BCSC Breast Cancer Surveillance Consortium

Evaluating Screening Performance in Practice

National Cancer Institute
Division of Cancer Control and Population Sciences
Applied Research Program

April 2004

Table of Contents

Foreword

We have good news to report about breast cancer early detection. Research has shown that early detection, combined with effective treatment, can reduce mortality from this second leading cause of cancer deaths in women. Since the early 1990s, breast cancer mortality rates have dropped steadily, in large measure due to improvements in screening and treatment. American women have taken these findings to heart—in 1987, less than 30% of women 40 years old and older had had a mammogram, the primary mode of breast cancer screening. Ten years later, that percentage had doubled to 67% of women in the same age group, and is now at 70%. American women have increasingly come to include breast cancer screening as part of their regular health care.'

Our growing understanding of the value of breast cancer screening and the widespread use of mammography has led to a need to understand this technology as it is actually practiced in the community. How accurate is screening mammography in detecting cancer under a variety of conditions? Do differences in the practice of screening mammography and resulting diagnostic evaluation influence detection rates, stage at diagnosis, and survival? How can data from research be used to influence clinical practice? These questions and more are explored by the National Cancer Institute's (NCI) Breast Cancer Surveillance Consortium.

A centerpiece of NCI's goal of eliminating suffering and death due to cancer is the "discovery-development-delivery" approach to cancer research. Discovery is the process of generating new information about fundamental cancer processes from the genetic to the population level. Development is the process of creating and evaluating tools and interventions that are valuable in detecting, diagnosing, predicting, treating, and preventing cancer. Delivery involves promoting and facilitating the application of evidence-based cancer interventions to all people who need them. Each of these components is integrally related to the others and all three are necessary for future progress. The Breast Cancer Surveillance Consortium, a key program of NCI's Division of Cancer Control and Population Sciences, exemplifies the "delivery" component, and its research portfolio is helping to accelerate the rate at which proven interventions are put into widespread clinical and public health practice.

I am pleased to introduce this report describing the work of the Breast Cancer Surveillance Consortium. By linking surveillance data on breast screening practices with data from population-based cancer registries and by combining the expertise of seven research sites around the country, the Consortium has been able to address issues that can be adequately examined only in large samples of women, radiologists, and mammography facilities drawn from varied geographic and practice settings. The Consortium has made a major scientific contribution by creating a unique and collaborative research resource and by greatly extending our knowledge about the factors that influence the accuracy and performance of breast cancer screening technologies.

Andrew C. von Eschenbach, MD
Director, National Cancer Institute

Introduction

Detecting cancer early is critically important because, if effective treatment is provided, the burden of both illness and death can be reduced. Improvements in breast cancer treatment and early detection have resulted in a steady drop in breast cancer mortality rates since the early 1990s, but additional efforts are necessary to ensure that this trend continues.

For decades, breast cancer early detection technologies have centered on x-ray mammography, and it is the only evidence-based screening technology currently available. A number of scientific and national organizations have published guidelines supporting periodic breast screening examinations. Other organizations do not make any specific recommendations but encourage women to discuss the issue with their health care providers.

Recent studies have caused debates in the scientific community and the media about the efficacy of screening mammography and the women who are best served by regular exams. This debate has focused on a number of issues, particularly the age at which screening should begin, the optimal frequency of screening, the magnitude of the impact on mortality, and the quality of the data obtained from randomized trials. These debates have made it all the more important to assess mammography's performance in clinical practice and clarify its potential for contributing to reduced breast cancer mortality rates.

The Breast Cancer Surveillance Consortium (BCSC) was established in 1994 to enhance the understanding of breast cancer screening practices in the United States and their relation to changes in stage at diagnosis, survival, or breast cancer mortality. The BCSC is funded and coordinated by the Applied Research Program (ARP) of NCI's Division of Cancer Control and Population Sciences (DCCPS). Through integrated programs of genetic, epidemiologic, behavioral, social, applied, and surveillance cancer research, DCCPS examines the causes and distribution of cancer in populations. It also supports the development and implementation of effective interventions, and monitors and explains cancer trends in all segments of the population.

