Nov 30

Breast Cancer poll

- platform + voter guide reins
- Tuesday issue voter guide
- radio PSAs TV PSAs
  grassroots

vote breast cancer theme

CDC treatment bill remains our priority - to get into the budget 315 billion over 5

- 273 cosponsors in hs - Lazio-Eshoo bill in the house
- 54 in senate

- What can we do together to make this happen?
- on will the interest is the admin?
- we have been able to get beyond issues by setting a precedent

Everyone touts screening - pgms, but then they don't have no $ for treatment - make existing pgms include. dem govs support + would like to see Red Cty. Reps. have some state-level support

---

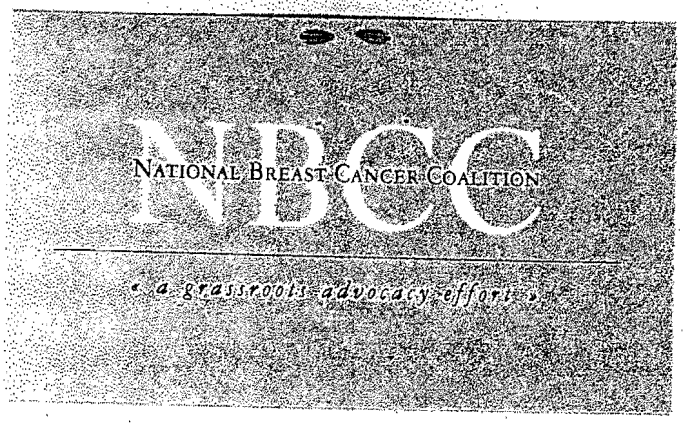
Answer the argument - why bc is different?
- complex disease - w many parts
* does not address bc -

Chris says we will support it (w/o $)

NATIONAL BREAST CANCER COALITION

« a grassroots advocacy effort »

1707 L Street, NW, Suite 1060
Washington, DC 20036

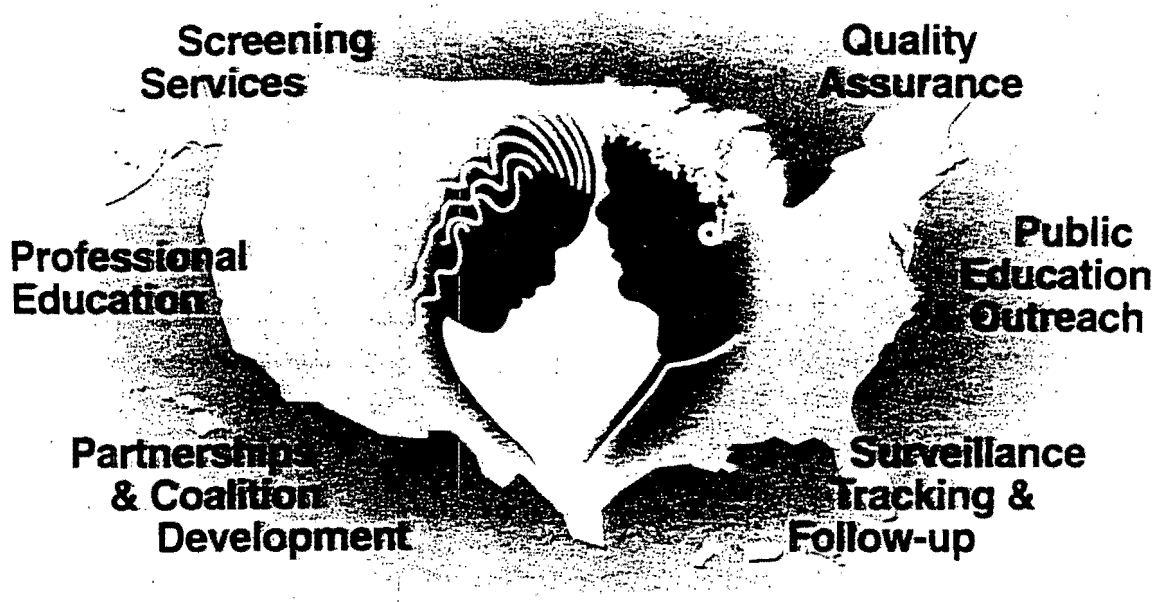


Jennifer L. Katz
Manager, Government Relations
National Breast Cancer Coalition

1707 L Street, NW, Suite 1060
Washington, DC 20036
phone: (202) 296-7477
direct line: (202) 973-0595
fax: (202) 265-6854
e-mail: jkatz@natlbcc.org

The National Breast and Cervical Cancer Early Detection Program

AT-A-GLANCE
1999



"Over 1.2 million women have taken advantage of services provided through CDC's National Breast and Cervical Cancer Early Detection Program. Less than a decade old, this program now operates in every state in the country, providing recommended screening to low-income women. Yet we are still only able to reach 15% of the eligible population. As a nation, we must step up our commitment to reaching all women."

Jeffrey P. Koplan, MD, MPH
Director, Centers for Disease Control and Prevention

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Breast and Cervical Cancer Screening: Preventing Unnecessary Deaths Among Women

An estimated 2 million American women will be diagnosed with breast or cervical cancer in this decade, and half a million women will lose their lives to these diseases. A disproportionate number of deaths will be among women of minority and low-income groups.

Many of these deaths could be avoided by making screening services available to all women at risk. Such screening measures could prevent approximately 15%–30% of all deaths from breast cancer among women over the age of 40 and virtually all deaths from cervical cancer.

Excluding skin cancer, breast cancer is the most common cancer among American women and is second only to lung cancer as a cause of cancer-related death. An estimated 175,000 new cases of breast cancer among women will be diagnosed in 1999, and 43,300 women will die of this disease.

The incidence of invasive cervical cancer has decreased significantly over the last 40 years, in large part because of early detection efforts. Even so, an estimated 12,800 new cases of invasive cervical cancer will be diagnosed in 1999, and 4,800 women will die of this disease.

In most cases, the earlier breast cancer is detected, the better the survival rate. When breast cancer is diagnosed at a local stage, the 5-year survival rate is 97%. When breast cancer is diagnosed after it has spread, the 5-year survival rate decreases to 21%.

Benefits of Screening

Mammography is the best way to detect breast cancer in its earliest, most treatable stage—an average of 1.7 years before the woman can feel the lump. Mammography also locates cancers too small to be felt during a clinical breast examination.

The primary purpose of **cervical cancer screening**—which is performed by the Papanicolaou (Pap) test—is not to detect cancer but to find precancerous lesions. Detection and treatment of such lesions can actually prevent cervical cancer.

Cervical cancer screening also offers great benefits. For a woman found to have precancerous cervical lesions or to have cancer in its earliest stage, the likelihood of survival is almost 100% with timely and appropriate treatment and follow-up.

CDC's National Breast and Cervical Cancer Early Detection Program

Recognizing the value of screening and early detection, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990. This act authorized CDC to provide critical breast and cervical cancer screening services to underserved women, including older women, women with low incomes, and women of racial and ethnic minority groups.

Through its landmark National Breast and Cervical Cancer Early Detection Program (NBCCEDP), CDC now supports screening activities in all 50 states, in 5 U.S. territories, in the District of Columbia, and through 15 American Indian/Alaska Native organizations. By October 1997, more than 1.5 million screening tests had been provided by the NBCCEDP.

Fiscal year 1999 appropriations of approximately $158 million enable CDC to establish greater access to screening and follow-up services, increase education and outreach programs for women and health care providers, and improve quality assurance measures for screening. Despite its success in screening more than a million women, with existing resources the NBCCEDP is able to screen only 12%–15% of the eligible population for these two cancers.

The legislation for NBCCEDP does not authorize CDC to pay for treating breast and cervical cancer. However, participating state programs have been determined and creative in ensuring that treatment services are available for women diagnosed with breast cancer or cervical abnormalities. The availability of treatment sources reflects the extent of state and local government support, the generosity of medical providers, and the commitment of communities.

Screening alone is not sufficient to prevent unnecessary illness and death. Essential technical and scientific underpinnings must be in place at the national level to support state-based programs. CDC collaborates with state health agencies, professional and voluntary organizations, academia, and other federal agencies to ensure that the following elements are in place to serve as resources for states:

- Quality assurance.
- Program tracking and evaluation.
- Professional education.
- Public education and outreach.

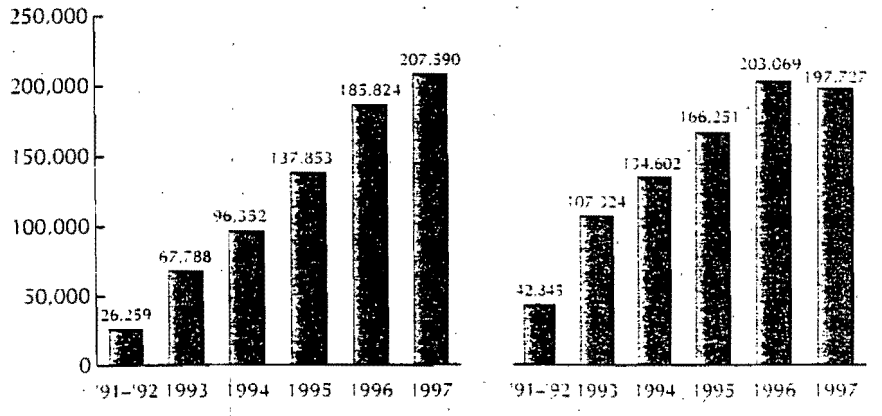
Ensuring Quality Screening and Follow-Up Services for Women

Quality assurance is essential if screening for early detection is to be an effective tool for controlling cancer. To help ensure the quality of the screening and follow-up process, CDC has collaborated with the American College of Radiology to improve and certify the quality of mammography screening, developed guidelines on the evaluation of common breast problems, used program data to monitor health outcomes, and issued recommendations on a public health response to the regulatory closure of cervical cytology laboratories. In addition, CDC provides screening and diagnostic guidelines to all state-based programs and assists states in evaluating their clinical services.

CDC recently evaluated how early detection programs in seven participating states (California, Michigan, Minnesota, New Mexico, New York, North Carolina, and Texas) developed strategies to obtain resources not only for diagnostic services, for which the NBCCEDP provides funding, but also for treatment services, which the NBCCEDP requires participating states to provide but cannot (by law) reimburse. Results of the study indicate that treatment had been initiated for almost all NBCCEDP clients in whom cancer was diagnosed. However, the programs pointed out that the approaches used to obtain these services were short-term, labor-intensive solutions that diverted resources away from screening activities.

As more women are screened by the NBCCEDP, participating health agencies and providers will experience greater challenges in obtaining sufficient resources for treating women with breast and cervical cancer. CDC has expanded its case management services to help women overcome financial, logistical, and other barriers to these services. However, more formalized and sustained mechanisms need to be instituted to ensure that all women screened have ready access to appropriate treatment and follow-up.

Number of Screening Examinations Among NBCCEDP* Participants, FY 1991–1997



Mammograms
Total = 721,666

Papanicolaou tests
Total = 851,818

Total examinations = 1,573,484

*CDC'S National Breast and Cervical Cancer Early Detection Program.

Tracking Program Outcomes

To better target critical screening activities, CDC works with states to collect critical information to monitor program progress in reaching women and detecting cancer. Since its inception, the NBCCEDP has

- **Provided over 700,000 mammograms to women.**

  Of this number, over 48,000 were abnormal, and over 3,600 cases of breast cancer were diagnosed.

- **Provided over 850,000 Pap tests.**

  Of these, over 25,000 were abnormal, and over 26,000 cases of precancerous lesions were diagnosed. Over 400 cases of invasive cervical cancer were diagnosed.

CDC also provides and tracks diagnostic evaluations for women who have had abnormal results through screening initiated by providers not involved with the NBCCEDP.

Public Education and Outreach: Eliminating Barriers to Screening

CDC collaborates with health care professionals and organizations, human service and voluntary organizations, academia, and health agencies participating in the program to address barriers to screening.

National Collaboration

Examples of CDC collaboration with national organizations include the following:

- CDC collaborates with the **American Cancer Society** (ACS) to develop and disseminate comprehensive information on cancer prevention and early detection. Through CDC, ACS divisions have formed partnerships with state health departments to increase screening services to medically underserved women. CDC and ACS collaborate in many programmatic areas, including establishing program infrastructure and public and professional education activities.
- A unique public-private partnership was established among CDC, **Avon Products Inc.**, the **YWCA of the U.S.A.**, the **National Alliance of Breast Cancer Organizations** (NABCO), and the **National Cancer Institute**. Avon's Breast Cancer Awareness Crusade has raised more than $25 million for breast cancer programs nationwide through the sale of its Breast Cancer Awareness pink ribbon products. Since 1993, about 300 community-based programs in 49 states and Puerto Rico have received funding from Avon's program through the YWCA of the U.S.A. and NABCO to educate women about breast cancer and to provide underserved women with access to early detection services. Beginning in 1998, all funding of community-based programs was consolidated under the Breast Health Access Fund administered by NABCO.

Barriers to Screening

Fear. Women may be afraid to discover that they have cancer.

Cost. Many women cite cost as the reason they do not use early detection programs. Many are not aware of the availability of low-cost programs.

Lack of Transportation. For many women who lack transportation, convenient location of screening facilities is important.

Communication Barriers. Communication styles and methods appropriate for one group may be inappropriate for another.

Lack of Physician Referral. Studies have shown that women are more likely to be screened if their physician recommends screening.

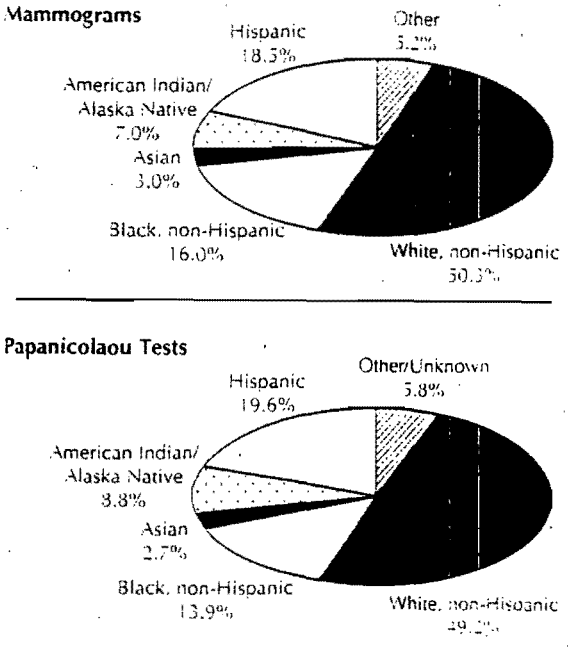
Lack of Child Care. Some women need assistance with arranging child care to be able to use screening services.

States Take Action to Educate Women

With CDC's leadership, state-based programs have made significant progress in building state and community partnerships to reach women about the benefits of screening and early detection. Various outreach activities have been designed to educate women and motivate them to be screened. For example,

- **New Jersey**'s state health department is collaborating with the University of Medicine and Dentistry of New Jersey and the YWCA to reduce screening barriers by offering educational outreach and access to screening. Program staff make monthly visits to senior housing complexes and other settings where women congregate (e.g., beauty parlors and supermarkets) to present an educational program designed for minority women aged 50 and older and to schedule appointments for screening in a mobile mammography unit that comes to the site 2 weeks later.
- **Arkansas**' "Hats Off to Health" is a light-hearted but informative skit in which characters confront reasons women often give for not having breast cancer screening. Over 600 women have attended the program; surveys found that this nonthreatening approach to breast cancer screening education was effective in reducing perceived barriers to mammography.
- **Massachusetts**' Breast and Cervical Cancer Initiative has established partnerships with a variety of community agencies already active in conducting outreach in racial and ethnic minority communities. Using a health circle model, groups meet in spaces that are familiar, accessible, and comfortable (e.g., homes, churches, and local agencies such as immigration offices). The health circle model has proved especially successful in promoting screening among older Southeast Asian women.
- **Washington, D.C.**'s breast and cervical cancer program has recruited a woman minister to work with Project WISH to raise breast health awareness in the faith community. Over 20 activities have been implemented, including the hosting of prayer breakfasts, workshops and forums, and pink ribbon teas; the distribution of literature and pink ribbons; and the publication of announcements in religious bulletins. In addition, on Sundays activities focusing on screening awareness have been conducted with testimonies from survivors and educational talks on breast health.
- The **Cherokee Nation of Oklahoma** has developed an educational video on the importance of breast self-examination for American Indian women. Funded through the Avon Breast Health Access Fund, the video highlights three American Indian cancer survivors advocating for early detection through breast self-examination.

Percent Distribution of Screening Examinations Among NBCCEDP* Participants, by Race/Ethnicity, FY 1991–1997



*CDC's National Breast and Cervical Cancer Early Detection Program.

Partnerships for Cancer Control in Populations at Higher Risk

Partnerships that focus their prevention efforts on those at greater risk are essential for understanding and alleviating disparities. Both mammography and Pap tests are underused by women who are members of racial and ethnic minority groups, have less than a high school education, are older, or live below the poverty level.

CDC funds a strong and effective network of partners that are well-positioned in communities at risk. These partners have developed projects that are focused on underserved populations and cover a wide range of public and professional education interventions. For example, many projects are involved with developing low-literacy, bilingual, and culturally appropriate educational materials that are used in diverse training and outreach programs and educational campaigns. The various interventions used by the different projects result in the common goal of increasing access to and use of screening services for priority populations.

Professional Education: Enhancing Health Care at the Source

Professional education is designed to enhance the quality of care that women receive. Through education, the NBCCEDP has assisted a wide range of health care professionals—including physicians, nurses, radiology technologists, and cytologists—to better understand their key roles in the early detection of breast and cervical cancer.

