DRAFT

INVENTORY OF BREAST CANCER ACTIVITIES:

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Framework: Proceedings of the Secretary's Conference
To Establish A
National Action Plan on Breast Cancer
December 14 and 15, 1993

Prepared by:

Office on Women's Health
Public Health Service
U.S. Department of Health and Human Services

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Introduction

Breast cancer, the most commonly diagnosed cancer and the second most likely cancer to result in deaths among American women, has been identified as a public health priority in the United States. Breast cancer represents 32 percent of all cancers in women, and the lifetime risk of developing breast cancer today is 1 in every 8 women, up from 1 in every 20 women just two decades ago. In 1993 alone, 183,000 new cases of breast cancer were diagnosed; 46,000 women died of this disease. In the decade of the 1990s as a whole, epidemiologic studies estimate that breast cancer will be diagnosed in 1.5 million American women and that breast cancer will claim nearly half a million lives. These mortality rates remain higher for older, minority, and low-income women.

Understanding how breast cancer develops and how to prevent, diagnose, and treat breast cancer and promote breast health in women across age groups and across different socioeconomic and cultural backgrounds is a priority for the Department of Health and Human Services (HHS). On December 14 and 15, 1993, HHS Secretary Donna Shalala convened the Secretary's Conference To Establish a National Action Plan on Breast Cancer. This conference marked the first step taken in direct response to the presentation of 2.6 million signatures of American citizens to President Clinton in October 1993, signatures of women and men, young and old, petitioning for establishment of a comprehensive strategy to end the breast cancer epidemic. The conference brought together a wide-ranging group of consumers, clinicians, scientists, government officials, and other experts to develop a national action plan for fighting breast cancer and promoting breast health.

The outcome of this conference—*Proceedings of the Secretary's Conference To Establish a National Action Plan on Breast Cancer*—provides an action-oriented framework for the pursuit of breast cancer activities in three major areas: the delivery of health care, the conduct of research, and the enactment of policy. The proceedings reflect areas of shared concern by pairing scientific knowledge and expertise with social insights and advocacy to create meaningful partnerships at the Federal, State, and local levels, crossing the public and private sectors to achieve a single goal. In so doing, the proceedings affirm the importance of collaboration, consensus building, and public–private partnerships among those individuals, organizations, corporations, and agencies intent on making meaningful progress toward the eradication of breast cancer. The resulting plan represents a statement of national opportunities upon which to build and strengthen knowledge, resources, and commitment in the prevention, diagnosis, treatment, care, and, ultimately, elimination of breast cancer as a threat to American women.

The Deputy Assistant Secretary for Women's Health, who directs the Department's Office on Women's Health, is responsible for coordinating implementation of the goals and action steps in the *National Action Plan on Breast Cancer.* By working with HHS components, other Federal departments and agencies, and with public and private sector organizations, the Office has already begun to establish different mechanisms for promoting a national public–private approach that emphasizes a cross-pollination of thinking, resources, and outreach across all the entities concerned with this issue.

The *Inventory of Breast Cancer Activities: U.S. Department of Health and Human Services* identifies numerous activities that support the achievement of goals outlined in the *National Action Plan on Breast Cancer.* A major premise guiding development of this inventory is that advancing and applying knowledge about breast cancer requires a thorough and ongoing assessment of relevant activities. As the inventory illustrates, HHS supports a broad range of breast cancer activities in the areas of health care, research, and policy. While meaningful progress is being made on many fronts, challenges persist in making a substantial and enduring impact on breast cancer mortality and morbidity. Just as the *National Action Plan on Breast Cancer* is intended to be an evolving document, this inventory will grow with additional development activities and partnerships in health care, research, and policy. The measure of success in this endeavor will be the eradication of breast cancer as a serious threat to the health of women today and in the generations to come.

U.S. Department of Health and Human Services
Organizational Mission

As part of its overall mission to promote and protect the Nation's health, the U.S. Department of Health and Human Services (HHS) provides leadership, direction, coordination, and support for women's health issues. HHS supports a broad range of activities to promote the health and well-being of women across the lifespan, to empower them to make informed choices about their health, and to translate policy decisions into effective women's health programs.

The Departmental components identified in the *Inventory of Breast Cancer Activities: U.S. Department of Health and Human Services* have the following responsibilities:

OFFICE OF THE SECRETARY

The Office of the Secretary (OS) provides advice and assistance in the administration and oversight of the Department's organization, programs, and activities.

Office of the Assistant Secretary for Legislation (OSL) provides advice and assistance to the Secretary regarding all aspects of the Department's legislative program and congressional relations activities.

Office of the Assistant Secretary for Planning and Evaluation (OASPE) serves as principal advisor to the Secretary on policy development, program analysis, and economic policy.

Office of the Assistant Secretary for Public Affairs (OASPA) serves as the Secretary's principal public affairs policy advisor through continuous leadership, evaluation, and coordination of Departmental policies, procedures, and practices regarding public affairs activities.

U.S. Office of Consumer Affairs (OCA) advises the President on consumer affairs and ensures appropriate consideration of consumer perspectives in policy development across Federal agencies.

ADMINISTRATION FOR CHILDREN AND FAMILIES

The Administration for Children and Families (ACF) provides national leadership and direction in the planning, management, and coordination of comprehensive programs for vulnerable children and families. ACF coordinates the development and implementation of

family-centered strategies, policies, and linkages among its programs and with other Federal and State programs serving children and families.

ADMINISTRATION ON AGING

The Administration on Aging (AOA) advises the Secretary, HHS components, and other Federal agencies on the characteristics, circumstances, and needs of older people, and develops policies and programs to promote their welfare. AOA advocates for the needs of older persons and disseminates information and guidelines on relevant services supported by HHS.

HEALTH CARE FINANCING ADMINISTRATION

The Health Care Financing Administration (HCFA) provides operational direction and policy guidance for the nationwide administration of the Medicare and Medicaid programs in a manner that promotes the timely delivery of appropriate quality health care to over 70 million of our nation's most vulnerable individuals.

PUBLIC HEALTH SERVICE

The Public Health Service (PHS) promotes the protection and advancement of the Nation's physical and mental health by conducting biomedical research; sponsoring comprehensive programs for the development of health resources; preventing and controlling disease and alcohol and drug abuse; and providing resources and expertise to the States and other public and private institutions, and to tribes, councils, and organizations concerned with the health of American Indians and Alaska Natives, in the planning, direction, and delivery of physical and mental health care services.

Office of the Assistant Secretary for Health (OASH) supports the role of the Assistant Secretary for Health (ASH) through the development, implementation, and coordination of crosscutting policies and programs.

- ***Office of Disease Prevention and Health Promotion (ODPHP)*** provides leadership in the formulation of national health goals and objectives; the coordination of HHS activities in disease prevention, health promotion, preventive health services, and health information services; and the stimulation of public and private programs to enhance the health of the Nation.

- ***Office of Minority Health (OMH)*** develops policies and programs for the improvement of the health status of minority and disadvantaged populations and coordinates all PHS minority health activities.

- ***Office on Women's Health (OWH)*** provides leadership in the development, implementation, evaluation, and coordination of women's health issues, policies, programs, and activities.

Agency for Health Care Policy and Research (AHCPR) enhances the quality, appropriateness, and effectiveness of health care services through scientific research and clinical practice guideline development.

Centers for Disease Control and Prevention (CDC) serves as the national focus for activities related to disease prevention and control, environmental health, health promotion, and health education.

Food and Drug Administration (FDA) protects the Nation's health by ensuring that food is safe and wholesome and that human and animal drugs, cosmetics, biological products, therapeutic devices, and radiological and diagnostic products are safe and effective.

Health Resources and Services Administration (HRSA) promotes the delivery of primary and preventive health services to underserved populations and the development of health resources to meet the health needs of the Nation.

Indian Health Service (IHS) provides comprehensive health care services and assistance to American Indians/Alaska Natives (AI/AN) in the development of health programs, health management training, and human resources development.

National Institutes of Health (NIH) provides leadership and support for scientific research on human health and the application of that research to extend healthy life and reduce the burdens of illness and disability.

The focal point for women's health research at the NIH is the *Office of Research on Women's Health,* which (1) strengthens research on women's health conditions and ensures that NIH-supported research adequately addresses women's health issues; (2) ensures that women are appropriately represented in NIH-supported research; and (3) supports the recruitment, retention, reentry, and advancement of women in scientific careers.

Substance Abuse and Mental Health Services Administration (SAMHSA) provides leadership and support for the prevention and treatment of addictive and mental health

problems and disorders, including the integration of scientific research discoveries into primary health care applications.

The central focus for women's issues within SAMHSA is the *Office for Women's Services,* which (1) identifies the substance abuse and mental health services needs of women; (2) recommends and implements relevant policies; and (3) collaborates across SAMHSA's Centers for Substance Abuse Prevention, Substances Abuse Treatment, and Mental Health Services regarding relevant services for women.

SOCIAL SECURITY ADMINISTRATION

The Social Security Administration (SSA), the Nation's primary income security agency, administers the Federal retirement survivors and disability insurance programs as well as the supplemental security income (SSI) program for aged, blind, and disabled beneficiaries.

Inventory of Breast Cancer Activities: U.S. Department of Health and Human Services

The following activities relate to current and planned programs that help to meet the goals outlined in the *National Action Plan on Breast Cancer.*

I. HEALTH CARE

Effective health care delivery is critical to reducing morbidity and mortality from breast cancer. In turn, the health care delivery system depends on the effective dissemination of information about breast health and breast care. Responsibility for breast health services is shared by a wide range of participants including consumers, providers, patients, and educators, as well as industry, the media, and the research community. This section identifies five key goals and corresponding HHS activities that address health care issues related to breast health and breast cancer.

A. Improve access to and utilization of breast health services.

1. Mandate public health agencies at all levels to provide all women with essential breast health services through service as system providers, coalition builders, data collectors, quality assurance professionals, public educators, health care provider educators, and community organizers.

Current Activities

PHS/CDC

The CDC National Breast and Cervical Cancer Early Detection Program provides a foundation for supporting effective screening and early detection of breast cancer at the State and community level. Through cooperative agreements, CDC provides support and technical guidance to 45 State health departments and up to five Indian tribes to:

- Establish, expand, or improve community-based screening services for women at risk;
- Deliver education programs to send the public clear, consistent, and culturally sensitive messages on the benefits of screening;

- Deliver education programs for health care professionals to improve skills in health education, screening, and diagnostic services;

- Improve quality assurance measures to ensure adherence to standards and guidelines related to screening mammography and cervical cytology;

- Establish a surveillance and evaluation system to determine where prevention efforts have the most impact, examine health policy, evaluate necessary resources, and monitor program progress;

- Establish State-level cancer coalitions that include representation from key public, private, and voluntary organizations affecting the early detection process.

CDC has convened a workgroup, comprised of representatives from NCI, CDC, the American Cancer Society (ACS) and State health departments, to address issues related to the development of the public health infrastructure for cancer control, including breast cancer, in States.

PHS/FDA

Through the implementation of the Mammography Quality Standards Act, the FDA is involved in improving access to breast health services. See III-D for a full description of FDA activities under MQSA.

PHS/IHS

The Indian Health Service (IHS) is actively collaborating with the CDC National Breast and Cervical Cancer Early Detection Program to bring mammography services to Native American women. A CDC Public Health Advisor has been assigned to IHS Headquarters Cancer Prevention and Control Program in Albuquerque to help implement this screening program. Mammography has always been difficult to obtain in remote reservation sites; the CDC grants have been used in New Mexico to fund mobile mammography units in a very successful program. As more reservation states receive the CDC grants, improved mammography screening rates are anticipated as well as improved public and provider education.

PHS/NIH/NCI

The Cancer Patient Education Network, comprised of patient educators at each of the NCI-designated comprehensive, clinical, and consortium cancer centers is convened annually by NCI for training and for development of new patient education programs. Breast health education issues are included on the agenda and many general patient education sessions are directly applicable to the management and delivery of education programs for breast cancer patients.

NCI funds the research initiative, "Public Health Approaches to Breast and Cervical Cancer Screening," to demonstrate and test how community consortium projects can increase availability and utilization of breast and cervical cancer screening among low-income, low-education attainment, and minority women over 40 years of age. Projects are characterizing local utilization of services, assessing barriers, and testing interventions.

A Program Announcement (PA) entitled "Model Cancer Control Delivery Systems," first published in 1992, invites applications for studies to develop, implement, and evaluate effective organizational models for integrating cancer prevention and early detection services into existing prevention and primary care services provided by health care systems such as community and migrant health centers, public health clinics, and public university hospitals. Most of the grants focus on breast cancer.

See also I.A.3.

HCFA

The mission of HCFA is to formulate policy and guidelines to govern the financing of health care services, including screening, diagnosis, and treatment for breast cancer, for the nation's elderly and disabled through the Medicare program and, in partnership with the States, for needy Americans through the Medicaid program.

General Program Policy—Medicare and Medicaid

Coverage of services under Medicare and Medicaid is generally not disease-specific. Thus, services rendered to breast cancer patients are covered if the services are medically necessary to diagnose and treat the illness.

There are no specific coverage provisions relating to the treatment of breast cancer under Medicaid. State programs are required to cover medically necessary breast cancer treatments that may be provided under mandatory Medicaid service categories. States may also make additional services available under optional Medicaid service categories.

All States provide mammography as a diagnostic service. According to HCFA's 1992 survey, 47 States also provide screening mammography. All Medicaid managed care plans also cover mammograms.

HCFA encourages mammography by providing Medicare reimbursement for screening and diagnostic mammograms.

* In 1991, Medicare instituted coverage for screening mammograms (that is, for women without any signs or symptoms of breast cancer). Women over the age of 65 with part B coverage can receive this benefit on a biennial basis.

* Women suspected to have breast cancer after a self- or health care provider exam can receive Medicare coverage for diagnostic mammograms as often as medically indicated.

* HCFA pays 80% of the costs of screening and diagnostic mammograms, and that only after the yearly Part B deductible of $100 has been met by the beneficiary.

* In 1994, HCFA reimbursed screening mammograms up to the statutory cap of $59.63. In the same year, the average fee schedule amount for bilateral diagnostic mammography was about $64.

Planned Activities

PHS/CDC

CDC provides leadership in carrying our critical activities at the national level to address the significant geographic, economic, and knowledge barriers which prevent many women, especially low income, elderly, and minority women, from taking advantage of lifesaving early detection services for breast cancer.

CDC will support a comprehensive national strategy to reduce mortality from breast and cervical cancers through implementation of community-based early detection

programs in every State and territory and the enhancement of the State-based cancer surveillance infrastructure. This proposal would support breast and cervical cancer early detection programs and cancer registries in all 50 States and territories.

Currently, CDC funds breast and cervical cancer early detection activities in only 45 States. At the current level of support, these activities address only a portion of the unmet need for education, outreach, surveillance, quality assurance, and clinical services. Only 40 States have established cancer registries for use in monitoring breast cancer burden and planning breast cancer control efforts. Most of these States do not have the resources for complete coverage of their population or the ability to ensure minimum standards of quality. Population-based, high-quality State cancer registries are needed in every State to: (1) monitor trends in cancer occurrence, by site, age, ethnicity, and geographic region for use in intervention design; (2) target intervention efforts and health resources; and (3) monitor the impact of intervention efforts. CDC will increase resources to State health agencies to assure that: (1) women and health care providers are aware of the benefits of routine screening and women are motivated to seek screening through innovative community-based programs; (2) systems to ensure the quality of the screening tests are in place and operational; (3) breast cancer trends can be identified and monitored for timely intervention; (4) breast cancer control resources can be targeted for greatest impact; and (5) the short- and long-term impacts of breast cancer control efforts can be assessed.

2. ***Act immediately to establish breast health services as a priority in all relevant programs funded by the Federal Government. Foster partnerships between the agencies of the Federal Government and the private sector.***

Current Activities

PHS/CDC

CDC provides technical assistance and training of health care providers for breast health to the Indian Health Service (IHS). CDC has met with representatives of the Health Care Financing Administration (HCFA) to explore collaborations to increase utilization of the Medicare benefit for screening mammography. CDC funds the American College of Physicians to develop and implement an office-based screening and recall system to promote breast screening by primary care providers.

PHS/NIH/NCI

The CIS Outreach Coordinators worked with the YWCA and grantees of the Centers for Disease Control and Prevention (CDC) to assist them in recruiting volunteers for conducting breast cancer screening awareness programs.

NCI participates in national meetings of physicians and other health care providers to promote their use of early detection practices.

Posters and other office materials promoting mammography have been pretested among physicians and their staffs to refine the materials and to encourage these professionals to promote early detection practices.

NCI conducted focus groups in cooperation with the American College of Physicians, the American College of Obstetricians and Gynecologists, and the American Medical Women's Association to explore ways in which it can support physician efforts to educate their patients about screening mammography.

Planned Activities

PHS/NIH/NCI

The Cancer Patient Education Network will be expanded to include educators from community cancer centers, hospitals, and large health care delivery systems such as the Veterans Administration Medical Centers.

3. ***Summarize, disseminate, and implement proven strategies for improving access to and use of breast health care, such as providing vouchers for transportation to and from breast health services and using mobile systems to bring such services to those who need but do not have easy access to them.***

Current Activities

PHS/CDC

CDC supports the development, implementation, and evaluation of strategies for improving access to and use of screening mammography through support for 45 State-based early detection programs described in I.A.1.

In May 1993, the CDC-supported Regional Training center for the Early Detection and Control of Breast and Cervical Cancer conducted a four-day training course for States which focussed on innovative and proven strategies for recruiting women into screening. Strategies for improving access and use of screening mammography are also disseminated at CDC's annual national conference on breast and cervical cancer early detection.

CDC has also commissioned public health experts to develop papers for publication on topics related to access and utilization of screening services, including mass media strategies and channels, interpersonal strategies and channels, target audiences and primary messages, and resources for State and local mobilization.

PHS/IHS

IHS has been purchasing mammography equipment in a number of rural sites where screening was previously unavailable.

PHS/NIH/NCI

The NCI's Cancer Information Service (CIS) provides cancer prevention, detection, diagnosis and treatment information to the public, patients and professionals through a toll free phone service (1-800-4-CANCER) and through regional outreach activities. Each year the CIS responds to over 100,000 direct inquiries concerning breast cancer. CIS Information Specialists respond to a wide variety of questions and refer callers to

treatment centers, clinical trials, diagnostic and screening services and support groups.

NCI recently developed and disseminated through CIS Outreach Coordinators *The Picture of Health*, a description of six community demonstration programs on breast cancer screening. If the handbook is well received at the state and local levels, it will be reprinted in greater quantities for use by community programs.

4. ***Encourage a pyramid system of health care delivery in which physicians lead a collaborative team that gives qualified nurses, other health care professionals, community outreach workers, advocacy groups and support groups a prominent role in providing care.***

Current Activities

PHS/CDC

See I.A.1. above. States participating in the CDC National Breast and Cervical Cancer Early Detection Program provide services through multidisciplinary collaboration with:

- physicians, nurses, and other health professionals for clinical care and education on breast health and the benefits of screening mammography;
- community-based organizations and community outreach workers, to reach underserved women and provide culturally appropriate information on the benefits of screening and how to access care (*see* I.A.5); and
- advocacy groups, including the ACS, the Young Women's Christian Association of the USA (YWCA) and others, which offer educational materials, support groups, and other follow-up services.

PHS/NIH/NCI

NCI supports clinical training programs for physicians leading to sub-specialty accreditation in medical and pediatric oncology, and radiation oncology. In addition, NCI supports training programs for oncology nurses and pharmacists. Breast cancer

(and other cancer) patients are cared for at the NCI by a multidisciplinary team of health professionals validating this multidisciplinary approach to patient care.

5. ***Use community-based organizations and outreach workers as lay advisors, patient advocates, disseminators, and interpreters of breast health information.***

Current Activities

PHS/CDC

See I.A.1. and I.A.3. above. CDC fosters the use of community-based organizations and outreach workers in States participating in the National Breast and Cervical Cancer Early Detection Program. Some examples:

- In California, an effective approach educating women has been developed by a consortium of community-based organizations. The "comadre," or community gatekeepers, inform, educate, and recruit into screening women who are unfamiliar with the health care system. This approach brings the program to women in need by establishing outreach sites in housing units and local churches.

- In Missouri, rural women are served through collaboration with the Missouri Family and Community Educators, a group of 9,000 rural women who have agreed to support the breast and cervical cancer early detection program in their communities.

- In New Mexico, community outreach to African American women is facilitated through training of low-income community women and guided by a committee of community leaders, the African American Breast and Cervical Cancer Prevention Committee.

- In Nebraska, a seminar on breast and cervical cancer, developed by and for women in the community, was jointly sponsored by the Omaha Black Nurses Association, the Nebraska Department of Health, the Delta Sigma Theta Sorority, and ACS. One young women who attended the seminar had a palpable lump and had been unsuccessful in gaining access to the health care system. This outreach program provided her with the support and services she required.

6. ***Require federally funded hospitals and health care centers to screen all women who enter the health care delivery system and for whom guidelines recommend regular mammography screening, as soon as possible if they have not already received such services, and provide necessary and appropriate follow-up.***

Current Activities

PHS/HRSA

The Maternal and Child Health Bureau (MCHB) focuses on improving the health of women during the child-bearing years through the administration of the Maternal and Child Health Services Block Grant to the States (Title V of the Social Security Act). Screening for breast cancer is included as part of the delivery of health services to women that are funded through Title V, as are comprehensive services (including services related to breast health) for adolescents.

A recent survey of State Health Agencies indicated that Title V monies support breast cancer screening as a stand-alone in at least 26 States through Maternal and Child Health units. In addition, Title V funds support stand-alone breast cancer screening through Family Planning units in an unknown number of other States. Some additional breast cancer screening services are also delivered as an integral part of the delivery of primary care and family planning services funded under Title V. Through comprehensive clinical services for adolescents, some services related to breast health, including health education, are provided.

Planned Activities

PHS/NIH/NCI

See I.C.1.

7. ***Make clinical breast exams a part of every general physical examination conducted by qualified health care providers.***

Current Activities

PHS/CDC

See III.D.5.

B. Improve coordination and information management among providers, patients, consumer organizations, scientists, the media and other involved groups to disseminate information on breast health and breast health services.

1. ***Use the full range of electronic media, print media, consumer-oriented publications, and interactive multimedia approaches (1) to disseminate research findings to scientists and the general public and (2) to inform both health care providers and consumers about new scientific knowledge.***

Current Activities

PHS/CDC

CDC maintains the Combined Health Information Database (CHID), a computerized resource for information on health. The Cancer Prevention and Control Database Subfile provides bibliographic citations and abstracts for journal articles, book chapters, technical reports, proceedings, papers, policy documents, reports, legislation, monographs, unpublished documents, educational materials, curricula and descriptions of cancer prevention activities and risk reduction efforts at the national, State, and local levels.

PHS/FDA

Several of the offices that make up the Office of External Affairs (OEA) work with external constituencies—including the Congress, numerous breast cancer advocacy organizations, health professionals, the scientific community, the media and

industry—on issues of breast cancer prevention, screening, and treatment. Examples include:

* Office of AIDS and Special Health Issues (OASHI) provides advance notice to organizations in the breast cancer community about upcoming FDA Advisory Committee meetings on issues concerning breast cancer and interacts widely with breast cancer advocates.