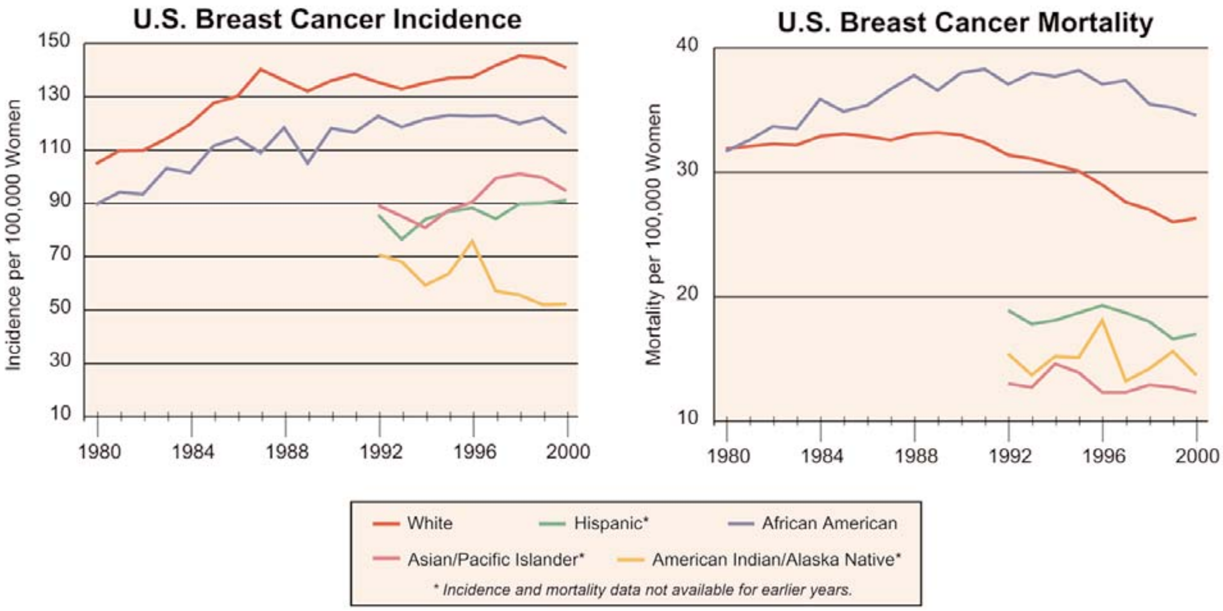
The Applied Research Program's mission is to evaluate patterns and trends in cancer-associated health behaviors, practices, genetic susceptibilities, outcomes, and services. Research within ARP is also targeted to identifying, improving, and developing databases and methods for cancer control-related surveillance, outcomes, and applied research; maintaining, updating, and disseminating these databases and methods; and promoting and facilitating their use among investigators. The BCSC's activities are carried out as part of ARP's efforts to monitor and evaluate cancer control activities in general and in specific populations in the United States and to determine the influence of these factors on patterns and trends in cancer incidence, morbidity, survival, and mortality. Rachel Ballard-Barbash, MD, MPH, the Associate Director, Applied Research Program, is the program director for the BCSC.

This report describes the BCSC and its unique research contribution. The first section provides an overview of the BCSC's mission, history, and structure. This overview is followed by two sections that describe the BCSC's current areas of research and other accomplishments to date. Findings from published studies are described throughout. The report closes with a discussion of the challenges that lie ahead for the Consortium, both in terms of its research agenda, as well as potential opportunities for using BCSC data and findings to influence clinical practice.

> "The BCSC has proved to be an invaluable resource for all American radiologists, in its collection and dissemination of robust data on the current practice of mammography in a representative cross-section of the U.S. All participating radiologists in San Francisco directly benefit by receiving annually a comprehensive set of audit data that are used for continuing quality improvement. At UCSF, we have used audit data to facilitate the transition to providing mammography interpretive services only by radiologists who do full-time breast imaging, at a documented higher level of performance than the usual-care practice of general diagnostic radiologists. On a personal level, I have used San Francisco Mammography Registry (SFMR) data in several of my own clinical research studies and collaborated with BCSC investigators on other studies. I have used SFMR data to facilitate the successful recruitment of breast-imaging radiologists to UCSF (access to clinical material of this quality and scope almost guarantees a successful academic career), and to facilitate the successful recruitment of radiology residents to one-year fellowships in breast imaging at UCSF (these physicians will be an important part of the future of mammography in the United States).
>
> I very much look forward to working with the BCSC to develop interactive Internet-based tools that all American radiologists can use for the same kind of continuing quality improvement that is now available primarily to BCSC participants."
>
> Edward A. Sickles, MD
> Professor in Residence
> Department of Radiology
> University of California at San Francisco (UCSF) School of Medicine

