control body. The creation of this Advisory Committee by the General Assembly in 1993 (G.S. 130A-33.50) was an indication of the Legislature's commitment to reducing deaths and the cost of cancer in North Carolina (*Table 3*). Serving as the first Chairman of the Advisory Committee, Jonathan B. Howes applied his notable skills in coalition-building to the task of formalizing the Advisory Committee and its work.

In its first seven years, the Advisory Committee's Legislation and Education Subcommittee has educated members of the General Assembly about cancer-related issues and has been involved in passing additional cancer control-directed legislation, as described below.

- **North Carolina Central Cancer Registry:** In 1995, a legislative appropriation expanded the Central Cancer Registry for the purpose of collecting follow-up and treatment data about cancer, for publishing cancer data for public education, and for supporting cancer research and control efforts in the state. In 1999, legislation was passed requiring all facilities that detect, diagnose, or treat cancer patients to report all cancers to the North Carolina Central Cancer Registry (*Table 3*). This 1999 legislation was passed in support of increasing the percentage of cancers reported to the Registry. Its enactment would not have been possible without the efforts of the Ad hoc Subcommittee of the Advisory Committee formed in January 1998 to examine reporting of cancer incidence in North Carolina. Led by Len Preslar, this Subcommittee was charged with the task of identifying and recommending solutions to the incomplete reporting of new cancer cases to the North Carolina Central Cancer Registry.

- **North Carolina Cancer Control Plan 1996-2001:** Illustrating its ongoing commitment to reducing cancer incidence and mortality in the state, and its support for comprehensive cancer control efforts, in 1997 the North Carolina General Assembly appropriated

\$500,000 to implement the *North Carolina Cancer Control Plan 1996-2001*. \$250,000 in recurring funds for cancer control was passed in 1998 and \$250,000 in 1999. The Plan consists of initiatives focused in three areas central to comprehensive cancer control: Prevention, Early Detection, and Care.

- **Discrimination based on genetic status:** In the mid-1990s, in response to concern that discrimination in health insurance and employment based on genetic information was occurring across the nation, legislation was passed in several other states to protect citizens from such discrimination. The Advisory Committee on Cancer Coordination and Control decided to make enactment of such legislation in North Carolina a foremost priority and in 1997 secured passage of G.S. 58-3-215 and G.S. 95-28.1A.

- **Screening technology:** A 1998 bill to fund the acquisition of a new cervical cancer screening technique, ThinPrep, did not pass, but staff of the Advisory Committee worked diligently with the Secretary and State Health Director to fund the purchase of this critical new equipment. This technology, ThinPrep, has been demonstrated to improve Pap test quality and increase the detection of abnormalities. Repeat Pap tests, which had previously been necessary because of poor smear quality, have been reduced by 50% or more.

- **Insurance coverage of cancer clinical trials:** An issue critical to the Advisory Committee is the coverage of medical care for cancer patients enrolled in clinical trials. Legislation passed in 1998 requiring the State Employees' and Teachers' Comprehensive Major Medical Plan to cover patient costs incurred as a result of treatment provided in a clinical trial (*Table 3*). The following year, a similar bill to require coverage by all insurers regulated by the state was introduced but not referred from Committee.

This second Cancer Control Plan for 2001-2006 identifies cancer control needs for the next five years, some of which require funding or policy action by the General Assembly. It is the mission of this Subcommittee to develop a strategic plan for developing effective legislation and educating legislators concerning its passage. Following are the recommendations from each of the other sections of the Plan which require action by the General Assembly.

**Table 1. Cancer Control Program Legislation**

G.S. 130A-205, 213-214	Administration for Cancer Control Program, Rules.
G.S. 130A-206	Financial Aid for Diagnosis and Treatment.
G.S. 130A-207	Cancer Clinics.
G.S. 130A-208-12	Cancer reporting, North Carolina Central Cancer Registry.

**Table 2. Cancer Claims Paid and State Expenditures (in round thousands of dollars) 1987-1999**

	1987	1989	1991	1993	1995	1997	1999
Claims Paid*	2,045	2,371	2,423	2,696	4,051	8,232	6,450
Amount (\$1,000)	No data	\$785	\$919	\$627	\$1,401	\$2,968	\$2,012

\*More than one claim may be paid per person.