* Office of Health Affairs (OHA) interacts with health professionals and uses a number of vehicles, including the *Medical Bulletin*, and a quarterly FDA column in the *Journal of the American Medical Association*, to provide information on breast cancer prevention and therapies. OHA also interacts with NIH, including the Office of Alternative Medicine. OHA is engaged in the implementation of the MedWatch adverse reporting system, which facilitates the reporting by health providers of adverse events from regulated products.

* Office of Public Affairs (OPA) has produced two video news releases on breast cancer prevention and mammography, has developed talk papers and press releases on a variety of issues pertaining to breast cancer (e.g., MQSA), and has published numerous articles in the magazine *FDA Consumer* on breast health (e.g., mammography, breast implants).

PHS/NIH/NCI

NCI developed a database describing all materials for cancer patient education. This file is now part of the larger CDC Combined Health Information Database (CHID) and contains a large section on breast cancer patient education programs and resources. The database is accessible in public and medical libraries, as well as health care institutions. Several interactive learning programs refer to NCI educational resources within their patient and health professional programs.

NCI disseminates research findings to the general public via the news media through statements, backgrounders, and fact sheets about current research and findings. Examples are "Improving Methods of Breast Cancer Detection," "Lifetime Probability of Breast Cancer in American Women," and "Canadian Study Prompts Health Officials to Review Mammography Recommendations," as well as a new statement on "Breast Cancer Screening" and a backgrounder on the scientific basis for this statement. All such materials are disseminated to the news media and to breast

cancer organizations, and to the CIS via E-mail. They also are issued electronically to national news organizations, and are retrievable on CompuServe. Major clinical research findings or new studies are announced to the public via press conferences, with participation by the electronic news media. Efforts have included video news releases, television and talk show interviews, and electronic dissemination of the results in print format.

An NCI service, CancerFax, can disseminate professional, patient, and public education materials via the facsimile machine, including statements from PDQ, an electronic database on cancer treatment, prevention and detection for physicians and the public. Included are publication lists of all NCI printed material available for ordering and nearly 100 NCI fact sheets, of which 19 are breast cancer-related. Spanish language materials are also available. (See also I.D.)

NCI has created and disseminated a full range of video materials to help communicate NCI messages on breast cancer screening, including:

* Video footage of women (white, African-American, older American, Hispanic American) obtaining mammograms and learning about mammography. This material has been widely disseminated in hard copy and through satellite distribution. Footage can be used by news shows and other producers to develop stories on breast cancer screening.

* "Una Vez Al Ano...Para Toda Una Vida," a television show on mammography with an internationally known Hispanic cast. "Una vez" was designed to be culturally relevant and appealing to Hispanic women over 50 years of age. Developed with Revlon, it was broadcast in over 600 cities by the Hispanic Univision television network.

Radio public service announcements are routinely produced and distributed for mammography campaigns.

Media interviews via satellite are produced and promoted to television stations around the country to communicate NCI breast health messages to the public.

OASH/OMH *See* I.C.9.

Planned Activities

PHS/CDC

CDC will maintain the CHID database and will expand information on innovative, effective service delivery, education, outreach, quality assurance, evaluation, surveillance, and coalition-building activities for breast cancer at the State and local level.

PHS/NIH/NCI

The NCI is exploring joint promotions with a number of physician groups to educate members and their patients about screening mammography. Other efforts to educate health professionals will include workshops, direct mail, targeted media placements and cable broadcasts.

The PDQ Cancer Patient Education database will be evaluated during 1994 to determine user satisfaction and usage.

PHS/SAMHSA

Task II of the contract for a Women's Resource Center provides for a Technical Expert Group on "Information Dissemination and Community Mobilization." This group will consider the dissemination of information on women's issues. We can ensure that the information will include breast health.

The Center for Substance Abuse Prevention's (CSAP) Perinatal Addiction Prevention Branch will begin a Women in Transition and alcohol, tobacco and other drug abuse prevention initiative in February 1995. This initiative will give the Center an opportunity to look at older women and other groups not focused on before. In looking at alcohol, tobacco, and other drug abuse prevention and its relationship to women's health, breast health care will be an important issue to include in the development of the demonstration program and the related media campaign.

ACF *See* I.B.6.

HCFA *See* I.D.3.

OASPA

OASPA will continue to work with DHHS components to effectively communicate messages about breast health and breast cancer. Communication tools will include a variety of written materials, public events, and audiovisual materials targeted to a wide range of populations.

OCA

The U.S. OCA can assist with outreach to underserved communities, the media, consumer groups and agencies. The primary vehicle for doing so is the monthly newsletter, *Consumer News*, with a mailing list which includes many of the organizations and publications who would benefit from breast health information. The U.S. OCA can also advise on making messages and information sources more consumer-friendly. While budget and staff resources are extremely limited, OCA can help with liaison and outreach efforts.

New Collaborative Activities

PHS/NIH/NCI

The advisory board for the Combined Health Information Database voted to promote and increase use of the entire database. The information within the database is an important resource for planning breast cancer educational interventions.

NCI uses a system called CancerNet to disseminate professional and public education materials via the Internet computer network. NCI is exploring the feasibility of modifying its public and patient education booklets for dissemination on CancerNet. Breast cancer publications are the pilots in this project.

2. *Employ community-based and outreach workers to improve, disseminate, and explain breast health information to health care consumers and providers.*

Current Activities

PHS/CDC

See I.A.5. above.

PHS/NIH/NCI

NCI's CIS currently supports 24 Outreach Coordinators nationwide who in 1993 helped more than 2,000 state and regional organizations to conduct education activities related to mammography.

Project Awareness, a collaborative program designed to provide underserved women with breast cancer education, mammography, clinical breast exams, and followup medical care, was completed in 10 cities including Washington, D.C., Detroit, Los Angeles, Baltimore, Atlanta, Raleigh/Durham, St. Louis, and Miami. Evaluation data on the effectiveness of the education campaign was being completed in early 1994. A revised program manual has been produced and will be available to interested cities through the CIS outreach coordinators. The lessons learned from the community-based model are now being used by the YWCA in cooperation with NCI, CDC, the Avon company, and the National Alliance of Breast Cancer Organizations (NABCO) to institutionalize the program.

The NCI-funded Black, Hispanic and Appalachian Leadership Initiatives on Cancer are designed to stimulate the participation of community leaders (lay and professional) in cancer prevention and control activities to mobilize the community at the national, state, local, and grassroots levels. The goals of these initiatives are to (1) reduce cancer incidence and mortality rates; (2) improve cancer survival rates, and (3) address the barriers that limit or prevent Black, Hispanic and Appalachian populations from gaining access to quality cancer control services. All three initiatives include a focus on breast cancer and the barriers to effective screening.

3. ***Sponsor conferences and meetings to facilitate a continuing process whereby relevant organizations at the national, regional, and local levels—including consumers and consumer groups—share information on successful approaches to breast health care, develop consensus on needs for improved and new remedial approaches, and mobilize appropriate participant organizations to take action among their constituencies.***

Current Activities

PHS/AHCPR

The small conference grant program provides support to organizations conducting conferences that further the interests of health services research. AHCPR is interested in conferences that: (1) facilitate the sharing of information, especially among groups not traditionally brought together; (2) establish health services research agendas; (3) disseminate research and clinical information; and/or (4) work to develop or improve research methodologies. An example is a small conference grant awarded this year for a conference entitled, "Cultural Values and Health Research: A Methods Conference." It is expected that this will stimulate a greater awareness of the need to look at research questions with careful consideration of the subject population's perspective.

PHS/CDC

See I.A.1. above. The infrastructure maintained through the CDC's National Breast and Cervical Cancer Early Detection Program provides an important vehicle for the Public Health Service to communicate information on breast health and the benefits of screening, and to encourage policy changes at the State and local level. CDC sponsors a national conference for 45 State partners and more than a dozen national partners to encourage discussion on issues related to the early detection of breast cancer, share information on successful approaches to educating women and providers, and develop strategies to mobilize resources for early detection.

In collaboration with Baylor University and M.D. Anderson Medical School, CDC co-sponsored an annual conference on cancer in minority populations.

In February 1994, CDC co-sponsored a conference with the American Cancer Society (ACS) on cancer in the older adult population.

PHS/NIH/NCI

The Board of Scientific Counselors for the NCI Division of Cancer Treatment established the Breast Cancer Research Working Group as an open forum for discussion of new and planned research initiatives with breast cancer patients and other breast cancer advocates. Meetings are attended by representatives of all NCI divisions and address all areas of breast cancer research, not only treatment.

NCI cosponsors NIH Consensus Development Conferences on breast cancer care as relevant issues emerge.

Planned Activities

PHS/SAMHSA

The Center for Substance Abuse Prevention (CSAP) programs include the April 1994 Synthesis Workshop meeting to review what is known about women's health regarding alcohol, tobacco, and other drug abuse can disseminate relevant research results on breast cancer, particularly as they relate to alcohol and tobacco use. Breast health can be included as a discussion point in CSAP's role to help create healthy lifestyles. CSAP would work with NIH to develop the appropriate information to be disseminated and discussed.

The Center's Resource Links III perinatal conference, to be held in July 1994, can also be a vehicle to disseminate information to participants about breast cancer prevention, availability of clinical trials, particularly for low-income minority women, etc.

New Collaborative Activities

PHS/NIH/NCI

The Association of Community Cancer Centers has expressed interest in working with the NCI on the development of regional workshops to enhance patient education services within their 400 member institutions.

4. ***Coordinate breast health educational programs among Federal, private, and voluntary agencies to minimize redundancies and deficiencies in programs and conflicts in messages. Include consumers in the process.***

Current Activities

PHS/CDC

CDC encourages constituents to use education materials developed by the National Cancer Institute (NCI), the American College of Radiology (ACR) and the ACS to minimize redundancy and inconsistencies. CDC promotes the use of ACR lexicon and quality assurance standards for mammography.

PHS/HRSA

The Bureau of Primary Health Care's (BPHC) has undertaken the following:

- The Division of Community and Migrant Health met with NIH's Office of the Women's Health Initiative to discuss future collaborative efforts.
- C/MHCs are collaborating with NCI in the area of breast cancer education and screening.
- The Migrant Health Branch has met with NIH's Office of Research on Women's Health to discuss future collaboration on farmworker women's health.

PHS/NIH/NCI

NCI staff meet quarterly with CDC and the American Cancer Society (ACS) to ensure that programs are coordinated. In addition, NCI asks individuals from other related programs to serve on CIS task forces to develop information resources and referrals and promotion and outreach plans.

NCI participates in the Board of Sponsors for National Breast Cancer Awareness Month, which meets annually. NCI communicates through the year with the Board members, 15 other national organizations interested in mammography promotion.

NCI worked with CDC and FDA to develop the National Strategic Plan for the Early Detection of Breast and Cervical Cancers.

NCI consults with numerous advocacy groups and other partners in the design of new breast cancer educational resources and programs. Regular mailings inform the groups about new programs or initiatives.

HCFA

In developing its initiative to foster informed decision-making on breast health by its beneficiaries, HCFA is coordinating its information dissemination activities with appropriate government, private, and voluntary groups. Based on the information and feedback from these groups, HCFA will develop a comprehensive strategy for assuring that beneficiaries receive meaningful information.

SSA

Under the SSA's Social Security Disability Insurance and Supplemental Security Income Programs, disability benefits are paid to those persons with breast cancer whose condition fulfills specific SSA criteria. Usually these are women (and some men) with advanced disease that is not well-controlled with treatment.

SSA is committed to ensuring that all potential applicants for disability benefits have access to and knowledge about SSA programs. SSA's linkages with other agencies enables informing DHHS components about relevant programs and sharing information with health care provider constituents.

OASPA

OASPA currently coordinates all DHHS publications and has undertaken an extensive effort to coordinate the production of educational materials on breast cancer. This is a collaborative effort involving various DHHS Operating and Staff Divisions involved with breast cancer issues. In particular, OASPA is working closely with the PHS Office of Communications.

OASPA advocates the development of targeted, non-duplicative consumer friendly literature to educate women about activities that can potentially reduce the incidence of breast cancer.

Planned Activities

PHS/CDC

CDC will assist State health departments to negotiate a consistent message with their State and local chapters of ACS to minimize confusion regarding mammography screening recommendations.

PHS/SAMHSA

CSAP intends to fund a new contract for a Women's Resource Center. This new Center will be supported by the Center for Substance Abuse Treatment, the Center for Mental Health Services, the SAMHSA Office for Women's Services and the Maternal and Child Health Bureau at the Health Resources Services Administration. Some of the planned tasks for this Center can play a role in the implementation of the National Action Plan on Breast Cancer.

HCFA

HCFA's initiative to foster informed health decisions by providing useful information derived from HCFA empirical data builds on existing partnerships while encouraging new relationships with related organizations. Participation by these entities is crucial to the success of the initiative.

See I.A.1. and I.D.4.

OASPA *See* I.B.1.

OCA *See* I.B.1.

New Collaborative Activities

PHS/NIH/NCI

Women in underserved populations will be introduced to activities known to reduce morbidity and mortality from chronic disease such as breast cancer in collaboration with CDC, the Substance Abuse and Mental Health Administration, the National Institute on Alcohol Abuse and Alcoholism, the National Heart, Lung and Blood

Institute (NHLBI) and the National Institute on Child Health and Human Development (NICHD). The goals are to develop and evaluate prevention and control methods for these women and bring the successful interventions toward national application.

NCI will collaborate with NICHD to develop and evaluate interventions that involve behavior change in families in areas of diet, tobacco use, exercise, and screening attendance to reduce risk for certain diseases, including breast cancer.

5. *Provide incentives for employers and schools to participate in comprehensive, on-site breast health programs for employees and students.*

Current Activities

PHS/CDC

CDC conducted an occupational study using mortality data and found that teachers, librarians, and nuns were among the occupational groups that were found to have higher mortality rates from breast cancer. CDC has met with representatives from the National Education Association and the American Federation of Teachers to discuss study findings and explore intervention opportunities directed to early detection.

CDC supports the American Federation of Teachers and the National Education Association Health Information Network to promote workplace breast health education for female school employees.

PHS/HRSA

The Federal Employees Occupational Health Program (FEOH) provides ongoing education programs through both lecture and written materials on employee health, including breast health and breast cancer screening, to employees of Federal agencies with whom FEOH has interagency agreements. Breast clinical examinations and mammography screening are offered onsite through use of ACR-accredited mobile mammography units. In addition, FEOH will take the lead in assuring that all future FEOH breast health education and screening programs are implemented in accordance with the NCI guidelines.

PHS/NIH/NCI

NCI actively promotes encouragement of breast cancer screening at the workplace through its efforts as part of National Breast Cancer Awareness Month. In 1993, a PBS Adult Education Satellite program on employee screening was promoted by the CIS to local businesses. In addition, an awards ceremony was conducted to honor businesses that have taken the lead in breast cancer screening.

Materials targeted to businesses include: *Screening Programs Make Good Business Sense* and *Establishing Workplace Breast Cancer Screening Programs—A Blueprint for Action.*

See I.E. for discussion of regional breast cancer education summits.

Relevant initiatives are also described in I.D.

SSA

SSA is strongly committed to the health of its employees, as evidenced by an array of disease prevention programs. For example, the University of Maryland Medical System's mobile mammography van is available to employees at designated times.

Planned Activities

PHS/CDC

In FY 94, CDC will fund the American Federation of Teachers and the National Education Association Health Information Network to promote workplace breast health education for female school employees.

6. Develop mechanisms for the centralized collection and distribution of existing and available consumer-oriented information on breast cancer. Materials would be drawn from national, state, and local organizations including private for-profit and nonprofit organizations, voluntary and professional organizations, and academic and medical institutions.

Current Activities

PHS/AHCPR

CRDL provides writing, editing and production support services for all AHCPR publications. The AHCPR Clearinghouse distributes agency publications and we are developing electronic dissemination capabilities for the clinical practice guidelines. Public/private partnerships are sought to maximize the dissemination of AHCPR products.

PHS/CDC

The infrastructure maintained through the National Breast and Cervical Cancer Early Detection Program provides an important vehicle for the Public Health Service to communicate information on breast health and screening recommendations and to encourage policy changes at the state and local level.

CDC maintains the Combined Health Information Database (CHID), a computerized resource for publications, documents, reports, legislation, educational materials, curricula and descriptions of cancer prevention activities and risk reduction efforts at the national, state and local levels. This database is accessible to universities, health departments and others via modem.

PHS/FDA

Within the Office of External Affairs, the Office of Consumer Affairs (OCA) informs consumer organizations about initiatives, such as MQSA and breast implants, the latter through an "800" number telephone hotline. OCA has engaged in serious outreach efforts to a number of minority (see below) and other underserved communities, such as the lesbian community, older women, rural women, economically challenged women, where the incidence of breast cancer is high and/or there may be cultural resistance to certain medical procedures or interventions. OCA interacts with a wide variety of women's groups, including, Women of Color (e.g., National Black Women's Health Project), Native American (e.g., Native American Women's Health Education Resource Center), Hispanic, Latina (e.g., COSSMHO) and Asian (e.g., Asian Forum) women's health groups on these and other issues.

PHS/OASH/OMH

OMH's Resource Center has a fact sheet on cancer and minorities which does also cover some breast cancer information. Additionally, the Resource Center produces a list of sources of health materials for each of the racial/ethnic populations with which OMH works. These lists identify organizations and the kinds of materials they have, by subject (such as cancer) and language, as appropriate. Lastly, the Resource Center has compiled a source list of audiovisual materials directed to minority audiences, which includes cancer among its subjects, and lists a Spanish and English video on breast cancer.

Planned Activities

PHS/CDC

CDC will continue to maintain this database and will expand information on innovative, effective service delivery, education, outreach, quality assurance, evaluation and coalition-building activities for breast cancer early detection at the state and local levels.

PHS/IHS

IHS is collaborating with the Office of Minority Health to develop a clearinghouse for health education materials that are specifically aimed at Native Americans. This will include breast cancer informational pamphlets, posters and videos.

PHS/SAMHSA

Task VI of CSAP's planned Women's Resource Center (*see* I.B.4) provides for the development of resources packages and positions papers. A resource package or position paper on ethnic/minority/underserved women and health could certainly include information on how at risk populations are affected by breast cancer.

See also I.B.4.

ACF

ACF has the capacity to provide mailing labels from their extensive publications distribution list for breast health and services information dissemination. This list includes a variety of public and private constituencies such as: federal agencies; federal and state elected officials; community-based grantees (e.g., Head Start Centers, Community Action Agencies); and numerous educational, volunteer, professional and charitable organizations.

AOA

AOA's Older Women's Initiative is intended to (1) highlight the many contributions of older women and (2) create an action plan for addressing older women's needs in critical areas such as income security, health care, housing and caregiving. The health care component of the Initiative focuses on health promotion and disease prevention. AOA intends to launch a major public education effort to inform older women and their families about breast cancer and the importance of regular breast cancer screenings.

Planned Activities

PHS/SAMHSA *See* I.B.1.

7. ***Utilize targeted survivor presentations to change perceptions about breast health. Work with media to broadcast group-specific survivor messages; evaluate and disseminate results.***

C. Increase participation of underserved and at-risk populations in breast cancer programs related to risk factors, early detection, diagnosis, and treatment.

1. Increase participation of target populations in breast cancer programs. Include, for example, older women, rural women, women of lower socioeconomic status, lesbians, African Americans, Native Americans, Latinos, Asians, Pacific Islanders, and women who have recently arrived in the United States.

Current Activities

PHS/CDC

See also I.A.1. The CDC National Breast and Cervical Cancer Early Detection Program benefits all women but specifically targets those most likely to be underserved: low income, older and minority women. This program supports the development of a public health infrastructure for breast cancer early detection through support and collaboration with State health departments, voluntary organizations, professional organizations and universities.

In FY 1994, 45 States and up to five Indian tribal organizations will receive support for early detection activities. These States develop and implement community based programs tailored to the cultural, educational, and psychosocial characteristics of women most likely to be underserved. Participating States are required to establish linkages with other organizations and programs, including the federal Health Resources and Service Administration (HRSA) primary care and community health centers, Title X Family Planning programs, State offices for Aging and Minority Health, the IHS and other appropriate State and local agencies. Linkages are also encouraged with public and private sector organizations such as the ACS, the Young Women's Christian Association of the USA (YWCA), the American Association of Retired Persons (AARP), survivors of breast and cervical cancer, local women's groups, community leaders and other agencies and businesses in the community that provide health care and related support services to women.

CDC has appointed a coordinator for Indian Health Service (IHS) Activities to work in collaboration with the IHS Headquarters West Cancer Prevention and Control Program. They have helped State health departments target and provide early detection cancer screening services to Native American women. The activities

encompass a range of consultation, data analyses, and issues identification. CDC has assigned a Public Health Advisor to the IHS Cancer Program to assist in planning, developing, and conducting breast and cervical cancer control and health promotion activities among Native Americans.

CDC co-sponsored a regional conference, "Challenges in Health Care for Underserved groups: Cancer Screening in American Indian Women," in Minnesota in 1993. This conference brought together representatives from Native American communities, State health departments, and academic leaders from seven States in the Bemidji and Aberdeen Areas of the IHS. Participants worked to develop a specific plan of action for implementation of more effective breast and cervical cancer screening and follow-up services for native American populations. Six of the seven participating States receive funding through the National Breast and Cervical Cancer Early Detection Program. CDC has also supported the initiation of the development and delivery of cancer surveillance and epidemiology training to IHS Cancer Program staff.

In addition, CDC funds 11 national organizations, including the National Migrant Resource Program, the AARP, the American Indian Health Care Association, the National Caucus on Black Aged Incorporated, the National Hispanic Council on Aging, the YWCA and the World Education Organization (for immigrants) to develop interventions to educate their constituents and target populations about breast cancer. They will also assist State and local health agencies in implementing model educational interventions, developing technical assistance and training tools, and adopting breast cancer early detection objectives as an organizational priority.

CDC collaborates with the YWCA in implementing the Encore and Encore-Plus programs o conduct outreach to educate women about breast health and provide support for women, especially African American women, with breast cancer. See also I.E.1.

CDC and the Nebraska Department of Health support a project with the University of Nebraska College of Pharmacy to conduct training programs on breast and cervical cancer early detection for selected rural pharmacists. The pharmacists will provide information, education and referral for breast and cervical cancer screening to their women customers.

See also I.C.2.

PHS/FDA *See* I.B.6. and I.C.1.

PHS/IHS

IHS funds mammography for Native American women who attend the Women in Wellness conferences, convened this year in Phoenix, Arizona, and Portland, Oregon.

PHS/NIH/NCI

The CIS Outreach program works with a wide variety of organizations serving African Americans, Hispanic Americans, older Americans and low literate audiences to deliver breast cancer screening messages. *See also* I.A.1.

Planned Activities

PHS/CDC

An expansion of Public Health Approaches to Breast and Cervical Cancer Screening (see current activities, above) is planned to include high risk populations not currently targeted. Priority will be given to proposals specifically designed to reach rural residents, Puerto Rican and Cuban women, Asian women, and women served by Community and Migrant Health Centers.

See Public Health Approaches to Breast and Cervical Cancer Screening and Cancer Prevention and Rural Health in I.A.1.