In 1998, CDC's National Training Center provided two training programs and one self-study informational packet for health professionals. For 1999, CDC is developing a self-study packet on follow-up of abnormal findings from clinical breast examinations and mammograms and a workshop and self-study packet on evaluation-based work plans that will assist personnel in state and local health agencies and tribal organizations.

CDC funds the following partners to promote screening among populations at higher risk:

- American Social Health Association
- Association of Asian Pacific Community Health Organizations
- Baylor College of Medicine: Salud en Accion Program
- Institute for the Advancement of Social Work Research
- Mautner Project for Lesbians with Cancer
- National Asian Women's Health Organization
- National Association of Community Health Centers
- National Caucus and Center on Black Aged, Inc.
- National Center for Farmworkers Health, Inc.
- National Education Association Health Information Network
- National Hispanic Council on Aging
- U.S. Conference of Mayors' Research and Education Foundation
- The Witness Project
- World Education

For more information or additional copies of this document, please contact the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Mail Stop K–64, 4770 Buford Highway NE, Atlanta, GA 30341–3717, (770) 488-4751. Voice Information System: 1 (888) 842-6355 Fax: (770) 488-4760 cancerinfo@cdc.gov http://www.cdc.gov/cancer

Follow-Up and Treatment Issues in the National Breast and Cervical Cancer Early Detection Program

Study Results
January, 1998

Acknowledgments

- Funding for this study was from the Centers for Disease Control and Prevention, Division of Cancer Prevention and Control
- The study was designed and implemented by a team of investigators from Battelle Centers for Public Health Research and Evaluation and the University of Michigan School of Public Health

Research Team

Battelle Centers for Public Health Research and Evaluation:

Lowell Sever, Ph.D.
Martha Hare, Ph.D.
Carlyn Orians, M.A.
Jane Schulman, Ph.D.

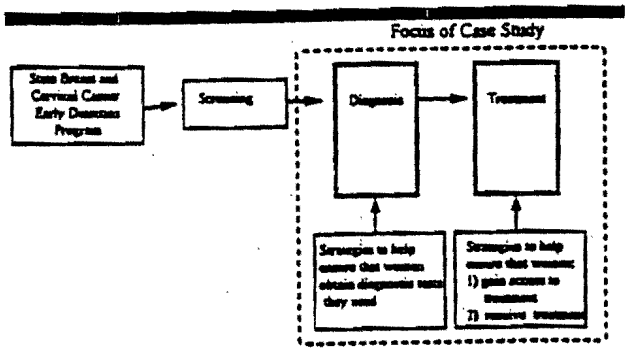
University of Michigan School of Public Health:

Paula Lantz, Ph.D.
Lisa Richardson, M.D., M.P.H.
Deb Mackiem, M.Ed.

Goals of the Study

- To document strategies and methods used by states to obtain follow-up diagnostic services not covered by NBCCEDP funds.
- To document strategies and methods used by states to obtain treatment services for clients diagnosed with CIN or cancer.
- To identify strategies that are perceived as successful or innovative in securing diagnostic and treatment resources.

Flow of Follow-Up and Treatment Activities



Research Questions

- What guidelines, policies or methods have been developed and implemented by states to ensure that women with abnormal screening results and women diagnosed with cancer or precancerous lesions receive diagnostic follow-up and treatment services?
- How is the component of the program that identifies and secures diagnostic and treatment services organized?
- What role do coalitions or other partnerships play?

Research Questions

- Have the methods or tactics being used to identify and secure diagnostic and treatment resources changed with time, and do they differ within the individual state programs or across programs?
- What are the key lessons learned regarding diagnostic and treatment services in a program such as the NBCCEDP?

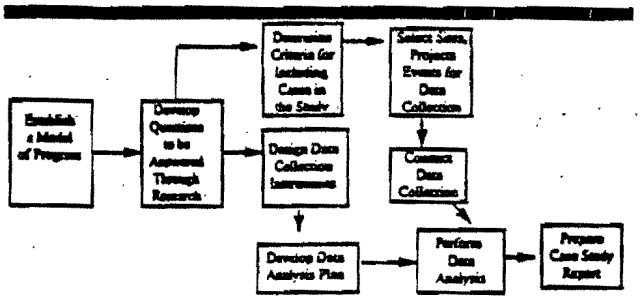
Phases of the Study

- Phase I: Core set of data on 35 programs
- Phase II: In-depth case study of 7 states
- Phase III: Linkage study (in process)—Tumor registry data and program data from 3 states (CA, MI, NM) were linked to document timing of treatment initiation and initial course of cancer treatment

What is a Case Study?

- A case study seeks to understand the way in which a program, system, or organization works within its everyday setting
  - » It focuses on a particular problem, issue, or structure which is studied in relationship to the larger program, system, or organization
- While describing this relationship, the case study may or may not lead to conclusions about outcomes
- A case study uses all appropriate sources of evidence – written, observational, and interview – that may be analyzed both qualitatively and quantitatively

Conducting a Case Study



Case Study Selection Criteria

- Provided screening for at least three years
- Diagnosed 60 or more breast cancers since screening began
- Representative of the following stratification criteria:
  - » Centralized versus decentralized programs
  - » Geographic region of United States
  - » Urban/rural mix of the population
  - » Racial and ethnic diversity among program clients

Case Study States

State	Number of Breast Cancers Diagnosed	Region
California	168	West
Michigan	249	Midwest
Minnesota	137	Midwest
New Mexico	169	West
New York	173	Northeast
North Carolina	106	South
Texas	307	South

How Did We Conduct the Case Study?

- Contacted the coordinator for each of the seven programs to schedule site visits, and to obtain background information
- Reviewed documents supplied to us by the state program, such as organizational tables, reports and articles
- Traveled to each state and briefed state BCCEDP staff regarding the project at the beginning of each state's site visit

How Did We Conduct the Case Study?

- Interviewed State BCCEDP Coordinator and other staff who work with diagnosis and treatment issues
- Interviewed local coordinators and providers in a variety of settings throughout the state
- Interviews were tape recorded, transcribed, and entered into a word processing database

How Did We Analyze the Data and Write the Case Study State Summaries?

- The Project PI and the Case Study Coordinator developed a codebook based on the research questions in the Case Study Protocol
- Using the codebook, the PI and Coordinator worked together to achieve 80% inter-rater agreement on the use of codes for text, and then trained one other team member
- All interviews were coded and entered into a text analysis software

How Did We Analyze the Data and Write the Case Study State Summaries?

- Using the analyzed transcripts, a member of the site visit team developed a state summary
- Each member of the site visit team reviewed the state summary
- The summary was then sent to state program staff and other interviewees for review
- Reviewer feedback was incorporated into a revised state summary

Case Study Results

- Site visits were conducted February-June, 1997
- A total of 126 interviews were conducted
- A total of 192 people were interviewed

Number of Interviews by State and Role

	TOTAL	CA	MI	MN	NM	NY	NC	TX
State staff	58	13	4	11	4	9	10	7
Local staff	15	2	2	2	4	4	-	1
Screening provider	60	3	6	8	5	7	23	8
Dx or Tx provider	45	7	4	9	3	3	13	6
Advisory Board\ Coalition member	10	2	-	1	3	1	2	1
Other	4	-	-	1	2	-	1	-
TOTAL	192	27	16	32	21	24	49	23

Strategies Used to Ensure Provision of Diagnostic and Treatment Services

Common Approaches at the State Level:

- Clients followed through use of tracking and follow-up systems
- Requirements in contracts with providers
- Appeals to providers through state medical societies, professional associations, etc.

Strategies Used to Ensure Provision of Diagnostic and Treatment Services

Common Approaches at the Local Level:

- Bill insurance
- Assist clients in applying for Medicaid, Hill Burton funds, other assistance programs
- Referral to public hospital
- Charity care, donated services
- Case rotation
- Reduced fees
- Negotiated payment plans
- Clients pay fee for service

Additional Strategies Used by States

• Blue Cross Foundation treatment fund	CA*
• Race for the Cure fund	MN*
• State breast cancer programs	NY*
• Other state funds	TX*, NC
• Tobacco excise tax fund	CA*, MI
• Providers of last resort	NM, TX
• County indigent funds	NM, TX

* funds used for breast services only

General Findings Across States

- States have found supplemental funds (primarily for breast cancer diagnostic services)
- Women diagnosed with cancer who want to be treated are receiving treatment
- Strong reliance on providers to find resources
- Follow-up handled on case-by-case basis

General Findings Across States

- Solutions, strategies and networks are tenuous and fragile
- Programs operate within changing health care environments (i.e. growth of managed care)
- Information lacking for many important issues:
  - payment source for diagnostic and treatment services
  - out-of-pocket expenses for women
  - impact of financial barriers on time delays/refusals

Strengths

- Women who need and want cancer treatment are receiving it
- Creative responses and strong partnerships have emerged at state, local and provider level
- Availability of state or foundation funds to supplement Federal resources

Strengths

- Centralized tracking systems work well
- Program has had positive effect on tracking and follow-up in larger community

Areas of Concern

- Lack of financial support for diagnosis and treatment
- Time and energy required for follow-up is tremendous
- Burden of follow-up has led to restrictions in number of women screened
- Several barriers to provider recruitment:
  - low reimbursement rates (mandated by Congress)
  - lack of coverage for all diagnostic follow-up services
  - liability for treatment
  - administrative burden of follow-up

Areas of Concerns

- Some women experience time delays or are lost to follow-up (especially in regard to cervical services)
- A small number of women have refused cancer treatment
- Coordinating diagnostic follow-up is greater burden than arranging treatment
- Resources states have developed are short-term solutions, and difficult to manage/administer

Areas of Concern

- Categorical nature of program prohibits a more comprehensive approach to women's health
- Financial access is only one dimension of access to health care services. Many non-financial barriers impede follow-up care:
  - logistical barriers (e.g. transportation, scheduling)
  - cultural barriers (e.g. language barriers, fatalistic attitudes, fear)
  - immigration issues

Respondent Recommendations

- Program should pay for all diagnostic and treatment services, or at least through definitive diagnosis
- Allow state resources used for all diagnosis and treatment services to be counted in the 3:1 match
- Cover anesthesia and other affiliated services
- Increase reimbursement rate for services covered
- Increase support for case management and community infrastructure
- Universal health insurance

Conclusions of Case Study

- Strong response to provision of diagnostic follow-up and treatment services has emerged
- Wide range of strategies is employed within states; effort at local level is tremendous
- Responses that have emerged are administratively cumbersome and unstable; long-term solutions are needed
- Strong commitment to continued growth and success of the NBCCEDP exists at state and local level

Linkage Study – Research Questions

- What proportion of women identified through selected states' BCCEDPs as having breast or cervical cancer did not receive an initial course of treatment, based on registry records?
  - » What characteristics of women and their cancers are associated with not receiving treatment?

Linkage Study – Research Questions

- What are the components (surgery, radiation, chemotherapy, hormonal therapy) of the initial course of cancer treatment for women identified through the BCCEDPs as having breast or cervical cancer?
  - » What characteristics of women and of their cancers are associated with the content of the initial course of treatment?

Linkage Study – Research Questions

- What is the time interval between abnormal screening and diagnosis?
- What is the time interval between diagnosis and treatment?
  - » What characteristics of women and their cancers appear to be related to these time intervals?

Linkage Study – Research Questions

- How does the information from the program database compare with the corresponding information from the cancer registry database?
- How do women screened through the program compare with all women in the registry with regard to patterns of diagnosis and treatment?

CDC

March 27, 1998 / Vol. 47 / No. 11

MMWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

Imported Dracunculiasis — United States, 1995 and 1997

Dracunculiasis is a parasitic infection caused by a filarial worm (*Dracunculus medinensis* [i.e., Guinea worm]) that is transmitted through contaminated drinking water. Approximately 1 year after a person is infected, one or more meter-long adult female worms begin to emerge through the skin, often incapacitating the patient for ≥2 months. Despite a dramatic decrease in cases worldwide, dracunculiasis is still occasionally imported into the United States. Since 1995, two cases of dracunculiasis have been reported in the United States, both imported from Sudan. This report summarizes the investigation of these cases.

Patient 1. A 9-year-old girl residing in Tennessee had emigrated from Sudan in September 1995 (*1*). Before the girl left Sudan, a Guinea worm had emerged and had been extracted from her right lower leg. The lesion had healed when she arrived in the United States. After she had been in the United States for 3 weeks, another Guinea worm began to emerge from her left leg. Medical examination at a local health clinic revealed a string-like worm dangling from a lesion on her left leg, and she was referred to an infectious disease specialist. The leg was secondarily infected and swollen, and the girl was unable to walk. Despite antibiotic treatment, her cellulitis did not improve, and the lesion was surgically opened, drained, and debrided of pus, necrotic debris, and fragments of the Guinea worm. The patient was hospitalized for 2 weeks, requiring surgery to stretch a contracture of her ankle and to apply a skin graft to the wound. After outpatient physical therapy, she was able to walk without crutches.

Patient 2. A 31-year-old woman residing in Connecticut had emigrated from Sudan in January 1997. In April 1997, she was evaluated at a university clinic for possible tuberculosis (TB). A radiograph revealed lung lesions consistent with TB and a worm-like calcification in her left chest. Physical examination revealed multiple, indurated, oval lesions 4–8 cm in diameter on both lower legs. The patient reported the lesions had been present for 1 year and were intermittently painful. She recalled that a long string-like worm had emerged from her leg during the previous year. Biopsy of the leg lesions revealed erythema induratum, consistent with Bazin disease, a cutaneous manifestation of TB. The patient had evidence of a dead and calcified Guinea worm in her chest and a history suggesting a live Guinea worm had emerged from her leg before she arrived in the United States. She also had pulmonary TB with a cutaneous tuberculid skin manifestation. Treatment with isoniazid, rifampin, and pyrazinomide

HIV Counseling and Testing — Continued

ing that persons who receive preliminary results understand the meaning of the result and prefer rapid testing (*4*). When additional rapid tests become available for use in the United States, the PHS will re-evaluate algorithms using specific combinations of two or more rapid tests for screening and confirming HIV infection.

References

1. Kamb ML, Bolan G, Zenilman J, et al. Does HIV/STD prevention counseling work? Results from a multi-center randomized trial (Project Respect) [Abstract 0134] In: Program and abstracts of the International Congress of Sexually Transmitted Diseases. Seville, Spain: Association for Research in Clinical Microbiology, 1997:83.
2. CDC. HIV counseling and testing in publicly funded sites: 1995 summary report. Atlanta: US Department of Health and Human Services, CDC, September 1997.
3. George JR, Schochetman G. Detection of HIV infection using serologic techniques in AIDS testing: a comprehensive guide to technical, medical, social, legal, and management issues. 2nd ed. Schochetman G, George JR, eds. New York: Springer-Verlag, 1994.
4. Kassler WJ, Dillon BA, Haley C, Jones WK, Goldman A. On-site, rapid HIV testing with same-day results and counseling. AIDS 1997;11:1045–51.
5. CDC. Interpretation and use of the Western blot assay for serodiagnosis of human immunodeficiency virus type 1 infections. MMWR 1989;38(suppl 7):S4–S6.
6. Stetler HC, Granade TC, Nuñez CA, et al. Field evaluation of rapid HIV serologic tests for screening and confirming HIV-1 infection in Honduras. AIDS 1997;11:369–75.
7. Kassler WJ, Haley C, Jones WK, Gerber AR, Kennedy EJ, George JR. Performance of a rapid, on-site human immunodeficiency virus antibody assay in a public health setting. J Clin Microbiol 1995;33:2899–902.

Strategies for Providing Follow-Up and Treatment Services in the National Breast and Cervical Cancer Early Detection Program — United States, 1997

The Breast and Cervical Cancer Mortality Prevention Act of 1990* authorized CDC to establish the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) to increase screening services for women at low income levels who are uninsured or underinsured (*1*). Although the NBCCEDP covers most diagnostic services that women need after receiving an abnormal mammography or Papanicolaou (Pap) test result, the program does not reimburse for breast biopsies. In addition, the Act prohibits the use of NBCCEDP funds for cancer treatment. Participating health agencies must ensure that NBCCEDP clients receive timely, appropriate diagnostic and treatment services. In 1996, CDC began a case study to determine how early detection programs in seven participating states (California, Michigan, Minnesota, New Mexico, New York, North Carolina, and Texas) identified resources and obtained diagnostic and treatment services. This report summarizes the results of the study (*2*), which indicate that respondents in these states reported that treatment had been initiated for almost all NBCCEDP clients in whom cancer was diagnosed. However, respondents also considered the strategies used to obtain these services as short-term solutions that were labor-intensive and diverted resources away from screening activities.

In the seven states, NBCCEDP-sponsored screening services had been provided for ≥3 years, and breast cancer had been diagnosed in ≥60 women. The states were se-

*Public Law 101-354.

National Breast and Cervical Cancer Early Detection Program — Continued

lected to provide a range of geographic locations, a combination of urban and rural populations, and racial/ethnic diversity among program clients. Researchers conducted semi-structured interviews with 192 persons affiliated with the seven state programs. Of these interviewees, 120 (63%) were providers of screening, diagnostic, and/or treatment services; 58 (30%) were state program staff; and 14 (7%) were coalition members. Interviews included topics such as guidelines related to diagnostic and treatment services, strategies used to obtain and pay for services, level of effort required to secure these services, and changes in strategies over time. Each interview was tape recorded and transcribed. Using a systematic scheme derived from the research questions, three researchers coded the same transcripts until an inter-rater agreement of 80% was reached. Thereafter, all transcripts were coded independently. Coding results were entered into text analysis software that sorts text from transcripts into sets of information, themes, and evidence relevant to the specific research questions (*3*). The results reflect a synthesis of the interviewees' responses.