**Table 3. Additional Cancer Control Legislation**

G.S. 58-50-155	Standard and basic health-care plan coverages.
G.S. 58-50-156 G.S. 58-51-59 G.S. 58-65-94 G.S. 58-67-78	Coverage of certain prescribed drugs for cancer treatment.
G.S. 58-51-57 G.S. 58-65-92 G.S. 58-67-76	Coverage by health insurers regulated by the state for mammography and Pap smears.
G.S. 58-51-58 G.S. 58-65-93 G.S. 58-67-77	Coverage by health insurers regulated by the state for prostate-specific antigen (PSA) tests.
G.S. 130A-33.50	Creation of Advisory Committee on Cancer Coordination and Control.
G.S. 58-3-215 G.S. 95-28	Laws prohibiting discrimination in health insurance and employment based on genetic information.
G.S. 58-51-62 G.S. 58-65-96 G.S. 58-67-79	Coverage by health insurers regulated by the state for reconstructive breast surgery following mastectomy.
G.S. 135-40	Requirement that the State Employees' and Teachers' Comprehensive Major Medical Plan cover clinical trials, provided that the treatment in the trials has been proven as efficacious as standard treatment.
G.S. 130A-209	Requirement that all facilities that detect, diagnose, or treat cancer patients report all cancers to the North Carolina Central Cancer Registry.

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## ***Legislation and Education Goals, Objectives, and Strategies***

**Goal: To provide policy and funding support for cancer control in North Carolina.**

### **PREVENTION**

#### **Objective 1**

To promote and increase dietary consumption of foods and nutrients that are known to decrease cancer.

#### **Strategies**

1. Introduce legislation to provide for development and implementation of a multi-faceted, statewide intervention program to increase intake of fruits and vegetables and limit fat consumption, particularly from animal sources.
2. Secure stable, core funding for local programs and build/maintain central state-level capacity to continue the intervention program.

#### **Objective 2**

To increase participation by North Carolinians in regular physical activity and thereby reduce the human and economic burden of diseases related to inactive lifestyles.

#### **Strategies**

1. Introduce legislation to provide for development of media and social marketing campaigns to promote increased physical activity to diverse populations and groups.
2. Provide leadership and support for policy level changes needed to promote increased physical activity.

#### **Objective 3**

To increase knowledge among the general population in North Carolina about the hazards of ultraviolet light and about prevention and early detection of skin cancer.

#### **Strategies**

1. Introduce legislation to provide for the identification or development and dissemination of targeted educational messages about the hazards of ultraviolet exposure and the early detection of skin cancer.

### **EARLY DETECTION**

#### **Objective**

To promote and increase the appropriate use of high-quality colorectal cancer screening and follow-up services.

### **Strategies**

1. Pass Senate Bill 132, AN ACT TO REQUIRE HEALTH INSURANCE PLANS TO PROVIDE COVERAGE FOR COLORECTAL CANCER SCREENING, filed February 12, 2001 to require State-regulated insurance plans to provide coverage for colorectal cancer screening in accordance with the most recently published American Cancer Society guidelines for colorectal cancer screening.
2. Introduce legislation to provide for identification or development and dissemination of culturally appropriate educational materials addressing colorectal cancer. Materials will be designed to increase public awareness about risk for colorectal cancer, the benefits of colorectal cancer screening, and the availability of effective means of prevention and early detection.

## **CARE**

### **Objective 1**

To minimize or eliminate financial barriers to appropriate clinical trial protocols as an essential means of advancing state-of-the-art therapy.

### **Strategies**

1. Introduce legislation to require State-regulated insurance plans to provide coverage for National Cancer Institute-approved clinical trials.

### **Objective 2**

To quantify and reduce the number of patients who have unmet financial needs for diagnostic, treatment, and supportive cancer care not reimbursed by third party payers.