The Breast Cancer Surveillance Consortium: An Overview

Breast cancer is the second leading non-skin cancer among women and the second leading cause of cancer deaths in women. Although the breast cancer mortality rate has dropped since the early 1990s, approximately 40,000 women died from the disease in 2002 and an estimated 211,000 cases have been diagnosed in 2003. Within these overall numbers, some important disparities persist among various population groups. For example, although the breast cancer incidence rate is lower for African Americans than for whites, their mortality rate is higher. Women of other racial and ethnic groups have incidence and mortality rates that are lower than those of whites and African Americans.



Source: NCI Progress Review Groups, "Charting the Course: Priorities for Breast Cancer Research—The Report of the Breast Cancer Progress Review Group." http://prg.nci.nih/gov/snapshots/Breast-Snapshot.pdf

Large randomized clinical trials conducted over the last four decades have shown that by detecting breast cancer at an early stage, mammography, combined with effective treatment, can reduce breast cancer mortality, especially among women 50 years old and older. To ensure standardized delivery of quality mammography services and encourage use of this screening technology, the Congress passed the Mammography Quality Standards Act (MQSA) of 1992. This Act required that mammography facilities meet certain quality standards and be certified by an approved accreditation body. The Act also authorized the Secretary of Health and Human Services to establish a surveillance system that could provide reliable and comprehensive data on the performance of breast cancer screening.

In response to this legislative mandate, the NCI established the Breast Cancer Surveillance Consortium. Two premises guided the NCI in designing this consortium of research sites. The first was the longstanding recognition that results from controlled clinical trials can differ from the results of screening that is practiced in community settings. To optimally evaluate breast cancer screening, it needed to be studied within the context of routine clinical practice. The second was that, to obtain truly useful information, screening patterns and associated performance parameters needed to be linked to cancer outcomes—stage at diagnosis, morbidity, and mortality. With these two premises in mind, NCI designed the BCSC to:

- ➢ Enhance the understanding of breast cancer screening practices in the U.S. through an assessment of the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer stage at diagnosis, survival, or mortality
- ➢ Foster collaborative research among surveillance consortium participants to examine issues such as regional and health care system differences in providing screening services and subsequent diagnostic evaluation
- ➢ Provide a foundation for clinical and basic science research, especially basic research on biologic mechanisms that can improve understanding of the natural history of breast cancer.

The BCSC concept was initially tested through pilot studies carried out at three locations. In 1994, NCI funded three Consortium research sites through a cooperative agreement mechanism and then further expanded the number of sites in 1995. This expansion allowed the Consortium more latitude to explore issues related to geography, urban-rural differences, and racial and ethnic diversity. In 1995, NCI also funded a Statistical Coordinating Center (SCC) to serve as the repository of data from all sites. This has allowed the Consortium to analyze data pooled across all sites. In addition, the SCC was designed to establish and evaluate data collection and quality control procedures and to help individual sites analyze data from their own sites. In 2000, the cooperative agreements for the Consortium sites were renewed for an additional five years.