Respondents described several strategies used to ensure necessary diagnostic and treatment services for women screened through the NBCCEDP. State-level strategies in all states included 1) computerized tracking and follow-up systems that used program surveillance data to identify and manage clients in need of diagnostic and treatment services; 2) provisions in contracts requiring screening providers to arrange for diagnostic follow-up and treatment before screening women; and 3) arrangements with provider groups and state professional associations for free or reduced-cost services for NBCCEDP clients. All states also had access to public or private funds to help support services not covered by the program; such revenue sources included state appropriations from general or tobacco tax revenues or funds from private foundations. These funds were available primarily for breast diagnostic services.

Local strategies tailored to the needs of individual clients were used to obtain diagnostic and treatment services. Common strategies reported by respondents included the following: providers billed public or private insurance plans; providers or local health departments helped clients apply for public assistance programs; providers referred clients to public hospitals; county indigent-care funds and hospital community-benefit programs financed services; clients received services through individually negotiated payment plans; and clients paid reduced or full fees for services.

Respondents strongly supported the continued growth of NBCCEDP and its goals but expressed several concerns. First, considerable time and effort were involved in developing and maintaining systems for diagnostic follow-up and treatment. Second, the process of identifying available resources within states for diagnostic and treatment services was considered labor-intensive. Third, the lack of coverage for diagnostic and treatment services negatively affected recruitment of providers and restricted the number of women screened. Fourth, respondents believed that an increasing number of physicians will not have the autonomy, because of changes in the health-care system, to offer free or reduced-fee services to NBCCEDP clients.

Respondents reported that arrangements for treatment were made for almost all NBCCEDP clients who received a diagnosis of breast cancer or invasive cervical cancer. Respondents stated that some women experienced time delays between screening, definitive diagnosis, and initiation of treatment. State program officials reported that, according to 1992–1996 surveillance data, small numbers of clients in whom cancer was diagnosed (i.e., from three to 13 women in each state) subsequently refused

National Breast and Cervical Cancer Early Detection Program — Continued

treatment. Because these clients were not interviewed, it could not be determined whether financial barriers contributed to their decisions to refuse treatment or their loss to follow-up.

Respondents were concerned that the NBCCEDP did not provide funding for all diagnostic procedures and treatment for the diseases for which clients were being screened; approaches for delivering services were fragmented; and the process of obtaining resources required substantial effort at the state, local, and provider levels. Respondents reported that the continuation of every strategy for diagnostic and treatment services beyond the next few years is uncertain.

Reported by: PM Lantz, PhD, Univ of Michigan School of Public Health, Ann Arbor. LE Sever, PhD, Battelle, Centers for Public Health Research and Evaluation, Seattle, Washington. Program Svcs Br, Office of the Director, Div of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, CDC.

Editorial Note: During July 1991–March 1997, the NBCCEDP provided 576,408 mammograms to women aged ≥40 years, and 3409 cases of breast cancer were diagnosed. During this same period, the program provided 732,754 Pap tests; 23,782 cases of cervical intraepithelial neoplasia and 303 cases of invasive cervical cancer were diagnosed. These totals included women referred to the program for diagnostic evaluation of an abnormal screening result. The NBCCEDP internal estimates suggested that during this period only 12%–15% of uninsured women aged 40–64 years in the United States had been screened by the program (CDC, unpublished data, 1997).

Screening alone does not prevent cancer deaths; it must be coupled with timely and appropriate diagnostic and treatment services. The Congressional mandate for NBCCEDP requires grantees to take all appropriate measures to ensure provision of services required by women who have abnormal screening results. CDC provides funds for case management to help these women access health-care services. To increase the comprehensive nature of the program, CDC recently approved the use of NBCCEDP funds for breast biopsies.

The results of this study indicate that state health departments and their partners in the seven states had developed a wide range of strategies for diagnostic and treatment services in the absence of program resources. However, the time and effort required to arrange and maintain these services diverted resources away from screening activities.

This study was subject to at least two limitations. First, the results were based solely on the experience and opinions of informed professionals affiliated with the program and did not include the perspectives of NBCCEDP clients. Second, the results may not reflect the program experiences in other states. Case-study methods, however, are an appropriate and well-accepted approach to gaining in-depth understanding of complex programs in real-life situations (*4*). The validity of the findings was enhanced by developing standard instruments to guide the semi-structured interviews, protecting the confidentiality of respondents' remarks, using interview transcripts for data analysis rather than relying on interviewer notes, and obtaining feedback concerning state summary reports from respondents.

As more women are screened by the NBCCEDP, a greater burden will be placed on participating health agencies, providers, and other partners to obtain resources for breast and cervical cancer treatment. Case-management services will continue to be essential in helping underserved women overcome financial, logistical, and other bar-

National Breast and Cervical Cancer Early Detection Program — Continued

riers to receiving these services. Other long-term solutions to ensure that women in the program receive necessary treatment services are being pursued.

References

1. Henson RM, Wyatt SW, Lee NC. The National Breast and Cervical Cancer Early Detection Program: a comprehensive public health response to major health issues for women. J Public Health Management and Practice 1996;2:36–47.
2. Lantz PM, Macklem DJ, Hare M, Richardson LC, Sever LE, Orians CE. Follow-up and treatment issues in the National Breast and Cervical Cancer Early Detection Program: results from a multiple-site case study—final report. Baltimore: Battelle, Centers for Public Health Research and Evaluation, 1997.
3. Miles MB, Huberman MA. Qualitative data analysis: an expanded sourcebook. 2nd ed. Thousand Oaks, California: Sage, 1994.
4. Yin RK. Case study research: design and methods. Sage: Newbury Park, 1989.

Notice to Readers

World Health Day — April 7, 1998

"Invest in the Future: Support Safe Motherhood" is the theme in the United States for World Health Day, April 7, 1998. In the United States, this day will focus on the continued importance of maternal health and opportunities to improve this aspect of women's health. Although the risk for women dying from pregnancy has decreased substantially during the past 50 years, the maternal mortality ratio for the nation has not decreased since 1982 (*1*). Approximately 50% of pregnancy-related deaths remain preventable (*2*), and the extent of morbidity associated with pregnancy is often unrecognized.

Safe motherhood begins before pregnancy with healthy lifestyles that include good nutrition, physical activity, preconception care, and avoidance of harmful substances. Safe motherhood continues with planned pregnancies; early, quality prenatal care; knowledge of warning signs of problems; and the delivery of a healthy, full-term baby with the minimum of necessary interventions. Postpartum support for women and their families in a positive, nurturing environment also is important.

In 1998, in the United States, women can plan, carry, and deliver a pregnancy more safely than in the past. However, additional efforts need to be taken to make safe motherhood a reality for all women. Improved public health surveillance, prevention research, and prevention programs are needed to continue improving the health of women before, during, and after pregnancy and delivery. Examples include new surveillance methods to monitor and understand pregnancy complications; prevention research on the essential content of prenatal care; and prevention programs to ensure the adequate intake of folic acid by women of reproductive age to prevent neural tube defects (*3*).

The World Health Day Advisory Committee of the American Association for World Health coordinates World Health Day activities in the United States. Additional information about special events and resource materials about World Health Day 1998 are available from the American Association for World Health, 1825 K Street, N.W., Suite 1208, Washington, DC 20006; e-mail: AAWHstaff@aol.com; or from the World-Wide Web site: http://www.aawhworldhealth.org.

Mammography or Mammography Referral

sliding scale	200% FPL	250% FPL	other
Florida	Alabama	Alaska	Mississippi (150% FPL)
Kentucky (up to 250% FPL)	Arizona	CNMI	Nebraska (no information)
	Arkansas	Delaware	New Mexico (185% FPL)
	California	D.C.	
	Colorado	Hawaii	
	Connecticut	Indiana	
	Georgia	Maryland	
	Idaho	Massachusetts	
	Illinois	Michigan	
	Iowa	Minnesota	
	Kansas	New Jersey	
	Louisiana	New York	
	Maine	Oregon	
	Missouri	Pennsylvania	
	Montana	Rhode Island	
	Nevada	South Carolina	
	New Hampshire	Utah	
	North Carolina		
	North Dakota		
	Ohio		
	Oklahoma		
	Repub. of Palau		
	South Dakota		
	Tennessee		
	Texas		
	Vermont		
	Virgin Islands		
	Virginia		
	Washington		
	West Virginia		
	Wisconsin		
	Wyoming		

THE CANCER LETTER INTERACTIVE

Vol. 25 No. 29
July 23, 1999

Price $275 Per Year

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Hearing Probes CDC On Cancer Treatment For Working Poor In Screening Program

Welcome to Oncopolitical Theater. In this episode, the players gather in a hearing room of Rayburn House Office Building to discuss a bill that aims to correct a paradox in the U.S. health care system:

The Centers for Disease Control and Prevention pays for breast and cervical cancer screening of low-income women. However, if cancers are found, women who have no insurance and don't qualify for Medicaid are not assured treatment.

Legislation pending in the House and Senate seeks to give additional money to state-run Medicaid programs to cover the care for these women.

(Continued to page 2)

In Brief:

Pazdur To Direct FDA Oncology Division; Ganz Awarded ACS Clinical Professorship

RICHARD PAZDUR has been appointed director of the FDA Division of Oncology Products, effective Sept. 26. Pazdur has been a faculty member at the University of Texas M.D. Anderson Cancer Center for almost 12 years, most recently as professor of medicine in the Division of Medicine and director of the division's educational programs. Pazdur is board certified in internal medicine and oncology. He served for five years as the Associate Director of the Clinical Trials Administration at M.D. Anderson, has been principal investigator on numerous trials, and has been a consultant to FDA. Pazdur received a B.A. from Northwestern University and an M.D. from Loyola Stritch School of Medicine. He trained in internal medicine at Loyola University, and in oncology at Rush Presbyterian-St. Luke's Medical Center, with hematology/oncology training at University of Chicago Medical Center. Pazdur succeeds **Robert Delap**, who directed the oncology division from 1995 to 1998. Delap was promoted to deputy director in the agency's Office of Drug Evaluation V last spring (**The Cancer Letter**, May 29, 1998). **Robert Justice**, deputy director of the division, has served as acting division director since Delap's promotion. **Julie Beitz**, medical team leader, has served as acting deputy director. In the division director's position, Pazdur will report to **Robert Temple**, director of the Office of Drug Evaluation I, and **Rachel Behrman**, deputy director of ODEI. . . . **PATRICIA GANZ**, director of cancer prevention and control research at the Jonsson Cancer Center at University of California, Los Angeles, was awarded an American Cancer Society Clinical Research Professorship. Ganz conducts research on

(Continued to page 8)

Waxman's Lament: "So, What Are We Arguing About?"

(Continued from page 1)

"This is not a large bill," said Rep. Anna Eshoo (D-CA), a co-sponsor of the bill (H.R. 1070) at a hearing July 21. "This is not a bill that's directed toward curing breast and cervical cancer. It doesn't make a gigantic promise to people across the country. I do think that within that context, we need to develop the political will to get this done."

Not so fast! The traditions of oncopolitics require that before anything gets done, all players engage in ferocious wrangling over turf and data.

The first step is to find a brave soul willing to deny that the problem exists—or at least to obfuscate its existence:

"The most current program data indicate that 92 percent of the women diagnosed with breast or cervical cancer have initiated treatment," said Nancy Lee, director of the CDC Division of Cancer Prevention and Control, testifying before the subcommittee.

"The remaining 8 percent refused the treatment, have not yet initiated it, or are lost to follow-up," she said. "For women diagnosed with breast cancer, data show a median of eight days between the cancer diagnosis and initiation of the treatment."

This seemingly neutral bureaucratic statement proved to be a gold mine for members of the Subcommittee on Health and Environment of the House Committee on Commerce.

Do the women who *initiated* treatment complete it? Is the treatment delayed while health officials scramble to provide care? Is the care appropriate?

"We know that 92 percent have initiated treatment; that's all we know," said Lee, responding to a question from Rep. Michael Bilirakis (R-FL), chairman of the subcommittee and a supporter of the bill. "We don't know if it's a full course, [but] they have initiated treatment."

As Bilirakis persisted, Lee responded with a something of primer in elementary statistics and data collection:

"We have information on every woman's diagnosis. Date of diagnosis. Date when treatment initiated. The median is eight days, and there are women in our data set whose treatment was initiated over a year later. They are what we call in statistics, sort of, the end of the curve."

"The median—half of the women—receive their treatment initiation within eight days. That's what 'median' means. But there are women who are very far out. There aren't many of them, or the median wouldn't be eight."

BILIRAKIS: "Well, why are they far out?"

LEE: "For a whole variety of reasons, and we don't have the information in our data set as to why they are far out... I do have a plane to catch to San Diego."

BILIRAKIS: "At what time?"

LEE: "At three-something. And I have a conference call before then."

BILIRAKIS: "We have to vacate this room before two o'clock."

LEE: "Well, everybody is going to eat lunch, too; right?"

The time was just shy of 11 a.m., and Lee's ordeal was to continue for nearly another hour.

The committee's lack of sympathy for CDC could be attributed to heavy lobbying by the National Breast Cancer Coalition, a Washington-based patient advocacy group that made the CDC bill its top legislative priority. In the Senate, the bill is estimated to cost about $315 million over five years. The measure has not been scored in the House.

This is the coalition's third attempt in as many years to push through the legislation. The measure has 263 co-sponsors in the House and 41 in the Senate. On the Health and the Environment

THE CANCER LETTER

Member, Newsletter Publishers Association

World Wide Web: http://www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg

Editorial: 202-362-1809 Fax: 202-362-1681
PO Box 9905, Washington DC 20016
E-mail: kirsten@cancerletter.com or paul@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

Subscription $275 per year worldwide. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc.

Founded Dec. 21, 1973 by Jerry D. Boyd

Subcommittee, the bill has the support of 25 of the 30 members.

Facing a barrage of questions from the panel, Lee acknowledged that the necessity to line up care stresses the screening program.

The program screens only 12 to 15 percent of the eligible population, which means that about 11 million women don't take advantage of breast and cervical screening, Lee said.

"Although states are currently meeting their commitment to help women access treatment, programs have told us of concerns regarding their ability to expand screening services to more women, because the systems for obtaining care and treatment are becoming overburdened," Lee said at the hearing.

"As long as the numbers of cancers diagnosed through the program remain at their current level, the burden should not be too great," she said. "However, increased screening, which is our goal, is accompanied by increased numbers of cancers diagnosed, and many physicians who contract with programs are concerned about bringing more uninsured patients into their care."

This statement, too, proved to be a gold mine for the panel:

"The fact of the matter is that only 15 percent of eligible women are getting screened," said Rep. Henry Waxman (D-CA), a supporter of the bill. "Maybe it's because they don't have assurance that they would have treatment available; and maybe it's because a lot of resources that could be used for screening have been diverted to try to [find] care. Are those factors important?"

LEE: "I think the main factor is the level of our current resources [$158 million during the current fiscal year] that we have to give out to states don't allow more women to get screened."

WAXMAN: "What percentage of the money has to be used to seek out treatment?"

LEE: "We have never quantified that. I can tell you that additional funds we have allocated for case management will augment some case management funds that are there."

WAXMAN: "[Finding] treatment services diverts resources from the program."

LEE: "That's true. We have not quantified what proportion; how much that is, though."

WAXMAN: "And the lack of treatment services negatively affects the recruitment."

LEE: "True."

WAXMAN: "So what are we arguing about?"

Proponents vs. The "Undecided"

The debates at the hearing were marked by a striking absence of *opponents* of the measure. Instead, proponents of the measure crossed swords with the undecided.

The latter camp includes the Administration and the Susan G. Komen Breast Cancer Foundation.

"The only information I have from the Administration is what the CDC testified to this morning," NBCC president Fran Visco said at the hearing. Visco said the coalition is seeking White House endorsement of the measure. "We have had discussions with them, but we don't have an answer," she said. "If the Administration refuses to endorse this bill, NBCC will take it to task. They will hear from members of NBCC."

The position described by the Komen Foundation required textual analysis.

"Contrary to some accounts we have heard, the Komen Foundation is not opposed to this legislation," Susan Braun, president and CEO of the Dallas-based group, said in her written testimony. "We are concerned, however, that any treatment initiative provides a comprehensive and effective solution and reaches those most in need of assistance."

This claim of neutrality notwithstanding, Rep. Rick Lazio (R-NY), the original sponsor of the bill, said his reading of Braun's testimony points to opposition to the measure.

"I am, quite frankly, disappointed in the testimony of the Komen Foundation," Lazio said. "At my request, my staff reached out to them months ago to discuss this legislation and any concerns they may have about the bill. Despite this invitation, they did not bring any concerns to me or my staff, until yesterday, when I read their testimony. Please, don't get me wrong, I am a strong supporter of the Race for the Cure, and I enjoy working closely with Priscilla and Sen. [Connie] Mack [(R-FL)]. But I wanted to register my disappointment over the lack of Komen Foundation's response to my request months ago."

Eshoo, too, said she was having difficulty interpreting Braun's testimony. "I have a difficult time connecting the dots," she said at the hearing.

Indeed, a reading of the Komen testimony submitted for the record is more consistent with opposition than no position on the part of the foundation:

—Komen advocates framing the problem beyond the boundaries of the CDC screening program. "Insured women who have lost their

coverage or have reached a lifetime maximum, particularly those being treated for a recurrence of their breast cancer can be in need," Braun said in her submitted remarks.

—"Need" can be defined as a need for bone marrow transplantation and other experimental procedures. "Women with healthcare coverage, but with a policy that excludes some forms of treatment may also be in need," Braun said.

—Braun said that a study by Komen concurs with the findings by CDC that "treatment was initiated for the vast majority of women" diagnosed through the program. "While imperfect and needing further resources, the system has been providing treatment for most women who need and want it," Braun said.