### **Strategies**

1. Pass Senate Bill 537, AN ACT TO APPROPRIATE FUNDS TO MATCH FEDERAL FUNDS TO PROVIDE FULL MEDICAID COVERAGE TO ELIGIBLE WOMEN DETERMINED TO NEED TREATMENT FOR BREAST CANCER OR CERVICAL CANCER filed March 15, 2001.
2. Provide legislative support to maintain adequate funding for the North Carolina Cancer Control Program.

## **COORDINATION**

### **Objective**

To coordinate, facilitate and monitor cancer control activities in North Carolina.

### **Strategies**

1. Provide legislative support for continuation and evaluation of two regional cancer coordination and control initiatives, the Blue Ridge Cancer Coalition and the Eastern Carolina Cancer Coalition.
2. Should the evaluation conducted on these two initiatives yield positive outcomes, provide legislative support for implementation of new regional initiatives in additional areas of the state.

## **EVALUATION**

### **Objective**

To increase cancer data collection and reporting and to assure availability of resources adequate to complete an effective evaluation of the Cancer Control Plan.

### **Strategies**

1. Provide legislative support to maintaining adequate funding to support the collection of statewide risk factor and health behavior data through the Behavioral Risk Factor Surveillance System (North Carolina Health Promotion and Disease Prevention Section, Office of Epidemiology).

## **V. Coordination**



*Enhanced cancer control in North Carolina and the success of this Plan depend upon the extent to which effective communication and coordination among agencies and organizations are achieved.*

A major responsibility of the Advisory Committee on Cancer Coordination and Control is to facilitate coordination of cancer control activities within the state. Coordination is the process of achieving unity of effort among diverse participants and diverse activities so that the goals and objectives of an individual, group, organization, or society are attained.<sup>1</sup> Because of the number and variety of organizations in North Carolina that are committed to cancer control, the Advisory Committee's responsibility to ensure coordination will be a major challenge. This complex array of organizations includes professional societies, state agencies, voluntary associations, patient advocacy groups, and research and academic institutions, among others. They provide us with an extraordinary opportunity to reduce cancer incidence and mortality, as well as to improve the care of cancer patients. By assuring and improving coordination among these groups, the outcomes of their efforts will be greatly enhanced.

There are two fundamental components to coordination of cancer control activities in North Carolina. The first is the ongoing identification of the many cancer control activities occurring within the state. To accomplish this objective, an inventory of cancer control activities was begun in 1996. This process has continued with the identification of agencies and organizations that have volunteered responsibility for, or participation in, the various strategies delineated in this second cancer control plan, the *North Carolina Cancer Control Plan 2001-2006*. A comprehensive inventory promotes information-sharing and communication among the diverse groups.

The second component is to foster communication and networking and thus a synergy among groups. Through the implementation of the first cancer control plan for the state, the *North Carolina Cancer Control Plan 1996-2001*, linkages among many agencies and organizations committed to working collaboratively on particular strategies were

initiated. The potential for accomplishing the strategies outlined in the *North Carolina Cancer Control Plan 2001-2006* will be greatly enhanced by the synergistic efforts of multiple organizations. Continued development of an on-line information service will further facilitate coordination and communication among the various organizations engaged in cancer control activities.

Enhanced cancer control in North Carolina and the success of this Plan depend upon the extent to which effective communication and coordination among agencies and organizations are achieved. The following objectives and strategies have been developed to support the need for coordination of cancer control activities.

1. Longest BB, Klingensmith JM. Communication and Coordination. In: Shortell SM, Kaluzny AD, eds. *Health Care Management: Organization Design and Behavior*. 3<sup>rd</sup> edition. Albany, NY: Delmar Publishers, 1994:182-211.

## *Coordination Goals, Objectives, and Strategies*

**Goal: To coordinate, facilitate, and monitor cancer control activities in North Carolina.**

### **Objective 1**

To identify and maintain an inventory of those organizations and programs that engage in or support cancer control-related activities.

#### **Strategies**

1. Identify, on a continuing basis, cancer control organizations and activities in North Carolina.
2. Maintain a database of all organizations, their activities, locations, directors, and funding.

### **Objective 2**

To monitor and coordinate cancer control activities.