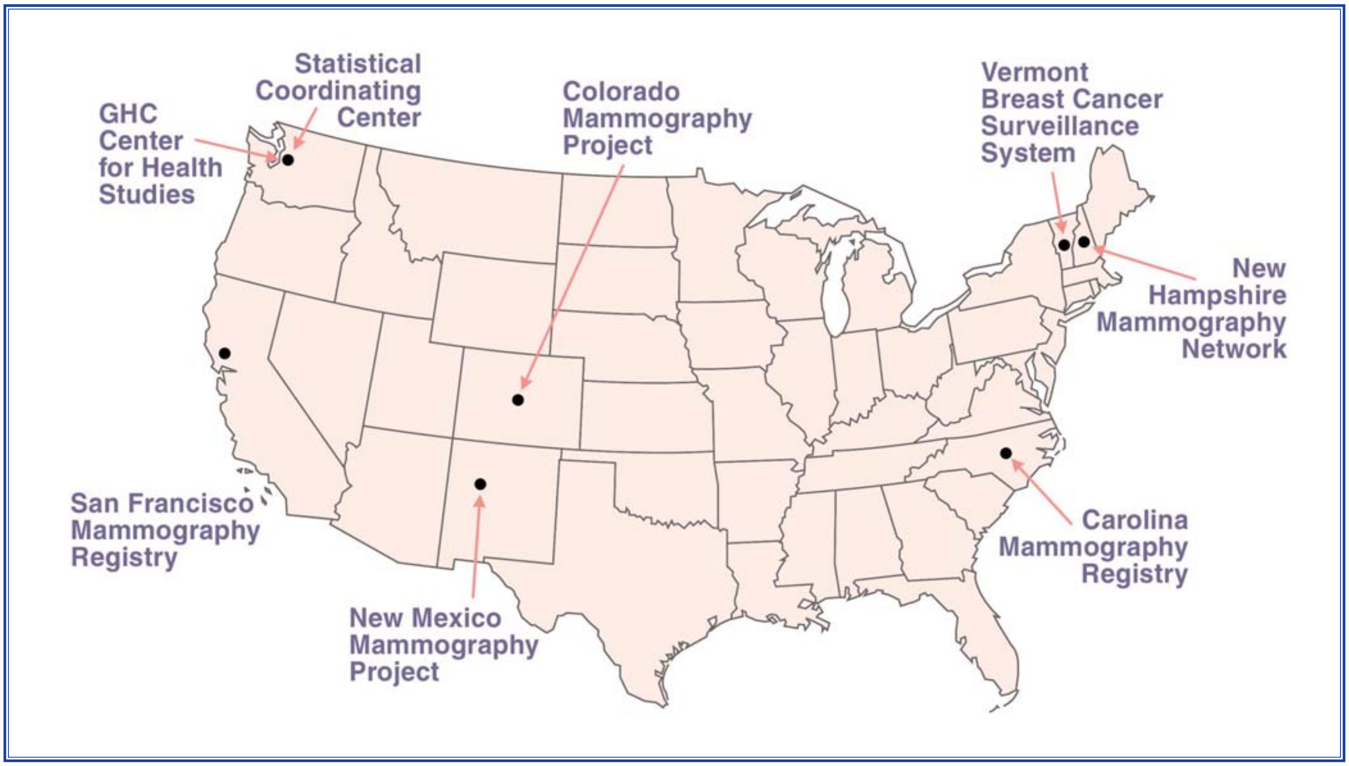
BCSC: A Snapshot of Progress

Phases	Research	Group Interactions
Pilot studies, 1990-2	Conducted at three sites	
First RFA release, Phase I, 1993 3 centers funded	Sites: ➢ Agree on goals and data elements ➢ Set up systems	
Second RFA release, Phase II, 1994 Added 3 centers and created SCC as supplement to one center	Sites: ➢ Establish data standards and Certificates of Confidentiality for women and providers ➢ Begin transition from paper to electronic systems ➢ Improve data editing ➢ Actively conduct research ➢ Begin planning for pooled analyses	➢ Establish governance and research priorities ➢ Institute publications committee and management system
Renewal Phase III, 2000-2004 Independent SCC	Sites: ➢ Add new data ➢ Make major progress in site and pooled research	➢ Refine systems ➢ SCC develops interactive research Web site for BCSC sites

The Consortium currently consists of the SCC and seven data collection and research sites. Six sites are defined by geographic region; the seventh (Group Health Cooperative) is defined by membership in a health maintenance organization:

- Carolina Mammography Registry
- Colorado Mammography Project
- Group Health Cooperative, Center for Health Studies
- New Hampshire Mammography Network
- New Mexico Mammography Project
- San Francisco Mammography Registry
- Vermont Breast Cancer Surveillance System.