PHS/NIH/NCI

A Cancer Prevention and Rural Health initiative is planned to develop, implement and evaluate cancer prevention and early detection education programs for rural populations. Public and professional education interventions will be aimed at cancer prevention and at increasing access to and utilization of cancer screening and early detection services in rural populations. Research results will be disseminated through appropriate NCI programs such as the Appalachian Leadership Initiative on Cancer, the CIS, NCI-designated cancer centers, and Community Clinical Oncology Program (CCOP).

AOA

AOA is currently funding a rural long-term care resource center at the University of Kansas Medical Center. In April of this year, the Resource Center, in conjunction with the University of Kansas Medical Center Cancer Center, convened a Breast Cancer Summit. Videotapes of the summit were prepared to be used in educational programs in rural communities. A training manual is also being developed for facilitators of training programs.

The Resource Center plans to conduct eight workshops throughout the State of Kansas to train facilitators who will, in turn, develop educational programs on the importance of early detection of breast cancer. The programs will be targeted to rural and minority women. The Resource Center will assist in developing approaches for reaching rural and minority women and in the implementation of the training workshops.

AOA's Aging Network, comprised of 10 Regional Offices, 50 state units on aging and 670 area agencies on aging, serves as a critical link to older adults throughout the United States. The Aging Network could serve well as a dissemination vehicle for getting out information on breast health and breast cancer to older women and their families.

2. ***Involve organizations and individuals that have direct access to and a unique understanding of underrepresented and high-risk population groups in targeting and improving education and services related to breast cancer. Provide a broad range of incentives to promote their involvement.***

Current Activities

PHS/CDC

CDC funds states to develop and implement community-based programs tailored to the cultural, educational and psychological characteristics of women. In addition, CDC funds private, public and not-for-profit organizations to develop strategies appropriate for each community and setting. *See* I.C.1.

PHS/HRSA

The Bureau of Primary Health Care's (BPHC) Community and Migrant Health Centers (C/MHCs) provide preventive health services as part of the high quality, comprehensive, family-oriented primary health services delivered to almost 7 million poor and underserved persons. The BPHC funded programs have a long history of providing health services to underserved women and minorities, populations that constitute a large proportion of the poor and underserved people in this country. In Calendar Year 1993, over 3.8 million poor and underserved women received health care services through the C/MHC program.

The BPHC has a clinical strategy to assure that users of the C/MHCs receive appropriate health services. This strategy, based on the principle of comprehensive, primary health care encompasses all of the five lifecycles (perinatal, pediatric, adolescent, adult, and geriatric). An essential component of the strategy are life cycle specific clinical measures. In the adult and geriatric lifecycles, breast and cervical cancer prevention and screening are part of the clinical measures.

Recently a task force report on Primary Care Preventive Services Availability and Provider Practices in C/MHCs gathered specific information on the extent to which preventive services are integrated into their individual programs. The C/MHC program does not award any categorical grants and preventive services, as they are considered a part of the comprehensive primary care services offered. The data on breast cancer screening - mammography indicated that a high percentage of responding centers reported providing mammography services to asymptomatic women.

See also I.C.9.

PHS/NIH/NCI

NCI has an active breast cancer outreach program to serve minority and underserved communities at the national level and through the CIS. For example, NCI distributes its mammography programs with the National Medical Association (NMA), the Auxiliary to the NMA, Links, YWCA, and Chi Eta Phi, and NCI produces a range of materials for ethnic and low literacy populations.

PHS/OASH/OMH

The Healthy People 2000 Asian and Pacific Islander Work Group is also involved in examining existing Healthy People 2000 objectives and sub-objectives; identifying specific health areas that need to be addressed by Healthy People 2000; recommending additional objectives or changes to existing objectives to make them more inclusive and/or appropriate for Asian and Pacific Islander populations. The Work Group is considering several recommendations for additional objectives/sub-objectives. One such recommendation is the addition of a specific sub-objective on breast cancer in Native Hawaiian women. The current objective (Objective number 16.3 "Reduce breast cancer deaths to no more than 20.6 per 100,000 women") does not specify any baseline or targets for specific race/ethnic subpopulations which experience different mortality rates for breast cancer. Native Hawaiian women have the highest breast cancer mortality rate of any race (37.8) as well as the highest age-adjusted breast cancer incidence rate of any race (108.5). The Work Group hopes that inclusion of a sub-objective for Native Hawaiian women will help the nation focus more attention and resources to breast cancer research, prevention and control in Native Hawaiian women.

See also I.C.9.

Planned Activities

PHS/CDC

In FY 94, CDC will fund the National Migrant Resource Program, the American Association of Retired Persons, American Indian Health Care Association, National Caucus and Center on Black Aged Incorporated, National Hispanic Council on Aging, Young Women's Christian Association (YWCA) and the World Education Organization (for immigrants) to develop education programs at the community level for underserved women. CDC will also collaborate with organizations representing the concerns of lesbians. CDC will fund approximately five Native American tribal organizations for comprehensive breast and cervical cancer control programs. IHS Cancer Program is working closely with CDC to develop this RFA and help the grant recipients deliver the services.

In FY 94, CDC will fund the American Nurses Association to develop curricula for nursing students, registered nurses and nurse clinicians on methods of educating low-income, African American women about breast cancer.

PHS/IHS *See* I.C.9.

PHS/NIH/NCI

Demonstration projects will be conducted in the NCI-designated comprehensive cancer centers to test the use of the PDQ/Patient Information File statements, including those on breast cancer treatment options. Cancer centers will be selected based on the diversity of the populations that they serve. NCI also plans to invite breast cancer patient advocates to review and comment on statements on breast cancer in the File.

PHS/SAMHSA

CSAT can incorporate information on breast cancer prevention and treatment into existing TIPs manuals for women. In addition, CSAT is considering developing a TIP specifically addressing health issues of substance abusing women across the life span that could include information on breast health. Finally, CSAT is considering adding the issue of breast health to the program evaluation protocols in its women's programs (i.e., does the program address breast health of the women, and if so, how?).

AOA *See* I.C.1.

3. ***Develop and disseminate information on breast health care that is tailored to the cultural, educational, and psychosocial characteristics of women and their families. Report this information in multiple languages.***

Current Activities

PHS/CDC *See* I.C.1.

PHS/SAMHSA

As part of its ongoing responsibility to provide leadership to the field regarding state-of-the-art treatment services, CSAT has published, and continues to publish, several Treatment Improvement Protocols (TIPs) on a wide range of service delivery issues. TIPs published to date address services for *Pregnant, Substance-Using Women*, *Drug-Exposed Infants*, and *Alcohol- and Other Drug-Abusing Adolescents*.

PHS/OASH/OMH *See* I.B.6.

Planned Activities

PHS/SAMHSA *See* I.C.2.

ACF *See* I.B.6.

4. ***Increase the number and use of culturally sensitive, large-scale programs among minorities, such as the National Cancer Institutes's Cancer Information Service and Centers for Disease Control and Prevention (CDC) community programs.***

Current Activities

PHS/CDC *See* I.C.1.

PHS/HRSA *See* I.B.4.

PHS/NIH/NCI

NCI recently completed a needs assessment to determine the perceptions of health professionals regarding the recruitment of minority patients to cancer clinical trials, including breast cancer trials. The target audience for the study included physicians, nurses, social workers, and educators from NCI's minority-based CCOPs and NCI's clinical trials cooperative groups. These groups, responsible for entering large numbers of patients on clinical trials, are composed of investigators who join together to develop and implement common protocols. A central operations and statistical office supports the administrative requirements of the research and performs central data collection and analysis.

NCI-sponsored projects, including the National Black Leadership Initiative on Cancer, Appalachian Leadership Initiative on Cancer, and the National Hispanic Leadership Initiative on Cancer, are working with NCI staff to develop action steps to carry out the specific survey recommendations.

Through the CIS, NCI disseminates over 20 million publications each year. Due to the emphasis on mammography screening in NCI education programs since 1990, many of these materials have related to breast cancer and breast cancer screening.

Specific materials have targeted African Americans, Hispanic Americans and low-literate populations. NCI has an entire array of materials on mammography and early detection that are tailored for minority and low-literate women and community partners.

Planned Activities

PHS/NIH/NCI *See* I.C.2.

PHS/SAMHSA *See* I.C.2.

5. ***Use target audience research and other social marketing techniques to help customize programs and intervention strategies to specific communities and settings. Develop and apply new and innovative techniques for hard-to-reach populations and individuals.***

Current Activities

PHS/HRSA *See* I.C.9.

PHS/NIH/NCI

Extensive pretesting, including the use of focus groups, is done before any educational resource is submitted for final scientific clearance. Suggestions and recommendations received from the intended target audiences are incorporated in the final design. NCI resources are promoted through mailings to professional associations and advocacy groups, exhibits, ads, and through the CIS. Many of NCI's resources are also mentioned in newspaper and magazine articles.

See also Public Health Approaches to Breast and Cervix Screening and Model Cancer Control Delivery Systems in I.A.1.

OMB approval is required for the CIS to collect data on users of the system, identify callers from particular populations, and explore how the CIS program can be improved to meet their specific information needs.

Target audiences are consulted in the development and review of all new breast cancer publications and programs or general patient education resources and programs.

Refer to activities in I.A.3. *The Picture of Health: How to Increase Breast Cancer Screening in Your Community*.

Planned Activities

PHS/NIH/NCI

As a result of the needs assessment survey (see above), new activities to be undertaken by NCI include: development of training programs and resources for health professionals working directly with minority patients on cancer clinical trials issues, specialized training for CIS staff, and mass media efforts designed to reach minority populations.

While initial consumer research has been conducted on communicating changes in the mammography guidelines, more research is planned on how to translate information about breast cancer screening into acceptable consumer messages. In addition, consumer research is planned on how to communicate the concept of regular screening.

6. *Involve consumers with relevant cultural and ethnic backgrounds in the development of culturally sensitive breast health information.*

Planned Activities

PHS/CDC *See* I.C.1.

PHS/NIH/NCI *See* I.C.2.

7. ***Provide for the funding of mobile mammography units which could increase access to screening among rural and working women.***

Current Activities

PHS/CDC *See* I.C.1.

PHS/HRSA *See* I.B.4. and I.C.9.

SSA *See* I.B.5.

Planned Activities

PHS/HRSA

The Migrant Health Branch is interested in establishing demonstration projects that will build coalitions at the local and State level to help fund services currently unavailable to migrant/seasonal farmworker women. The primary focus will be on breast cancer screening, detection, treatment and follow-up.

8. ***Establish community-based comprehensive school health programs to reach young women with breast health messages for themselves and their families. Pilot breast health programs in other education/social settings, such as low-literacy and welfare programs, and school health curricula.***

Planned Activities

PHS/CDC *See* I.C.2. and I.C.9.

9. ***Provide financial and technical support to local community-based programs that target low-utilization groups to assist in program evaluation and expansion, and to coordinate with program planners.***

Current Activities

PHS/HRSA

BPHC-funded health centers in Region II were awarded a four-year NCI grant for a collaborative effort to improve the early detection of several cancers among low-income and minority women in 62 C/MHCs from the states of New York, New Jersey and Connecticut. Over a two year period, the study evaluated physician recommendations and performance of a number of tests and screening procedures, including pap smears, mammogram and breast self-examinations. The study found that community based primary care clinicians, who primarily serve low-income and minority individuals, attained rates of recommendations and/or performed breast and cervical cancer early detection services consistent with the Healthy People 2000 Objectives.

In BPHC's Division of Programs for Special Populations, program funds are directed to efforts for improving the health status of women of all ages. This includes the early detection of breast cancer. A review of specific activities will be pursued in 1994.

Several other C/MHCs are involved in activities focusing on breast cancer screening, detection, and treatment. Below are some of the examples:

* The "Michele Project" was developed in 1991 in memory of Michele Ann Stern who died of metastatic breast cancer, August 10, 1988 at age 35. The project provides early detection of breast cancer through mammography performed on-site at the Southwest Community Health Center (Bridgeport, Connecticut). The project's focus is to provide a screening program for Connecticut women who are not currently being screened. This is an effort to detect cancers in early stages and to decrease breast cancer mortality. Since 1991, the Health Center has offered on-site mammography to medically underserved women who use the Center for their primary care. The screening is scheduled regularly on a bi-weekly basis. The radiological services are donated to the Health Center by a local radiology group. Each women who receives a mammogram is taught self-breast exam and is either seen by her provider or scheduled for a medical visit at the Health Center if warranted. Since 1991, over 700 underserved women, the majority of whom are Hispanic and African American, have received mammograms on-site.

* The Community Health Centers, Inc. (Apopka, Florida) with a grant from Johnson and Johnson and additional monies from fund raising efforts is heading a rural consortium with four other Community and Migrant Health Centers in offering reduced cost ($30/exam) mammography services to low-income and farmworker women at area hospitals for 2 years. This consortium, in cooperation with the three hospitals within their health services areas want to provide ACR accredited low-cost screening to these disadvantaged women-at-risk of developing breast cancer.

  These hospitals: Florida Hospital - Apopka under the sponsorship of the Center for Women's Medicine at Florida Hospital; Health Central, and South Lake Memorial Hospital have agreed to lower their costs by approximately fifty percent providing both the screening and the radiology report for fifty five dollars. In addition, they have provided funds to help defray some of these costs. Funds raised will be used to subsidize the costs for sliding-fee eligible women. The hospitals have also agreed to help the centers develop a secondary level of care for women with suspicious findings.

PHS/NIH/NCI

The goals of NCI's "Avoidable Mortality from Cancers in Native American Populations" initiative are to identify key factors that contribute to avoidable mortality from specific cancers, such as cervical and breast cancer as well as to develop and evaluate the effectiveness of community interventions. All grants fund randomized trials of interventions to address the knowledge, attitudes, and screening practices of these populations.

To stimulate intervention research on activities designed to reduce cancer morbidity and mortality in Hispanic populations, NCI funded five breast and cervical cancer screening research projects in FY 1989-1990. These five-year cooperative agreements focus on preserving positive health behaviors associated with the Hispanic culture while simultaneously developing interventions to address their barriers to effective cancer control.

Research projects are identifying mechanisms to implement systematic and coordinated programs that will reduce cancer incidence and mortality, as well as improve survival rates in underserved populations. Methods to increase accrual to clinical trials and participation in screening and early detection programs will also be investigated. A major portion of this research effort is directed to breast cancer.

PHS/OASH/OMH

The OMH, through a MOA with the ODPHP, supported a cooperative agreement to the National Medical Association (NMA) in 1992 to build upon the NMA's community health coalition program for healthy people 2000. OMH supported NMA's media campaign aimed at African Americans at risk for high blood pressure, cancer (which also included breast cancer), and other chronic and preventable diseases. The NMA worked with coalitions of volunteers in 14 cities to bring health messages, concerning also preventive health care, to African American communities.

PHS/SAMHSA

The Center for Substance Abuse Treatment (CSAT) has developed a Comprehensive Treatment Model for Alcohol and Other Drug Abusing Women and Their Children that includes the provision of medical services. Services relating to breast health can be specifically mentioned in the CSAT Comprehensive Treatment Model as services to be included among the medical services needed by substance abusing women.

Planned Activities

PHS/CDC

CDC will collaborate with the YWCA in implementing the Encore and Encore-Plus programs to conduct outreach to educate women about breast health and provide support for women, especially African American women, with breast cancer.

See also I.C.2.

PHS/IHS

In FY 94, CDC will fund approximately five Native American tribal organizations for comprehensive breast and cervical cancer control programs. IHS Cancer Program is working closely with CDC to develop this RFA and help the grant recipients deliver the services.

HCFA

HCFA is in the very early stages of its breast health initiative. A significant first step is the identification of underserved subpopulations within its beneficiary community. HCFA will then work with the public health and provider communities to develop strategies targeted to these subpopulations (such as minorities, the oldest elderly, and residents in rural areas) to increase breast health services.

HCFA can use its administrative data to reduce breast disease and mortality among its beneficiaries. Preliminary national estimates for Medicare claims indicate only 35 percent of elderly Medicare women had a mammogram in the two year period between January 1991 and December 1992. Medicare data also indicate that the rate of mammography declines markedly with increasing age. National surveys indicate the oldest old, minorities, and women living in rural areas are least likely to undergo mammography screening.

D. Ensure that research results relevant to breast cancer reach community health care providers, patients, consumers, the elderly, and the general public in a timely fashion.

1. Communicate clinical research results to the involved community, immediate family members, significant others, and clinical trial participants once valid results have been confirmed.

Current Activities

PHS/AHCPR

CRDL is responsible for disseminating AHCPR-supported medical treatment effectiveness (MEDTEP) and health services research findings, assessments of health care technologies, and AHCPR-supported clinical practice guidelines to newspapers (trade and major dailies), television and radio outlets, professional and trade journals, and consumer magazines as well as other government agencies.

See also I.B.6.

PHS/NIH/NCI *See* I.D.2. and I.D.3.

2. *Establish a registry of ongoing and published clinical trials that is accessible to the public.*

Current Activities

PHS/NIH/NCI

The Treatment Referral Center (TRC), based at NCI-supported cancer centers, provides information on standard treatment options, clinical trials and investigational drugs for optimal patient management. The TRC has also served as a resource for information about the use of taxol and other investigational agents. Two trials in women with metastatic, chemotherapy refractory disease have been coordinated through the TRC, an expanded access trial of taxol, and a trial randomizing women to receive vinblastine or taxol. The results of these trials will contribute to the FDA's assessment of the use of taxol for women with advanced breast cancer.

PDQ - Developed and introduced in 1984 by NCI, PDQ is the Nation's most up-to-date source of clinical cancer information. PDQ consists of cancer information summaries covering treatment, supportive care, screening/prevention, and investigational drugs; summaries of over 1500 active and more than 7000 closed clinical trials conducted throughout the world; and directories of physicians and organizations active in cancer treatment or screening. Annual online usage in 1992 for all vendor implementations was 15,000 hours of use. In addition, over 600 subscriptions to CD-ROM products containing the PDQ database were sold in 1993.

NCI publishes a semi-annual one-page newsletter, UPDATE, which is sent to about 5,000 health professionals interested in cancer clinical trials-related issues. The need for accrual to NCI high priority trials is always included.

CANCERLIT - a comprehensive database of abstracts of published cancer literature; estimated 1993 online usage was 5,300 hours at the National Library of Medicine (NLM) plus an additional 9,300 hours of use on other commercial vendor systems. Subscriptions to CD-ROM products containing the CANCERLIT database totaled more than 700.

Planned Activity

PHS/FDA

With specific regard to the establishment of a new comprehensive resource data bank and improving access to clinical trials, these areas may be perhaps amenable to interagency collaboration in which FDA could work with service-providing organizations (e.g., NCI, ACS) to improve the existing network and to create a data-base targeted to address breast cancer initiatives. The FDA could, for example, send letters to sponsors of efficacy trials in breast cancer patients *requesting* that they list their study in the data-base. This would allow the patient-provider community to have access to information on ongoing clinical trial options and help accelerate accrual to efficacy studies in an effort to expedite discovery of promising new agents. This collaboration would entail additional resources.

3. ***Disseminate and make widely available information on breast cancer research in forms suitable for different audiences (e.g., consumers, providers, and payers). Conduct research to determine the best way to disseminate knowledge among the different populations. Report research results simultaneously to health care providers and consumers.***

Current Activities

PHS/AHCPR

The Center for Research Dissemination and Liaison (CRDL) initiated the AHCPR applied dissemination research program in 1991. AHCPR's focus on effective dissemination has increased awareness of the need to conduct research on how best to disseminate health and clinical information, to stimulate better use of information, improved decisionmaking, and behavior change.

CRDL's User Liaison Program works with State and local policymakers to identify the issues and information needs of its target audiences and conducts workshops to address them. Workshops have contributed policies implemented in various states, e.g., the Minnesota Health Plan has acknowledged the role of the User Liaison Program in providing the knowledge and tools necessary to grapple with the health policy issues central to developing the plan. Further examples of workshop topics

include health insurance reform, containment, child health, infant mortality and women's health.

See also I.B.3.

PHS/NIH/NCI

The CIS currently responds to over 40,000 inquiries each year on clinical trials, including providing information on available trials for breast cancer. The CIS serves as an integral partner in the promotion of cancer prevention trials such as the Breast Cancer Prevention Trial (BCPT). CIS staff are specially trained to provide objective information on clinical trials in an effort to ensure that participation is based on an informed decision.

CancerFax and CancerNet - NCI's CancerFax and CancerNet services make cancer information available quickly and easily via fax or Internet electronic mail. Cancer information statements from the PDQ database are available in English or Spanish, as are fact sheets on various cancer topics from NCI's Office of Cancer Communications (OCC) and citations and abstracts on cancer topics extracted monthly from the bibliographic database CANCERLIT (in English only). CancerNet is also available through selected secondary distributors who are not on the Internet. Over 5,000 calls per month are logged to CancerFax, and requests from CancerNet approached 13,000 per month at the end of 1993.

NCI is developing the capacity to distribute documents that contain text, graphics, sound, and full motion video over the Internet using the Mosaic software, permitting NCI to distribute the *Journal of the National Cancer Institute*, the *Journal of the National Cancer Institute Monographs*, OCC educational booklets, and other special reports from the NCI using full multi-media capabilities.

A multimedia CD-ROM product is being developed featuring interactive information on breast cancer to educate health professionals and patients about screening and treatment options and their implications for benefits, risks, quality of life, and side effects. The format will be totally digital and "platform-independent" so that text, images, and sound can be transmitted interactively in any communications medium including high speed communication networks. The CD-ROM will contain peer-reviewed information from PDQ on cancer detection, prevention, treatment, and supportive care linked to citations. A breast cancer patient advocate is a consultant to the project from its earliest stages.

NCI has developed a broad range of breast cancer materials that are targeted to special populations (African Americans, Native Americans, Spanish-language, low literacy). NCI produces 147 pieces of breast cancer material in support of patients and family members, general awareness campaigns, and community education and intervention programs. In the past year, NCI has distributed nearly 4 million copies of breast cancer education material.

In FY 1994 a publication entitled *How to Increase Breast Cancer Screening in Your Community* was distributed to health departments, community organizations, the ACS, and to cancer centers across the country. This book shares practical and detailed descriptions of the six NCI Breast Cancer Screening Consortium projects--health education programs which have increased screening, particularly mammography rates, in the communities targeted for intervention.

NCI is funding four regional projects that comprise a National DES Educational Program for Health Professionals and the Public. An increased risk of breast cancer for mothers and daughters exposed to DES is one of the issues to be addressed.

Planned Activities

PHS/AHCPR

The revision of the applied dissemination research program announcement is expected this year. A main focus will be research about the effectiveness of dissemination strategies of health care and clinical information to consumers/patients. The NRSA institutional grant program announcement will be revised in FY 95. Health services research issues central to breast cancer diagnosis and treatment or that address the needs of targeted populations could be highlighted as an AHCPR area of interest. Something similar could be done in the small conference grant program announcement when it is revised.

PHS/NIH/NCI

Pending availability of FY 1995 funds, several new strategies will be tested for disseminating information on ways to increase breast cancer screening, including the state-of-the-art manual *How to Increase Breast Cancer Screening in Your Community*.

There are plans to support additional research on ways to communicate DES information involving the national DES education program.