#### **Strategies**

1. To keep apprised of, and disseminate information on, the activities of organizations engaged in implementing or supporting cancer control activities.
2. Continue development of an on-line information service for cancer control in North Carolina.
3. Continue and evaluate existing regionalization initiatives (Blue Ridge Cancer Coalition, Eastern Carolina Cancer Coalition).
4. Should the evaluation conducted on these two initiatives yield positive outcomes, implement new regionalization initiatives in additional areas of the state.

## **VI. Evaluation and Surveillance**



*Evaluation* refers to the process of determining whether particular projects or initiatives are effective, and why. Evaluation of the *North Carolina Cancer Control Plan 2001-2006* will require evaluating the effectiveness of individual projects proposed in the Plan as well as the effectiveness of the comprehensive cancer control initiative represented by the Plan as a whole. Surveillance involves monitoring the health status of a population; in this case, it entails tracking cancer incidence and mortality over time, as well as monitoring the prevalence of cancer-related knowledge, attitudes and behaviors such as tobacco use, diet, or use of mammography. When measuring the success of the *North Carolina Cancer Control Plan*, surveillance and evaluation are related, because surveillance data are an important part of determining the extent to which the Plan's ultimate goal – reducing the burden of cancer for the citizens of North Carolina – is being achieved.

Evaluation and surveillance have several purposes. Although evaluation is often thought of as an activity occurring at the end of a project, information from earlier evaluation and surveillance has been important from the very beginning of the *North Carolina Cancer Control Plan*. It was used in planning to identify needs, define the burden of cancer, determine the prevalence of cancer-related risks, identify populations with greater needs, select strategies based on proven cancer-control methods, and set appropriate goals and targets.

Evaluation and surveillance will be used to monitor the effectiveness of programs and progress toward goals, which will provide an opportunity for continued improvement of plans and programs. Data from evaluation and surveillance will be used to educate the public, the health care community, and policy makers about cancer issues.

The task of evaluating the *North Carolina Cancer Control Plan* can be divided into three categories: process evaluation, impact evaluation, and outcome evaluation.

## **Process Evaluation - Strategies**

Process evaluation will be carried out to determine the extent to which the strategies and

activities proposed by the Plan are implemented as intended. This includes monitoring the planning and implementation processes for the Plan as a whole as well as those of individual strategies and projects.

The North Carolina Advisory Committee on Cancer Coordination and Control has a continued role in coordinating the implementation of this Plan with partner agencies throughout the state. It is important to monitor the health and effectiveness of these partnerships to assure continued support for implementation of the Plan. This will require monitoring the membership and participation in Subcommittees and Workgroups and reviewing the accomplishments of these committees. It will include documenting new partnerships, enhancements to the state's cancer-control infrastructure, and progress toward institutionalizing cancer-control initiatives. This information will be used to review the Advisory Committee's partnerships and take steps to assure the continued growth of their ability to plan and implement cancer control strategies.

### **Evaluation and surveillance will be used to monitor the effectiveness of programs and progress toward goals, which will provide an opportunity for continued improvement of plans and programs.**

In order to measure progress toward implementing the Plan, a regular review of strategies will be conducted to determine which have been implemented, which have funding available, and which have the necessary staff to carry them out. This review will be reported to the Subcommittees and Workgroups so they can ensure that implementation of the Plan is proceeding as intended and revise plans or reallocate resources as necessary.

It is important that each individual project have its own evaluation plan for the purposes of monitoring progress and making any necessary adjustments, documenting lessons learned that would be helpful for expanding or replicating a project, and providing accountability. Projects supported by the Advisory Committee will be required to have an evaluation plan that describes the program, documents implementation, gathers evidence regarding impact, and uses this information to determine the level of success and reasons for success, partial success, or failure.

Because individual projects may have limited resources and expertise for evaluation, the Evaluation Subcommittee will identify a selection of projects or program areas for more in-depth process and impact

evaluations. The Subcommittee will work to identify additional sources of data to measure the impact of efforts of a given project or set of strategies.