The investigators working across these sites are a multidisciplinary team that includes radiologists, primary care clinicians, pathologists, epidemiologists, statisticians, physicists, and advocates.

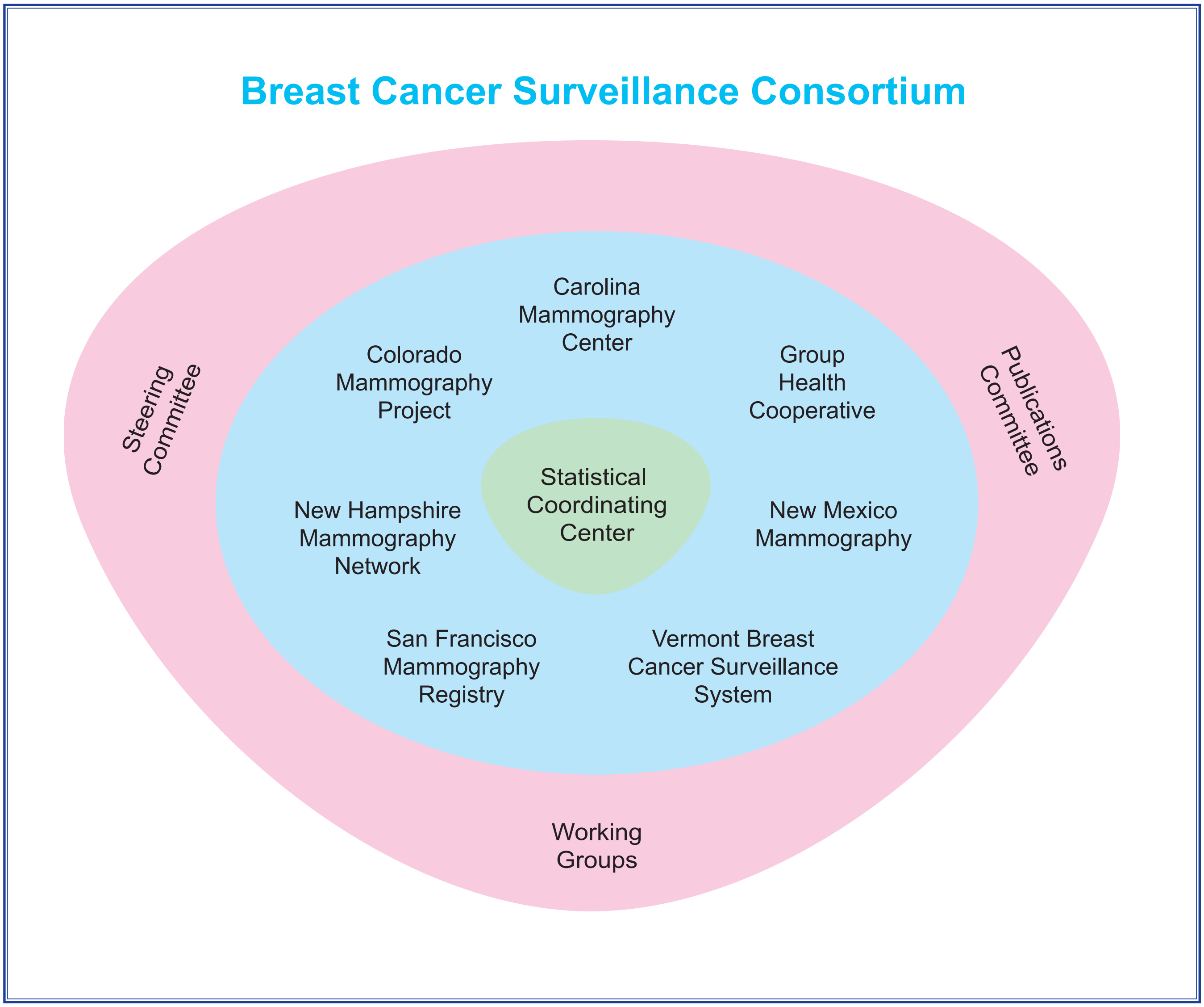


BCSC: Principal Investigators and NCI Staff

Carolina Mammography Registry Bonnie C. Yankaskas, PhD	Department of Radiology University of North Carolina Chapel Hill, NC
Colorado Mammography Project Gary Cutter, PhD Mark Dignan, PhD	University of Nevada at Reno Reno, NV Kentucky Prevention Research Center Lexington, KY
Group Health Cooperative Stephen Taplin, MD, MPH 1994–2003 Diana Buist, PhD 2003–Present	Group Health Cooperative, Center for Health Studies Seattle, WA
New Hampshire Mammography Network Patricia Carney, PhD	Department of Community and Family Medicine Dartmouth Medical School Hanover, NH and Lebanon, NH
New Mexico Mammography Project Charles Key, MD, PhD 1995–1997 Robert Rosenberg, MD 1997–Present	Department of Radiology Health Sciences Center University of New Mexico Albuquerque, NM
San Francisco Mammography Registry Virginia Ernster, PhD 1995–2000 Karla Kerlikowske, MD 2000–Present	Department of Medicine, Epidemiology and Biostatistics University of California at San Francisco San Francisco, CA
Vermont Breast Cancer Surveillance System Berta Geller, EdD Don Weaver, MD	University of Vermont Office of Health Promotion Research Burlington, VT
Statistical Coordinating Center William Barlow, PhD	Group Health Cooperative, Center for Health Studies Seattle, WA
National Cancer Institute Rachel Ballard-Barbash, MD, MPH Robin Yabroff, PhD, MBA Kathleen Barry Stephen Taplin MD, MPH 2003–Present	Applied Research Program Division of Cancer Control and Population Sciences Rockville, MD

Structure of the BCSC

The Consortium has three co-chairs (the NCI project director, a site principal investigator, and the SCC principal investigator). Additional oversight is provided by a Steering Committee (composed of the principal investigators of all the sites, a pathologist co-investigator, and the NCI project director), a Publications Committee, and Working Groups. Working Groups are formed for specific projects and disband when no longer needed.



Collecting Data Within the Context of Routine Clinical Practice

Unlike a multicenter clinical trial, which uses a common protocol and common data collection instruments, the BCSC sites conduct research within existing health systems and within the context of routine clinical practice.