—Braun's testimony points to a preference for a private sector solution to the problem. "Eight states have legislated breast cancer treatment funds, and local programs also exist," Braun said. "Pro-bono care is provided in many communities. In the case of failure of these funding options, federal assistance may be required."

—Medicaid may be an inappropriate program for addressing the problem, Braun said, citing variability in state Medicaid benefits. "Medicaid participation is optional in the proposed bill," she said. "States with limited funds in their Medicaid programs may be reluctant to cover care for people who would otherwise be ineligible."

Unlike Braun, NBCC's Visco said the problem can be framed narrowly and solved through Medicaid.

"We are not asking you to put every woman who doesn't have insurance on Medicaid," Visco said at the hearing. "We are asking you to enact legislation that completes an existing program. We are asking that women diagnosed through the CDC program be made Medicaid-eligible at the same rate that they have to be eligible to get into the program. If they are eligible for screening, they should be eligible for Medicaid treatment."

If the screening bill is signed into law, NBCC will have to mobilize its grassroots constituencies to force state legislatures to take part in the Medicaid program. While CDC admits to having no data beyond "initiation" of treatment, NBCC has put together a horrifying armamentarium of anecdotal evidence. These include the testimony of Carolyn Tapp, president of Women of Color, a Los Angeles-based support group of about 120 women.

"Some of the women I know took six months to actually start their treatment," Tapp said at the hearing. "I know one woman who was diagnosed; she passed away the very next day after she found out she qualified for treatment. I know women who have used a balloon with water as a prosthesis.

"I know that I loaned many women some of my medication. It costs hundreds of dollars, and they couldn't afford to buy it. So we share."

Physicians, too, have stories to contribute.

"The patients who come through the [CDC program] are six months to a year out when they come to see me," Stanley Klausner, a Long Island breast cancer surgeon, said at the hearing. "Sometimes the referral slip is yellow."

Subcommittee Postpones Markup Of HHS Funding Bill

The House Appropriations Subcommittee on Labor, HHS, Education and Related Agencies earlier this week postponed work on a fiscal year 2000 funding bill that would have included NIH appropriations.

The markup of the appropriations bill was to have taken place July 21. There was no indication when legislators planned to take up the bill.

Subcommittee Chairman John Porter (R-IL) has said that drafting a bill would be pointless because the budget allocation for the subcommittee is $11 billion below last year's appropriation (**The Cancer Letter**, July 9).

Dave Kohn, a spokesman for Porter, said the subcommittee was planning to draft a bill that would have funded the departments at the same level as the current fiscal year by obtaining offsets for spending. Thus, the bill would not have exceeded the caps put in place by the Balanced Budget Act. "The offsets have not materialized," Kohn said to **The Cancer Letter**. "We are in a hold pattern waiting to see if the offsets can be obtained, and if not, funding decisions would be made in the fall."

The appropriation for NIH would have been about an 8 percent increase over the Institutes' current budget, or about $16.9 billion, Kohn said. "Mr. Porter still intends to shepherd through an increase for NIH that would be somewhere in the 8 to 9 percent range," he said. "He has been clear in saying it would be absolutely unacceptable to go backwards. We need to increase resources for this type of research. He's going to keep fighting for it."

No action has been taken on NIH appropriations in the Senate.

The Breast and Cervical Cancer Treatment Act
H.R. 1070
Bill Summary

- The bill would establish an optional State Medicaid benefit for coverage of certain women who were screened and diagnosed with breast or cervical cancer under title XV of the Public Health Services Act's National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

- To be eligible, women would have to satisfy the income and resource eligibility requirements established under NBCCEDP; be under the age of 65; have been diagnosed with breast or cervical cancer under the title XV Program; and not otherwise have health insurance coverage.

- Women who qualify for NBCCEDP would be allowed presumptive eligibility for Medicaid coverage for the duration of the treatment of their breast and cervical cancer.

- States who elect to provide breast and cervical cancer treatment as an optional benefit would receive an enhanced match to encourage participation in establishing this benefit.

NBCC

NATIONAL BREAST CANCER COALITION

grassroots advocacy in action

Testimony of Fran Visco, President
National Breast Cancer Coalition
before the
House Commerce Committee
Subcommittee on Health and Environment
July 21, 1999

Thank you Mr. Chairman, and members of the Committee for inviting me to testify today. I am Fran Visco, President of the National Breast Cancer Coalition, and a breast cancer survivor. I am one of the 2.6 million women living with breast cancer in the U.S. today.

The National Breast Cancer Coalition (NBCC) is a grassroots advocacy organization dedicated to eradicating breast cancer. We are made up of 500 member organizations and more than 60,000 individual women, their families and friends. NBCC seeks to increase the influence of breast cancer survivors and other activists over public policy in cancer research, clinical trials, and access to quality health care for all women.

BACKGROUND

The National Breast Cancer Coalition has made passage of H.R. 1070, the Breast and Cervical Cancer Treatment Act, a top priority. As you know, this legislation would establish a federal treatment component for the Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) that Congress enacted as part of the Breast and Cervical Cancer Mortality Prevention Act in 1990. That program – which has screened more than one-half a million women for breast cancer – does not provide any federal resources to pay for the treatment when women are diagnosed with breast or cervical cancer. Instead, Congress asks participating states to assure that the women who are screened get the treatment they need.

The fact that the CDC Early Detection Program does not cover any costs of treatment for breast and cervical cancer has created a very serious public policy gap. State and local providers and women themselves have been left to scramble for resources to pay for treatment. Women are relying on charity and donated care when it is available and sometimes going into debt when no public or private dollars can be found. The NBCCEDP is a program dedicated to serving low-income women, but at times fails to come through.

Let me be perfectly clear. The individuals who run this program and the thousands of volunteers who help find women treatment do all that they can everyday to ensure that patients diagnosed through the program get the treatment they need. It is the people who do the screening and spend countless hours trying to find treatment who have identified the problems with a system that lacks a treatment component. It is the system that is broken, and we need to fix this problem so that they can screen more women, and not have to spend the majority of their time finding treatment services.

What H.R. 1070 Would Do

NBCC-Personal Stories

Not long after the CDC screening program was enacted into law, Jan Eick-Swigart, an NBCC advocate from California, launched an effort to guarantee treatment for women screened and diagnosed with breast cancer through the federal program.

Prior to losing her battle with breast cancer, Jan wrote a compelling memorandum on the need for a federal treatment component to CDC's Early Detection Program. Her memorandum states:

"One of the heartbreaking ironies about the BCCEDP and other programs that offer underserved women free or low cost mammography is the lack of resources to treat the women who are diagnosed with breast cancer as a result of these programs."

In the years following Jan Eick-Swigart's efforts to ensure that women screened and diagnosed with breast cancer through CDC's federal program are guaranteed treatment through Medicaid coverage, many NBCC advocates have reaffirmed the need for a federal treatment component to this program. Our members have witnessed the delay that can result from having to scramble to find treatment – and the physical and emotional result that delay has on women screened and diagnosed through the program.

A woman in Florida had to wait 5 months before a volunteer found her treatment dollars. This woman had five agonizing months of knowing she was sick and having no way to get the treatment she so desperately needed.

Moreover, we have heard from women who ultimately got treatment, but were then saddled with medical bills that they couldn't pay. Instead of focusing on getting well, these uninsured women have had to focus on how they are going pay for their care.

A woman in Massachusetts, for instance, has already spent her children's college fund for her treatment and is paying off more than $20,000 in medical bills. Her story is incorporated in a statement from Mary Ann Waygan, coordinator for the CDC Breast and Cervical Cancer Initiative for Cape Cod, Massachusetts. *(Mr. Speaker, may I introduce this statement into the record?)*

A woman in New York said that during her treatment, it seemed that her conversations with her doctors were more about the bills than how to save her life.

There are other women who after having a mammogram find out they need follow-up diagnostic services but refuse to get them. They do not want to know they have cancer without knowing exactly where the treatment dollars come from.

A woman from Virginia explained she "feels that if she is not diagnosed it is better because she will not have to worry about treatment."

A woman from Maine had an initial mammogram through the NBCCEDP program and the results were "highly suggestive of malignancy." Due to the cost, rather than pursue a biopsy and the treatment, which may have been needed, the client decided to wait and have a repeat mammogram in six months.

Surely, these scenarios are not what Congress intended when it enacted the National Breast and Cervical Cancer Early Detection Program into law. Yet, these scenarios are the reality of what happens when women are screened and diagnosed with breast and cervical cancer through a federal program that does not guarantee federal treatment coverage.

CDC-Case Study

NBCC is not alone in our belief that the CDC Early Detection Program needs a system that provides sufficient funding for treating women. In response to concerns about treatment raised across the country (and raised by advocates like us), CDC conducted a case study which illustrated a similar conclusion. The study focused on participating states (California, Michigan, Minnesota, New Mexico, New York, North Carolina and Texas) and looked at the treatment following a diagnosis of breast or cervical cancer through the program.

The results of that study, released in January 1998, found that although treatment had been initiated for most of the women in whom cancer was diagnosed, the system of treatment is "tenuous and fragile at best."

(Mr. Chairman, may I introduce the report which summarizes the results of the study into the record?)

The Numbers Don't Tell Us the Whole Story

I want to make very clear that the issue is not just that some women don't get treated. We have had to look beyond the numbers to find the real story. It is behind these numbers that the story exists – the story that women from all over the country come and talk to me about. It's the story that CDC's own study underscores. The story of women – diagnosed with breast and cervical cancer – wondering how and whether and when

they'll find treatment for their disease, and then often left with a lifetime of bills to pay for that treatment.

Lack of Treatment Funding Is Diverting Resources Away From the Screening Program

There are several findings that are very telling in the conclusions of CDC's study. First, the study highlights the considerable time and effort involved in developing and maintaining systems for diagnostic follow-up and treatment. It illustrates the labor-intensive process required to identify resources within states to provide diagnostic and treatment services.

NBCC has heard about the serious problems people who run the screening programs across the country have in finding treatment for women diagnosed through the program. The hours spent searching for treatment are diverting resources away from the screening program. As a result, fewer women are being screened. This is very serious - the program currently serves only 12% to 15% of age eligible, uninsured women nationally.

The threat that the lack of treatment funding poses – not only to the woman who have been diagnosed through the program – but also to the women who may rely on the screening services in the future – is lethal. **This** is the story behind the numbers.

It is our hope that in enacting a Medicaid option for these women, they will be presumed eligible for Medicaid on the first day that they are diagnosed. This way – they know they'll get the immediate care they need instead of facing delays and wondering how and whether they'll get treated. This way – program coordinators can focus their efforts on increasing the number of women they are able to screen for breast and cervical cancer.

In the Context of an Evolving Health Care System

Second, the CDC study puts this issue in the context of an evolving health care system. The study highlights what we too are hearing from our advocates around the country, and what Dr. Stanley Klausner has testified about today – an increasing number of physicians who do not have the autonomy, because of the changes in the health care system, to offer free or reduced-fee services to NBCCEDP clients.

Mr. Chairman, I point you to a letter from Robert Brooks, MD, Secretary of the Department of Health for the Florida Department of Health and Human Services.

(Mr. Chairman, may I submit this letter for the record?)

In his letter, Dr. Brooks writes, "We are starting to see the strain our providers are experiencing through their support of the program...One county program had had three women diagnosed with breast cancer during their first two years in operation; each one cared for by a different provider. Since October, 1998, five additional women have been diagnosed and approximately 10 to 15 more have abnormal clinical breast exam or

mammogram results and could be diagnosed with cancer. Needless to say, the providers are concerned with these increasing numbers. Some of the providers have asked the local program coordinator not to refer additional patients to them for the remainder of this program year..."

"...Another county program has seen a total of 10 women with cancer and they have two to three physician providers and one hospital provider who agrees to see program clients. Three providers have also expressed alarm at the number of women with abnormal exams who are referred to them for care. We have been told that these current providers may not be willing to support the Program when this county renews their program agreement this October..."

And the stories go on.

Dr. Brooks concludes with the fear that Florida's providers continue to show signs of abandoning this program unless they are provided with some assistance that is not available through the CDC grant.

Florida, a state with the highest degree of managed care penetration in the country, is perhaps one of the best (but certainly not the only) example of a situation where the lack of availability of treatment can only get worse, and where any attempts to expand the screening program are hindered.

It is important to note that as managed care continues to expand across the country, more and more doctors may have less autonomy to provide the charity care relied on by NBCCEDP coordinators. To illustrate this point, a recent survey based on 12,000 U.S. physicians was published in the April 1999 issue of the *Journal of the American Medical Association*. The study finds that doctors whose income depends most heavily on health maintenance organizations and other managed-care health plans, on average, devote only half as much time to charity care as do their colleagues who don't participate in managed care.

What will this mean for the people who run the NBCCEDP programs who are already spending countless hours searching for treatment for women diagnosed with breast and cervical cancer? What will this mean for women who are already suffering a delay in treatment? Or who are saddled with treatment bills they can't pay? Or who are reluctant to get screened because they "prefer not to know" if there is no treatment available?

What will this mean for the ability of the National Breast and Cervical Cancer Early Detection Program to sustain itself?

Precedent in the Medicaid Program

Respondents in CDC's study suggest a similar solution to the lack of funding for treatment that we bring before you today – a solution that passage of H.R. 1070 would guarantee. That solution is a provision of treatment services assured through a federal

"Medicaid option" which would give state Medicaid programs permission to allow eligibility to BCCEDP clients who are diagnosed with cancer through the program. This would include those women who are eligible for BCCEDP services but whose incomes and/or assets exceed Medicaid limits.

There is a precedent for covering participants in the Breast and Cervical Cancer Early Detection Program under Medicaid. In 1993, Congress created the Tuberculosis Optional Benefit Program, making individuals who are infected with tuberculosis eligible for Medicaid.

Mr. Chairman, and Members of the Committee, as the stories of NBCC's advocates and as the results of CDC's own study show – what we have today is an ad-hoc system that is incapable of serving the future needs of the program and the women it serves. Solutions in the vast majority of states are short-term, tenuous and fragile. The fact that so many women eventually get treated reflects the dedication of providers and volunteers who spend enormous effort and time to find treatment services. Yet, while the majority of women get care, there is no system of care. As a result, some women experience unnecessary delays or are lost to follow-up care, and a few don't get treated at all.

Our message is not to put an end to the screening program. It is to finish the work Congress initiated in 1990 by adopting a treatment component that will serve all the women screened and diagnosed with breast and cervical cancer through this program.

How This New Treatment Program Would Work

Enactment of H.R. 1070 would allow the women who are eligible for the CDC Early Detection program -- that is women who are between 200% and 250% of poverty depending on their state and who are not already insured -- to receive their treatment through the state Medicaid program. States would not be required to participate, but those that do will receive an enhanced match – 75 percent federal dollars and 25 percent state dollars.

NBCC is heartened by the incredible support for this legislation from you, Mr. Chairman, and from the Committee. All but three Subcommittee members have signed on as cosponsors, and three quarters of the Full Commerce Committee has cosponsored H.R. 1070. We are pleased that in a bipartisan way – this Committee has come together in recognition that breast and cervical cancer screening alone does not prevent cancer deaths; it must be coupled with treatment if we are to achieve a reduction in mortality.

We now ask the Committee to ensure that happens as the screening program grows by enacting H.R. 1070, the Breast and Cervical Cancer Treatment Act this Congress.

Mr. Chairman, and members of the Committee, thank you again for the opportunity to testify. We look forward to working with you on this critically important issue. I'd be happy to answer any questions you may have.

Statement of Mary Ann Waygan
March 18, 1999

Hello, my name is Mary Ann Waygan and I am the coordinator for the CDC Breast and Cervical Cancer Initiative for Cape Cod, Massachusetts.

Before I begin, I would like to thank Senators Chafee, Mikulski, Snowe and Moynihan for sponsoring this legislation. I would also like to thank Senator Smith for his support of this bill.

Clearly, the single largest problem facing the Breast and Cervical Cancer Screening Program today is finding resources and caregivers to provide treatment to the women who are diagnosed with breast or cervical cancer. The lack of treatment dollars is one of the biggest policy gaps in the program – and the problem is only getting worse.

The barriers to recruiting providers for charity care are growing, and funding for the treatment is an ad-hoc system that relies on volunteers, state workers and others to find treatment services. In the community, we go to tremendous ends to find treatment – and raise money to help pay for it. I've organized luncheons, bake sales, raffles – you name it. Anything to raise money for women who could not afford to pay out of pocket for treatment. Despite these efforts, all too often, we come up short.

Funding for treatment through the CDC program is the biggest problem I face as a coordinator and frankly a barrier to screening and detection. Funding for treatment is tenuous at best. Without passage of the Breast and Cervical Cancer Treatment Act, future funding for treatment for these women will remain uncertain.

I want to tell you one story in particular that clearly illustrates the problem some of these women face. A woman who lives in Buzzard's Bay, Massachusetts who was diagnosed with breast cancer through the CDC program.

Arlene McMann is a married woman in her early forties with two teenage sons and no health insurance.

When Arlene was diagnosed with breast cancer through the CDC screening program, she was devastated – not just with the diagnosis, but with the fact that she had no way to pay for the treatment she needed.

Faced with that situation, she and her husband were forced to use the $20,000 they had been saving for years to pay for their children's college tuition. In less than a year, that money was gone. After that, she and her husband were forced to go into debt to pay for her ongoing chemotherapy/radiation treatment and other procedures including a craniotomy and gall bladder surgery. They are now more than $40,000 in debt, were forced to move into a much smaller house and lost their dream of sending their sons to college without going into further debt.