## **Impact Evaluation - Objectives**

There may be some degree of overlap between the categories of impact and outcome evaluation. In general, however, impacts are the immediate results of a program and outcomes are the long term effects that are intended to result from these impacts. Examples of impacts include increasing access to services, changing behaviors, improving the quality of care, or achieving policy or environmental changes. The desired impacts of the Plan's strategies are represented by the objectives listed throughout this Plan: measurable steps necessary to reach the Plan's goals. In addition to evaluating and summarizing the impact of individual projects, the impact of the cancer control plan as a whole will be measured by reviewing progress toward meeting the Plan's objectives.

The Subcommittees have identified areas where additional data for measuring objectives are needed. Questions about the prevalence of knowledge, attitudes, or behaviors can be incorporated into the Behavioral Risk Factor Surveillance System (BRFSS) or the North Carolina Cancer Survey. A variety of strategies for collecting data regarding cancer-related health care systems have also been proposed. These are referenced below under Objective 3.

## **Outcome Evaluation - Goals and Targets**

The ultimate goal of the North Carolina Cancer Control Plan is to reduce cancer morbidity and mortality, two key components of the burden of cancer in the state. Even if the Plan's strategies are highly successful, however, it will be many years before some of them result in fewer cancer deaths; this is particularly relevant for those strategies in the area of prevention. Thus, the targets selected for this plan focus on indicators that can be changed in the next five years, indicators for which there is good evidence that a reduction in cancer incidence and mortality will ultimately result.

Prevention targets focus on changes in environmental factors and behaviors that are known to influence the risk of cancer. There are also prevention targets for changing knowledge and attitudes related to these behaviors. The targets for

early detection involve improving screening rates and follow-up of positive tests. Care targets are chiefly related to changes in health care systems. Improvements in early detection and systems of care may have other positive results that can be observed several years later, such as cancers being diagnosed at earlier stages or even reduction in mortality for some cancers.

Surveillance data was essential for setting targets. It will be equally important for monitoring progress toward meeting the Plan's goals and targets.

## **Surveillance: North Carolina Central Cancer Registry**

The North Carolina Central Cancer Registry is the central cancer surveillance organization for North Carolina. The Registry collects data about new cancer cases, cancer treatment, and cancer deaths. Reporting of all cancer cases diagnosed in North Carolina is required by state law. These cases are usually reported by the hospital where a patient was treated, but cancer cases are also reported by clinics, laboratories, treatment centers, and doctors' offices.

The Registry monitors the cancer burden, including which cancers have the highest incidence rates and which have the highest mortality rates. Data showing the stage at which a cancer was diagnosed are also collected. The Registry also monitors trends and looks for problems in specific groups or communities.

Data from the Registry are used to identify needs in public health planning, to evaluate cancer prevention and control activities, and to guide decisions about allocating resources. Each year, the Registry prepares a projection of cases and deaths for the upcoming year, which is used by hospitals and health departments to plan for the expected need for services (screening, diagnosis, and treatment) and educational programs. Data on stage at diagnosis has important applications. If, for instance, there are large numbers of cases diagnosed at later stages, this may indicate a gap in screening. The Registry also regularly publishes facts about cancer in North Carolina, responds to public inquiries, and provides data for a wide variety of cancer-related research projects.

The North Carolina Central Cancer Registry has conducted statewide reporting since 1990. The Registry has been certified by the North American Association of Central Cancer Registries for

completeness, timeliness, and quality of data. An evaluation of the Registry in 2001 found a 95% case ascertainment rate.

The Registry has identified several areas for improvement. A target has been set to increase case ascertainment to 90% within one year of diagnosis and 98% within two years. Comparisons with national data indicate two categories that need particular emphasis to improve reporting: (1) non-hospital cases, especially cases of melanoma and prostate cancer, and (2) cancer cases among African-Americans, particularly in rural areas. There is also a need to improve the quality of racial and ethnic classifications to properly identify cancer cases among Native Americans and Hispanics. Finally, the Registry would like to improve dissemination and use of data. Efforts need to be made to identify potential users of data, provide data in formats that are the most useful, and educate program planners and policy makers about how to use data.