The BCSC: A Unique Resource

As of October 2003, the Consortium had collected data for more than 1.7 million women and more than 5 million mammograms. Within this group, about 38,000 breast cancers have been detected.

The size of the BCSC database, the longitudinal nature of these data, and the multidisciplinary teams of participating investigators make the BCSC a unique resource for understanding breast cancer screening practices and outcomes in the U.S.

Each BCSC site has developed voluntary partnerships with mammography facilities in its geographic area. In some cases, 100% of facilities in the area partner with the site. In other cases, fewer facilities participate. Participating facilities represent a wide range of health care settings, including traditional fee-for-service solo and group radiology practices; managed care organizations; mobile mammography vans; freestanding mammography programs; hospital-based services; and nonradiology practices, such as pathology laboratories, surgical practices that perform breast biopsies, and other medical practices where mammography is performed (e.g., obstetrics and gynecology, internal medicine, and family medicine practices).

> "I feel lucky to be a part of the BCSC group that has been working together pooling their information and answering questions of value for women all over the U.S. My presence makes me feel a part of the research process, and I think it also is a reminder to the researchers and doctors that patients are real people who are waiting for answers."
>
> Bambi Schwartz
> Patient Advocate, San Francisco
> Mammography Registry

Each participating facility collects several distinct types of data about women and their mammographic exams. The data collected about women include basic information about their demographics, health history, screening history, and current health status. Information collected about the exam includes the indication for the exam, breast density, exam assessment, and follow-up recommendation. As part of ancillary studies, some sites also collect data about radiologists, such as their specialty, practice patterns, and perceptions about screening and breast cancer risk. All data collection procedures have been approved by each site's Institutional Review Board (IRB) and are compliant with the Health Insurance Portability and Accountability Act (HIPAA).