HCFA

Critical to HCFA's breast health activities is the involvement of other Government agencies, the provider community, both public and private, and related organizations. The maintenance of ongoing dialogue will ensure that information is communicated in a timely fashion and in a useful, understandable format. *See also* II.D.2.

ACF *See* I.B.6.

E. Establish public and private partnerships to enhance breast health education.

1. Use multiorganization panels, programs, and forums to extend the scope, impact, and credibility of breast health education programs. For example:

- *Involve consumers at all levels in this effort.*
- *Create public-private partnerships for educational programs and efforts.*
- *Sponsor conferences to educate and involve the media in breast cancer issues and to facilitate breast health education. Enlist private, for-profit and nonprofit businesses and other organizations in this effort.*
- *Sponsor conferences in which biomedical, behavioral, and health care researchers can share information with each other and the communities they serve.*
- *Incorporate appropriate breast health information into all preventive services, health education programs, and medical and nursing school curricula.*

Current Activities

PHS/CDC

In March, 1993, CDC entered into a collaborative agreement with the YWCA, to work together on national and state-based activities for the early detection of breast and cervical cancers. Linking women to available services and providing appropriate health education activities is critical to the success of the CDC National Breast and Cervical Cancer Early Detection Program.

As partners in prevention and education, the CDC and the YWCA have initiated pilot activities in 13 States. YWCA Associations participate in national and local efforts to familiarize State health agencies with (1) their resources, programs, and expertise in health promotion, including the ENCORE Plus national breast health education, screening, and yearly reminder model program, (2) their capacity to provide ancillary services that remove barriers to access health education and medical services, including transportation, day care, counselling, education, and peer support, and (3) provide critical follow-up for women diagnosed with breast cancer.

CDC encourages States to develop linkages and active collaborations with local YWCA Associations in the areas of service delivery and health education. YWCA representation on State breast and cervical cancer control coalitions is also encouraged. CDC will provide technical assistance to the YWCA in the development and evaluation of new materials an the conduct of behavioral and interventions research.

In a public, nonprofit and private partnership, the YWCA and Avon Products are collaborating to help medically underserved women benefit from CDC's Breast and Cervical Cancer Early Detection Program. With $3 million contributed by Avon, the YWCA will create an infrastructure to support CDC early detection efforts. Through the Encore Plus program, the YWCA will train staff around the country to provide cancer education and counselling to underserved women over age 50 and to act as health advocates. The YWCA program will provide breast and cervical health education, peer support groups and screening referrals. An important aspect of the counseling will be to overcome the cultural inhibitions that prevent women from seeking screening or examining their breasts themselves. In October 1993, Avon launched its support of cancer early detection with the sale of pink enamel "awareness pins." Proceeds from the sale of the pins fund the YWCA initiative.

PHS/HRSA

Women's Health Training Study. HRSA's Women's Health Issues Coordinator is working closely with HRSA's Bureau of Health Professions (BHPr) and NIH's Office of Research on Women's Health to move forward on several fronts in response to congressional direction that the PHS complete a study of women's health training in the medical schools, and in other health professions, and that ultimately recommendations be sent to the Congress on the need, if any, of a women's health medical specialty.

Simultaneously, HRSA/BHPr is supporting the deliberations of a Subcommittee on Women's Health of the Council on Graduate Medical Education (COGME). The results of two commissioned papers were presented for the first time at the COGME meeting in early February 1994. COGME recommendations to the Secretary on physician workforce issues and on women's health training may influence other women's health training outcomes.

HRSA and ORWH have also joined with the newly formed National Academy on Women's Health Medical Education (NAWHME), created by the Medical College of Pennsylvania and the American Medical Women's Association. NAWHME's mission of blending "... women's health into every facet of medical education from medical student teaching, to the residencies, to the halls of academia and to physicians already in practice...." offers a rare opportunity for collaboration as the PHS addresses unanswered questions about women's health training in the health professions. ORWH, HRSA, and BHPr representatives will participate in NAWHME's inaugural meeting on March 21, 1994.

In addition, HRSA and ORWH will work with the Association of American Medical Colleges (AAMC) and other professional associations, to identify avenues by which to examine the current practices of medical schools and other health professions schools regarding inclusion of women's health training.

MCHB has a cooperative agreement with the National Center for Education in Maternal and Child Health (NCEMCH) at Georgetown University. One MCHB-supported activity of the NCEMCH is a maternal and child health information clearinghouse. NCEMCH clearinghouse staff regularly receive requests for information on breast health and services. The staff maintain supplies of printed materials on breast health, which they disseminate to requestors, and they also refer callers to sources of further help and information (e.g. The National Cancer Institute, American Cancer Society, etc.). Periodically the clearinghouse staff review their

literature collection and solicit appropriate organizations to obtain new and updated materials.

Thirteen MCH training programs in schools of public health cover screening for breast disease and the role of the breast in the reproductive cycle and in infant feeding. Many have courses in women's health that include components on the reproductive cycle as part of the curriculum. Beyond that, the schools are required to address the objectives of Healthy People 2000, including the reduction of breast cancer deaths.

In addition, there are seven interdisciplinary adolescent health training programs that address health assessment and prevention for female adolescents, including breast development, breast health, and teaching breast self-examination.

PHS/NIH/NCI

NCI and the Susan G. Komen Breast Cancer Foundation are co-sponsoring 16 large-scale regional breast cancer education summits and 10 mini-summits in 1993-1994 to educate leaders of businesses, community and voluntary organizations, and health organizations about breast cancer and to encourage them to sponsor breast cancer education and screening programs in their communities. The summits are hosted by NCI-funded cancer centers and other medical institutions in collaboration with local organizations. Reaching medically underserved and hard-to-reach populations is emphasized.

NCI is continuing its public/private partnership with Avon to help reach underserved women with the mammography message. Other partners include CDC, YWCA, and NABCO. This program will support expansion of the NCI pilot Project Awareness (*see* I.B.2) through the YWCA's Encore^{Plus}, as well as other locally implemented breast cancer screening education programs.

NCI is working with the National Education Association on a mammography education program to reach its more than 2 million members. A recent study showed that teachers have a higher mortality from breast cancer than do other professionals.

The news media are invited to participate in or attend workshops and conferences on breast cancer. Examples are an International Workshop on Breast Cancer Screening in February 1993, the 11 meetings of the President's Cancer Panel Special Commission on Breast Cancer and subsequent release of the Commission's report, a

conference on Breast Cancer in Younger Women, and a special science writer's seminar explaining the statistical basis for estimates of lifetime probability of developing breast cancer.

OASH/ODPHP

"Put Prevention Into Practice" Program. A PHS-private sector collaborative effort to improve the delivery of preventive health services is an example of the way to integrate early detection of breast cancer into a comprehensive health education program. Breast cancer detection is an important part of all materials developed for "Put Prevention Into Practice:" the *Clinician's Handbook* (a "how-to" book for health care providers), the *Personal Health Guide* (a passport-sized preventive health record for patients), and the office and clinic system tools (flow sheets, chart stickers and other materials for office staff).

HCFA *See* I.B.4.

Planned Activities

PHS/CDC

In FY 94, CDC will collaborate with the YWCA and the cosmetics company Avon to educate women about breast health through community outreach activities. CDC will also fund the Susan G. Komen Foundation to promote education about breast cancer.

PHS/HRSA

Once established, Office of Women's Health, HRSA (OWH/HRSA) will improve the coordination of specific women's health initiatives such as breast cancer education and screening across the Bureaus within HRSA and with other Federal agencies and external organizations.

OWH/HRSA will continue to work with the Federal Employees Occupational Health Program and the FEOH clinics to educate women within the Federal workforce of the need for breast screening and to provide periodic mammography and cervical cancer screening, combined with clinical breast exams, at reasonable cost to women within

the Federal workforce. Screening is also made available to the female spouses of employees.

New Collaborative Activities

PHS/NIH/NCI

NCI is discussing a public/private partnership with Matrix, a professional hair products company, to conduct an in-salon promotion of breast cancer health education targeting older women. (Frequent salon users tend to be over 50 years of age.)

HCFA *See* I.B.4.

II. RESEARCH

Research on breast cancer is multidisciplinary and is supported by all Federal agencies, institutions, and organizations that support and conduct research. New knowledge about the causes, diagnosis, prevention, and treatment of breast cancer is derived from many approaches and is accelerated through communication about promising areas of exploration and discovery. This section identifies 10 key goals and corresponding HHS activities related to basic, clinical, epidemiologic, health services, psychosocial, and translational research on breast cancer.

A. Support collaborative multidisciplinary research related to breast cancer.

1. Identify and foster promising new areas of basic research through interagency, interdisciplinary, and private- and public-sector collaboration.

Current Activities

PHS/IHS

IHS is collaborating with the NCI and the CDC on a study of organochlorine exposure and breast cancer among Alaska Native women.

PHS/NIH/NCI

In 1989, when Taxol, a natural product derived from the bark of the Pacific Yew tree (*Taxus brevifolia*), was found to have anti-tumor activity in pre-clinical studies, a CRADA was awarded to Bristol-Myers Squibb (BMS) after review of several competitive applications. Under a unique Memorandum of Understanding among the NIH, the U.S. Department of Agriculture (USDA), and the Department of Interior, supplies of Taxol-containing yew bark were harvested from public lands and provided to BMS for preparation of drug and research purposes. An unprecedented drug development effort led to the licensing of Taxol for use in patients with ovarian cancer in 1993. Taxol has proved to be an effective new agent in the treatment of breast cancer as well, and high priority clinical trials to define the optimal dose and route of this agent are now underway. Furthermore, NCI has supported the preclinical development and clinical testing of a semi-synthetic analog of Taxol, taxotere, under a second CRADA negotiated with Rhone-Poulenc Rorer. Preliminary

results from trials underway in Europe suggest that taxotere's efficacy in breast and ovarian cancer will be similar to that of Taxol.

Following a workshop held last year to assess the status of research on the biology of breast cancer, NCI issued an RFA, "Biology and Immunology of Breast Cancer: An Interdisciplinary Approach," for interactive research grant applications. The RFA was aimed at stimulating new collaborative, multidisciplinary approaches to breast cancer research. Thirteen groups of applications were submitted. Five groups were funded under the RFA along with two additional projects.

New Collaborative Activities

PHS/NIH/NCI

NCI and CDC are engaged in a collaborative effort to foster breast cancer research in several areas, including cancer control, environmental risk, and access to treatment and screening.

2. ***Facilitate collaboration among basic, clinical, behavioral, epidemiologic, and health services scientists across disciplines; among affected consumers; and among university, clinical cooperative group, Federal, and industrial investigators.***

Current Activities

PHS/NIH/NCI

NCI has organized and chairs an Inter-agency Working Group on Breast and Gynecologic Tumors, which meets monthly for information dissemination, cross-fertilization and coordination of government research on breast and gynecologic tumors. The group includes representatives from OASH, DOD, FDA, OD-NIH, ORWH, NCHGR, NCNR, NCRR, DCRT, DRG, NIA, NICHD, NIDDK, NIEHS, NIGMS, NHLBI, NIMH, and NCI, with a total membership of 55. Occasionally outside guests are invited to attend.

NCI joins with industrial partners through Collaborative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act (FTTA) of 1986 to promote the expeditious development and testing of new products.

NCI also negotiated a clinical trials agreement with Fujisawa for Phase I and II trials of the new compound Rhizoxin, which shows promising clinical activity in breast cancer.

To expedite the early clinical development of new agents with promising pre-clinical activity, and to expedite these drugs in combination with agents now in clinical use, NCI awarded contracts to competing academic institutions for Phase I/II and II/III studies and cooperative agreements for clinical trials of biological response modifiers.

In cooperation with the NIH Office of Research on Women's Health and NICHD, NCI held a conference last year on breast cancer in younger women to share information and develop strategies for future research. A monograph of the papers presented at the conference will be published by the *Journal of the National Cancer Institute*.

See also II.A.1.

HCFA

HCFA's Office of Research and Demonstrations is working with the National Cancer Institute on a data linkage of the tumor registry data from the Surveillance, Epidemiology, and End Results (SEER) Program with Medicare data. SEER is a system of nine population-based tumor registries that collect standardized clinical information on all cases diagnosed in separate, geographically defined areas covering about 10 percent of the U.S. population. Reported information includes date of diagnosis, site of cancer, stage at diagnosis, histology, and survival.

- HCFA's Office of Research and Demonstrations is conducting intramural research jointly with the National Cancer Institute to analyze cancer care using the linked data base. The link has been completed, and the data base is being used to study the costs of cancer care, access to cancer prevention and treatment services, and patient outcomes for elderly persons with cancer.

- Detailed Medicare claims and enrollment data for persons in the linked data base are available on a 100 percent basis from 1984 on (with the exception of detailed information on physician services, which is available on a 5 percent basis). Summary Medicare data are available from 1974 on for a five percent sample. In future, the National Claims History File will be used for more extensive Part B data.

- Medicare data will significantly expand the research potential of SEER by providing detailed information on use of services, especially ambulatory services; the cost of services (for cost effectiveness studies); comorbidities (identified from claims data); and recurrences (estimated from diagnostic information in the claims data).

- Currently, the records of SEER registry cases diagnosed at age 65 or over between 1973 and 1989 are linked to Medicare enrollment and claims files. Records of 610,000 persons, or 94 percent of SEER cases, have been successfully matched. The computer linkage was performed by the Bureau of Data Management and Strategy (BDMS); the files are periodically updated by BDMS.

- Several studies are planned or underway, using the SEER-Medicare data base. The cost of cancer care will be estimated from diagnosis to death (see next item). Patterns of care studies will examine the dispersion of new therapies, and variations in care by age, race, geographic area, and type of provider. Outcomes of care will also be examined. Other studies are comparing care rendered in HMOs and fee-for-service (see next item).

- HCFA anticipates updating the linkage to include SEER cases diagnosed in years after 1989. The SEER Program was recently expanded to the Los Angeles and San Jose areas, and we will contact those registries to determine their interest in participating in future linkages.

- A description of the SEER-Medicare linked data bases prepared by NCI and HCFA staff was published in the August 1993 issue of *Medical Care*.

Several research projects are currently underway using the SEER-Medicare data linkage.

HCFA is also assisting/collaborating with NCI on epidemiologic and economic analyses of mammography services.

- HCFA administrative data are being linked with self-reported utilization and cost data collected by the NCI Breast Cancer Screening Consortium (BCSC). This linkage will facilitate the BCSC evaluation on the impact of the 1/1/91 introduction of Medicare reimbursement for screening mammography, and its evaluation on economic and other factors influencing women's use of mammography. Linkage of self-reported

BCSC data with HCFA claims will help assess the validity of self-reported utilization, as well as costs. The results of this collaboration will be helpful in determining if HCFA's reimbursement structure and deductible present an access barrier to the use of this preventive service.

- ORD staff have participated in informal information-sharing and discussions of an analysis being conducted by NCI staff of survey data collected from mammography facilities. Information gathered includes relative percentages of screening and diagnostic mammograms, and insights into how HCFA reimbursement and facility certification may influence the submitted mix of services to Medicare.

- HCFA staff provide ongoing support to NCI researchers regarding HCFA data and information resources. ORD expertise developed in its intramural epidemiologic analyses using the National Claims History file and HCFA's new Decision Support Access Facility (DSAF) have been made available to NCI staff, as well as university and state public health officials conducting analyses of mammography services with NCI extramural funds.

Planned Activities

PHS/IHS

IHS is discussing other research projects with the Mayo Clinic, the University of New Mexico, and NCI.

PHS/NIH/NCI

Expand membership of Inter-agency Working Group on Breast and Gynecologic Tumors to include additional Federal agencies involved in breast cancer research, including CDC, Department of Energy and the Environmental Protection Agency (EPA).

New Collaborative Activities

NCI and the American Association for Retired Persons (AARP) are planning an observational cohort study to examine relationships of diet with breast, colorectal, and prostate cancer among several hundred thousand members of the AARP. A large sample of subjects will be asked to complete a dietary questionnaire, and a subsample, selected to include those with extreme dietary intakes, will be followed for disease incidence.

3. ***Organize and support multidisciplinary research and collaborative efforts, using a wide range of mechanisms which maximize individual and group efforts. Adapt and/or expand innovative models such as the SPORE mechanisms currently used by the NIH. Increase the amount of discretionary funds provided through the SPORE program and develop methods to provide similar discretionary funds outside the SPORE program.***

Current Activities

PHS/NIH/NCI

Digital Imaging Technology - The development of digital mammography, digital data archiving and teleradiology will be enhanced by collaborations with scientists within the Department of Defense (DOD) and NASA involved with the technology of image enhancement and analysis, artificial intelligence and the development of high-resolution digital detection systems. NCI provides grant support and encourages collaborations and technology transfer between DoD and NASA scientists, scientists in academic centers and small businesses, and industry for development of: 1) digital mammography; 2) software for computerized image enhancement, interpretation and archiving; and 3) teleradiology. NCI solicited grant proposals through a PA to create a National Digital Mammography Development Group (NDMDG). The NDMDG consists of six major components: 1) digital mammography; 2) image processing; 3) computer-aided diagnosis; 4) teleradiology; 5) pre-clinical and clinical technology evaluation; and 6) headquarters for the centralized development of experimental design and data processing. The NCI/NASA Working Group for Technology Transfer, an outgrowth of the NIH/NASA interagency agreement initiated in 1992, held a workshop in May 1993 to identify and evaluate prospective technological advances. Of 43 applications received in response to the PA, 13 technologies appear to be novel and promising, with potential breakthroughs in the areas of digital

detectors and high-performance, low-cost all-fiberoptic networks for teleradiology. Several awards are anticipated to begin over the next two years.

National Cooperative Natural Products Drug Discovery Groups (NCDDG) are multidisciplinary and multi-institutional consortia focused on the development of a new drug or therapeutic strategy, often targeted to a disease site, and are funded through cooperative agreements with NCI. This flexible funding mechanism fosters collaboration between the academic, nonprofit, and/or commercial/industrial sectors and permits a close liaison with NCI staff to enhance the efficiency of therapeutics development, including early conduct of clinical trials. Innovative therapeutic strategies such as immunotherapy, growth regulation, monoclonal antibodies, and gene therapy are emphasized. Several groups have focused on breast cancer.

NCI developed P50/Breast Cancer Specialized Programs of Research Excellence (SPOREs) specifically to support broad-based, multidisciplinary research programs and to foster the rapid translation of research findings into clinical practice.

NCI issued an RFA to promote collaboration between basic researchers and clinical investigators to advance research on clinical correlatives of treatment response in breast cancer. Correlative studies on new prognostic factors that are ready for large scale evaluation are encouraged. Three awards will be made in FY 1994.

HCFA

HCFA/NCI projects:

1. Costs of cancer: Both total Medicare costs and Medicare costs attributable to cancer care are being estimated from diagnosis to death for cancers of the lung, female breast, colon/rectum, prostate, and bladder. Data on costs of cancer care will be useful for studies of cost-effectiveness of specific cancer screening and prevention interventions. Cost data will also be used to estimate the cost impact of new therapies.

2. Stage at diagnosis: A study is underway by ORD and NCI researchers comparing stage at diagnosis for 12 cancer sites between aged Medicare beneficiaries enrolled in HMOs and those treated in fee-for-service (FFS). Data on over thirty thousand cases will be included, from approximately 35 HMOs (with risk, cost, and HCPP contracts), plus FFS.

3. Rates of HMO disenrollment after cancer diagnosis: ORD is examining rates of disenrollment from Medicare risk HMOs following a diagnosis of cancer. Disenrollment rates for cancer patients are compared to rates of disenrollment for samples of HMO enrollees without cancer. Data from 25 HMOs are included.

   - Disenrollment rates of cancer patients are of interest because there is concern that HMOs have the potential to persuade sick and costly patients to disenroll, perhaps through subtle means. Disenrollment of a small number of expensive patients could result in windfall profits for HMOs, who are paid a capitated rate under the AAPCC.

Another study using the linked data base include the Iowa SEER registry, which is using the linked file to examine access to cancer treatment services by geographic area in Iowa, and specifically urban-rural differences.

Medicare administrative data are also being used to augment estimates of cancer incidence made by the National Cancer Institute (NCI) via the Surveillance, Epidemiology and End Results (SEER) Program. Two ORD epidemiologic investigations (one published, one in press) have pioneered new uses of HCFA administrative data to supplement estimates of cancer incidence made via the SEER cancer registries.

These studies concluded that HCFA administrative data can be used by states or other geographic units to monitor the incidence of cancer in the elderly as well as to plan and evaluate cancer prevention and intervention programs.

Epidemiological analyses underway within ORD are using Medicare administrative data to describe mammography utilization by the elderly and address potential issues affecting their utilization. (See I-A description under HCFA.) In addition, research studies are planned to estimate the volume of mammography services provided to elderly Medicare women that are unaccounted by HCFA claims data. These may include managed care and free/low-cost public health settings.

Planned Activities

PHS/NIH/NCI

An RFA for P20 planning grants was issued to stimulate the development of formalized breast cancer research programs in NCI-designated cancer centers.

Increase funding for the National Digital Mammography Development Group (NDMDG). See description of this activity on p. 12.

The Breast Cancer Treatment Groups (BCTG), which will be funded in 1994, are another effort to stimulate collaborations between clinicians and laboratory scientists focused on the development of new therapeutic agents or strategies for breast cancer. Specific aims of this initiative are to provide support for (1) Phase I/II trials of promising new therapeutic strategies for the treatment of breast cancer; and (2) appropriate laboratory programs necessary for the clinical development of a novel therapeutic approach. The cooperative agreement mechanism allows for a high level of interaction between the private, commercial and Federal sectors.

Within the constraints of the FY 1995 budget and based on peer review of applications, five or more awards will be made for new and renewal breast cancer SPOREs (four current SPOREs must compete for renewal).

Interactive Research Project Grants will encourage collaborative, multidisciplinary research on the relationship of dietary factors and major cancers, with particular attention to breast cancer.

Program Project Grants (P01s) in Nutrition Research for Cancer Prevention will be funded to stimulate multidisciplinary research to elucidate the effects of nutrition on cancer initiation, promotion, progression and prevention and apply that knowledge to develop dietary interventions for the prevention of cancer with special emphasis on breast cancer, prostate cancer and cancer in women and minorities.

New Collaborative Activities

PHS/NIH/NCI

The RFA for P20 planning grants (see above) includes a special focus on breast cancer in the elderly (to involve collaboration between NCI and NIA) and research on

environmental and occupational risk factors in breast cancer (collaboration with NIEHS).

B. Establish comprehensive patient data registries and materials banks as research tools.

1. ***Convene a group consisting of clinicians, basic and clinical research scientists, industrial representatives, representatives of the health care industry, consumers, patients, and Federal agency representatives to develop and define requirements for national resource banks for biological materials relevant to breast cancer. The materials banks should: (1) continuously collect and make available paraffin-embedded and fresh frozen samples of malignant and nonmalignant tissue as well as other specimens—such as serum, urine, and DNA—from women at risk, women diagnosed as having breast cancer, and unaffected women, as requested; (2) ensure access to and the availability of specimens to diverse investigators through a peer review mechanism; and (3) provide data regarding the source of the specimens, such as patients' family medical history, occupational and epidemiological information, and clinical results.***

Current Activities

PHS/NIH/NCI

Four institutions received NCI funding in September 1993 to work together to establish a Cooperative Breast Cancer Tissue Registry. Its purpose is to improve access to breast cancer tissue with associated clinical and outcome data for evaluation of predictive and diagnostic markers. A central database is being established to maintain an inventory of available specimens and the categories of clinical data associated with the specimens. Over 20,000 specimens are expected to be included in the initial inventory. Access to registry specimens will require a brief application describing the planned research, and a committee of scientists will review the requests and set priorities. The registry institutions will then retrieve the specimens and provide the requested materials. The registry will not fund research, but will facilitate studies funded through other sources.