The additional stress and pressure placed on Arlene and her husband by this situation has turned a difficult situation into an almost unbearable one. To make it even worse, Arlene recently found out that the cancer has spread to her hip, pelvis, lungs and liver.

Through all of this, Arlene has showed tremendous resolve. Despite being in pain and discomfort and forced to use a wheelchair, Arlene desperately wanted to be here today to share her story with you directly. She thought it was important for everyone to understand not just what the cancer had done to her, but what the affect of having to take on this incredible financial burden had done to her physical health, mental strength and family resources.

Due to her condition, Arlene's treatment finally is being paid because she qualified for disability. But to this day, Arlene is convinced that her cancer would not have spread had she been able to afford regular visits to an oncologist.

Arlene's energy and determination to fight this disease and remain positive are amazing. I feel lucky to know her and to have worked with her. I only wish that as the program coordinator, I could have done more – that I could have assured her that any treatment she needed would be paid for and that she wouldn't have to spend time dealing with bank statements, mortgages or packing boxes on top of everything else.

In summary, we hear over and over again that early detection saves lives. In actuality, early detection alone does nothing but find the disease; detection must be coupled with guaranteed, quality treatment to actually save lives.

We must pass the Breast and Cervical Cancer Treatment Act to make sure that screening and treatment always go together.

I would like to thank the National Breast Cancer Coalition for its leadership role in working to get this legislation passed and thank the members of Congress here today for sponsoring and supporting this legislation.

Thank you.

Jeb Bush
Governor

HEALTH

Robert G. Brooks, M.D.
Secretary

June 22 1999

The Honorable Connie Mack
United States Senate
517 Hart Senate Office Building
Washington DC 20510

Dear Senator Mack

This letter in response to the May 4th telephone inquiry from Mark Smith to Margo Blake regarding cancer treatment for women enrolled in Florida's Breast and Cervical Cancer Early Detection Program (the Program). Thank you for allowing us the opportunity to furnish some details about the Program.

Florida received its award from the Centers for Disease Control and Prevention (CDC) in late summer 1994. We started operations in nine counties in September 1995 and grew to 20 counties in 1998. The 20 counties are comprised of large urban areas, mid-sized counties and small rural counties. (A map depicting all 20 participating counties is enclosed.) Population data show that there are approximately 275,000 women, ages 50-64 in Florida who are under or uninsured. Slightly over 175,000 of these women reside in the 20 participating counties.

Since late 1995, CDC grant funds have allowed the Program to provide screening services to slightly over 10,000 eligible women. Annually, the participating counties screen approximately 3,500 women, or about 2 percent of the eligible population. One hundred thirty women have been diagnosed with breast or invasive cervical cancer through this Program in Florida. As you know, CDC funds cover reimbursement, at the Medicare rate, for breast and cervical screening services such as Pap smears and mammograms. There are also limited funds for specified diagnostic procedurs such as colposcopies, biopsies, and breast ultrasounds. The CDC funds cannot be used for reimbursement for treatment or other associated costs. This is the Program's most vulnerable area as we are now entering a competitive application process for additional CDC grant funds to begin year six in October 1999.

We are starting to see the strain our providers are experiencing through their support of the program. Before providing case scenarios that demonstrate this strain, I would like to expand on the definition of provider as used throughout this letter. Normally, we refer to the general or oncologic surgeon as the principal provider or treatment. Many others also donate services to the breast and cervical program. These include oncologists, radiologists, radiation oncologists, pathologists and hospitals.

The scenarios mentioned include the following:

- One county program worked with a client diagnosed with cervical cancer in November 1998. The woman saw a gynecological oncologist in January 1999 and underwent a hysterectomy in March after filing for Medicaid. Her family had to pay $6825 'up front' to cover hospital costs, which may be covered retroactively by Medicaid.

- One county program had three women diagnosed with breast cancer during their first two years in operation; each one cared for by a different provider. Since October 1998, five additional women have been diagnosed and approximately 10 to 15 more have abnormal clinical breast exam or mammogram results and could be diagnosed with cancer. Needless to say the providers are concerned with these increasing numbers. Some of the providers have asked the local program coordinator not to refer additional patients to them for the remainder of this program year.

- Another county program has seen a total of 10 women with cancer and they have two to three physician providers and one hospital provider who agrees to see program clients. These providers have also expressed alarm at the number of women with abnormal exams who are referred to them for care. We have been told that these current providers may not be willing to support the Program when this county renews their program agreement this October.

- The fourth county program diagnosed 10 women with breast cancer during their first two years and since January 1998 diagnosed four more women with breast cancer. Ten providers who originally agreed to each see one to two clients per year have formed three separated groups who have agreed to see one to two clients per group, for a total of three to six clients per year. This would not be sufficient coverage if the rate of diagnosing cancer continues.

CDC has informally conveyed to us that they may award the Florida Program more funds for breast and cervical screening services in our next five-year grant cycle that begins this October. While this is positive news for the many thousands of women at need for these services, we also believe this will have a 'domino effect' on the providers who provide in-kind treatment. With increased numbers of women screened comes an increase in the numbers of cancers diagnosed, placing an ever-increasing burden on our already overwhelmed providers of cancer treatment! Please note these same providers more than likely also donate in-kind services to other clients diagnosed with cancer or other chronic diseases.

So while our information shows that a provider may furnish pro bono treatment for two or three women with breast or cervical cancer per year, in all likelihood that same provider is asked to donate treatment services for other clients as well. We are deeply indebted to all of these individuals and institutions for their support of the Program and would like to see them receive some measure of acknowledgement for their efforts.

In summary, the Florida Breast and Cervical Cancer Program has provided cancer services to over 10,000 women at or below the 200 percent poverty level, and found treatment services for over 130 women through the generosity of local providers in 20 counties. As screening numbers increase, so will the number of women diagnosed with breast or cervical cancer

Our providers are showing signs of abandoning this program unless we are able to provide them some assistance that is not available through the CDC grant.

Thank you for your personal interest in Florida's Program. If you have further questions, please feel free to contact me at (850) 487-2945, or Ms. Margo C. Blake, Program Manager for the Breast and Cervical Cancer Early Detection Program at (850) 488-2901. We look forward to a successful conclusion to this year's session and wish you our best.

Sincerely,

Robert G. Brooks, M.D.
Secretary, Department of Health

RGB/jg
Enclosure

Cc: Mark Smith

THE BREAST AND CERVICAL CANCER TREATMENT ACT

The NBCCEDP

- **In 1990, Congress enacted the National Breast and Cervical Cancer Early Detection Program** (NBCCEDP) into law (P.L. 101-354), enabling states to provide breast and cervical cancer screening services to women with no other source of payment for such services.

- **The program is administered by the Centers for Disease Control and Prevention (CDC)**, and works in partnership with state and local health agencies and other community partners to provide education, outreach, screening services, and follow-up care. NBCCEDP serves older women, women with low income, uninsured or underinsured women, and women of racial/ethnic minority groups who qualify.

- **Congress appropriated $159 million for FY 1999 for the NBCCEDP. The program is now in all 50 states**, the District of Columbia and 13 American Indian/Alaska Native organizations; however not all state programs are fully functioning.

The Success of the Screening Program

Since the NBCCEDP's inception through March 1998 it has:

- Provided mammography screening to 794,445 women aged 40 years and older;

- Found 56,119 (7%) abnormal mammograms;

- Diagnosed 4,137 cases of breast cancer; and

Of those diagnosed with breast cancer, 3,350 were under 65 years of age - and ineligible for Medicare coverage.

Current Approaches to Providing Treatment

- **As enacted by Congress, the NBCCEDP provides funding only for screening services.** Recently CDC agreed to cover diagnostic services- services necessary to determine whether or not a woman has breast cancer. However, there is still no federal funding to provide treatment services to the 3,350 women under age 65, who have been screened and diagnosed with breast cancer.

- **The current system for treatment is an ad hoc patchwork of providers, volunteers, and local programs scrambling to find treatment dollars.** Although health agencies at the state and local levels and breast cancer advocates have found creative ways to help women find treatment, these networks are overloaded and increasingly unreliable. Women are forced to rely on charity care, donated services, and bake sales to pay for their treatment.

- **The lack of financial support for treatment is hurting the NBCCEDP.** Time and effort required to arrange for treatment services have begun to divert resources away from screening activities. As a result fewer women are being screened-the program serves only 12% to 15% of age-eligible, uninsured women nationally.

A Long-term Solution: Covering Treatment Costs Through the Medicaid Program

- **The National Breast Cancer Coalition (NBCC) believes that women should not have to hold bake sales to fund breast cancer treatment.** NBCC believes it is irresponsible to enact a federal program that promises to reduce the number of deaths from breast and cervical cancer and not guarantee federal funding for treatment services to women who have been screened and found to have breast or cervical cancer.

- **Medicaid is the answer.** Congress should allow states the option of providing women diagnosed with breast or cervical cancer through the NBCCEDP, Medicaid coverage for their disease.

- **There is a precedent for covering participants in the NBCCEDP under Medicaid.** In 1993, Congress created the Tuberculous Optional Benefit Program, making individuals who are infected with tuberculosis eligible for Medicaid.

Summary of the Breast and Cervical Cancer Treatment Act

- The bill would establish an optional State Medicaid benefit for coverage of certain women who are screened and diagnosed with breast or cervical cancer under Title XV of the Public Health Services Act's NBCCEDP.

- To be eligible, women would have to satisfy the income and resource eligibility requirements established under NBCCEDP; be under the age of 65; have been diagnosed with breast or cervical cancer under the Title XV Program; and not otherwise have health insurance coverage.

- Women who qualify for NBCCEDP would be allowed presumptive eligibility for Medicaid coverage for the duration of the treatment of their breast and cervical cancer.

- States electing to provide breast and cervical cancer treatment as an optional benefit would receive an enhanced match to encourage participation in establishing this benefit.

HR 1070 IH

106th CONGRESS

1st Session

H. R. 1070

To amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program.

IN THE HOUSE OF REPRESENTATIVES

March 11, 1999

Mr. LAZIO (for himself, Ms. ESHOO, Ms. ROS-LEHTINEN, Mrs. CAPPS, Mrs. MORELLA, Mrs. KELLY, Mr. BROWN of Ohio, Mr. GEORGE MILLER of California, Mr. HORN, Mr. DIXON, Ms. PELOSI, Mr. LATOURETTE, Mr. WAXMAN, Mr. SERRANO, Mr. GILMAN, Mr. MALONEY of Connecticut, Mr. MEEHAN, Mr. WELDON of Pennsylvania, Mr. UNDERWOOD, Mr. SHOWS, Mr. ABERCROMBIE, Mr. MCHUGH, Mr. ETHERIDGE, Mr. SANDERS, Mrs. CLAYTON, Mr. WALSH, Mr. MCGOVERN, Mr. MCNULTY, Mr. FROST, Mr. NEY, Mr. OLVER, Ms. MILLENDER-MCDONALD, Mr. CROWLEY, Mr. SUNUNU, Mr. CLEMENT, Mr. STARK, Ms. CARSON, Mr. FOLEY, Mr. COYNE, Mr. LANTOS, Mr. INSLEE, Mrs. WILSON, Mr. SHERMAN, Mr. BALDACCI, Mr. BOEHLERT, Mr. LUTHER, Mr. HINOJOSA, Mr. DEFAZIO, Mr. QUINN, Mr. PRICE of North Carolina, Mr. RANGEL, Mr. WEYGAND, Mr. FORBES, Mr. MEEKS of New York, Mr. NADLER, Mr. BARRETT of Wisconsin, Ms. WOOLSEY, Mr. KUCINICH, Mr. KING, Ms. SLAUGHTER, Mrs. TAUSCHER, Mr. BILBRAY, Mr. THOMPSON of Mississippi, Mr. HINCHEY, Mr. KLECZKA, Mr. PAYNE, Mr. WYNN, Mr. JEFFERSON, Mr. SMITH of New Jersey, Mr. MASCARA, Mr. LOBIONDO, Mr. OBERSTAR, Mr. LEACH, Mr. RUSH, Mr. MATSUI, Mr. DINGELL, Mrs. EMERSON, Mr. FILNER, Mrs. MYRICK, and Ms. LOFGREN) introduced the following bill; which was referred to the Committee on Commerce

---

A BILL

To amend title XIX of the Social Security Act to provide medical assistance for certain women screened and found to have breast or cervical cancer under a federally funded screening program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. OPTIONAL MEDICAID COVERAGE OF CERTAIN BREAST OR CERVICAL CANCER PATIENTS.

(a) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP-

(1) IN GENERAL- Section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended--

(A) in subclause (XIII), by striking `or' at the end;

(B) in subclause (XIV), by adding `or' at the end; and

(C) by adding at the end the following:

`(XV) who are described in subsection (aa) (relating to certain breast or cervical cancer patients);'.

(2) GROUP DESCRIBED- Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended by adding at the end the following:

`(aa) Individuals described in this paragraph are individuals who--

`(1) are not described in subsection (a)(10)(A)(i);

`(2) have not attained age 65;

`(3) have been screened for breast and cervical cancer under the Centers for Disease Control and Prevention breast and cervical cancer early detection program established under title XV of the Public Health Service Act (42 U.S.C. 300k et seq.) in accordance with the requirements of section 1504 of that Act (42 U.S.C. 300n) and need treatment for breast or cervical cancer; and

`(4) are not otherwise covered under creditable coverage, as defined in section 2701(c) of the Public Health Service Act (45 U.S.C. 300gg(c)).'.

(3) LIMITATION ON BENEFITS- Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (F)--

(A) by striking `and (XIII)' and inserting `(XIII)'; and

(B) by inserting `, and (XIV) the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XV) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer' before the semicolon.

(4) CONFORMING AMENDMENTS- Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended in the matter preceding paragraph (1)--

(A) in clause (x), by striking `or' at the end;

(B) in clause (xi), by adding `or' at the end; and

(C) by inserting after clause (xi) the following:

`(xii) individuals described in section 1902(aa),'.

(b) PRESUMPTIVE ELIGIBILITY-

(1) IN GENERAL- Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1920A the following:

`PRESUMPTIVE ELIGIBILITY FOR CERTAIN BREAST OR CERVICAL CANCER PATIENTS

`SEC. 1920B. (a) STATE OPTION- A State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(aa) (relating to certain breast or cervical cancer patients) during a presumptive eligibility period.

`(b) DEFINITIONS- For purposes of this section:

`(1) PRESUMPTIVE ELIGIBILITY PERIOD- The term `presumptive eligibility period' means, with respect to an individual described in subsection (a), the period that--

`(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(aa); and

`(B) ends with (and includes) the earlier of--

`(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

`(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

`(2) QUALIFIED ENTITY-

`(A) IN GENERAL- Subject to subparagraph (B), the term `qualified entity' means any entity that--

`(i) is eligible for payments under a State plan approved under this title; and

`(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

`(B) REGULATIONS- The Secretary may issue regulations further limiting those entities that may become qualified entities in order to prevent fraud and abuse and for other reasons.

`(C) RULE OF CONSTRUCTION- Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities, consistent with any limitations imposed under subparagraph (B).

`(c) ADMINISTRATION-

`(1) IN GENERAL- The State agency shall provide qualified entities with--

`(A) such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and

`(B) information on how to assist such individuals in completing and filing such forms.

`(2) NOTIFICATION REQUIREMENTS- A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall--

`(A) notify the State agency of the determination within 5 working days after the date on which determination is made; and

`(B) inform such individual at the time the determination is made that an application for medical assistance under the State plan is required to be made by not later than the last day of the month following the month during which the determination is made.

`(3) APPLICATION FOR MEDICAL ASSISTANCE- In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively eligible for medical assistance under a State plan, the individual shall apply for medical assistance under such plan by not later than the last day of the month following the month during which the determination is made.

`(d) PAYMENT- Notwithstanding any other provision of this title, medical assistance that--

`(1) is furnished to an individual described in subsection (a)--

`(A) during a presumptive eligibility period;

`(B) by a entity that is eligible for payments under the State plan; and

`(2) is included in the care and services covered by the State plan;

shall be treated as medical assistance provided by such plan for purposes of section 1903(a)(5)(B).'.

(2) CONFORMING AMENDMENTS-

(A) Section 1902(a)(47) of the Social Security Act (42 U.S.C. 1396a(a)(47)) is

amended by inserting before the semicolon at the end the following: `and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section'.

(B) Section 1903(u)(1)(D)(v) of such Act (42 U.S.C. 1396b(u)(1)(D)(v)) is amended--

(i) by striking `or for' and inserting `, for'; and

(ii) by inserting before the period the following: `, or for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section'.

(c) ENHANCED MATCH- Section 1903(a)(5) of the Social Security Act (42 U.S.C. 1396b(a)(5)) is amended--

(1) by striking `an' and inserting `(A) an';

(2) by adding `plus' after the semicolon; and

(3) by adding at the end the following:

`(B) an amount equal to 75 percent of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of breast or cervical cancer-related treatment services; plus'.

(d) EFFECTIVE DATE- The amendments made by this section apply to medical assistance furnished on or after October 1, 1999, without regard to whether final regulations to carry out such amendments have been promulgated by such date.