A defining characteristic of the BCSC is that the data it collects from women and radiologists/facilities are linked to cancer outcomes data from population-based cancer and pathology registries. This linkage occurs at each site. Three sites—Group Health Cooperative, the New Mexico Mammography Project, and the San Francisco Mammography Registry—are linked to registries within NCI's Surveillance, Epidemiology, and End Results (SEER) Program. The Colorado Mammography Project is linked to its statewide pathology registry. The Carolina Mammography Registry, New Hampshire Mammography Network, and Vermont Breast Cancer Surveillance System collect benign and malignant breast pathology reports from laboratories in their defined regions and additionally link to their respective state cancer registries.

One of the Consortium's first tasks after it was established was to determine how to organize these various types of clinical data so that they could be used for research. This required Consortium investigators to identify the critical data elements

SEER: A Vital Source of Population-Based Cancer Data

The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute is an authoritative source of information on cancer incidence and survival in the United States. The SEER Program currently collects and publishes data on all types of cancer from 11 population-based cancer registries and three supplemental registries. Approximately 26% of the U.S. population is covered by the SEER Program. Information on more than 3 million *in situ* and invasive cancer cases is included in the SEER database, and approximately 170,000 new cases are documented each year within the SEER catchment areas. The SEER Registries routinely collect data on patient demographics, primary tumor site, morphology, stage at diagnosis, first course of treatment, and follow-up for vital status. SEER is the only comprehensive source of population-based information in the United States that includes stage of cancer at the time of diagnosis and survival rates within each stage. The mortality data reported by SEER are provided by the National Center for Health Statistics.

necessary for evaluating screening performance and to develop a consensus on a standard set of core variables, response categories, definitions for analysis, and standard definitions of screening and diagnostic mammography. Within this common data structure, the sites agreed to maintain their own data collection procedures, developed with their participating mammography facilities, cancer registries, and pathology databases. These procedures have evolved over time as electronic data collection methods have gradually supplanted paper-based systems.

How Representative are BCSC Data?

Two important goals of the BCSC are that the data collected reflect mammography practice as it is performed in the community and that the population of women in the BCSC reflect the distribution of women in the U.S. who undergo mammography.

A comparison of women represented in the BCSC against 2000 Census data shows that Consortium sites are located in counties that contain slightly more than 5% of the Nation's population. As the following table shows, data in the BCSC reflect the national population in several important respects.

		BCSC Counties	All other U.S. Counties
Sociodemographic Characteristics	Median Family Income	$55,189	$50,984
	Percent Unemployed	3.4%	4.1%
	Percent With High School Degree	84.5%	80.2%
	Percentage of women aged 40+	22.0%	22.7%
Sociodemographic Characteristics in Women Aged 40+	Percent Hispanic	6.9%	7.3%
	Percent Black	8.9%	10.9%

Data Source: 2000 Census

Data Collected by BCSC Sites

From Women

Demographic Variables

- Unique anonymous identification number
- Zip code
- Date of birth
- Race (white, black, Asian or Pacific Islander, Native American, other); ethnicity (Hispanic)
- Education (1-11 years, 12, 13-15 years, 16 years, 16+ completed years of education)

Health History

- Age at birth of first child (year)
- Age at menarche
- First-degree family history of breast cancer (mother, sister, daughter) and age: <50, >50
- Personal history of breast cancer (yes, no)
- Personal history of breast biopsy, surgery, or radiation (yes, no)
- Procedure history per breast (implants, needle biopsy, surgical biopsy, lumpectomy, mastectomy, radiation therapy, and reconstruction)

Screening History

- Ever screened by mammography (yes, no)
- Time since last mammogram (within last year, 1-2 years, 3-4 years, 5 or more years)
- Time since last clinical breast examination

Current Health

- Menopausal status at examination (pre-, peri-, postmenopausal)
- Hormone replacement therapy use at time of examination (yes, no) and type (e.g., estrogen, estrogen/progestin, over-the-counter supplements)
- Presence of symptoms in last three months (nipple discharge or lump; right or left breast)
- Main reason for current visit (routine screening, routine follow-up, concerns about breast problems)

From Radiologists and Technicians

Radiologic Site and Interpreting Mammographer Identification (encrypted)

Dates of Current Examination and Comparison Film

Use of Comparison Mammogram at Time of Evaluation (yes, no)

Indication for Examination

- Screening (asymptomatic), evaluation of breast problem (symptomatic), additional evaluation of recent mammogram, short interval follow-up