The breast cancer SPOREs are required to develop resources to make breast tissues available to SPORE researchers and to the research community at large, if quantity permits.

NCI maintained a Breast Cancer Serum Bank for over 15 years which was available to the entire research community. The specimens were collected from women participating in two different programs. Two serum specimens were collected one year apart from asymptomatic women undergoing routine mammographic examinations. In the second program, annual serial samples were collected from breast cancer patients prior to and following surgery. There are currently over 250,000 vials of serum from close to 14,000 patients. The most recent specimens were collected over five years ago, and there have been few requests for samples from the bank despite periodic advertisements. These samples will be transferred late this year from storage at the Mayo Clinic to programs in the Division of Cancer Prevention and Control and the Division of Cancer Etiology.

Planned Activities

PHS/IHS

IHS has agreed to develop two centers for recruiting Native American women into the 100,000 women specimen and data bank project (grant application currently under review).

PHS/NIH/NCI

NCI plans to hold a workshop in Spring 1994 to determine what the breast cancer data, registry, specimen, serum and other resource needs are; assess the available resources; determine whether additional resources are needed; and design a centralized tracking system to assure maximum accessibility of available tissue and other biologic resources. The workshop will include extramural investigators, representatives of drug and biotechnology companies, the National Center for Human Genome Research and consumers. Issues to address in a comprehensive plan include:

* peer review mechanisms to prioritize requests for materials
* storage standards
* funding requirements
* ethical considerations and informed consent

* confidentiality
* proprietary rights.

Based on the results of the workshop, NCI will establish and support an information registry to promote access to biologic materials for breast cancer research.

At present, NCI is moving to require that recipients of large grant awards for breast cancer activities (SPOREs, cancer centers, cooperative groups) agree to participate in a national registry of biologic materials for breast cancer research.

In order to establish the utility of existing and putative prognostic and predictive factors, the cooperative groups propose to prospectively collect tissue blocks on all phase III adjuvant trials and to have each group store them in a central facility. The tissues from these large randomized trials represent a valuable national resource that is unique to the groups in that uniform treatment and long term follow-up are available.

NCI plans to develop a Cooperative Family Registry for Epidemiologic Studies of Breast Cancer. Cooperative agreements will be awarded to institutions to collect pedigree information, epidemiologic data and related biological specimens from patients with a family history of breast cancer. The data and specimens will be organized into a registry resource for interdisciplinary studies on the etiology of breast cancer. The high risk population that will be identified could be enlisted for studies of new preventive and therapeutic strategies. Awards are anticipated in 1995.

New Collaborative Activities

PHS/NIH/NCI

NCI will collaborate with CDC in the development of breast cytology criteria and the assessment of breast cell genetics in surgical pathology.

2. ***Establish new, comprehensive registries of patient data that are centralized and easily accessible. Their purposes are for studies of etiology, prevention, detection, diagnosis, treatment, and follow-up surveillance of breast cancer patients. When possible, these patient data registries should be cross-referenced with the materials banks.***

Current Activities

PHS/CDC *See* I.B.6.

PHS/IHS

With funding from the NCI, IHS has established a comprehensive Cancer Registry for Alaska Natives. This registry is already proving to be a valuable tool for public health planning and research.

IHS collaborates with the New Mexico Tumor Registry (a SEER site) to register all Native Americans with cancer in New Mexico and Arizona.

PHS/NIH/NCI

The NCI Surveillance, Epidemiology, and End Results (SEER) database (1973-1990) currently contains information on over 1.5 million cancer cases (including breast cancer). It is the largest single system for monitoring changes in cancer incidence in the American population by geographic, demographic, and social characteristics, covering about 14 percent of the U.S. population. SEER now permits analysis of long-term trends in breast cancer incidence and patient survival and is a resource for studies concerning detection, diagnosis, treatment and patterns of care. It is estimated that approximately 18 percent of the SEER budget is breast cancer-related.

Planned Activities

PHS/CDC *See* I.B.6.

PHS/FDA *See* I.D.2.

PHS/IHS

IHS recently submitted a proposal to the CDC to establish a Native American Cancer Registry, following the model of the Alaska Native Cancer Registry. CDC has not funded us, and we will be looking for other funding sources.

C. Increase opportunities for research training in fields related to breast cancer.

1. Expand and provide diverse opportunities for interdisciplinary research training through such programs as the National Research Service Award, clinical investigator career development awards, and Minority Investigator Administrative Supplements.

Current Activities

PHS/NIH/NCI

In FY 1994, about seven percent of NCI's National Research Service Award (NRSA) funds support training specifically targeted to breast cancer research. The Research Career Program and Cancer Education Program also support breast cancer research training and career development.

The breast cancer SPOREs include a component to support research training.

AHCPR

The National Research Service Awards (NRSA) program is building capacity for research by providing the knowledge and skills necessary to develop future health services researchers. Institutional NRSA grants support both predoctoral and postdoctoral trainees. Individual fellowships support postdoctoral trainees only.

Planned Activities

PHS/NIH/NCI

The NCI FY 1995 ByPass Budget included a request for additional funds to increase the number of NRSAs, to increase the number of physician scientist/clinical investigator awards, and to expand the clinical oncology training program, which allows physicians, established in other scientific fields, to acquire training in cancer research. Increasing the number of trainees working on breast cancer research will be a priority for any increase in these training programs.

NCI will issue an RFA for Breast Cancer Education Initiatives in FY 1994. The goal is to develop both public and professional education programs on a broad range of breast cancer issues, with a special focus on the importance of the physician-patient relationship, and on the special needs of minority and underserved populations.

2. ***Support researchers and other professionals who wish to spend time in cross-disciplinary sabbaticals in research related to breast cancer.***

Current Activities

PHS/NIH/NCI

The Cancer Prevention Fellowship Program was developed in 1987 to provide opportunities for training in cancer prevention and control. The program, which includes two to three years of training at NCI, is designed to prepare physicians and scientists from a variety of disciplines for a career in cancer prevention and control research and application. Forty M.D.'s and Ph.D.'s have entered the program, and 23 have graduated. A number of current and past fellows have breast cancer prevention and early detection research as a career focus.

3. ***Revise the research training guidelines to allow support for two additional years of training for postdoctoral fellows who agree to pursue research related to breast cancer.***

New Collaborative Activities

PHS/NIH/NCI

The creation of breast cancer research fellowships is proposed for up to two years' duration, to be awarded to extramural scientists on a competitive basis. These extramural investigators would come to the NIH campus to collaborate with intramural investigators in basic and clinical breast cancer research.

4. ***Provide for debt forgiveness for physicians, nurses, and others (e.g., doctoral candidates) who have completed two years of research training and who agree to devote a minimum of two years to research related to breast cancer.***

5. ***Support re-entry program for scientists who have spent periods of time away from research. Use existing successful models to guide the development of such programs.***

D. Expand the scope and breadth of biomedical and behavioral research activities related to breast cancer.

1. ***Continue support for and increase the number of unsolicited meritorious investigator-initiated research grants.***

Current Activities

PHS/AHCPR *See* II.F.5.

PHS/NIH/NCI

NCI developed a plan for research on cancers of the breast and female reproductive tract for transmittal to Congress. The plan is drawn from a comprehensive research agenda for breast cancer that appears in the NCI FY 1995 Bypass Budget. All NCI research funding initiatives (RFP, RFA, PA) are issued only after review and approval by one of four NCI Boards of Scientific Counselors (BSC) composed of non-

federal experts in applicable areas of medicine and science. Such initiatives are often preceded by an NCI-sponsored scientific workshop. Intramural research activities are peer-reviewed on a regular basis by a site visit team organized by the relevant BSC.

NCI has issued an ongoing omnibus PA soliciting grant applications addressing the prevention, etiology, control, biology, diagnosis or treatment of breast cancer. In addition, meritorious grant applications in breast cancer research beyond the established payline are selected for exception funding by the NCI Executive Committee.

NCI supports a broad portfolio of innovative clinical research both within the intramural programs and through funding investigator-initiated research. Highlights include:

* Initiation of carcinoembryonic antigen (CEA) clinical trials to test if presentation of CEA with a strong immunogen will induce an anti-CEA response for tumor therapy. Approximately 50 percent of breast tumors are CEA positive.

* Clinical trials are underway to test the usefulness of MDR gene-transfected hematopoietic stem cells in breast cancer patients undergoing high dose chemotherapy and autologous bone marrow transplantation.

* NCI's preclinical drug development program includes a drug screen composed of 60 different human tumor cell lines. Among these is a sub-panel of breast cancer cell lines to assess the specific activity of new agents (synthetic and natural) against breast cancer. An initial 2,000 promising compounds were tested in the breast cancer sub-panel and, of these, 90 showed specific activity against breast cancer cell lines. Fifty-one compounds have been selected for expedited preclinical development.

The CCOP, initiated in the fall of 1983, is a major cancer control effort that links community-based physicians with clinical cooperative groups and cancer centers for participation in NCI-approved research. The objectives of the CCOP include the implementation of cancer prevention, control, and treatment clinical trial research in multi-institutional settings, the testing of intervention strategies such as chemoprevention in large populations, the assessment of the impact of targeted research on community practices, and the support of new community investigators in clinical cancer research. Breast cancer is a CCOP focus.

Planned Activities

PHS/NIH/NCI

Additional funds will be allocated to independent investigators at the beginning stages of their research careers for new clinical therapeutic trials in breast cancer employing drugs (including differentiating agents), biologics (including monoclonal antibodies), radiation or surgery, as single modalities or in combination as appropriate.

Expand preclinical development of new promising agents with activity against breast cancer cell lines.

Launch an increased effort in monoclonal antibody and vaccine development.

Continue and expand investigation of T-Cell response in breast cancer.

Extend research support in cell cycle regulation.

Develop a prolactin antagonist for treatment of hormone responsive breast cancer.

The NCI FY 1995 Bypass Budget requests funds to expand the CCOP (currently 48 programs) to additional regions of the United States in 1995 by funding 80 community programs. Expansion of the CCOP would provide access to NCI-approved clinical trials, including many for breast cancer, in previously underrepresented communities and would serve as a vehicle for diffusion of state-of-the-art cancer care.

2. *Support health services research, the development of outcome data, and studies that can determine racial/ethnic and subgroup differences.*

Current Activities

PHS/NIH/NCI

A case control study of breast cancer risk and other adverse effects in women with silicone breast implants is being carried out in collaboration with the FDA. Immunologic effects as well as increased risk for breast cancer are being evaluated.

The Minority-Based CCOP (MBCCOP) was initiated in 1990 to provide minority cancer patients and their physicians with access to state-of-the-art cancer treatment

and control technology. Eight MBCCOPs are funded through 1994 involving over 275 physicians. The MBCCOP plays a major role in minority recruitment to the Breast Cancer Prevention Trial as well as a number of other breast cancer research initiatives.

Planned Activities

PHS/NIH/NCI

Expand research on breast cancer risk factors in African American and Hispanic women.

See also II.D.6.

The minority recruitment to clinical trials effort includes a patient needs assessment survey that will investigate barriers to participation in research studies. (See I.C.).

See also II.A.2. and II.A.3., Planned Activities.

HCFA

Fundamental descriptive epidemiological data being developed from HCFA administrative data can help the medical and public health communities to identify and correct potential barriers to women's use of screening mammography.

* HCFA can distinguish mammograms billed as screening and diagnostic, although these billing codes correspond imperfectly with the real reason the mammogram was done.

* HCFA can document, publish, and publicize national and state rates of Medicare reimbursed mammograms for elderly women with Part B benefits who are not enrolled in managed care plans. HCFA can also describe the factors that may be associated with the chances that a woman has a mammogram, such as age, race, or urban/rural residence.

A strong proactive approach is planned for HCFA to carry out its own breast health initiatives and interact with breast health initiatives already underway within Public Health Service and voluntary agencies.

HCFA's Plans for Examining Breast Cancer Treatment Options:

Disseminate empirical information about variation in the use of breast cancer treatment options to help beneficiaries make informed health care choices. In the longer-term, profile and analyze measurable factors associated with variation in breast cancer treatment.

Proposed Methods for Analysis of Breast Cancer Treatment Options:

* A significant element of HCFA's breast health activities involves providing beneficiaries with accurate and useful information to help them make informed health care choices. HCFA plans to develop and disseminate empirical information about variation in the use of breast cancer treatment options to help beneficiaries make informed health care choices. In the longer term, HCFA plans to identify, profile, and analyze measurable factors associated with variation in breast cancer treatment. These factors include beneficiary demographic characteristics, provider characteristics, and geographic factors.

* Meet with medical and surgical specialty societies and other professional groups, including the American College of Surgeons, to discuss this initiative.

* Consult experts from within the Department and from the health care community to:

    * define and review patterns of care data developed from the Medicare claims data (hospital and ambulatory records);

    * define the profiling variables, e.g., geographic region, provider types, beneficiary demographics, time periods; and

    * identify information about treatment options and questions for the beneficiary to ask her physician.

3. *Increase support for research on alternative medicine and therapies.*

4. ***Extend throughout the Federal Government opportunities for support of investigator-initiated research on breast cancer. For example, continue support for the Department of Defense breast cancer research program administered by the Department of the Army under the strategy recommended by the Institute of Medicine. This program has attracted 2,400 new proposals for breast cancer research, many from investigators who were not previously involved in breast cancer research.***

5. ***Conduct studies of the relationships among nutrition, exercise, and endogenous/exogenous hormone levels. Explore the following topics: the improved measurement of hormones at the tissue level; hormone metabolism; and differences across age groups.***

Current Activities

PHS/CDC

In collaboration with the NICHD, CDC is serving as the coordinating center for a case/control study which looks at the relationship between oral contraceptives, hormone replacement therapy and breast cancer.

This case-control study will utilize an existing resource, the Janus Serum Bank, to provide serum for analysis of organochlorine levels. The serum was collected 5-20 years prior to diagnosis of the cancer. To increase the likelihood of finding elevated serum levels of organochlorines, cases and controls used in the study primarily will be selected from Janus Bank participants with occupations identified as likely to have exposure to organochlorines. Over 30 different organochlorines including PCBs, dioxins and pesticides such as DDT, mirex and dieldrin will be assessed. Many of the organochlorines selected for analysis are ones that have been putatively linked to breast cancer. A total of 276 cases and 276 controls will be frequency matched for age and date of specimen collection. Associations between serum levels and breast cancer will be computed using multiple logistic regression with adjustment for confounding by parity, diet, location of residence, and family medical history. Predictive value of organochlorines for breast cancer will be computed using receiver operating curves to establish threshold values.

PHS/FDA

CFSAN is also cooperating with the Department of Defense in studying breast cancer and dietary factors.

CFSAN is implementing the Nutrition Labeling and Education Act (NLEA) of 1990. Accurate and easily understood labels with the nutritional content of foods will enable consumers to develop healthier diets, diets lower in fat and higher in fiber and certain other nutrients, which may reduce the incidence of some cancers, such as breast cancer. Under NLEA, CFSAN sponsored a three day conference in November 1993, which explored the role of antioxidant vitamins in reducing the risk of cancer and cardiovascular disease. In addition, CFSAN regulates human milk banking and infant formulas, used by women who cannot breastfeed their babies.

PHS/NIH/NCI

A follow-up study is underway of 60,000 women from the Breast Cancer Detection and Demonstration Project (BCDDP). This cohort is a subset of women in the BCDDP who have been followed since the early '70s. Due to the size of the cohort, and the fact that a large proportion of women are moving into the high cancer risk age range, this is an extremely valuable resource to study a variety of potential risk factors for breast cancer, including dietary, hormonal and environmental. Also being studied are other health issues of concern to elderly women, such as the effects of hormone replacement therapy on risk for stroke and osteoporosis and risk factors for endometrial, colorectal and ovarian cancer.

A study of breast cancer risk factors in relatively young women includes women 45 and younger in Trenton and Seattle, and 55 and younger in Atlanta. Risk factors under evaluation include diet, alcohol consumption, reproductive factors and environmental exposures. Because a relatively large proportion of women in Trenton and Atlanta are African Americans, this study will be valuable in identifying reasons for the rate of breast cancer among relatively young women rising faster in African Americans than in whites.

A study of breast cancer in women being treated for infertility is focusing on possible breast cancer risk arising either directly as a consequence of infertility, possibly associated with luteal defects leading to prolonged exposure to estrogen, or because of the action of drugs used to treat infertility.

A large multigenerational study of breast cancer in Asian-American women seeks to clarify the factors involved in the increasing incidence of breast cancer seen in Asian women as they migrate to the west and in their daughters and granddaughters. Factors under analysis include diet, endogenous and exogenous hormone levels, exercise and reproductive patterns.

The field of inquiry on breast cancer is being expanded through an RFA issued September 1993, on the "Role of the Microenvironment in Breast and Prostate Cancer." Applications will be funded in FY 1994. This initiative focuses on two new areas of inquiry: (1) the role of the *host* environment (e.g., tissue hormonal influences, interaction of tumor with supporting stromal tissue or other cells in local microenvironment) in tumor growth and progression; (2) areas of commonality in these two hormone-responsive tumors which may provide new insights into their processes of growth regulation.

NCI is evaluating in animal models the independent effects of dietary fat, energy intake and energy expenditure on carcinogen-induced mammary cancer under specific feeding conditions, as well as evaluating the effect of types of fat and fatty acid ratios. These studies will provide a clearer understanding of the relationship of fat, calories, and breast cancer, as well as insight into the mechanisms whereby these dietary components might lead to increased risk of breast cancer.

NCI is collaborating on the trans-NIH Women's Health Initiative, which includes a research component investigating the effect of a diet low in fat and high in fruits and vegetables on the incidence of breast cancer.

NCI is performing a case control study of fats, total calories, selenium, and vitamins A, E, and C in women with breast cancer in Finland. The role of various anthropometric parameters, genetic markers for breast cancer, and reproductive factors are also being explored.

Nutrient intakes are being compared in cases and reference subjects from an existing large cohort with prediagnostic baseline dietary histories. Associations between various dietary components and several cancers, including breast cancer, are being assessed. In addition, the relationship of childhood nutrition to breast cancer risk factors, including age at menarche, adult height, weight, and fatness is being investigated.

Planned Activities

PHS/FDA

MCHB is in the process of defining its agenda in the area of women's health, and health needs and gaps in service for women ages 15 to 64 are being examined. While its specific initiatives are still in the formative stages, one activity under consideration is a review of the scientific literature on the benefits and risks of lactation, including the relationship between lactation and breast cancer.

PHS/NIH/NCI

Establish a new intramural Laboratory of Hormonal Carcinogenesis and Cellular Proliferation in order to develop improved analytical technology for performing steroid hormone analyses, and to support a variety of biochemical/molecular epidemiology studies of breast and other hormone-associated tumors.

Expand a study of the role of food-derived heterocyclic amines in experimental and human mammary carcinogenesis.

Investigate the role of Vitamin E in breast cancer prevention and treatment.

NCI is planning a prospective randomized clinical trial to test the hypothesis that reducing dietary fat intake will reduce recurrence and increase patient survival for post-menopausal women with localized breast cancer. Potential mechanisms of action include the influence of dietary fat on circulating steroid hormone concentration, prostaglandin synthesis, immune function, regulatory gene expression, and cancer cell membrane structure and function.

Studies are being planned to examine how body size, specifically, lifetime changes in weight and fat distribution, influences breast cancer risk. In addition, changes in metabolic mediators will be studied to more precisely identify a subgroup of women with patterns of sex steroid and glucocorticoid metabolism associated with weight change that could increase the risk of breast cancer.

New Collaborative Activities

PHS/NIH/NCI

Investigate xenoestrogens and phytoestrogens and breast cancer through exploratory studies in nutritional epidemiology in collaboration with NIEHS and (possibly) FDA.

NCI is establishing an umbrella agreement with the Beltsville Human Nutrition Center of the USDA under which collaborative studies will be conducted, including investigations into the role of alcohol and development of breast cancer; the influence of dietary components on hormone metabolism, and the effects of caloric restriction on breast cancer prevention.

6. ***Conduct investigations of environmental influences on breast cancer and on the influences of compounds that have been shown to possess estrogenic properties on the etiology and incidence of breast cancer. Enlist representatives in public and private partnerships from industry, regulatory authorities, the scientific community, and consumers in identifying strategies of research aimed at the reduction of carcinogenic exposures, and in assessing and identifying appropriate control strategies, including setting standards, labelling, controlling, and phasing out.***

Current Activities

PHS/FDA

CDRH conducts research activities with implications for breast health. Currently, CDRH is doing research on ultrasound detection of silicone leaks from breast implants. CDRH is also looking at the effects of electromagnetic fields on breast cancer. In addition, CDRH has a project to evaluate antibodies in serum of women with breast implants. CDRH, in conjunction with NIST, is doing research on a mammography beam reference standard for dosimetry and electro-optics sensitometry and densitometry calibration. These will improve the measurement of dose and processing related image quality. CDRH also requires the manufacturers of breast implants to research their possible effects on breast cancer risk.

See also II.F.6.

PHS/NIH/NCI

NCI and NIEHS jointly support a project that seeks to determine whether the risk for breast cancer and gynecologic tumors in females and for testicular and other cancers in males is increased as a consequence of transplacental or direct diethylstilbestrol (DES) exposure.

Studies on the relationship between exposure to ionizing radiation and breast cancer risk are in progress:

* Epidemiologic studies among A-bomb survivors
* Breast cancer after multiple chest X-ray fluoroscopies for TB
* Breast cancer following X-rays for scoliosis
* Interaction between radiation and p53 mutations to enhance breast cancer risk
* Breast cancer risk in X-ray technologists.

The Long Island Breast Cancer Study Project is investigating potential environmental and other risks contributing to incidence of breast cancer.

* Factors under study include pesticides, air pollution, organic solvents, herbicides and electromagnetic fields

* Organizations collaborating with NCI on the study are NIEHS, USDA, EPA, the New York State Department of Health, New York Port Authority, Suffolk County Department of Health Services, and the Long Island Lighting Company

* Six NCI-designated cancer centers in the greater New York area will be a resource for the study.

Other studies on the relationship between exposure to environmental agents and breast cancer risk include:

* Breast Cancer in the Northeast and Mid/Atlantic States, in collaboration with NIEHS
* The Agricultural Health Study, in collaboration with EPA and NIEHS
* PBB Exposure and Breast Cancer Risk in Michigan, in collaboration with CDC and the Michigan State Department of Health
* DDT Exposure and Breast Cancer Risk in Triana, Alabama, in collaboration with NIEHS and CDC.

See also II.D.5.