END

The Breast and Cervical Cancer Treatment Act of 1999
S. 662/H.R. 1070
Endorsing Organizations

National Breast Cancer Coalition
American Cancer Society
National Association of Public Hospitals & Health Systems
National Partnership for Women & Families
YWCA
National Women's Health Network
Oncology Nursing Society
Y-ME
Arm in Arm
Association of Women's Health, Obstetric, and Neonatal Nurses
Rhode Island Breast Cancer Coalition
Florida Breast Cancer Coalition
The Breast Cancer Coalition of Utah
Maine Breast Cancer Coalition
American Medical Women's Association
American Public Health Association
California Breast Cancer Organizations
Linda Creed Breast Cancer Foundation
Wisconsin Breast Cancer Coalition
Cancer Research Foundation of America
American Society for Therapeutic Radiology and Oncology
National Women's Law Center

TABLE 1

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Initiation of Treatment for Women Diagnosed with In Situ or Invasive Breast Cancer
Minimum Data Elements[1] through March 31, 1997

Program Name	Total Number of NBCCEDP Funded Mammograms	Total Number of Breast Cancers Diagnosed (InSitu/Invasive)[2]	Number of Breast Cancers with Complete Information	Median Days from Diagnosis to Treatment Initiation	Percent Initiated Treatment (N=)[3]	Number of Breas Cancers with Pending/Missing Information[4]
TOTAL for NBCCEDP (35 Programs Combined)[5]	594,436	4409	4242	10	95.8 (4064)	167

[1] The Minimum Data Elements (MDEs) are electronically submitted semi-annually (January 15 and July 15) to a data management contractor, who analyzes the data and submits a data file to the CDC. For example, the data used for this report were submitted on January 15, 1998 and included screening exams through September 30, 1997. The next data will be submitted on July 15, 1998 and will include screening exams through March 31, 1998. The interval of three and one-half months provides states time to prepare the data submission and gather information that may be missing. Routinely an additional six month interval is provided for completion of diagnostic follow-up and treatment information.

[2] The total number of breast cancers diagnosed include some women referred to the NBCCEDP for diagnostic evaluation of a non-NBCCEDP funded screening exam.

[3] Women who did not initiate treatment either refused treatment, were lost to follow-up, or died.

[4] Breast cancer cases have pending or missing information on one or more of the following variables: date of diagnosis; date of treatment initiation; or status of treatment initiation.

[5] Programs include AK, AZ, AR, CA, CO, CT, FL, GA, IL, IA, KS, LA, ME, MD, MA, MI, MN, MO, NE, NJ, NM, NY, NC, OH, OK, OR, PA, RI, SC, TX, UT, VT, WA, WV, WI

TABLE 2

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Initiation of Treatment for Women Diagnosed with In Situ or Invasive Breast Cancer
Minimum Data Elements through March 31, 1997
Program with ≥ 40 Cases of Breast Cancer

Program Name	Total Number of NBCCEDP Funded Mammograms	Total Number of Breast Cancers Diagnosed (InSitu/Invasive)	Number of Breast Cancers with Complete Information	Median Days from Diagnosis to Treatment Initiation	Percent Initiated Treatment (N=)	Number of Breast Cancers with Pending/Missing Information
AR	5,652	54	52	10	96.1 (50)	2
CA	50,767	489	478	11	93.1 (445)	11
CO	20,485	119	117	13	99.1 (116)	2
MD	35,788	314	305	11	96.7 (295)	9
MA	14,038	207	182	13	97.3 (177)	25
MI	58,473	435	424	0	94.3 (400)	11
MN	26,375	217	215	8	97.7 (210)	2
MO	24,041	143	140	8	96.4 (135)	3
NE	2,950	79	78	8	91.0 (71)	1
NM	47,613	244	244	18.5	95.9 (234)	0
NY	59,573	397	397	25	94.2 (374)	0
NC	42,191	274	269	11	94.0 (253)	5
OH	10,254	121	121	8	95.9 (116)	0
PA	5,593	48	43	13	100 (43)	5

5/5/98

TABLE 2 (continued)

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Initiation of Treatment for Women Diagnosed with In Situ or Invasive Breast Cancer
Minimum Data Elements through March 31, 1997
Program with ≥ 40 Cases of Breast Cancer

Program Name	Total Number of NBCCEDP Funded Mammograms	Total Number of Breast Cancers Diagnosed (InSitu/Invasive)	Number of Breast Cancers with Complete Information	Median Days from Diagnosis to Treatment Initiation	Percent Initiated Treatment (N=)	Number of Breast Cancers with Pending/Missing Information
SC	30,192	227	206	10	98.5 (203)	21
TX	71,662	526	514	4.5	97.9 (503)	12
UT	5,918	43	41	0	100 (41)	2
WA	12,812	71	61	8	90.2 (55)	10
WV	32,063	214	198	7	99.5 (197)	16
WI	10,860	40	36	10.5	97.2 (35)	4

TABLE 3

National Breast and Cervical Cancer Early Detection Program (NBCCEDP)
Initiation of Treatment for Women Diagnosed with In Situ or Invasive Breast Cancer
Minimum Data Elements through March 31, 1997
Program with < 40 Cases of Breast Cancer

Program Name	Total Number of NBCCEDP Funded Mammograms	Total Number of Breast Cancers Diagnosed (InSitu/Invasive)
AK	989	8
AZ	1,495	13
CT	1,302	8
FL	1,535	14
GA	6,234	31
IL	1,102	6
IA	416	5
KS	785	7
LA	174	1
ME	872	3
NJ	2,549	11
OK	1,328	15
OR	1,115	11
RI	1,269	7
VT	979	7

NOTE: Median days from diagnosis to treatment initiation and the proportion who have initiated treatment are not calculated because the total number of breast cancer cases are too small to produce statistically reliable information. However, those breast cancer cases are included in the overall NBCCEDP measures reported in Table 1. These states are still in the start-up stage and have been screening for approximately two years as of March 31, 1997.

Article

Strategies for Follow-Up and Treatment Services in State Breast and Cervical Cancer Screening Programs

Paula M. Lantz, PhD
Lisa C. Richardson, MD, MPH
Debra J. Macklem, MEd
Lisa R. Shugarman, BA
University of Michigan School of Public Health
Ann Arbor, Michigan

Donna B. Knutson, MSEd, CHES
Centers for Disease Control and Prevention,
Division of Cancer Prevention and Control
Atlanta, Georgia

Lowell E. Sever, PhD
Battelle Centers for Public Health Research and Evaluation
Seattle, Washington

This report describes strategies used to provide diagnostic follow-up and treatment services to low-income women screened through the National Breast and Cervical Cancer Early Detection Program.

The Breast and Cervical Cancer Mortality Prevention Act, enacted by the U.S. Congress in August 1990 (Public Law 101-354) authorized funds for a national screening program for breast and cervical cancer for medically underserved women.[1] This program—the National Breast and Cervical Cancer Early Detection Program or NBCCEDP—is administered by the Centers for Disease Control and Prevention (CDC). The goal of this large public health initiative is to reduce the morbidity and mortality associated with breast and cervical cancer in the United States.

The NBCCEDP is implemented through cooperative agreements with qualifying health agencies that provide free or low-cost screening to uninsured or underinsured low-income women, develop and disseminate public and professional education strategies, establish quality assurance systems, engage in surveillance and evaluation activities, and develop coalitions and partnerships.[2] To date, the health departments of all 50 states, the District of Columbia, 4 U.S. territories, and 15 American Indian and Alaska Native tribes or tribal organizations have received support for comprehensive Breast and Cervical Cancer Early Detection Programs (BCCEDPs). The age and income eligibility requirements for screening services vary across the programs, but all programs

Published by Elsevier Science Inc
1049-3867/99/$20.00
PII S1049-3867(98)00027-9

target high-priority groups, for example, older women, women in racial and ethnic minority groups, women with disabilities, lesbians, and women who live in rural or other hard-to-reach areas.

Through September 1997, more than 1.5 million free mammograms and Papanicolaou smear tests were provided through the NBCCEDP.[3] The program also covers a number of follow-up diagnostic procedures, including diagnostic mammography, breast ultrasound, surgical consultation, fine needle aspiration of the breast, and colposcopy. Because of limited resources, however, program funds have not been available to cover all of the diagnostic tests that women may need for follow-up of abnormal screening results and to reach a definitive diagnosis (including excisional breast biopsy, stereotactic localization for breast biopsy, or needle core breast biopsy). In addition, the federal legislation prohibits the use of national program funds to pay for treatment services for women diagnosed with cervical intraepithelial neoplasia (CIN) or for any component of treatment for breast or cervical cancer, including surgery, radiotherapy, chemotherapy, hormonal therapy, and breast reconstruction.

Through September 1997, more than 1.5 million free mammograms and Papanicolaou smear tests were provided through the NBCCEDP.

Despite these restrictions in funding, diagnostic and treatment services are recognized as essential components of this screening initiative. Federal legislation requires that participating programs ensure that women with abnormal screening results receive definitive diagnoses and that they have access to timely and appropriate treatment services for CIN or cancer if needed, regardless of their ability to pay.[1,4] Participating health agencies are expected to build collaborations and partnerships with hospitals and community-based organizations to obtain access to and resources for diagnostic, treatment, and support services.[2]

Anecdotal information reported to CDC suggests that participating agencies are indeed finding innovative and interesting ways to secure diagnostic follow-up and treatment services for women in need[2]; however, this aspect of the NBCCEDP has not been assessed in depth or systematically. Thus, we undertook a three-part study to document and investigate the strategies and approaches that state BCCEDPs have implemented to secure diagnostic follow-up and cancer treatment services for clients in the absence of federal dollars for these activities: 1) a descriptive study of the general strategies and activities regarding diagnostic and treatment services in 35 BCCEDPs; 2) an in-depth case study of 7 of the 35 state programs[5]; and 3) documentation of cancer treatment services received and the timing of these services by linking information from 3 state BCCEDPs with data from population-based tumor registries. In this report, we present the results from the first study component.

METHODS

All 35 state BCCEDPs that received federal funding for a comprehensive screening program before October 1, 1996 (and thus had significant experience dealing with clients in need of diagnostic follow-up and treatment services) were selected for study.[2] Data were collected with the assistance of 18 CDC program consultants, who are Atlanta-based staff who provide technical assistance to and serve as federal liaisons with the state programs. A standardized data collection form that consultants could self-administer as part of their general duties was designed and pilot tested. The form was used to document state-specific information on the organizational structure of the screening program, mechanisms for notifying women of results, and strategies for securing diagnostic and treatment services for clients in need. Written instructions for completing the form and a 3-hour training session were provided. Consultants completed a form for each of their assigned states in the sample

(ranging from 1 to 3 states per consultant), using their knowledge of the state program and available materials and documents. They also discussed specific issues in their routine technical assistance calls with states if clarification from the state program was needed. Completed forms ($N = 35$; 100% response rate) were forwarded to University of Michigan research staff along with any relevant written documents.

RESULTS

One way in which all state programs work to ensure that needed follow-up diagnostic tests and treatment services are received is by tracking clients using program surveillance data. State programs have designed and implemented a variety of management information systems to track women through the processes of screening, diagnostic follow-up, and treatment initiation. In addition, at the time of our data collection, most states had written guidelines or protocols for screening providers for notifying women of screening results and for tracking women needing diagnostic services after an abnormal screening result (Table 1). In addition, 89% of states had written guidelines for ensuring that women receive definitive diagnostic follow-up services, and 77% had written guidelines for ensuring that women initiate treatment for breast or cervical cancer or CIN. Similarly, most states had written guidelines or defined protocols for providers regarding appropriate clinical pathways for diagnostic follow-up (86% for breast diagnostics and 83% for cervical diagnostics), whereas fewer states had developed protocols for appropriate treatment pathways (69% for breast cancer, 66% for cervical cancer, and 60% for CIN).

States are required to report to CDC the date that cancer treatment was initiated for . . . breast or cervical cancer.

States are required to report to CDC the date that cancer treatment was initiated for women diagnosed with breast or cervical cancer. Even those states without written guidelines or protocols regarding how women should get from an abnormal screening result to treatment have implemented surveillance systems that include the treatment initiation date. Some state programs document additional information about treatment. For example, our results suggest that 21 state programs (60%) were routinely documenting each client's initial course of cancer treatment, and of these programs, 8 (23%) were documenting the content of treatment beyond the initial course. Five state programs (14%) were documenting how each client's cancer treatment was funded, although none were collecting information on out-of-pocket expenses for diagnostic or treatment services.

State-level resources used to fund or to provide diagnostic and treatment services to women in the absence of federal program dollars for these activities are listed in Table 2. The more common strategies were appeals through the state medical society for physicians to volunteer or donate procedures and referral of clients to designated providers (such as state-funded cancer centers, teaching hospitals, and public hospitals). Several states receive funding for diagnostic and treatment services from their legislatures. This funding comes from state appropriations provided through general public revenue or tobacco excise tax revenue. In some of these states, funds are provided exclusively for women screened through the BCCEDP, in other states, the funds are available to all citizens who meet state-established eligibility criteria for services. In some states, the funds are restricted to paying for breast cancer services (primarily for diagnostic tests).

A wide range of strategies and activities organized at the local level (ie, county, city or individual clinical facility) were being used to provide diagnostic and treatment services to women in the absence of program dollars for these activities (Table 3). The most common strategies used at the local level include referrals to designated providers who have agreed to serve program

Table 1. PREVALENCE OF WRITTEN GUIDELINES FOR NOTIFICATION, TRACKING, AND SERVICE DELIVERY IN STATE BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAMS (N = 35)

Does the State Program Have Written Guidelines for	*Yes*	*No*
Notifying women of screening results?		
Breast cancer screening results	32 (91%)	3 (9%)
Cervical cancer screening results	32 (91%)	3 (9%)
Breast cancer diagnostic test results	31 (89%)	4 (11%)
Cervical cancer diagnostic test results	31 (89%)	4 (11%)
Tracking women needing follow-up services?		
Breast cancer diagnostic services	35 (100%)	0
Cervical cancer diagnostic services	34 (97%)	1 (3%)
Breast cancer treatment services	32 (91%)	3 (9%)
Cervical neoplasia treatment services	32 (91%)	3 (9%)
Cervical cancer treatment services	32 (91%)	3 (9%)
Ensuring women receive needed diagnostic services?		
Breast cancer diagnostic services	31 (89%)	4 (11%)
Cervical cancer diagnostic services	31 (89%)	4 (11%)
Ensuring women initiate needed treatment?		
Breast cancer treatment services	27 (77%)	8 (23%)
Cervical neoplasia treatment services	27 (77%)	8 (23%)
Cervical cancer treatment services	27 (77%)	8 (23%)
Defining appropriate paths for diagnostic follow-up and treatment?		
Breast cancer diagnostic services	30 (86%)	5 (14%)
Cervical cancer diagnostic services	29 (83%)	6 (17%)
Breast cancer treatment services	24 (69%)	11 (31%)
Cervical neoplasia treatment services	21 (60%)	14 (40%)
Cervical cancer treatment services	23 (66%)	12 (34%)

clients for free or at a reduced cost, assistance to clients in applying for Medicaid, or referrals to other government-sponsored insurance programs. Another common strategy is the use of funds from local foundations, charitable organizations, or corporate sponsors.

Several different strategies that involve clinicians or providers (in hospitals, clinics, community health centers, and local health departments) were used to secure diagnostic and treatment services for program clients (Table 3). Many providers donate services or provide other types of charity care, offer services at a reduced fee, negotiate payment plans with clients, and write off diagnostic and treatment services as bad debt. In half of the states, a formal or informal system exists for rotating referrals for services not covered by program funds among providers in one or more locales.

More than 40 different strategies or activities were named as being used to secure diagnostic and treatment services for BCCEDP clients in need. These strategies, in the order of frequency with which they were named, were: 1) reduced fee-for-service or a sliding-fee scale for services, 2) negotiated payment plans between providers and clients; 3) in-kind charitable contributions of providers (including hospital indigent care programs); 4) assistance in

Table 2. USE OF STATE-LEVEL STRATEGIES TO PROVIDE DIAGNOSTIC AND TREATMENT SERVICES IN THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM (N = 35)

	Number of State Programs Using Strategy to Provide			
Strategies Organized and/or Administered at State Level	*Diagnostic Services Only*	*Treatment Services Only*	*Both Services*	*Not Used*
Organization of charity care/in-kind donation of services at state level	3 (9%)	0	15 (43%)	17 (48%)
Referral of clients to state-funded cancer center	0	0	5 (14%)	30 (86%)
Referral of clients to other designated providers who have agreed to serve program	1 (3%)	1 (3%)	13 (37%)	20 (57%)
Client assistance in applying for Medicaid or other state program	0	0	10 (29%)	25 (71%)
Indian Health Service funds	0	0	8 (23%)	27 (77%)
Race for the Cure funds	6 (17%)	1 (3%)	1 (3%)	27 (77%)
Other Komen Foundation funds	3 (9%)	0	0	32 (91%)
Blue Cross Foundation funds	0	1 (3%)	0	34 (97%)
General public revenue in fund	6 (17%)	0	4 (11%)	25 (71%)
Tobacco excise tax revenue in fund	1 (3%)	1 (3%)	1 (3%)	32 (91%)

applying to Medicaid or a state-sponsored insurance program; 5) referral to a designated cancer center or a publicly funded medical facility providing indigent care; 6) use of state appropriations for diagnostic or treatment services, or both; and 7) use of funds raised through a Susan G Komen Breast Cancer Foundation *Race for the Cure*.