### **Surveillance: North Carolina Behavioral Risk Factor Surveillance System**

The North Carolina Behavioral Risk Factor Surveillance System (BRFSS) is an ongoing telephone survey of state residents aged 18 and older conducted by the State Center for Health Statistics. Initiated in the early 1980's by the Centers for Disease Control and Prevention (CDC), the BRFSS is administered by state health departments and collects data on a variety of health behaviors and preventive health practices related to leading causes of death and disability, including cancer. The CDC has developed a standard core questionnaire that is used in all states so that data can be compared across states. In addition, the NCBRFSS has space allocated each year for other questions of interest to North Carolina public health planners and researchers.

The BRFSS collects data about cancer-related behaviors including tobacco use, diet, physical activity, protection from sun exposure, and screening for breast, cervical, and colorectal cancers. Data from the BRFSS show how many North Carolinians engage in behaviors that may affect their risk of developing cancer and how many people are being appropriately screened for cancers that can be detected early enough to improve the chance of successful treatment. The data can also help identify subgroups with higher risk or lower screening rates than the rest of the population. This information is important for planning and targeting

programs and for evaluating the success of efforts to increase screening rates or encourage behaviors that reduce cancer risk.

### **Surveillance: North Carolina Cancer Survey**

The BRFSS has limited space for questions about cancer-related behaviors. In addition, the BRFSS focuses on actual behaviors rather than knowledge or attitudes. Because many of the Cancer Control Plan's strategies aim to change knowledge and attitudes about various cancer-related issues, monitoring them as well is an important part of evaluating the Plan. For these reasons, the Advisory Committee has developed an additional telephone survey to supplement the BRFSS. This survey includes questions about what people think and do related to tobacco use, diet, exercise, cancer screening clinical trials, and pain management. There are also questions concerning people's access to health care and what recommendations they have received from their health care providers about preventing or screening for cancer. It is anticipated that the survey will be conducted biannually.

### **Dissemination**

The value of evaluation and surveillance data depends on whether and how the data are used. Data can and should be used for the following purposes: setting priorities; planning programs; providing accountability to funders and other stakeholders; educating the public, health care planners, and policy makers; and building support for cancer control.

In order for the data to be used effectively, audiences for the data must be identified and their data needs must be determined. Data should be reported and presented in ways that are appropriate and useful for the intended audience. Currently, a variety of reports based on evaluation and surveillance are prepared regularly for the Advisory Committee, the Governor, grant donors, health care providers, and the general public. The Evaluation Subcommittee will review these reports, determine where there are additional needs, and develop a plan for regular reporting and dissemination of evaluation and surveillance data.

## ***Evaluation and Surveillance Goals, Objectives and Strategies***

### **Goal 1:**

To evaluate the *North Carolina Cancer Control Plan 2001-2006* by assessing the implementation and effectiveness of its strategies, by determining its impact on the knowledge and behavior of the citizens of North Carolina, and by measuring changes in health outcomes.

#### **Objective 1**

To develop and implement a system for monitoring implementation of the *North Carolina Cancer Control Plan 2001-2006*.

#### **Strategies**

1. Contact partners annually to determine implementation status of each of the plan's strategies, including staffing and funding allocated for each strategy, and distribute report to the Advisory Committee and its Subcommittees and Workgroups.
2. Require all projects funded by the Advisory Committee to include an evaluation plan with plans for reporting results to the Advisory Committee and provide technical support for evaluation to selected projects.
3. Select projects or groups of projects for in-depth process evaluation to determine level of success of the projects and reasons for success or failure.

#### **Objective 2**

Develop and implement a system for monitoring coordination and development of the Advisory Committee's cancer control partnerships.

#### **Strategies**

1. Conduct annual review of membership and accomplishments of all Advisory Committee subcommittees and workgroups.
2. Conduct a biannual survey of Advisory Committee, Subcommittee, and Workgroup members and other partners to document coordination and development of cancer control partnerships.

#### **Objective 3**

Monitor and disseminate survey data on cancer-related knowledge, attitudes, and behaviors of North Carolinians.

#### **Strategies**

1. Conduct biannual telephone survey of cancer-related knowledge, attitudes, and behaviors to supplement the Behavioral Risk Factor Surveillance System (BRFSS).

2. Combine cancer survey data with cancer-related data from BRFSS and disseminate the results to the Advisory Committee and other groups involved with planning cancer control programs.