PHS/NIH/NIEHS

Environmental Risk Factors. NIEHS and NCI are collaborating on several large-scale epidemiologic studies to identify environmental exposures that are associated with increased risks of breast cancer development. In one study, residents of Long Island, New York, an area with a 27 percent higher rate of breast cancer than the rest of the nation, will be assayed for exposures to a number of environmental contaminants, including the pesticide DDT, its metabolite DDE, other pesticides, polychlorinated biphenyls (PCBs), dietary factors, and low level electric and magnetic fields. Another large study is tracking 75,000 pesticide applicators and their wives to detect increased incidences of a variety of cancers, including breast cancer. Outcomes of these and other studies will be pivotal in the understanding of the relationship between certain common environmental exposures and breast cancer development.

Environmental Estrogens. Many of the events known to raise a woman's risk of breast cancer—early puberty, late menopause, childlessness—are also events that increase a woman's lifetime exposure to the natural hormone, estrogen. Some environmental contaminants--such as DDT, DDE, PCBs, nonylphenol and plant estrogens--are able to biologically mimic estrogen, albeit weakly. An important question to answer is whether or not this increased estrogenic load can increase the likelihood that a women will develop breast cancer. One NIEHS/NCI-supported study has already shown that a group of women who had breast cancer also had higher levels of DDE in their blood than did women who did not have breast cancer. The NIEHS continues to explore this avenue both in epidemiologic studies (see above) and in studies designed to define the interaction of environmental estrogens with human tissue at the molecular level.

Low-frequency Electric and Magnetic Fields. Men working on high-power electric lines have an increased incidence of breast cancer. This finding raises the possibility that the low background level of these same electric and magnetic fields found in homes could in subtle ways increase a woman's risk of breast cancer. NIEHS is sponsoring a long-term study in rodents to assess the cancer-inducing properties of the weak magnetic fields to which all persons are exposed. This same project will examine the ability of these fields to decrease production of the hormone, melatonin. It is known that melatonin acts to decrease estrogen levels and, in cell cultures, melatonin can kill breast cancer cells. It is also suspected that low-frequency electric and magnetic fields can decrease melatonin production, possibly leading to an

increased risk for developing breast cancer. This promising avenue of investigation will be explored in these studies and will help clarify if low-frequency magnetic fields contribute to breast cancer development.

Planned Activities

PHS/NIH/NCI

NCI will issue two Pas for R21s (Exploratory Research), one in all aspects of innovative clinical research (prevention, detection, diagnosis, and treatment) and one for occupational and environmental carcinogenesis. Breast cancer will be an area of emphasis. Investigators will be able to obtain preliminary data on novel approaches and hypotheses and to seek more long-term and greater support through traditional grant mechanisms.

Expand a study of breast cancer risk in ataxia-telangectasia heterozygotes to assess the risk in this group of the small amounts of ionizing radiation used in screening mammographies.

Expand the Breast Cancer in the Northeast and Mid/Atlantic States project to evaluate additional environmental factors through supplementing ongoing grants funded under an RFA.

Initiate a study of environmental and genetic factors determining breast cancer risk in Alaskan natives.

A planning grant initiative (described in II.A.3.) will encourage the development of programs focused on environmental influences on the etiology and incidence of breast cancer.

The NCI Construction Program has offered to partially or fully fund existing peer reviewed, unfunded construction grants if the space is dedicated to breast cancer research. Particular focus is being placed on space and facilities for studies of the etiology of breast cancer or studies of environmental and/or occupational risk factors associated with breast cancer.

New Collaborative Activities

PHS/NIH/NCI

Expand the Long Island Breast Cancer Study Project to include measurement of environmental contaminants with collaboration of EPA.

Expand the Triana, Alabama study, which is looking at the effects of DDT on a population exposed through eating fish from a local river contaminated with high levels of DDT, by increasing the size of the study cohort and by including analyses for a variety of additional organohalides in specimens from cases and controls; include collaborators from EPA and the Alabama State Department of Health.

Initiate a study on long-term, high-intensity, occupational exposure to DDT and breast cancer risk in female latex workers, in collaboration with NIEHS and the University of Malaysia Department of Human Genetics.

7. ***Conduct clinical research on the hormonal treatment of menopausal symptoms that result from breast cancer treatment, including research on controlling the health effects of early menopause in young women being treated for breast cancer.***

Current Activities

PHS/NIH/NCI

The Breast Cancer Prevention Trial (BCPT) was implemented in the CCOP clinical trials network in 1992 by the National Surgical Adjuvant Breast and Bowel Project (NSABP). The study is testing the ability of tamoxifen, now used in postsurgical treatment of early stage breast cancer, to prevent the development of breast cancer in women at high risk for developing the disease.

See biomarker and prognostic indicator research in II.F.2.

Planned Activities

PHS/NIH/NCI

Phase II trial of Tamoxifen and fenretinide in ductal carcinoma in situ.

See also II.F.3.

8. ***Support behavioral studies on the experiences of persons living with breast cancer, particularly their strengths and coping mechanisms as well as their stresses. Support behavioral research relating to treatment effectiveness; study the role of psychological factors in survival.***

Current Activities

PHS/NIH/NCI

A new research initiative addresses the role of counseling interventions in improving quality of life and enhancing adjustment to risk notification or diagnosis of cancer, including counseling women at high risk for breast cancer.

PHS/SAMHSA

The ways in which the Center for Mental Health Services (CMHS) can contribute to the National Action Plan on Breast Cancer relate to the development of a psychosocial conceptualization of breast cancer treatment as being highly dependent for success on appropriate diagnosis, intervention, and follow-through. Studies of the psychological and emotional impact of breast cancer to date have highlighted the importance of appropriate social/emotional supports at every step in the progress through treatment in order to prevent serious problems in depression and self-esteem, particularly for the seriously mentally ill woman.

Planned Activities

PHS/SAMHSA

Recent efforts in quality-of-life research have concentrated on the development of a unitary measure for breast cancer survivors, incorporating length of survival and quality of life. This area is a newly launched research area, but it is an ambitious effort to evaluate treatment effectiveness through a combination of physical and subjective information which can be helpful to women and their doctors in assessing the outcomes of primary treatment options (in combination with appropriate social and emotional supports), in terms of the quality of survival.

9. Investigate psychosocial barriers to participation in breast cancer research studies, such as professional staff's and patients' attitudes and cultural and lifestyle factors, as well as identify strategies to overcome these barriers.

10. Support studies to develop an effective model for health care organizations and delivery systems.

Current Activities

PHS/CDC

CDC is collaborating with the Health Insurance Plan of New York, Group Health of Seattle and Prudential Insurance Company to develop effective models for breast cancer early detection in HMOs.

In collaboration with the Health Insurance Plan of Greater New York, CDC will evaluate mammography screening rates among women over the age of 50, and will identify potential interventions to improve screening rates. Special attention will be given to the comparison of screening rates between women on Medicaid and regular HMO group enrollees.

Working with Group Health Cooperative--Puget Sound, CDC will identify factors associated with response to an invitation for a second mammogram after the first screening.

CDC will serve as a consultant to Pru-Care Atlanta and Houston in the development of a package of preventive services--including mammography.

Planned Activities

As Medicaid enrollees are shifted into managed care as part of some State health care reform initiatives, CDC will collaborate with States to evaluate the delivery of clinical preventive services using automated data and individual risk factor information.

CDC will work with the Health Alliance Plan (HMO) of Detroit to evaluate practices and behaviors related to screening mammography among their clients.

E. Provide adequate resources and mechanisms to speed the translation from the laboratory to the clinic of new therapeutic opportunities.

1. Increase efforts to speed the translation of basic research findings into clinical applications wherever possible. Develop partnerships with industry employing such models as the existing National Institutes of Health Cooperative Research and Development Programs Agreements (CRADAs). Review the reasonable pricing clause in relation to CRADAs, as they impact the flow of industrial funds into clinical research and, thus, effect collaborations.

Planned Activities

PHS/NIH/NCI

Biomarker Development Project - The recognition of intraepithelial neoplasia as a precancerous lesion on the causal pathway to cancer provides a unique opportunity to develop chemoprevention drugs at an accelerated pace. Many of the common epithelial cancers, among them breast cancer, have histologically identifiable precancerous lesions. A new initiative will work to shorten the duration of chemoprevention drug development trials by using such precancerous lesions and their changes in response to intervention as surrogate biomarkers for the cancer incidence endpoint.

Transformation-associated genetic and biochemical endpoints that represent basic mechanisms of both the initiation and promotion of carcinogenesis will be used as rapid screening assays to evaluate the potential chemopreventive activity of new agents.

See expansion of the breast cancer SPORE program and development of formalized breast cancer programs in NCI cancer centers described in II.A 3.

See II.D.7., a new clinical program for Phase I and II trials for promising chemopreventive agents.

2. ***Address the issue of liability as an impediment to industrial participation in clinical studies.***

3. ***Convene a task force on translational research related to breast cancer to identify promising new areas of basic research and actions necessary for successful translation, and to identify responsibilities for recommended actions.***

Planned Activities

PHS/AHCPR

If resources become available, a meeting could be convened to establish a research agenda for health services research/medical treatment effectiveness studies in breast cancer, which in turn will result in an RFA for topics in breast cancer.

4. *Extend the "orphan drug act" to new breast cancer therapies and technologies.*

Current Activities

PHS/FDA

FDA has enlisted an array of mechanisms to speed safe and effective products to the market for the diagnosis, treatment, and supportive care of breast cancer. See II-F for a full description of these approaches.

Translation of Research Results—Product Approvals:

The Centers have joined together their respective oncology staffs and are implementing the following approaches to expedite the approval of products for breast cancer: (1) the Treatment Investigational New Drug (IND) application, which permits wider availability and cost recovery for products in the final stages of drug approval; (2) Subpart E of the IND regulations, which encourages drug sponsors to consult with the agency at a very early stage of drug development; (3) Accelerated Approval, which allows for the use of surrogate endpoints in the approval of products, with careful postmarketing monitoring. The Centers work proactively with product sponsors by assisting in the appropriate design of studies to provide sufficient safety and efficacy data, which, in turn, will help speed the approval process. These mechanisms will ensure faster review of new and emerging technologies and wider availability to high risk women.

F. Conduct basic, translational, clinical, and health services research to improve breast cancer detection, treatment, and monitoring.

1. *Establish a breast cancer study section with consumer representation focused on translational research studies.*

2. ***Identify, study, and use biomarkers for detection and/or prognostic indicators for breast cancer. for example:***

- ***Conduct translational research and use centralized multidisciplinary decisionmaking to rapidly define and bring promising biomarkers and prognostic indicators into clinical trials.***

- ***Conduct research to provide an understanding of the development of breast cancer in the majority of women who have no known risk factors. Employ these new detection biomarkers to define groups at risk for participation in new screening trials.***

- ***Define subsets of patients by potential for recurrence of breast cancer and select therapeutic approaches based on prognostic indicators developed form translational and clinical research.***

- ***Confine the use of putative biomarkers for detection and prognostic indicators to the translational and clinical research settings until their utility has been scientifically proven to apply to decisions regarding standard care.***

Current Activities

PHS/FDA

Basic and Applied Research:

FDA regulates and conducts premarketing approval and postmarketing surveillance of *all* medical products related to breast cancer, including preventive regimens, diagnostic tools, treatments, and supportive care products; these central activities of the Agency are supported by both basic and applied research.

FDA's Center for Food Safety and Applied Nutrition (CFSAN), in conjunction with the National Center for Toxicological Research (NCTR), conducts research to determine the role of plant-derived estrogens (phytoestrogens) and other dietary constituents in carcinogenesis and promotion of breast cancer and other malignancies.

NCTR conducts basic and preclinical research on the etiology and pathogenesis of breast cancer. It also develops assays and techniques that may prove useful in the regulatory evaluation of new products--to assess the potential benefits and adverse effects of products that may be used in the prevention, diagnosis, treatment, and supportive care of breast cancer. The Center studies: solid state toxicity (breast implants), biomarkers of effect for risk assessment, development toxicity (estrogenic and antiestrogenic toxicities of natural and synthetic compounds, such as plant-derived estrogens), and the effects of dietary constituents. Research projects include: Animal studies to determine the health effects of materials used in breast implants; animal studies to determine the roles of obesity, dietary lipids and fiber in the development and prevention of breast cancer; the development of an animal model to evaluate the properties of estrogen antagonists and agonists, such as Tamoxifen. The rat model system may prove useful in assessing the properties of newer, and potentially safer, antiestrogenic compounds.

FDA's Center for Biological Evaluation and Research (CBER) is examining the role of growth regulators and transcryptional suppressors on the proliferative potential of breast carcinoma cell lines. Other CBER activities with breast cancer research implications include the regulation of: (1) gene therapy; (2) monoclonal antibodies; (3) tumor growth factors; (4) cytokines; (5) tumor vaccines; and (6) the safety of the blood supply. CBER also participates in a Memorandum of Understanding with the National Heart, Lung and Blood Institute for bone marrow transplantation in advanced breast cancer patients.

See also II.F.3.

PHS/NIH/NCI

The final stage of development of an assay for a new prognostic marker depends on careful analysis of inter- and intra-laboratory assay variability. The ability of the marker to provide independent, clinically important information must be assessed using multivariate analysis which requires large numbers of specimens with clinical and outcome data. NCI uses contracts to develop a pool of organizations with access to specific numbers of archival breast tissue specimens from patients with node negative breast cancer with a minimum of eight years of follow-up. The organizations also must have demonstrated expertise in laboratory testing. Prognostic markers in early stage breast cancer are being evaluated. The studies performed under these contracts are designed by an NCI statistician and program staff with technical input from the contractors.

The role of nuclear transcription factors in controlling proliferation and transformation of human breast epithelial cells is under study.

NCI is evaluating biomarkers of the breast epithelium detectable in breast duct aspirate as a method of early detection of cellular changes.

Tests for putative prognostic indicators for breast cancer are proliferating and laboratories are marketing prognostic services for clinical use that include a variety of approaches that are not yet validated. NCI issued an RFA to encourage clinical correlative studies on new prognostic factors in breast cancer that are ready for large-scale evaluation. Three awards are planned in FY 1994.

The initiative described in II.A., the RFA for Clinical Correlative Studies in Breast Cancer, and the proposed initiative to establish tissue banks within the cooperative groups described in II.B. facilitate study of the role of markers of breast cancer risk. *See also* II.H.1.

PHS/NIH/NIEHS

Basic Biology of Breast Cancer. All disease is an outgrowth of events occurring at the cellular and molecular level. To understand how environmental exposures lead to breast cancer, it is necessary to understand the basic biology of breast cancer development. This information will be vital in designing therapeutic interventions for treating breast cancer or, more importantly preventing its development in the first place. A number of NIEHS research projects are examining the basic biology of breast cancer development. These projects examine a range of possible mechanisms, including the consequences to DNA fidelity of the increased cell division that estrogen-like substances induce in hormonally responsive tissues such as the breast, the consequences of DNA-damaging compounds in breast tissue, and the role of different protein receptors to which estrogen and estrogen-like compounds bind. Additionally the NIEHS has released a new Request for Applications (RFA) to solicit the university-based community for research they can do on the role of environmental agents on the cellular and molecular components of breast cancer development and the importance of the timing of these exposures during critical developmental periods as they relate to future risk of abnormal development and carcinogenesis.

Assays for Carcinogens. NIEHS has lead responsibilities for the National Toxicology Program (NTP), an interagency collaborative effort that studies the toxicologic effects of environmental agents. The cornerstone of this effort are life-time exposure studies

in rodents. Both male and female rodents are used in these studies. Mammary tissue is routinely collected and analyzed. In this way the NTP guarantees that the environmental agents it studies will always be assessed for their ability to alter cells in mammary tissues. These assays have already identified approximately 40 chemicals that induce mammary cancers. Additionally the NIEHS is exploring ways to use quick, inexpensive biological assays to assess the ability of large numbers of chemicals to affect breast cancer development. In collaboration with the Agency for Toxic Substances and Disease Registry (ATSDR), NIEHS is developing a functional toxicology assay in which the ability of environmental chemicals to bind to the estrogen receptor, an event thought to be critical in the development of many environmentally-associated breast cancers, can be assessed. This screen would enable researchers to assess the potential of thousands of chemicals to alter biological function via the estrogen receptor. Results from these assays could serve to identify which chemicals need to be more extensively tested for their ability to induce breast cancer.

Planned Activities

PHS/NIH/NCI

Plans for early detection research in breast cancer include testing the hypothesis that breast cancer cells in the process of early carcinogenesis express different levels of particular antigens than do normal breast cells. A range of biomarkers will be analyzed in breast cancer tissue to map the frequency of expression of certain classes of tumor associated antigens. The differential expression from normal, to hyperplastic, to neoplastic breast tissue will provide critical information in identifying a marker for early detection application.

A multidisciplinary team of clinicians and scientists from the NIH are developing a new type of Positron Emission Tomography (PET) Scanner for application to improving the early detection of breast cancer. The project requires the identification of biochemical differences in breast tissue involved in the early stages of carcinogenesis. The ultimate goal is to develop a sensitive breast cancer diagnostic imaging tool that could identify women who are candidates for early intervention approaches.

The search for easily detected, reliable biomarkers of breast cancer is an important direction of research. Nipple (ductal) aspirates of breast fluid provide a non-invasive technology that can be exploited for early detection research. The aspirates can be used to identify molecular, genetic and cytological alterations in early, premalignant, and malignant tumors. Funds permitting, NCI will conduct a feasibility study to

evaluate this technology in conjunction with biomarkers in the early detection of cancer.

NCI is planning to conduct Phase II studies of combined hormone replacement therapy (estrogen plus progestin) as (1) an alternative to estrogen replacement used to alleviate menopausal symptoms in healthy women and (2) as a means to counteract the effects of tamoxifen with regard to endometrial cancer risk in women with breast cancer who are treated with tamoxifen.

Prospectively collect breast fluid aspirates and serum specimens from a large cohort enrolled in a health maintenance organization to evaluate for the presence of biomarkers of exposure to potential breast carcinogens, such as mutagenic chemicals, as well as for the presence of genetic markers of especial susceptibility to cancer.

3. ***Target and expand both translational and clinical trials of new therapeutic opportunities including novel chemotherapeutic and hormonal agents, vaccines, gene therapy, anti-angiogenesis and antimetastatic strategies, and antigrowth factor approaches.***

Current Activities

PHS/FDA

FDA's Center for Drug Evaluation and Research (CDER) has been involved in research involving taxol treatment for metastatic breast cancer and in the review of research examining the use of tamoxifen as a preventive treatment for women at high risk for breast cancer. Other CDER activities with breast cancer research implications include the regulation of: (1) cytotoxic drugs; (2) radiolabeled products; (3) hormones and hormone receptors; (4) antihypercalcemia agents; (5) antiemetics and other drugs used to alleviate the side effects of chemotherapy; (6) chemopreventive drugs, which protect the other body systems against the side effects of chemotherapy; and (7) other drug clones when used for cancer therapy. RU-486, a hormonal product, has started trials for advanced breast cancer. CDER also inspects the Institutional Review Boards for compliance with federal laws and regulations governing human research subjects protection.

See also II.E.4. and II.F.2.

Another mechanism to speed the translation of new therapeutic opportunities from the laboratory to the clinic will be through implementation of the Prescription Drug User Fees Act of 1992, which will allow the expansion of the Agency's scientific and clinical staff at CDER and CBER. The Act authorizes FDA to hire several hundred product reviewers, which should greatly speed products to the public. The Agency is also actively exploring the possibility of seeking authority to get user fees on device applications.

Recent drug/biologics approvals include: (1) Neupogen, for the prevention of neutropenia (low white blood cell count), to minimize the risk of infection in cancer patients undergoing chemotherapy; (2) Procrit, for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy; (3) Aredia, for the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases; (4) Zofran, for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy; (5) Marinol, for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments; (6) Metastron, for the relief of bone pain in patients with painful skeletal metastases; and (7) tamoxifen, a new indication, for the treatment of male breast cancer.

PHS/NIH/NCI

The NCI internal Diagnosis Decision and Implementation Committee (DDIC) is charged with identifying the most promising diagnostic and prognostic tools and provides a forum for defining clinical needs. The DDIC has reviewed the ongoing research on breast cancer, focusing on the information needed to help make critical treatment decisions. Questions addressed include: what are the current treatment problems; will a change in the diagnosis or the treatment approach affect many patients; and what impact would additional diagnostic or prognostic information have on survival or cure? The Committee reviews the current research to determine whether investigators are developing new tools to address the identified needs and how far along the research is. If tools are being developed, studies that will be required before the tool can be used in the clinic are identified. If no ongoing research addresses the identified need, the Committee considers the most effective way to stimulate such research.

The Cooperative Breast Cancer Tissue Registry facilitates breast cancer research (see discussion in II.B.1.).

The Small Business Innovation Research (SBIR) Program has the potential to contribute to new test development. NCI participated in the 1993 NIH Special Solicitation for SBIR grant applications, requesting applications focused on research in breast, ovary, cervix and prostate cancers. Applications for this Special Solicitation are currently undergoing initial peer review.

Planned Activities

PHS/AHCPR

Intramural research planned for calendar year 1994 includes a study of "Black/White Differences in Treatment for Breast, Lung, and Prostate Cancer" (Elixhauser and Ball). This study will examine whether blacks and whites hospitalized with breast, lung, and prostate cancers receive similar treatment. Data from a national sample of hospitals participating in the Hospital Cost and Utilization Project (HCUP-2) will be used to assess black/white differences in length of stay, in-hospital mortality, and the likelihood of receiving therapeutic procedures, controlling for clinical, sociodemographic, and hospital characteristics. Patients will be grouped into clinically similar categories according to their cancer-related diagnoses to ensure that treatment differences are measured within groups of similar clinical status.

PHS/NIH/NCI

A Phase III trial of Tamoxifen coupled with pulse progesterone vs. Tamoxifen alone in node positive breast cancer will examine whether pulse progesterone will reduce the risk of endometrial cancer associated with Tamoxifen use.

Clinical trials of autologous bone marrow transplantation (ABMT) in the adjuvant setting (Stage III, and Stage II with 4-9 and)10 positive nodes).

Phase II trials of monoclonal antibodies, vaccines, orotinoid, new chemotherapeutic agents and vitamin D analogues in metastatic breast cancer.

A new program of Phase I and II trials for promising chemopreventive agents will begin in 1995. Breast cancer will be the highest priority for Phase II trials and at least three trials will be initiated with 4-HPR plus tamoxifen and DFMO, accompanied by evaluation of breast biomarker endpoints.

4. ***Increase research on molecular genetics targeted at defining breast cancer susceptibility gene(s). For example:***

- ***Develop sensitive, specific, and inexpensive tests for the gene(s).***
- ***Conduct prospective research regarding the psychosocial, quality of life, and ethical ramifications of genetic testing as such gene(s) are identified.***
- ***Conduct basic and translational research using existing and planned data banks and tissue, fluid, and DNA banks from carriers and relatives of carriers to detect new biomarkers and predictors for the development of breast cancer. Extend this research to members of the general population who do not have a genetic history of breast cancer.***

Current Activities

PHS/NIH/NCI

A molecular epidemiology case-control study is evaluating the role of a variety of putative genetic factors, including susceptibility of the 17q21 locus, germline mutation in androgen or progesterone receptor genes, p53 gene mutations, metabolic phenotypes, cytochrome P450 isozymes.

Breast and other cancers in patients with the hereditary Li-Fraumeni syndrome are under investigation.