State programs collaborate with a variety of public and private agencies and organizations in their attempts to bring diagnostic and treatment services to BCCEDP clients. Collaborating agencies include state health and human service agencies, county and city health departments, the Indian Health Service, the American Cancer Society, the National Cancer Institute's Cancer Information Service, state and local medical societies, state hospital associa-

Table 3. USE OF LOCAL-LEVEL STRATEGIES TO PROVIDE DIAGNOSTIC AND TREATMENT SERVICES IN THE NATIONAL BREAST AND CERVICAL CANCER EARLY DETECTION PROGRAM (N = 35)

	Number of State Programs Using Strategy to Provide			
Strategies Organized and/or Administered at Local Level	*Diagnostic Services Only*	*Treatment Services Only*	*Both Services*	*Not Used*
Referral of clients to designated providers	0	0	25 (71%)	10 (29%)
Client assistance in applying for Medicaid or other state program	2 (6%)	1 (3%)	22 (63%)	10 (29%)
Race for the Cure funds	3 (9%)	0	6 (17%)	26 (74%)
Other private foundation funds	3 (9%)	0	11 (31%)	21 (60%)
Assistance from local American Cancer Society	1 (3%)	0	5 (14%)	29 (83%)
County money in fund	0	0	3 (9%)	32 (91%)
Donation of services or charity care (including indigent care programs)	1 (3%)	1 (3%)	32 (91%)	1 (3%)
Reduced fee-for-service	2 (6%)	0	27 (77%)	6 (17%)
Negotiated payment plan	0	1 (3%)	31 (89%)	3 (9%)
Services written off as bad debt	0	0	25 (71%)	10 (29%)
System for rotating referrals	1	0	16 (46%)	18 (51%)

tions, private foundations, local corporations, churches and synagogues, YWCAs, and community health centers.

In Maryland, a centralized response organized at the state level was implemented to ensure that women screened for breast and cervical cancer receive all needed diagnostic and treatment services. In July 1992, the Maryland legislature allocated funds for the Maryland Breast and Cervical Cancer Diagnosis and Treatment Program. This program, funded through general public revenue and tobacco tax revenue, provides a means by which women can receive free breast and cervical cancer diagnostic tests and treatment services. Providers under contract with this fund offer a wide range of diagnostic and treatment procedures for women meeting specific eligibility criteria. This state-funded program is not restricted to women screened through the BCCEDP, although the eligibility criteria are similar

By contrast, the Minnesota BCCEDP does not have access to state funds to supplement the federal program. Rather, the Minnesota program has developed a relationship with the Susan G. Komen Breast Cancer Foundation *Race for the Cure* in the Twin Cities. The majority of the money raised in this annual walking/running fundraising event is allocated to the Minnesota Breast and Cervical Cancer Control Program to pay for breast ultrasounds and outpatient breast biopsies for women throughout the state This strategy involves a partnership between the state health department and a private foundation in an attempt to secure breast diagnostic tests for program clients This strategy, however, does not provide resources for the treatment of breast cancer, cervical cancer, or CIN, and, in fact, only half of the breast biopsies received by program clients are paid for through *Race for the Cure* funds (J Korn, personal communication, June 1997). To secure additional crucial services for program clients, the Minnesota BCCEDP also refers women to Medicaid or MinnesotaCare (a state-sponsored health insurance program for low-income people) and negotiates payment plans, reduced fee-for-service, or charity care for individual cases.

Multiple strategies are being used to ensure that program clients receive essential diagnostic and treatment services.

DISCUSSION

Through the NBCCEDP, low-income uninsured and underinsured women receive important clinical preventive services: breast and cervical cancer screening. These women, however, are among those with the fewest resources to pay for diagnostic follow-up tests or for treatment services for a subsequent diagnosis of CIN, cervical cancer, or breast cancer. The NBCCEDP's goal to reduce morbidity and mortality from breast and cervical cancer cannot be realized unless women with abnormal screening results receive a definitive diagnosis and receive prompt and efficacious therapy for cancer or precancerous lesions.[6,7]

The NBCCEDP does not cover all the diagnostic services that clients may need, and it covers no treatment costs at all. Our study of 35 state screening programs shows that multiple strategies are being used to ensure that program clients receive essential diagnostic and treatment services. Some strategies use centralized funds administered at the state level (eg, state funds appropriated by the legislature or funds raised through partnerships with private foundations). Other strategies are decentralized and informal, reflecting partnerships and collaborative arrangements that have been worked out at the level of a community or a within a single health care institution. There is great reliance on providers of diagnostic and treatment services to offer NBCCEDP clients different types of charity care, reduced fees, or long-term payment plans. Many of the strategies or approaches on which state programs rely to provide diagnostic and treatment services involve some charge (either full fee or a

reduced fee) to the client. The number of BCCEDP clients being charged for follow-up tests and treatment services, the amount of these charges, and the degree to which financial barriers contribute to time delays or refusals for care are not known.

Approaches providing diagnostic and treatment services vary greatly across states. This is not surprising, given the different sociopolitical environments of the states and the different ways in which they have organized or structured their BCCEDPs.[3,9] Strategies and tactics also vary within states. Communities and individual facilities within a state have access to different resources, and health service delivery systems vary across regions of a state. Thus, local programs within the same state have devised different means of providing diagnostic and treatment services to their clients.

At the time of this study, some state programs did not have any written guidelines or protocols for clinical providers for tracking clients or for ensuring the initiation of follow-up or treatment services. The NBCCEDP-sponsored programs are required to have an active medical advisory committee or consultant that approves clinical protocols/guidelines and provides oversight to the quality of the services being delivered. The CDC recommends that NBCCEDP-sponsored programs use clinical practice guidelines established by nationally recognized organizations as a basis for developing clinical protocols for their programs. Some state programs were in the process of designing or approving such guidelines at the time of our study.

The results of this study are limited in several ways. We do not have detailed information regarding the history behind the development of certain policies or the strengths and weaknesses of various strategies or tactics. We also do not have information regarding the effort or resources required to implement various strategies or the efficacy or specific approaches. In addition, while we have identified a wide variety of activities that are underway to provide women with diagnostic follow-up and treatment services, these results do not tell us if women are actually receiving the services they need in a timely fashion. Yet the results of this study can answer important questions about the NBCCEDP and the need for its participating health agencies to obtain resources for some diagnostic tests and for all treatment services. This research represents the first systematic look at how state health agencies are working to provide NBCCEDP clients the diagnostic and treatment services that the program does not cover. In addition, this study sheds light on how a large federal program has been implemented at the state and local levels and how funding restrictions in the federal program have been addressed in innovative ways by collaborating institutions and organizations. Myriad health agencies and organizations sponsor free or reduced-cost screening programs for a diseases other than breast or cervical cancer without offering coverage for definitive diagnostic and treatment services. The strategies and approaches of the 35 state BCCEDPs described here may be useful and relevant to those implementing other types of disease screening programs

ACKNOWLEDGMENTS

Lisa C. Richardson, MD, MPH, is now with the CDC. This project was funded by the CDC Division of Cancer Prevention and Control, and was approved by the University of Michigan Health Sciences Human Subjects Review Committee. Rosemarie Henson, MSSW, MPH, Stephen Wyatt, DDM, MPH, Nancy C Lee, MD, Diane Duner, MPA, Jane Schulman, PhD, Martha Hare, PhD, Carlyn Orians, MA, and Madelaine Pfahler contributed to the design and implementation of the project. In addition, the authors thank the CDC Program Consultants for their cooperation with and effort on this project.

REFERENCES

1. The Breast and Cervical Cancer Mortality Prevention Act of 1990, 42 USC 201 et seq §1501–1509 (1990).
2. Henson RM, Wyatt SW, Lee NC. The National Breast and Cervical Cancer Early Detection Program: a comprehensive public health response to two major health issues for women. J Public Health Management Pract 1996;2:36–47.
3. U.S. Department of Health and Human Services. The National Breast and Cervical Cancer Early Detection Program: At-A-Glance 1998.
4. Reynolds T. States begin CDC-sponsored breast and cervical cancer screening. J Natl Cancer Inst 1992;84:7–9.
5. Lantz PM, Sever LE, et al. Strategies for providing follow-up and treatment services in the national breast and cervical cancer early detection program—United States, 1997. MMRW 1998;47:215–8.
6. Caplan LS, Helzlsouer KJ. Delay in breast cancer: a review of the literature. Public Health Rev 1993;20:187–214.
7. U.S. Department of Health and Human Services. The national strategic plan for the early detection and control of breast and cervical cancers. Atlanta: Centers for Disease Control and Prevention, 1994.
8. Maralit M, Orloff TM, Desonia R. Transforming state health agencies to meet current and future challenges. Washington (DC): National Governor's Association, 1997.
9. Studnicka J, Steverson B, Blais HN, Goley E, Richards TB, Thorton JN. Analyzing organizational practices in local health organizations. Public Health Rep 1994;109: 485–90.

During the House Commerce Subcommittee on Health and Environment Hearing on H.R. 1070 in July, the tremendous need to enact this bill was illustrated through compelling testimony. Following are a few highlights:

Mr. Biliraks:

"..I am an early cosponsor of this legislation, and I do feel that something like this is needed. You heard during the prior testimony and the questioning, that we have only been able to reach approximately 15 percent of the eligible population as far as the screening is concerned. So, something has to be done, I think we would all agree, for improvement there, which would take additional funds..."

Dr. Stanley Klausner:

"Yes, the issue is really the fact that it is very difficult to do charity work, pro bono work, work at the markedly reduced rates, when you have to pay your staff, your rent and so on. I think that making an effort, even if it is at the Medicaid level, the government is making that effort. It is putting the signal out to the physicians, if the government is moving funds in that direction, we have to meet them halfway..."

Ms. Carolyn Tapp
(President, Women of Color Breast Cancer Survivors Support Project:

"Many of the women who are in our group were screened through the CDC program, and they must have been the ones that fell through the cracks, because it wasn't as easy as I have heard, you know, to get treatment. Some of the women I know took about 6 months to actually get treatment...I have known women who have had t borrow medication from other women in the group, because they couldn't afford to buy the medication. I know that I loaned many women some of my medication Tamoxifen especially, because they were left out to get this kind of medication, and it costs hundreds of dollars. So they couldn't afford to buy it. So we share...

Mr. Lazio:

"...What would the impact be in terms of the breadth of service is you had a Medicaid option, if there was a Medicaid reimbursement in our backyard?"

Dr. Klausner:

"...The bill would be effective, because after I do my portion, which is surgery for a diagnosis and definitive care, sometimes they require – the lymph nodes are positive. They require chemotherapy. That is when we start running into problems. I have an oncologist who does a lot of work for me in the private sector, so he is more apt to be favorable for this, but he has to fill out reams of paper to get medication under indigent –

there is an indigent drug plan. So here is fellow I am asking to do something for free, and he is filling out reams of paper just to get medication to give to the patient. There are a lot of oncologists around they won't do it for me and I don't blame them. They are not bad people."

Ms. Fran Visco
(President, National Breast Cancer Coalition:

"I think Josefina's testimony summarizes it for all of us, and there are many like her. These women initiated treatment, but they are sitting with second mortgages and third mortgages. They are sitting with $40,000 in bills, with creditors knocking on their door. They are sitting with – begging the health care community to help them; and the health care community wants to, but the evolving health care system is harming them and is stopping them from doing this."

Mr. Lazio:

"...So we don't really know in any real sense about the continuity of care. When you say, for example, that a treatment was "initiated," we don't know whether that was an appointment, or whether it was surgery or radiation, chemotherapy, reconstruction, Tamoxifen. We have no idea what that means and whether it was spotty and sporadic or whether it was initiated."

Ms. Nancy Lee:
(Director, Division of Cancer Prevention and Control, CDC):

"As stated in my testimony, we are not able to collect data on the type of treatment, or even more difficult on the quality of treatment either from the perception of the providers or the perception of women. That is not something we are able to do."

Dr. Klausner:

"...Even more disturbing is my gradual awareness that the working poor are afraid to elect breast conserving surgery. They are so terrified of their medical bills that their medical judgment is biased. Take for example a working mother supporting two children and not qualified for Mediciad. Even if her breast cancer is amendable to breast conserving surgery, she often elects a mastectomy because she knows the cost of the additional treatments needed in breast conservation, such as radiation and chemotherapy, are too expensive. What a difficult decision this woman must make when she opts to sacrifice her breast rather than incur medical bills she can't pay. As for plastic surgical reconstruction of her mastectomy site, this has simply never been an option."

After the House Hearing on H.R. 1070, a hearing was held in the Senate Finance Subcommittee on Health (on the companion legislation – S. 662). Following are a few highlights:

Ms. Barbara Matula:
(Director, Health Care Programs, North Carolina Medical Society Foundation
Former Chairperson, National Association State Medicaid Directors
Raleigh, North Carolina):

"Imagine now that you come home tonight and you learn that someone in your family has a potential diagnosis of breast or cervical cancer. Your only concern is getting the best care. You have a sense of relief that she has regular care, regular exams. So you are hoping that it was caught early. And all you look for is full recovery...

But if you are that same woman and your income is below 200 percent of poverty, which is so very little – if you are a single person that is $16,480 a year, if you are married and it is $22,000 for the couple. That is very low, but twice what Medicaid eligibility is. You have run out of funds and you are left to your own devices..."

This is unconscionable. For all the little administrative wrinkles in Medicaid eligibility, I hope this bill will pass."

Senator Chafee:

Ms. Matula and the others...Some have suggested that CDC provide the treatment as well as the screening, in other words forgo Medicaid. What would you say to that?

Ms. Matula:

"If it was the last resort, I would say do it, of course."

Senator Chafee:

"Do not put it in the last resort category. Move it up. Let us say you were queen...Would you have a CDC treatment program?"

Ms. Matula:

"...The only reason I would not do it is that, and this was after talking to a fellow with many years experience with CDC programs, they have no experience as third party administrators. Their job is to do public education and outreach which they do very very well. To duplicate what an existing program is already doing..."

Senator Chafee:

"Meaning Medicaid?"

Ms. Matula:

"Meaning Medicaid. Learning how to reimburse physicians and hospitals and pharmacies and clinics and doing it in a quick turnaround time so that they will continue to participate would be a waste of our time and resources to duplicate this in another agency."

Ms. Barbara Flett:
Director
Women's Health Partnership of Suffolk County

"Lack of guaranteed treatment means there is no way to tell how long a woman will have to wait to get the care following a diagnosis of breast or cervical cancer. Moreover, once a woman receives treatment, she often must spend her time arguing with doctors and hospitals and sometimes creditors over her bills rather than focusing on recovering from her devastating illness."

Senator Chafee:

"...Would Medicaid have problems interfacing with another program's eligibility standards? Will Medicaid be able to easily enroll and cover those who are found eligible in screening done under the CDC program?"

Ms. Matula:

"If you would have asked me this 15 years ago, I would say we do not even speak to our public health agencies, but in that interim, we have learned how to do it with the pregnant women coverage to reduce infant mortality where the determination of pregnancy services as the presumptive eligibility, where the income tests at that time were easily twice as high as we had for the women on welfare who were the only other women. I do not that this would be a problem. The State Medicaid agency and the public health agency could have a cooperative agreement that would spell out those 200 percent of eligibility as a trigger. And it could be as smooth as silk"

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

October 20, 1999

Contact: HHS Press Office
(202) 690-6343
NCI Press Office
(301) 496-6641
FDA Press Office
(301) 827-6242

Breast Cancer: Advancing the Science, Enhancing Education, and Improving Diagnosis and Treatment

---

Overview: ***Breast cancer*** *is the most commonly diagnosed* ***cancer*** *and the second leading cause of* ***cancer*** *deaths among American women. Early detection through mammography and clinical* ***breast*** *exams are essential for effective* ***breast cancer*** *screening.*

For women age 50-69, having regular mammograms can reduce the chance of death from ***breast cancer*** *by approximately 30 percent. Even in women age 40-50, regular mammograms can reduce mortality rates by approximately 17 percent.*

The Clinton Administration has responded to the significant threat posed by ***breast cancer*** *with increased efforts in research, prevention and treatment. HHS Secretary Donna E. Shalala convened a conference in December 1993 to establish a National Action Plan on* ***Breast Cancer*** *(NAPBC). The NAPBC, which is being carried out today by public, private and volunteer sectors, is a key element of the Administration's commitment to fighting* ***breast cancer****.*

Ongoing ***breast cancer*** *education efforts are making a difference. A 1994 survey by the Centers for Disease Control (CDC) revealed that 66 percent of all women ages 50-64 and 55 percent of all women age 65 and older had received a mammogram during the previous two years. However, a study by the National* ***Cancer*** *Institute (NCI) and the Health Care Financing Administration (HCFA) released today suggests that the number of women age 65 and older receiving routine mammograms increased to 70 percent in 1998. And a CDC survey of 38 states in 1997 found that approximately 71 percent of all women over age 40 had a mammogram in the previous two years.*

At the same time, HHS discretionary funding for ***breast cancer*** *research, prevention and treatment has increased from approximately $283 million in FY 1993 to $599 million in FY 1999. President Clinton's FY 2000 budget includes $623 million for* ***breast cancer****-related activities.*

HHS also helps provide screening and treatment for ***breast cancer*** *through the Medicare and Medicaid programs and through the Indian Health Service. In January 1998, Medicare coverage expanded to help pay for annual mammograms for all Medicare beneficiaries age 40 and over.*

To spread the word about the importance of mammography in early detection of ***breast cancer****, especially in minority communities, HHS Secretary Shalala also released two public service announcements today featuring singer and actress Whitney Houston and First Lady Hillary Rodham Clinton. Since 1995, both the President and the First Lady have appeared in televised public service announcements encouraging older women to get mammograms and promoting the use of Medicare coverage for mammography.*

Background: More Women Can Survive Breast Cancer

A woman's chances of getting **breast cancer** change with age: by age 40, one of 217 women will face **breast cancer**; by age 70, one of 14 will be diagnosed with the disease. Although death rates from **breast cancer** have declined in recent years, **breast cancer** accounts for 30 percent of all cancers among women.

- Approximately 175,000 new cases of **breast cancer** will be diagnosed in 1999, and about 43,300 women are expected to die from **breast cancer**. Epidemiologic studies estimate that **breast cancer** will be diagnosed in 1.5 million American women in this decade and that **breast cancer** will claim nearly half a million lives. Death rates from the disease are highest among older, African-American and low-income women. During the 1980s, **breast cancer** incidence for women increased, but in the 1990s, it has leveled off.