## **Objective 4**

Monitor availability, accessibility, and quality of health care resources related to cancer.

**Note:** These strategies are cross-referenced in the Early Detection and Care sections that address collecting data about cancer-related health care resources.

### **Strategies**

1. Determine the proportion of sites using expanded clinic hours for primary care providers (see Cervical Cancer: Objective 6, Strategy 4).
2. Monitor the proportion of trained cytotechnologists in the state to assess person power and explore initiatives to address shortages (see Cervical Cancer: Objective 9, Strategy 2).
3. Using geographic mapping technology, conduct an assessment of available and necessary capacity for colorectal cancer screening (see Colorectal Cancer: Objective 2, Strategy 3).
4. Assess current colorectal cancer screening practices in North Carolina (see Colorectal Cancer: Objective 3, Strategy 1).
5. Measure the number and percentage of insurance plans covering clinical trials, the extent of coverage for clinical trials vs. standard therapy, and the number of North Carolinians whose plans would cover clinical trials (see Financial Access: Objective 1, Strategy 1).
6. Measure the percentage change in awareness of and expanded support for the North Carolina Cancer Control Program among providers and patients, as evidenced by the change/increase in numbers of patients served as a result of an increase in the budget for the North Carolina Cancer Control Program or more inclusive standards for access to the program (see Financial Access: Objective 2, Strategy 1).
7. Measure and quantify unmet needs, change in unmet needs (\$, %, or number of people with unmet needs), number of cancer patients and survivors with insurance/third party coverage, number or percentage of services/needs covered, number of patients/survivors with available health care coverage (see Financial Access: Objective 3, Strategy 1).
8. Quantify uncompensated care, change in uncompensated care (in terms of dollar amounts, percentages, or number of claims), number of institutions changing provided services or accepted patients due to uncompensated care (see Financial Access: Objective 4, Strategy 1).
9. Determine whether data from the North Carolina Central Cancer Registry, insurance claims data, and/or hospital discharge data could be used to analyze the type of cancer care being provided to North Carolinians (see Appropriateness of Care: Objective 1, Strategy 1).
10. Analyze data collected on pain management portion of the 2001 survey of end-of-life care curricula of North Carolina institutions (see Cancer Pain Management: Objective 4, Strategy 2).

11. Collect baseline data to determine the incidence and prevalence of lymphedema in North Carolina over the five-year period from 2001-2006 (see Lymphedema: Objective 1).

### **Objective 5**

Improve the completeness and quality of data collected by the North Carolina Central Cancer Registry.

(Target: at least 90% complete case ascertainment within one year of diagnosis and 98% complete case ascertainment within two years of diagnosis.)

#### **Strategies**

1. Design and implement a plan to improve reporting of non-hospital cases.
2. Design and implement a plan to improve reporting of cases among African-Americans, particularly in rural areas.
3. Identify hospitals without tumor registries, send a letter of support for reporting cases to the Central Cancer Registry, and provide a copy of the administrative rule (see Geographic Access Objective 2, Strategy 1).
4. Design and implement a plan to improve the quality of race and ethnicity variables in cancer registry data.

### **Goal 2:**

**To regularly disseminate information from evaluation and surveillance activities in ways that will be useful for planning, improving, and providing accountability for cancer control programs.**

### **Objective 1**

Develop and implement a system for regularly disseminating evaluation and surveillance information.

#### **Strategies**

1. Review existing reporting methods, identify potential audiences for evaluation and surveillance information, and develop regular reports designed for these audiences.

**Partner Organizations:** The following partner organizations will contribute to the implementation of strategies shown (listed as Goal, Objective, Strategy).

North Carolina Advisory Committee on Cancer Coordination and Control-Evaluation Subcommittee: 1.1.1, 1.1.2, 1.1.3, 1.2.1, 1.2.2, 1.3.1, 1.3.2, 1.5.1, 1.5.2, 1.5.3, 1.5.4, 2.1.1

North Carolina Central Cancer Registry: 1.5.1, 1.5.2, 1.5.4, 2.1.1

State Center for Health Statistics: 1.3.2, 2.1.1