Several funded grants are attempting to identify a breast cancer susceptibility gene on chromosome 17. Each grant includes counseling procedures for informing patients of the results of their tests and their implications. The counseling procedures will be evaluated.

PHS/NIH/NIEHS

Breast cancer research at the NIEHS focuses on the complex interactions of individual genetic susceptibility, environmental exposures, age and the underlying causes of this disease so that successful prevention and treatment programs can be developed. Areas of focus include:

Genetic Susceptibility. Not all women are at equal risk of developing breast cancer. It is known that some women carry a mutation in one copy of an important tumor-suppressor gene, BRCA1, which makes them more likely to develop breast and ovarian cancer. NIEHS scientists are collaborating with other researchers to identify this gene. This work could lead to development of an assay that could be used to counsel women about their genetic susceptibility for developing breast cancer. Furthermore, the possibility exists that once this gene is isolated, it could lead to development of therapies targeted at this critical gene involved in breast cancer.

Planned Activities

PHS/NIH/NCI

Identification of familial breast cancer loci mapped by admixture linkage disequilibrium and analyzed by positional cloning.

Genetic, racial and environmental factors in breast cancer risk.

Investigate potential interactions between viruses and p53 (a tumor suppressor gene) to determine risk for breast and other tumors.

A workshop will be held in April 1994 to discuss the state of the science of testing for hereditary breast, breast/ovarian, and colon cancers. Issues regarding the ethical and social problems of screening for susceptibility genes as well as future research needs will be discussed.

New Collaborative Activities

NCI staff will serve on an expert panel convened by the American Society for Clinical Oncology to develop practice guidelines for the use of tumor markers in breast cancer.

See RFA on Genetic Testing and Counseling with NCHGR, III.A.1.

Initiatives described in II.A. are also relevant to this point.

5. ***Develop better methods of breast cancer detection. For example:***

- ***Develop a system to ensure communication between those who refer patients for detection procedures and those who provide the final diagnosis.***

- ***Support research to determine appropriate interventions for women at high risk of breast cancer.***

Current Activities

PHS/AHCPR

AHCPR's Center for Medical Effectiveness Research (CMER) supports the Medical Treatment Effectiveness Program (MEDTEP), which is focused on determining the effectiveness, cost effectiveness, and appropriateness of health care to prevent, diagnose, treat, and manage common clinical conditions. The "outcomes" of interest include: mortality, morbidity, symptom relief, patient reported quality of life, functional status, satisfaction with care, and costs.

In August 1993, AHCPR published a Request for Applications (RFA) for the second phase of its Patient Outcome Research Team (PORT) activities (PORT II). The PORT II solicitation requests "applications to conduct innovative and timely research that will provide convincing evidence for or against the effectiveness and cost effectiveness of alternative clinical interventions for the prevention, diagnosis, treatment, and management of common clinical conditions." Several of the PORT II applications address breast cancer issues.

AHCPR's Center for General Health Services Extramural Research (CGHSER), which supports extramural research on accessibility, quality, and cost of health care services, is currently funding the following research related to health care delivery and breast cancer:

* Testing the skills of readers of mammograms and determining the factors which affect their accuracy; and developing a method for gauging the performance of mammography centers. [Beam/HS07845]

* Identifying barriers to access and use of cervical and breast cancer screening in low income, uninsured minority women. [Burnett/HS07406]

* Evaluating the effectiveness of screening for colon cancer and breast cancer. [Colditz/HS07038]

* Demonstrating the extent to which interventions of a fiscal intermediary (Copic Insurance Co.) can effect changes in primary care physicians' cancer detection procedures, determine whether the company's evaluation activities are effective in facilitating change, and evaluate the extent of diffusion to practices not receiving interventions. [Cohen/HS06992]

* Investigating whether tamoxifen is a risk factor for cancer of the uterine corpus and/or ovary among women diagnosed with unilateral breast cancer. [Cook/HS08004]

* Determining the magnitude of the problem of inadequate follow-up to abnormal screening mammograms, and determining why some women do not receive adequate follow-up. [McCarthy/HS07516]

* Developing estimates of reliability of women's self-reports of receiving mammograms and their costs, relating accuracy to patient characteristics (such as age, education, race, income), and comparing the accuracy of self-reports in response to mail versus telephone questionnaires. [Zapka/HS06874]

A program announcement was published in March 1993 on "Primary Care and Health Care Reform" inviting research on the relationship between primary care and overall costs, quality and access to care. Because women often receive primary care and preventive services from more than one practitioner, methods to coordinate services effectively were explicitly identified in the announcement. Studies of the effectiveness of preventive service delivery for Medicaid patients enrolled in managed care are also encouraged.

Other ongoing CGHSER grant announcements include: Health Care Quality Improvement and Quality Assurance Research, Cost and Financing Issues in Health Care Reform, Medical Malpractice and Liability Research, Home Health Care and Supportive Services for Older Adults, Health Services Research on Rural Health. In addition, a Clinical Preventive Health Care Services grant announcement is in final development. We anticipate that breast cancer research will be the focus of many research applications submitted in response to these announcements.

CGHSER is co-sponsoring with the National Cancer Institute a program announcement encouraging research on the costs of cancer treatment.

AHCPR's Center for General Health Services Intramural Research (CGHSIR), which is responsible for designing and carrying out research projects that contribute to the development of health policy, maintains two large research databases: (1) the Hospital Cost and Utilization Project (HCUP-1 and HCUP-2), which includes inpatient data from a national sample of hospitals; and (2) the State Hospital Data Project, which includes inpatient data from all hospitals in selected States. Analyses of data on breast cancer treatment are included in these two databases.

A June 1993 conference on Primary Care for Women was co-sponsored by AHCPR, the Maternal and Child Health Bureau (HRSA), and others to define important research issues. Topics addressed included access to care, preventive services, and financing of services.

PHS/NIH/NCI

See the digital mammography initiatives described under II.A.3. Also relevant are initiatives to define the role of stereotaxic breast biopsy in diagnosis of early breast lesions, the role of magnetic resonance imaging and other novel non-ionizing radiation technologies for breast imaging. For example, electron paramagnetic resonance (EPR) is a technique currently being developed by NCI scientists that has the capability of detecting free radicals and will use a circulating stable free-radical compound as a "contrast" imaging material.

NCI staff performed an analysis of the growth of mammography resources relative to usage, and published a paper discussing implications for the availability of low-cost, quality mammography services. A follow-up study describes the economic determinants of mammography and health care personnel resources for local areas.

Analysis of data from the first phase of a national representative random sample survey of 1000 mammography facilities (about 10 percent of all U.S. facilities) has made possible a national profile of the current practice of screening mammography. NCI is examining the market dynamics for the provision of screening mammography, including the impact of changing insurance provisions and the entrance of low-priced, high-volume facilities on pricing, utilization, and quality patterns in local markets.

NCI issued an RFA for surveillance research that examines the operational aspects of breast cancer screening practices in the U.S. Projects are to assess the effectiveness,

efficiency and cost of screening programs as they relate to reduction of breast cancer mortality. Collaborative research among clinical practice, basic research in breast cancer screening, and population-based cancer registration is encouraged. Awards will be made in FY 1994.

To encourage economic studies in cancer prevention, screening and care, NCI issued a PA for research applications in three broad areas: (1) the cost of cancer treatment and care in various organizational settings, (2) cost-effectiveness of cancer prevention and screening trials and interventions, and (3) collection of economic data in the context of clinical trials. Applications that address breast cancer prevention, screening or care are anticipated.

During 1994, several studies are underway to assess the economic burden of cancer on the nation, including studies using a database that links SEER and Medicare files to explore costs and utilization of health care services by cancer patients. Costs of cancer in health maintenance organizations are being analyzed, and a workshop and subsequent study on the economic impact of cancer on the family are planned.

Planned Activities

PHS/AHCPR

Development of a program announcement that specifically encourages research to improve the effectiveness, and assess the cost-effectiveness, of clinical preventive services, including early detection of breast cancer. AHCPR is collaborating with NIH, ODPHP, and CDC in this activity.

Exploration with HRSA on methods to facilitate primary care research in underserved populations (i.e., to bring together researchers with patients and providers from community health centers and similar settings to develop competitive proposals that address the needs of underserved patients).

AHCPR is interested in working with NCI and others to develop research to improve the predictive value of mammography reading.

See also II.E.3.

PHS/NIH/NCI

Expansion of digital mammography projects and other studies of novel breast imaging technologies.

6. ***Conduct clinical research on early detection of breast cancer, including continued analysis of follow-up data from screening trials done to date. Clarify the efficacy of mammography screening for women ages 40 to 49 and women over 75 years of age.***

Current Activities

PHS/FDA

Other CDRH activities with breast cancer research implications include the regulation of: (1) oncology test kits; (2) magnetic resonance imaging equipment; (3) diaphanography products; (4) breast implants (including issues related to continued availability for reconstruction patients); and (5) products that emit electromagnetic fields. CDRH regulates the use of new and emerging technologies, such as radioactive implants inserted during surgery, which is currently under study for the treatment of early stage breast cancer. CDRH is also working with manufacturers to encourage the development of alternatives to the current generation of breast prostheses. CDRH is planning future activities to discuss and encourage innovation in this area.

See also II.D.6.

Planned Activities

PHS/NIH/NCI

NCI plans to sponsor the expansion of the Pan European Mammography Study, in particular the ongoing trial in Great Britain. This study is testing the hypothesis that screening women in their forties will be beneficial with respect to overall mortality. Support from NCI will help to enlarge the population of women ages 40-41 accrued to the trial. NCI will also consult on strengthening the study design and is encouraging other European countries to initiate similar studies or expand ongoing studies.

G. Make clinical trials more widely available to women with breast cancer and women who are at risk for breast cancer.

1. Conduct research to determine optimal methods and/or incentives (1) to facilitate widespread enrollment in clinical trials and (2) to improve compliance once enrolled. Determine ways to incorporate safeguards to ensure the anonymity/confidentiality of women enrolled in breast cancer studies.

Current Activities

PHS/FDA

The FDA is committed to making clinical trials more widely available to women, including women with breast cancer and women who are at risk for breast cancer. To that end, FDA has recently published in the *Federal Register* new guidelines for the study and evaluation of gender differences in the clinical evaluation of drugs.

PHS/NIH/NCI

Members of cooperative groups have conducted research to assess ways to increase enrollment and improve compliance. This research has resulted in the use of videocassettes to explain trials, improved patient-friendly consent forms, and physician newsletters. Compliance has been improved on cooperative group trials through the use of patient diaries, pill counters, return of unused vials to group pharmacies, patient support groups and immediate access to Institutional Review Board representatives through phone numbers.

All cooperative group trials safeguard patients' confidentiality/anonymity carefully. Only those agencies specified in the informed consent are permitted to review trial records and patient anonymity is safeguarded in any publication/ discussion of clinical trials data.

See description of CCOP and MBCCOP in II.D.1. and II.D.2.

Planned Activities

PHS/NIH/NCI

NCI plans to survey a sample of the cooperative groups, CCOPs, and MBCCOPs to identify effective strategies for enrolling and keeping patients in clinical trials.

NCI will convey survey results via presentations, articles, and training workshops.

New Collaborative Efforts

Pharmaceutical companies have expressed an interest in assisting NCI with the development of educational programs.

2. ***Establish a mechanism of outreach to ensure that all women have access, within a reasonable geographic area, to centers conducting approved clinical research. Include outreach to areas geographically distant from research centers so that all women choosing to participate in the most promising clinical trials can do so more easily. Include the Medicare and Medicaid populations.***

Planned Activities

PHS/IHS

IHS is working with the Southwest Oncology Group on a mechanism for increasing the participation of Native Americans in clinical trials.

PHS/NIH/NCI

The development of formalized breast cancer programs in NCI cancer centers will expand regional access.

See II.D.1. for proposed expansion of CCOP.

As indicated earlier (I.C., II.D.), a needs assessment survey to facilitate participation of minority patients in clinical trial research is planned. NCI also plans to interview cancer patients in focus group settings.

3. ***Redefine quality of care to include participation in a peer-reviewed and approved clinical research trial. Develop a mechanism to offer preferential coverage for therapies and diagnostic methods offered through clinical trials or for those proven effective in peer-reviewed and approved clinical trials. Support the individual's right to refuse participation in clinical trials.***

Current Activities

PHS/NIH/NCI

Multiple levels of peer review of NCI-funded clinical trials ensure that patients receive high quality care, including adequate informed consent, appropriate treatment for a particular stage of disease, and state-of-the-art follow-up. All informed consent forms for NCI-supported trials include the statement that patients have the right to refuse treatment on a protocol and such refusal will not lead to bias concerning their subsequent treatment.

At present, there is no clearly defined mechanism to offer preferential coverage for therapies and diagnostic methods offered through peer-reviewed clinical trials. NCI, in ongoing talks with major national insurance companies, has discussed the importance of clinical trials in answering key treatment questions. One tangible result of these efforts was agreement by the national Blue Cross/Blue Shield to support the current NCI-sponsored bone marrow transplant trials in breast cancer.

4. ***Involve consumers, especially from populations historically underrepresented in clinical trials, in the design, planning, and evaluation of clinical investigations. Conduct research regarding the optimal means of prospective involvement of patients and their advocates in clinical trials.***

Current Activities

PHS/NIH/NCI

The cooperative groups have recently begun to invite lay advocates to participate in their biannual meetings and to be members of planning committees. These efforts are just evolving but have so far been well received by both the scientific and lay communities.

H. Support research on the prevention and causes of breast cancer.

1. ***Target and expand basic an clinical studies of key prevention opportunities, including prevention research (exploratory studies as well as studies based on large-scale populations), specific studies of prevention by hormonal modulation, and chemoprevention therapies.***

Current Activities

PHS/FDA

FDA devotes a substantial amount of its research effort to examining issues related to the prevention and causes of breast cancer. For a full discussion of FDA's research activities, see II.F.2., II.F.3, and II.F.6.

PHS/NIH/NCI

An NCI- and NHLBI-supported trial that is assessing 40,000 nurses over age 50 for the combined effects of beta-carotene, vitamin E and low dose aspirin on lung cancer prevention also is examining any change in the expected incidence of breast and other cancers in this cohort.

Planned Activities

NCI will release an RFA to stimulate investigator-initiated chemoprevention research involving agents that may effect gene expression and cellular growth with respect to several cancers, including breast cancer. The development of short-term clinical trials will be encouraged to evaluate the modulation and/or function of gene products by chemopreventive agents.

2. ***Increase funding for primary prevention research, including multisite and/or large-scale population-based trials.***

Current Activities

PHS/NIH/NCI

See responses to II.D.1, 4, 5, 6, 7, and 8, including Breast Cancer Prevention Trial. Trials of the type mentioned are now in the planning stages, especially for vaccines and hormonal modulation. Treatment trials provide the toxicity and efficacy data that is required prior to consideration of a prevention trial.

Planned Activities

PHS/NIH/NCI

The Breast Cancer Detection and Demonstration Project (BCDDP) is being used to search for causes of breast cancer and ways to prevent it. Exposure data on exogenous hormone use, physical activity, body size, diet, and other risk factors have already been collected and will be linked with endpoint data being collected. This will be a prospective study with over 2,000 cases of cancer from major sites in women (including 1,200 breast cancers) for the evaluation of hypotheses related to cancer etiology and prevention. Expansion in 1995 would allow for more detailed special studies among breast cancer cases and matched controls, including collection of blood, fat biopsies, and other biologic specimens to examine levels of hormones, antioxidant, and fatty acids.

An initiative is proposed to define the behavioral and genetic factors associated with breast cancer in black women. Through a population-based study, researchers will follow a cohort of black breast cancer patients in up to five urban centers across the

U.S. and use individual and family medical histories, nutritional intake, alcohol consumption, socioeconomic status, genetic and age factors, as well as other potential risk factors to explore the association of these determinants to breast cancer incidence.

New Collaborative Activities

PHS/NIH/NCI

See collaboration with the Beltsville Human Nutrition Center in II.D.5.

I. Extend the scope, depth, and applications of quality of life and psychosocial research related to breast cancer.

1. Conduct research on end-stage disease including psychosocial factors and questions of quality of life, supportive care, when to stop care, and how to deal realistically with incipient death.

Current Activities

PHS/NIH/NCI

The cooperative groups and cancer centers are actively involved in quality of life research in breast cancer. The Southwest Oncology Group has a trial with taxol in metastatic disease in which the prime endpoint is not only clinical response but quality of life improvement as measured by a sophisticated battery of psychometric exams designed for patients with breast cancer. The cooperative groups have organized specific committees (Psychosocial, Quality of Life, and Cancer Control) to evaluate such issues in breast cancer and in other diseases.

An RFA for grants on pain research was released with funding planned for FY 1994. The goals of this initiative are to develop and test interventions to improve the management of cancer pain outside of the acute care or hospice settings, thereby improving the quality of life of persons with cancer living at home or being managed on an outpatient basis. A portion of this initiative focuses on breast cancer.

Recognition of the importance of quality of life (QOL) in cancer treatment decisions has led to incorporating QOL endpoints in clinical trials and the use of QOL measures in evaluating supportive care practices. To address the need for culturally sensitive assessment tools, in 1993 NCI funded research for development or adaptation, validation, and pilot testing of techniques for measuring health-related quality of life in cancer patients from culturally diverse backgrounds. The goal of this initiative is to provide culturally sensitive QOL measures that will allow full participation of patients from diverse backgrounds in cancer clinical trials and will help identify specific cancer rehabilitation needs. Quality of life is a major concern for women with breast cancer who participate with their physicians in selecting treatment options.

Planned Activities

PHS/NIH/NCI

NCI will continue to support research on psychosocial aspects of breast cancer, the results of which will be published in peer-reviewed scientific journals.

2. ***Support studies on consumer decisionmaking and the influences that affect women's use of breast health care services. Develop and implement strategies to overcome barriers to the provision and utilization of breast health care services.***

Current Activity

PHS/NIH/NCI

The cooperative groups have studied consumer decision-making related to mastectomy versus lumpectomy and radiotherapy, as one pertinent example. In addition, the groups have provided education to physicians and nurses to improve communication with breast cancer patients.

New Collaborative Activities

PHS/NIH/NCI

The development of Breast Care Centers is an interest of the NCI-designated cancer centers, as well as the Association for Community Cancer Centers. The development of educational interventions might be supported by outside organizations.

3. ***Incorporate questions related to psychosocial factors and quality of life issues prospectively in treatment and follow-up studies.***

Current Activities

PHS/FDA

The Commissioner's Special Assistant for Women's Health Issues and colleagues have published reports on a qualitative analysis of self-reported experiences among women encountering difficulties with silicone breast implants and a descriptive analysis of physical complaints from women with silicone breast implants.

PHS/NIH/NCI

For women ages 15-44 years, breast cancer is the most common cause of cancer mortality. Issues faced by young women with a diagnosis of breast cancer may differ from those of older, postmenopausal women. To address this, NCI and NICHD issued an RFA for research directed at decreasing the medical and psychological morbidity and disability associated with breast cancer diagnosis and treatment in younger women. Awards are expected to be made in FY 1994.

NCI, NIA and NINR are supporting studies on how to best address issues of breast cancer diagnosis, management and sequelae in older women. Researchers are identifying barriers to diagnosis and treatment in this age group and testing interventions that will reduce or eliminate the barriers.

See II.D.8., research on the role of counseling interventions in quality of life and adjustment to risk and diagnosis of cancer.

4. ***Design behavioral research to develop, test and incorporate psychosocial interventions based on socioeconomic variables and psychosocial needs (e.g., race, culture, location, income, and stage of life).***

Planned Activity

PHS/NIH/NCI

NCI has plans to develop educational interventions based on survey work done by other groups that target health professionals and administrators who work with existing breast care services or establish new services.

J. Support culturally sensitive researchers and research programs related to breast cancer.

1. ***Expand support for studies on breast cancer in special populations (e.g., minorities, young women, older women, women in low socioeconomic status groups and lesbians).***

Current Activities

PHS/AHCPR

AHCPR's Center for Medical Effectiveness Research (CMER) has awarded eleven (11) cooperative agreements to establish MEDTEP Research Centers on Minority Populations. The research centers are designed to support patient outcomes research, technical assistance, research training, and information dissemination that will improve the appropriateness and effectiveness of health care services provided to minority patients. The following centers include cancer in their outcomes research portfolio:

* The University of California in San Francisco, was funded as a full center, for a period of five years. The research agenda for the center includes breast and cervical cancer issues among African American and Latinas.

* The Henry Ford Hospital in Detroit, Michigan was funded as a developmental center, for three years, and will focus on health issues in African American populations. The center will be conducting research related to cancer.

* The University of New Mexico in Albuquerque has been funded as a developmental center, for three years, and will focus on problems of cervical and breast cancer. The target populations will include American Indian and Hispanic groups.

* The Morehouse School of Medicine in Atlanta, Georgia has been funded as a developmental center, for three years. The center will address research issues related to breast and cervical cancer among African Americans living in urban and rural areas.

PHS/NIH/NCI

See earlier discussions of the minority recruitment to clinical trials and the work with the Leadership Initiatives on the development of culturally sensitive materials and programs for special audiences (I.C.).

In keeping with the recent Congressional mandate, all NCI sponsored clinical trials in breast cancer (and in all cancers) include ethnic and culturally diverse groups.

III. POLICY

Many issues related to breast health and breast cancer require policy decisions to effect meaningful changes. Policies of government agencies are one key focus, but policy changes in all the organizations having a role in breast health are also important. This section identifies six key goals and corresponding HHS activities that address policy issues related to breast health and breast cancer.

A. Implement a comprehensive plan to address the needs of individuals carrying breast cancer susceptibility gene(s).

1. Implement safeguards and standards to prevent uncontrolled use of these new genetic testing technologies.

Current Activity

PHS/NIH/NCI

NCI is launching a project to determine the cancer information needs that may result from testing women with a familial history of breast cancer for a gene that may confer risk of developing the disease.

Planned Activity

See April 1994 workshop on hereditary cancer in II.F.4.

New Collaborative Activity

NCI plans to co-sponsor an RFA with NCHGR to develop and assess ways to deliver genetic testing and counseling. The major objective of this research is to identify clinical activities that best increase individual, patient and provider understanding of genetic testing for cancer risk and the implication of test results, as well as strategies for health promotion and cancer prevention. Investigators will study approaches to reduce the risk for test-related psychological harm, stigmatization, and discrimination to individuals tested and their families.

2. ***Develop and enact legislation to ensure the confidentiality of the patient's genotype.***

3. ***Create a task force on safeguards and standards with participation from patients and their advocates, geneticists, physicians, consumers, as well as genetic counselors.***

B. Increase participation of breast cancer advocacy groups in health policy decisionmaking.

1. ***Involve advocacy groups and women with breast cancer in setting research priorities, in evaluation, and in patient education. Ensure consumer input at all levels in the development of public health programs, research studies, and clinical trials.***

Current Activity

PHS/CDC

CDC, with NCI and the FDA, collaborated in the development of the National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers. The development of the Plan included extensive participation from a broad spectrum of public, private and voluntary organizations, including the Susan G. Komen Foundation. More than 250 persons reviewed the drafts of various components of the Plan and attended meetings to discuss the drafts. The Plan comprises a vision of the strategic components needed to ensure that every women, for whom it is deemed appropriate, receive regular screening for breast and cervical cancers, prompt follow-up if necessary, and certainty that tests are performed in accordance with current recommendations for quality assurance.