- The death rate for women with **breast cancer** has declined on average 1.7 percent per year since 1989. Between 1992 and 1996, the greatest reductions in death rates were among younger women (5.7 percent) and white women (5.5 percent), with more modest reductions among African Americans (0.4 percent) and women age 65 and older (3.9 percent).

- During 1992-1996, death rates among white and African-American women declined for all decades of age from 30 to 79 years. Among both groups, the greatest improvements in mortality were seen in the younger age groups. For women age 30 to 39 years, rates dropped about 4.24 percent among whites and 2.8 percent among African-Americans. For women aged 40 to 49 years, rates dropped 8.78 percent among whites and 0.97 percent among African-Americans.

HHS Spending On Breast Cancer

HHS discretionary funding for **breast cancer** research, prevention and treatment has increased from approximately $283 million in FY 1993 to $599 million in FY 1999. President Clinton's FY 2000 budget includes $623 million for all **breast cancer**-related activities. As CDC has worked to increase access for all women to mammography screening and follow up services, the resources devoted to **breast cancer** services have increased from an estimated $43 million in FY 1993 to $93 million in FY 1999. **Cancer** research is vital to our understanding of how to prevent, detect and treat **breast cancer**. The Clinton Administration has invested in **breast cancer** research at the NIH by increasing funding from $237 million in FY 1993, to $478 million in FY 1999. HHS also helps provide screening and treatment for **breast cancer** through the Medicare and Medicaid programs and through the Indian Health Service.

HHS Action To Combat Breast Cancer

Under President Clinton, HHS has directed a wide array of activities and new initiatives:

Medicare's Annual Mammography Benefit

Since January 1998, Medicare coverage has helped pay for annual mammograms for all Medicare beneficiaries age 40 and over. Under this new benefit, Medicare waives the Part B deductible for screening mammograms.

In 1998, NCI and HCFA formed a partnership to raise awareness of the importance of regular mammography screening among women age 65 and older, and of the expanded mammography screening benefit for Medicare beneficiaries. According to a joint HCFA/NCI study, the vast majority (88 percent) of older women have had at least one mammogram in their lifetime, representing a 25 percent increase from a similar survey conducted by American Association of Retired Persons (AARP) in 1992. And 70 percent received their most recent mammogram two years ago or less -- again a substantial increase from 35 percent in 1992.

Still, data from the survey also show that more than one-third of women age 65 and older are not as concerned about getting **breast cancer** as they were when they were younger. Additionally, only 57 percent of the nationally representative sample of 814 women ages 65 and older know they should have

a screening mammogram every one or two years. To spread the word about the importance of mammography in early detection of **breast cancer**, especially in the minority community, HHS Secretary Shalala released two public service announcements in October featuring singer and actress Whitney Houston and First Lady Hillary Rodham Clinton. Information about the Medicare benefit also is included in the new Medicare and You handbook, mailed to all Medicare beneficiaries and is on the Internet at http://www.medicare.gov.

Mammography Quality Standards and Technology

The final regulations to implement the Mammography Quality Standards Act (MQSA) of 1992 went into effect April 28, 1999, ensuring universal access to high quality mammography services in this country. Under the final rules, FDA sets high standards for mammography facilities and certifies those that meet the standards. The roughly 10,000 mammography facilities nationwide accredited by the FDA must meet quality standards for equipment and personnel and are inspected annually.

These regulations spell out the details for requiring facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled interpreting physicians to interpret the results both accurately and efficiently. The rules also require that doctors be fully and quickly informed of results so that any follow-up testing or treatment can begin immediately. In fact, the Mammography Quality Standards Reauthorization Act of 1998 required every U.S. mammography facility to notify patients of their mammogram results promptly and in easy-to-understand language.

The names and locations of FDA-certified mammography facilities are available by calling NCI's **Cancer** Information Service at 1-800-4-**CANCER**. In addition, the FDA has included a list of all FDA-certified mammography facilities in the United States on its Internet home page. The address is http://www.fda.gov/cdrh/faclist.html.

National Action Plan on Breast Cancer

HHS' Office on Women's Health coordinates the *National Action Plan on **Breast Cancer** (NAPBC)*. The NAPBC was initiated under President Clinton's direction and Secretary Shalala's leadership and serves as a catalyst for national efforts in six priority areas:

- The *Information Action Council Working Group* is identifying strategies to disseminate information about **breast cancer** using state-of-the-art information technologies. This group developed and maintains the NAPBC Web site and oversees a pilot project in which community-based organizations link informationally underserved women with **breast cancer** information available through the Internet.

- The ***Breast Cancer** Etiology Working Group* is expanding the scope and breadth of biomedical, epidemiological and behavioral research activities related to the etiology of **breast cancer**. This group has convened workshops to review the current state of knowledge and to develop research recommendations in the areas of viruses, hormones and the environment, physical activity, medical ionizing radiation, electromagnetic fields and light-at-night, early life exposures, multicultural aspects of **breast cancer** etiology, and tissue architecture. The group also developed the "**Breast Cancer** Comprehensive Questionnaire," a series of high-quality questionnaire modules that can be used to clarify emerging risk factors and to make possible meta-analyses.

- The *Consumer Involvement Working Group* is outlining issues related to the involvement of **breast cancer** consumer advocates and implemented surveys to explore the nature of the involvement of **breast cancer** patients and survivors in consumer organizations, **cancer** centers and government programs.

- The *Clinical Trial Accessibility Working Group* is examining ways to make clinical trials more widely accessible to women with **breast cancer** and women who are at risk for **breast cancer**. They have extensively reviewed the literature on barriers to participation in clinical trials, and are developing strategies to overcome these barriers.

- The *Heredity Susceptibility Working Group* addressed the social, ethical and legal issues related to

genetic testing. The group produced and distributed an educational video, developed an educational curriculum and convened workshops on research priorities and on privacy and confidentiality in genetics research. This group also spear headed efforts to ensure that policies are established to protect women from workplace and health and life insurance discrimination. This group has achieved its goals and will sunset this year.

- The *National Biological Resource Banks Working Group* is the first group to accomplish its objectives and sunset. The Working Group advanced efforts to establish a national inventory of biological specimen banks to facilitate **breast cancer** research, conducted a needs assessment focused on determining the nature and extent of the need for biological resources, and developed guidelines for the ethical use of biological tissues in **breast cancer** research.

The NAPBC also administered a one-time grant program for innovative research and outreach projects in each of the six priority areas. More information about the NAPBC's activities and products can be found on the Web site, http://www.napbc.org.

Discovery of Genes for Breast Cancer

Breast cancer research and discovery has expanded rapidly at the NIH. Promising news first came in 1994 when a team of investigators at the University of Utah, Myriad Genetics and the National Institute of Environmental Health Sciences (NIEHS) identified a **breast cancer** susceptibility gene (BRCA1) that may account for 5-10 percent of the **breast** cancers diagnosed each year. The discovery of a second, entirely different **breast cancer** susceptibility gene, BRCA2, has helped us understand even more about the genetics of **breast cancer**. Researchers more recently discovered a particular variant of the BRCA1 susceptibility gene in Jewish women of eastern European descent (Ashkenazi Jews). While only 5-10 percent of all **breast** cancers are the result of an inherited anomaly, these findings hold promise for the development of new prevention and treatment strategies.

On October 27, 1996, President Clinton announced $30 million in new funding for research into the genetic basis of **breast cancer** through a collaborative initiative between the Department of Defense and the National Institutes of Health. A recent initiative under NCI's **Cancer** Genome Anatomy Project, the Tumor Gene Index, a partnership with academic centers and private companies to compile on the Internet the first comprehensive record of genes involved in human **cancer**, is identifying and cataloguing genes in the **breast** that are active in **cancer**.

Breast Cancer Prevention Trials

As part of a large North American study conducted by the National Surgical Adjuvant **Breast** and Bowel Project (NSABP) with support from NCI, more than 13,000 women volunteered to take tamoxifen or an inactive pill to see if the drug would help prevent new cases of **breast cancer**. In 1998, the trial showed 49 percent fewer cases of **breast cancer** reported in the high-risk women in the trial who took the drug versus those on the inactive pill. The study highlighted the fact that while a reduction in new cases is significant, there are risks associated with tamoxifen that must be carefully weighed against the benefits of **breast cancer** reduction. NSABP and NCI developed information for individual decisionmaking that will help women at increased risk of **breast cancer** consult with their health care providers about whether or not to begin tamoxifen therapy.

In October 1998, Secretary Shalala announced the largest-ever **breast cancer** prevention clinical trial involving more than 400 sites across the United States and Canada. The Study of Tamoxifen and Raloxifene, (STAR), will include 22,000 postmenopausal women at increased risk of **breast cancer**. STAR will build on the success of the **Breast Cancer** Prevention Trial by determining whether raloxifene, a drug similar to tamoxifen, is also effective in preventing **breast cancer** but with fewer side effects than tamoxifen. Women interested in becoming part of the study will receive individualized assessments about their risk for developing **breast cancer** and detailed information about the potential risks and benefits of both drugs.

Privacy of Genetic Information and Breast Cancer

President Clinton has supported bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage, set premiums or to distribute confidential information.

In many diseases, such as **breast cancer**, we are beginning to identify genetic alterations that may place a woman at increased risk. Women who test positive may increase **cancer** detection efforts, may choose to have preventive surgery or may join a **cancer** prevention research study. However, insurance companies and others also can misuse genetic testing to discriminate and stigmatize individuals and groups of people. In fact, studies show that women often do not get genetic testing for **breast cancer** because they fear the information will be used to discriminate against them.

National Breast and Cervical Cancer Early Detection Program

CDC's National **Breast** and Cervical **Cancer** Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, minority and Native American women nationwide. Resources devoted to **breast cancer** screening services have grown from an estimated $43 million in FY 1993 to $93 million in FY 1999. The program, which has been operating in an increasing number of states over the past nine years, has provided more than 2.2 million screening tests, including 1 million mammograms, to medically underserved women. Currently, the program provides funding for all 50 states, six territories, the District of Columbia, and 15 American Indian/Alaska Native organizations.

Breast Cancer Among the Elderly

The Agency for Health Care Policy and Research (AHCPR) is currently funding a five-year Patient Outcomes Research Team study on the care, costs and outcomes of early stage **breast cancer**. The study will examine three alternative treatments for early-stage **breast cancer** in the elderly: modified radical mastectomy, **breast**-conserving surgery with radiotherapy and **breast**-conserving surgery without radiotherapy. The project will look at quality and cost-effectiveness in these projects and will develop clear recommendations for treating early-stage **breast cancer** in the elderly.

New Frontiers In Breast Cancer Early Detection

HHS has been working with the Department of Defense, the Central Intelligence Agency, National Aeronautics and Space Administration, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of **breast cancer**. In particular, the computer technologies that have been used to improve imaging satellites may help improve **breast cancer** detection as well. In October 1996, HHS awarded $1.98 million to the University of Pennsylvania to conduct a series of clinical trials of imaging technology from the intelligence community -- originally used for missile guidance and target recognition -- to improve the early detection of **breast cancer**.

Centers of Excellence

Since October 1, 1996, HHS has established 17 National Centers of Excellence in Women's Health to serve as national models for improving the health care of American women. The Centers of Excellence program, with facilities located at academic institutions in different areas of the country, is integrating health care services, research programs, public education and health care professional training.

Mammography Clinical Practice Guidelines

Recognizing the importance of the quality of screening mammograms in the early detection of **breast cancer**, AHCPR in October 1994 developed a Clinical Practice Guideline--*Quality Determinants of Mammography*--with separate versions for mammography providers, health care professionals and consumers. The guidelines detail the roles and responsibilities of each health care professional involved in mammography services, and include information and recommendations for women.

Mammography for Women with Addictive and Mental Disorders

Women who are in need or who receive substance abuse or mental health services often lack appropriate primary health care, including **breast cancer** education, detection and treatment. Women-focused substance abuse and mental health programs funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) are designed to be comprehensive, delivering primary health care services to women who often are medically underserved. These services include education on **breast** self-examination and mammography services and counseling on risks for **breast cancer**.

Environmental Factors and Breast Cancer

The HHS Office on Women's Health has established a Federal Interagency Coordinating Committee on the Environment and Women's Health that focuses on how home, work, atmospheric pollutants, exogenous hormones, drugs, and other environmental factors may contribute to the risk of **breast cancer** and other disorders. In May 1999, NCI awarded a $4.8 million contract for development and implementation of a prototype geographic information system for **breast cancer** studies as part of the Long Island **Breast Cancer** Study. In October 1999, NCI held town meetings on Long Island, N.Y. to call for available background information about possible environmental hazards in the region.

Cancer Survivorship

In October 1996, President Clinton unveiled the new Office of **Cancer** Survivorship at NCI. Recent success of **cancer** prevention, early detection and treatment efforts have created a new need: research into the physical, psychological and economic well-being of the growing number of **cancer** survivors. The Office of **Cancer** Survivorship supports research covering the range of issues facing **cancer** survivors, including long-term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following **cancer** treatment; impacts on the family; insurance and employment issues; and interventions that result in improved quality of life and reduced morbidity and mortality.

In March 1998, NCI began including consumer advocates as full voting members of the peer review groups evaluating grant applications. This is much like the two dozen **cancer** patients and/or advocates who have assisted in **cancer** drug approval decisions since 1996 as voting members of FDA advisory committees.

NCI formed in 1997 a Director's Consumer Liaison Group, a formal committee of 15 **cancer** survivors who directly advise the NCI director and bring the patient's perspective to bear on the full range of NCI activities. This year, NCI will fully integrate patients and advocates into activities such as reviewing grant proposals and planning policy.

In September 1998, NCI earmarked $15 million over five years for new research into the physical and emotional well-being of **cancer** survivors who are alive five or more years after diagnosis. This is in addition to $20 million already earmarked by NCI for survivorship-related studies.

Mental Health Issues for Children when a Parent has Cancer

Beginning with a groundbreaking November 1998 meeting, SAMHSA and NCI have been collaborating to help elucidate the effect of a parent's illness, such as **breast cancer**, on the family in general, and on children or teens in the family, in particular. That conference emphasized the need for new research, better program development, enlightened training for health and social services professionals, and changes in public health policy, each with a focus on better "listening to families." A second meeting a year later is taking a reading of the progress being made in this critical area affecting families touched by **breast cancer**, as well as by other cancers or illnesses.

###

Note: For other HHS Press Releases and Fact Sheets pertaining to the subject of this announcement, please click here for our Press Release and Fact Sheet search engine at: http://www.os.dhhs.gov/news/press/.

STAR
Study of Tamoxifen And Raloxifene

EMBARGOED FOR RELEASE
10 a.m. EDT
Tuesday, May 25, 1999

NCI Press Office
(301) 496-6641

NSABP Operations Center
(412) 330-4657

Important Points About the Study of Tamoxifen and Raloxifene (STAR)

- The Study of Tamoxifen and Raloxifene, known as STAR, is one of the largest breast cancer prevention trials ever undertaken.
- STAR is also the first trial to compare a drug proven to reduce the chance of developing breast cancer with another drug that has the potential to reduce breast cancer risk. All participants receive one or the other drug for five years.
- 22,000 postmenopausal women at high-risk of breast cancer will participate in STAR.
- There are more than 400 STAR sites in the United States, Puerto Rico, and Canada.
- Women of all races and ethnic groups are encouraged to participate in STAR.
- Every woman considering STAR will have her risk of breast cancer assessed by a computerized program that will show how her risk compares to other women her age.
- Breast cancer risk is based on age, family history of the disease, and personal medical history.
- Tamoxifen (trade name Nolvadex®) was proven in the Breast Cancer Prevention Trial to reduce breast cancer incidence by 49 percent in women at increased risk of the disease. The U.S. Food and Drug Administration (FDA) approved the use of tamoxifen to reduce the incidence of breast cancer in women at increased risk of the disease in October 1998. Tamoxifen has been approved by the FDA to treat women with breast cancer for more than 20 years and has been in clinical trials for about 30 years.

A Study of the National Surgical Adjuvant Breast and Bowel Project (NSABP) supported by the National Cancer Institute

(more)

- Raloxifene (trade name Evista®) was shown to reduce the incidence of breast cancer in a large study of its use to prevent and treat osteoporosis. This drug was approved by the FDA to prevent osteoporosis in postmenopausal women in December 1997 and has been under study for about five years.

- The trial is limited to postmenopausal women because one of the drugs, raloxifene, has not been adequately safety tested in premenopausal women. Such safety testing is under way.

- Both tamoxifen and raloxifene have known side effects. Any women interested in participating in the trial will be fully informed of the benefits and potential risks of these drugs.

- The most common side effects of either drug are hot flashes and vaginal discharge. Treatments to eliminate or minimize side effects are available.

- Serious side effects are known to occur in women taking tamoxifen, namely endometrial cancer, blood clots in the leg or lung, and possibly stroke. Women who have had a hysterectomy are not at risk for endometrial cancer.

- Serious side effects are known to occur in women taking raloxifene, namely blood clots. Since this drug has not been under study as long as tamoxifen, not as much is known about any side effects from long-term use.

- Women with certain medical conditions will not be eligible to participate in STAR: Women with a history of cancer, blood clots, stroke, or certain types of heartbeat irregularities cannot participate. Women whose high blood pressure or diabetes is uncontrolled cannot participate.

- Postmenopausal women in the United States and Puerto Rico who are interested in participating in STAR can call the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for information in English or Spanish. The number for callers with TTY equipment is 1-800-332-8615.

- Postmenopausal women in Canada who are interested in participating in STAR can call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333 for information in English or French.

- For more information via the Internet, visit NSABP's Web site at **http://www.nsabp.pitt.edu** or NCI's clinical trials Web site at **http://cancertrials.nci.nih.gov**

###