In compliance with the Preventive Health Amendments Act of 1993, CDC will establish the Breast and Cervical Cancer Coordinating Committee for breast and cervical cancer early detection activities related to the Healthy People 2000 Objectives. Nominees for this Committee will include representatives of other PHS agencies, experts in the fields of public health, clinical care, health education and community outreach, and representatives of consumer organizations.

PHS/FDA

FDA's Office of AIDS and Special Health Issues (OASHI) was established with a mandate to increase the participation of advocacy groups, including breast cancer advocacy groups, in health policy decisionmaking. For a full discussion of OASHI, see I-B.

PHS/NIH/NCI

Patients and consumers are involved in all aspects of the development of NCI breast cancer patient education interventions and materials.

Breast cancer patient advocates serve on the National Cancer Advisory Board, the President's Cancer Panel and the Breast Cancer Research Working Group established by the Division of Cancer Treatment and its Board of Scientific Counselors.

NCI has encouraged the SPOREs to include members of advocacy groups in the development of multidisciplinary projects and in the review of protocols (this has been very successful at the University of California San Francisco SPORE); an advocacy group representative was invited to speak at the annual SPORE meeting.

The NCI-supported cooperative groups are seeking input from patient advocates on the clinical trials process and design of education interventions.

PHS/OASH/OWH

OWH is working to sustain the collaborative spirit and build on the consensus evidenced in the *National Action Plan on Breast Cancer* by fostering the active participation of breast cancer advocacy groups in relevant policy issues.

Planned Activities

PHS/CDC

In compliance with the Preventive Health Amendments Act of 1993, CDC will establish the Breast and Cervical Cancer Coordinating Committee for breast and cervical cancer early detection activities related to the Healthy People 2000

Objectives. Nominees for this committee will include representatives of advocacy and consumer organizations.

PHS/IHS

IHS has been planning for two years to establish an Office of Women's Health, to coordinate women's health issues throughout IHS and serve as a contact point for advocacy groups. Because of the PHS hiring freeze, the Director's position is unfilled.

PHS/NIH/NCI

Members of advocacy groups will be invited to participate in the planned workshop on tissue procurement and distribution issues described in II.B.

2. ***Exempt the Public Health Service from Office of Management and Budget regulations regarding consumer research to allow ready use of proven social marketing techniques in beast cancer research and education. Use these techniques to determine consumer perspectives.***

Planned Activities

PHS/NIH/NCI

There is a tremendous need to incorporate private sector research methods into the development and evaluation of health interventions, including communications. Effective programs must be consumer-research driven, and OMB clearance is a significant barrier in the implementation of consumer research. The timing and expense of clearance are also barriers. NCI education staff have prepared a consumer-research process, and have discussed with PHS staff the possibility of using it as a model for OMB clearance.

3. ***Include as part of health care reform proposals mechanisms to obtain consumer feedback on health care delivery for patients with breast cancer and make this information available to consumers. Invite breast cancer advocacy organizations to monitor and report on breast cancer health care.***

Current Activity

PHS/OASPE *See* III.C.2.

4. ***Include as part of health care reform provision for: universal access to care and universal coverage (including necessary specialized care), elimination of coverage gaps and restrictions based on preexisting conditions, costs and treatment arising from participation in peer-reviewed clinical trials, and mammography screening.***

C. ***Eliminate unnecessary confusion about breast health issues.***

1. ***Develop scientifically valid national guidelines about prevention, detection, diagnosis, and treatment of breast cancer for both women and health care providers.***

Current Activities

PHS/AHCPR

AHCPR's Office of the Forum for Quality and Effectiveness in Health Care (FORUM) is facilitating the development of a clinical practice guideline on quality determinants of mammography. The guideline is being developed by a multi-disciplinary panel that includes radiologists, radiologic technologists, a breast surgeon, family practitioners, a nurse, medical physicists, a pathologist, and consumers. PHS Federal liaisons representing FDA, HRSA, NIH, and CDC are invited to all panel meetings and serve as a resource to the panel members.

The practice guideline will comprehensively cover procedures from the time a woman schedules an appointment for a screening or diagnostic mammogram until she receives the results. Specifically, the guideline will address the procedures necessary to obtain a quality mammogram after the decision to receive a test (whether screening or

diagnostic) has been made. The guideline will not consider the issue of when or how often to screen women for breast cancer using mammography.

AHCPR will publish and widely disseminate the Mammography practice guideline in three useful formats: The Clinical Guideline; a quick reference guide for clinicians; and a consumer guide which will be available in English and in Spanish.

PHS/NIH/NCI

PDQ is a database that provides up-to-date cancer information to physicians and consumers (see I.D.), including statements of state-of-the-art treatment and screening and summaries of clinical trials.

2. ***Develop and disseminate clear messages about what consumers, providers, and payers should do to improve breast health.***

Current Activity

PHS/NIH/NCI

NCI will continue to consult with the ACS and other voluntary and professional organizations with the goal of transmitting consistent and scientifically sound messages to the public and professionals.

PHS/OASPE

OASPE is actively participating in the overall HHS health care reform initiative in the areas of benefits design, coverage policy, technology assessment, quality management and consumer protection. A specific area of interest is participation in the development and dissemination of clear messages about what consumers, health care providers and third party payers should do to improve breast health and breast health services.

Planned Activity

PHS/FDA

FDA is in the process of formally establishing an Office of Women's Health, which should, from an FDA standpoint, help eliminate unnecessary confusion on breast health issues, and help insure that the FDA (along with the rest of government) speaks with one voice on issues of breast health.

D. Make breast health management, diagnosis, treatment, and follow-up care comprehensive, compassionate, widely available, and of high quality.

1. Initiate intragovernmental and intergovernmental agency coordination of breast cancer research in conjunction with patient and provider education and the provision of patient care. Provide for periodic reporting to the Secretary by all relevant Federal agencies and involved non-Federal organizations in the public and private sectors.

Current Activities

PHS/CDC

CDC supports cooperative agreements with several professional organizations, including the American Medical Women's Association, the American College of Physicians, the American Academy of Physician Assistants and the National Medical Association to enhance practitioner skills and knowledge directed to the early detection of breast cancer.

PHS/FDA

FDA works closely with and provides expertise to other governmental (e.g., HCFA, AHCPR, CDC, and NIH [including NCI]) and nongovernmental entities (e.g., the American Cancer Society). FDA staff belong to an NCI-FDA (Division of Cancer Treatment) working group that meets monthly to discuss the development and progress of products for breast cancer. The FDA participated actively in the development of *The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers*, a report of the U.S. Public Health Service.

PHS/SAMHSA

OWS has been working with SAMHSA's three Centers to identify appropriate activities to be undertaken as part of the National Breast Cancer Plan. OWS will continue to work with the Centers to implement the activities identified by each of the Centers pertaining to breast cancer, facilitating communication and coordination among the three Centers as well as with other relevant PHS and DHHS agencies.

Planned Activities

PHS/CDC

CDC will review issues related to providing comprehensive, quality breast health management and will explore policy issues related to the use of Comprehensive Breast Care Centers to concentrate services ranging from early detection through treatment and medical and psychological follow-up in a facility dedicated to breast health.

CDC will collaborate with the American College of Surgeons to develop guidelines for management of women with abnormal breast exams or mammograms.

PHS/NIH/NCI

NCI will collaborate with advocacy groups and professional associations such as the National Association of Oncology Social Workers to identify services that are responsive to needs of women with and at risk for breast cancer and their families.

2. ***Work through state licensure agencies and professional national certifying and accrediting organizations to mandate competence in evaluating signs and symptoms related to breast health. Make licensure and certification contingent on such competency.***

3. ***Improve mammography systems through the Mammography Quality Standards Act (MQSA). Improve the implementation and development of feedback mechanisms linked to registries.***

Current Activities

PHS/CDC

CDC supports and promotes the standards for mammography established by the Mammography Quality Standards Act (MQSA) and requires states participating in the National Breast and Cervical Cancer Early Detection Program to contract for services only with mammography facilities which meet ACR standards. These states are also required to develop effective tracking systems and assure prompt, appropriate follow-up of women with abnormal mammograms.

PHS/FDA

Upgrading and expansion of CDRH's calibration facility is in progress in order to provide necessary support for the inspection program. Acquisition of computer hardware and software to meet the program's Automated Data Processing needs is under way. Development of the curriculum for training inspectors is in progress.

FDA has held a mammography database meeting with other PHS agencies to coordinate data collection. MQSA inspections, certification, accreditation, and audits will provide FDA with a rich database on the delivery of mammography services in the United States. FDA is working with NCI, AHCPR, HRSA, CDC, and others to facilitate database linkages, which both serve an important informational purpose and eliminate unnecessary, wasteful duplication. In addition, FDA has met with researchers with experience in mammography facility-cancer registry linkage to learn from their experiences.

4. ***Implement final standards of medical quality assurance for mammography. Finalize and implement the regulations for MQSA, which were recently issued by the Food and Drug Administration, so that all women can be guaranteed safe, high-quality mammograms.***

Current Activities

PHS/CDC

CDC supports and promotes the standard for mammography established by the Mammography Quality Standards Act (MQSA) and requires States participating in the National Breast and Cervical Cancer Early Detection Program to contract for mammography services only with facilities that meet American College of Radiology (ACR) standards. These States are also required to develop effective tracking systems and assure prompt, appropriate follow-up of women with abnormal mammograms.

CDC has collaborated with the Center for Devices and Radiologic Health of the FDA, and the Conference of Radiation Control Program Directors to gather and publish: (1) data on the performance of mammography inspections by State inspectors; and (2) legislation relevant to mammography quality assurance throughout the United States. This collaboration has also produced model State legislation for mammography quality assurance, a standardized protocol for State inspectors to utilize during inspections of mammography equipment, and a proposal for implementation of MQSA that emphasizes the unique concerns and capabilities of State health department and State offices of radiologic health.

CDC has also entered into a cooperative agreement with the ACR for development and implementation of a broad professional education effort. This project has yielded valuable survey data on manpower needs for implementation of MQSA. In addition, technical documents on equipment standards and professional practices relevant to mammography quality assurance have been published as a result of this cooperative agreement. A major accomplishment has been the development and presentation of educational curriculum for radiological technologists, medical physicists, radiology residents, and practicing radiologists at professional conferences and meetings.

PHS/FDA

FDA is responsible for implementing the Mammography Quality Standards Act (MQSA), which is designed to assure the availability of and access to quality

mammograms for all women. Specifically, MQSA, enacted in 1992, requires national, uniform quality and safety standards for mammography facilities. FDA will set federal standards for mammography quality assurance. By October 1, 1994, FDA's CDRH must certify all mammography facilities in the U.S. as providing quality mammography. To be certified, a facility must be accredited by a federally-approved accreditation body. Accreditation will be granted upon a satisfactory review of equipment, personnel qualifications, quality assurance programs, record keeping and reporting to ensure quality mammography.

A new division, the Mammography Quality and Radiation Programs, has been organized within CDRH to administer the MQSA system. The National Mammography Quality Assurance Advisory Committee has been chartered and selection of members is complete.

In September 1993, CDRH sponsored a three-day public conference, "Implementing the Mammography Quality Standards Act of 1992: Roles in Improving Mammography Services." On December 1, 1993, Commissioner Kessler announced interim final rules that set forth the standards that mammography professionals and facilities will have to reach by October 1, 1994. The regulations were published on December 21, 1993. The public comment period ended on January 21, 1994. The interim regulations acquire the force of law on February 22, 1994. These interim final regulations cover quality standards for personnel engaged in mammography, equipment used, radiation dose, quality assurance procedures, record keeping, reporting, and clinical outcomes audit.

The final regulations will be developed with the input of the National Mammography Quality Assurance Advisory Committee, which is comprised of professional and consumer representatives. The first meeting of the Advisory Committee was held on February 17-18, 1994.

Coordination of state programs and MQSA is an ongoing process. The January 11, 1994 meeting of state radiation control program directors and FDA's Division of Mammography Quality and Radiation Programs was to acquire state input into all aspects of implementing MQSA. The majority of states plan to contract with FDA to do MQSA mammography facility inspections.

Training of MQSA inspectors began on January 24, 1994. Training will continue intensively for two years to meet the demand for 300 inspectors. The training program consists of a pretest, basic course in radiation physics, mammography quality control and quality assurance, and the MQSA inspection protocol and procedures.

Laboratory and hands-on field experience are incorporated into the training. A final mentored experience completes the training.

In a collaborative activity, FDA and HCFA are coordinating mammography inspection programs to minimize confusion for the facilities and to ensure compliance with quality standards. In a further example of interagency collaboration, the Centers for Disease Control and Prevention have also been included in this coordination effort for their breast and cervical cancer screening program.

FDA is currently accepting and reviewing applications for Accrediting Bodies. Decisions will be made beginning in March 1994.

FDA is in the process of developing its certification program. The target date to begin certifying accredited facilities is late Spring 1994.

FDA has been actively conducting community outreach on MQSA, both through CDRH's MQSA program and the Offices that comprise FDA's Office of External Affairs (OEA). CDRH's program has been working with mammography facilities, radiologists, state health agencies, and consumers about MQSA. CDRH has produced a quarterly newsletter that starts distribution in February, 1994. The Center has also exhibited and presented at meetings, published articles, and done mailings to inform the public about MQSA. In addition, CDRH has worked with OEA's Office of Legislative Affairs (OLA) and briefed Congressional staff on MQSA implementation.

5. ***Provide incentives for development of educational programs for health care providers to incorporate learning objectives and curricula models on breast health and cancer management.***

Current Activities

PHS/CDC

See I.A.1. above. Through the National Breast and Cervical Cancer Early Detection Program, State health departments provide educational opportunities in breast health for health care providers. More than 334 training programs for 1,900 providers have been implemented to enhance the practice of health care professionals in breast cancer early detection.

CDC also supports cooperative agreements with several professional medical associations, including the American Medical Women's Association, the American College of Physicians, the American Academy of Physicians Assistants, the American Nurses Association and the National Medical Association, to enhance practitioner skills and knowledge directed to the early detection of breast cancer.

CDC supports the American Medical Women's Association in a project to design a training program that is expected to reach 4,000 primary care physicians. Training material will be developed and a 20-member master faculty will be recruited and trained to teach other physicians about proper performance and evaluation of clinical breast exams, the importance of mammography, and appropriate interpretation of screening results.

CDC funds the American College of Physicians to develop and implement an office-based systems to support physician screening activities. Systems are in place in over 40 physician practices in two States. Designated offices receive a "tool kit" containing staff and patient prompts as well as patient reinforcers. The medical education component is a self-study package of monographs and instructional videos for which physicians may earn up to 6 credit hours.

CDC supports a project with the American Academy of Physicians Assistants to design, disseminate and test the effectiveness of an Early Cancer Risk Identification program, for physician assistants practicing in primary care settings, including family medicine, internal medicine, obstetrics, gynecology and other areas. More than 50 percent of the 21,000 physician assistants in the United States are primary care practitioners.

CDC supports a project with the American Nurses Association to develop curricula for nursing students, registered nurses and nurse clinicians on methods of educating low-income, African-American women about breast cancer.

CDC also collaborates with the National Medical Association to develop and implement a strategic plan of action to influence physicians to increase screening for breast and cervical cancer among African American women.

CDC is collaborating with the American College of Surgeons to develop guidelines for the medical management of abnormal breast exams.

PHS/FDA

The FDA Commissioner's Special Assistant for Women's Health Issues is involved extensively in breast implant regulation, including: (1) coordination functions for the FDA; (2) publication of scientific journal articles and editorials on psychological and physical benefits and problems associated with breast implants; (3) participation in seminars; (4) participation in advisory panel meetings; and (5) involvement in issues related to continued availability of breast implants for reconstruction patients under controlled research protocols. The Special Assistant has focused on several other issues related to breast cancer, including: (1) revision of FDA's guidelines on women in clinical trials; (2) labeling issues concerning contraceptives and the use of estrogen therapy in postmenopausal women; (3) and FDA's review of contraceptive product applications.

PHS/SAMHSA

As the focal point within SAMHSA for policy development and coordination relating to women's issues, the Office for Women's Services (OWS) can play a role in SAMHSA's efforts to ensure that issues relating to breast cancer are included in SAMHSA's programs for women.

P.L. 102-321 (the "ADAMHA Reorganization Act of 1992) mandates that the Office for Women's Services establish, maintain and operate a program to provide information on women's substance abuse and mental health services. While the program is still in developmental stages, information relating to the issues surrounding breast cancer can be included as part of this effort.

Planned Activity

PHS/FDA

FDA plans to establish an Office of Women's Health (OWH), to serve as an agency focal point for women's health issues. Once formalized, OWH will work to correct gender disparities in drug, device, and biologics testing and regulation policy and monitor the implementation of the revised clinical trial guidelines to ensure that women are adequately represented. OWH will also work within the Agency to insure that all functions, regulatory and oversight, are gender sensitive and responsive. In addition, in collaboration with all OEA offices, OWH will work closely with all external constituencies to insure sensitivity and responsiveness.

6. ***Define a range of comprehensive psychosocial services that encompass all the needs of women at risk for breast cancer as well as those women with the disease. Include in such services, where appropriate, family members and other significant persons in the woman's life.***

Current Activity

PHS/FDA

The second targeted initiative of the FDA Commissioner involves the recent creation of the aforementioned Office of AIDS and Special Health Issues, which focuses on cancer and other serious and life-threatening illnesses. This office has recently been expanded to include new full-time staff devoted exclusively to cancer issues. These two offices are central to FDA's commitment to high risk women and breast cancer patients.

See also III.D.5.

7. ***Expedite the review and approval of new drugs and diagnostic test, as well as devices and technologies related to breast cancer.***

Current Activity

HCFA

Through Medicare's Technology Advisory Committee, various matters are considered for possible national coverage decisions. One such matter recently recommended by the Committee for referral to the Office of Health Technology Assessment in the Public Health Service is autologous bone marrow transplantation as a treatment for breast cancer.

8. ***Ensure reimbursement for all costs for patients enrolled in peer-reviewed clinical trials on research related to prevention, screening, diagnosis, and treatment of breast cancer.***

Current Activities

PHS/NIH/NCI

NCI is exploring third party payment for clinical trials with the Health Insurance Association of America (HIAA) and the National Blue Cross-Blue Shield Association. See current activities, II.G. about Blue Cross/Blue Shield support of NCI-sponsored bone marrow transplant trials.

Planned Activities

PHS/NIH/NCI

Training programs will be developed for HIAA staff nationwide. PDQ will be provided on the HIAA HI-Wire communication system to member companies.

OASPE

Examination of third party payment for clinical trials. P.L. 103-43, the NIH Revitalization Act of 1993, requires the Secretary, through the NIH, to conduct a study of participation of third party payers in clinical trials. The study will determine the coverage policies of third party payers and will include recommendations concerning these policies. OASPE is assisting the NCI with this study, which is in the preliminary stage.

9. *Develop mechanisms of validation and quality control for all new and existing technologies to ensure against improper and substandard use.*

Current Activities

PHS/FDA

Another way that FDA activities affect breast cancer prevention, diagnosis, treatment, and supportive care is through the utilization of principles of risk assessment and quality assurance, overseen by the Centers and FDA's Office of Regulatory Affairs (ORA). At the core of FDA's public health protection and promotion duties is the assessment of risks and benefits of medical products. FDA protects consumers by assuring that product labels permit informed choice. FDA ensures the safety and efficacy of regulated products through scientific review and inspection of manufacturers.

In addition, ORA enforces FDA laws against health fraud. Health fraud often targets those with serious and life-threatening illnesses. For example, the FDA took action when an unapproved device consisting of a "special glove" was being promoted as an aid for self breast exams, in the absence of evidence of its efficacy for this purpose.

E. Develop new and stable sources of funding for health-related research and public health activities.

1. *Work cooperatively to identify new revenue sources.*

Current Activity

PHS/CDC

CDC assists States participating in the National Breast and Cervical Cancer Early Detection Program to identify sources of non-federal revenue to match federal dollars invested in the program. California, for example, uses revenue from a tobacco tax to support breast cancer activities. Other sources of revenue include in-kind contributions of services and educational materials from community businesses and organizations.

F. Develop a mechanism to coordinate the implementation of action steps identified in the Proceedings of the Secretary's Conference To Establish a National Action Plan on Breast Cancer.

1. Initiate intra- and intergovernmental agency coordination of beast cancer activities, including relevant research, education, and health care delivery activities.

Current Activities

PHS/OASH/OWH

The Office on Women's Health (OWH) is working to establish mechanisms for ensuring appropriate direction, coordination, monitoring, and support for the goals and action steps outlined in the *National Action Plan on Breast Cancer.* The coordination of implementation efforts emphasizes the importance of collaboration, consensus-building, and public-private partnerships among the individuals, organizations, corporations, and agencies intent on making meaningful progress toward the eradication of breast cancer.

The following organizational structure is under consideration for coordination of implementation efforts:

* *National Steering Committee* - provides leadership and overall direction for implementation of the *National Action Plan on Breast Cancer.* The purposes of this committee, which represents a broad range of public and private constituencies concerned about breast cancer, are: (1) to evaluate and monitor progress in the implementation of goals and action steps outlined in the plan's three major areas—health care, research, and policy; and (2) to identify new opportunities and make recommendations to strengthen and sustain national efforts related to breast health and breast cancer.

* *HHS Executive Staff Committee* - comprised of a core group of senior intradepartmental representatives who provide leadership and overall coordination for Departmental implementation of the *National Action Plan on Breast Cancer.*

* *Interagency Coordinating Committee* - provides a mechanism for promoting the active and collaborative participation of Federal departments and agencies

in the implementation of goals and action steps outlined in the *National Action Plan on Breast Cancer.*

2. ***Establish a national task force that meets periodically to evaluate progress and identify new opportunities in each of the three major areas—health care delivery, research, and policy—outlined in the plan.***

PHS/OASH/OWH *See* III.F.1.

Summary

The *Inventory of Breast Cancer Activities: U.S. Department of Health and Human Services* identifies a number of key Departmental activities that support achievement of goals in three major areas of the *National Action Plan on Breast Cancer:* health care, research, and policy. **Health care activities** focus on improving the delivery of clinical and educational breast health services, especially to underserved and at-risk populations; fostering the effective coordination and dissemination of information and research findings on breast health and related services; and promoting breast health education through public-private linkages. The Department also supports a broad range of basic, clinical, epidemiologic, health services, psychosocial, and translational **research activities** on breast cancer. Departmental **policy activities** include efforts to support the participation of advocacy groups in breast cancer policy development; facilitate the development of consistent information on breast health and breast cancer; ensure the delivery of comprehensive, quality breast health services; and coordinate the implementation of action items outlined in the *National Action Plan on Breast Cancer.*

Most important, the *Inventory of Breast Cancer Activities: U.S. Department of Health and Human Services* illustrates the importance of collaborations, consensus building, and partnerships between the Department, other Federal government agencies, consumer, scientific, and health professional organizations, and other interested groups in an effort to make meaningful progress in the fight against breast cancer. This inventory, just like the action plan on which it is based, is intended to be an evolving document, one that serves as an ongoing benchmark of progress in the prevention, diagnosis, treatment, care, and ultimate eradication of breast cancer.

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Proceedings

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