Perspective

Breast Cancer Surveillance Consortium: A National Mammography Screening and Outcomes Database

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Mammography is the primary method of detecting early stage breast cancer and has been shown in randomized clinical trials to reduce breast cancer mortality, especially among women 50 years old and older [1–5]. Authorities in cancer screening have long recognized that the level of efficacy of screening demonstrated in randomized clinical trials may not pertain to community practice for several reasons [6]. These reasons include possible differences in the population groups receiving screening, lower accuracy of screening mammography in the community, and lower compliance with diagnostic follow-up and treatment in community practice, which may result in more adverse outcomes. Screening effectiveness in community practice today could exceed that estimated in trials because the technical and interpretative quality of mammography has improved since the trials were performed. Furthermore, clinical trial efficacy has been estimated on the basis of assignment to receive screening; to the extent that women assigned to screening were not screened or that women in the control groups were screened, efficacy in trials may have been underestimated.

To optimally evaluate the performance of mammography in a community setting, the screening prevalence and patterns and the associated sensitivity, specificity, and predictive value of mammography in community screening programs should be determined by linkage with cancer outcomes [7, 8]. A program of monitoring should also provide data on specific populations, such as rural and minority subgroups, that are traditionally underserved by screening programs and that may have different breast cancer mortality rates [9]. Before the Mammography Quality Standards Act (MQSA) of 1992, most mammography facilities in the United States did not maintain records that could provide reliable and comprehensive data to evaluate the performance of screening mammography [10]. The concept of a medical audit of outcomes data had been proposed [11] but has not been routinely practiced in the community. The interim regulations of the MQSA mandated maintaining mammography data and performing a medical outcomes audit [12]. In practical terms, the medical audit requirement of the MQSA was limited to an analysis of patients with tests interpreted as "suspicious abnormality" or "highly suggestive for malignancy," which permits evaluation of the positive predictive value of such interpretations. However, the MQSA does not require linkage to population-based cancer registry data or another source of pathology data, without which it is impossible to accurately assess the outcomes of patients with mammograms interpreted as having normal findings. To understand the full effect of

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breast cancer screening on cancer outcomes, data on breast cancer screening practices should be linked to data from population-based cancer registries. Moreover, data on pathologic or biologic characteristics of tumors, together with patient demographic and risk factor information, can be linked to population-based registries to better understand staging and survival of patients with mammographically detected compared with non–mammographically detected breast cancers.

Rationale and Research Objectives

A section of the MQSA authorized the secretary of the Department of Health and Human Services to fund research establishing a breast cancer screening surveillance system. In response to this legislative mandate, the National Cancer Institute (NCI) established the Breast Cancer Surveillance Consortium (Appendix 1) in 1994. The three major objectives of the surveillance consortium are to enhance our understanding of breast cancer screening practices in the United States through an assessment of the accuracy, cost, and quality of screening programs and the relation of these practices to changes in breast cancer mortality or other shorter term outcomes, such as stage at diagnosis or survival; to 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; and to provide a foundation for conducting clinical and basic science research, especially basic research on biologic mechanisms, that can improve understanding of the natural history of breast cancer. The intent of the last objective is to ensure that a core set of pathologic data on established prognostic indicators is collected and to provide the capability to examine the prognostic potential of other more investigational indicators. The NCI developed a consortium of research sites to address issues that can be adequately examined only in a large sample drawn from diverse geographic and practice settings. The first major effort of the consortium was to create a set of defined variables to facilitate pooling of data with sample sizes sufficient to examine issues in subgroups for which the number of cancers is relatively low, such as younger women, women with a family history of breast cancer, or some ethnic or racial groups.

To address these research objectives, the surveillance consortium is working to develop standardized data collection and linkage mechanisms for mammography practice data and population-based cancer registry data. This linkage can provide cancer characteristics and follow-up of patients for vital status and cause of death and will allow an assessment of the performance of screening mammography in diverse community settings. Furthermore, linking these data will provide a unique opportunity, in the short term, to determine whether differences in the practice of screening mammography and subsequent diagnostic evaluation influence breast cancer detection rates and stage at diagnosis. In the long term, such linked data may have the potential to provide information on whether differences in practice patterns influence breast cancer mortality. Therefore, the surveillance consortium will provide a model for evaluating screening mammography in the United States. It will also yield important information regarding what type of surveillance data requirements are feasible and useful for mammography facilities in the United States to collect and will provide standards of performance for quality assurance.

In the following sections, we present the structure and development of the surveillance consortium; describe the elements and process of data collection and definitions of accuracy and other measures; and discuss procedures followed to assure confidentiality, major areas of analysis, and future directions and uses of these data. We also discuss the challenges in establishing a database that will allow comparison of the performance of screening mammography in diverse health care settings across the United States.

Institutional Review Board approval was obtained for each separate project by the appropriate local board.

Structure and Development of the Surveillance Consortium

In response to the research needs identified by the MQSA, NCI funded several pilot studies at Surveillance, Epidemiology, and End Results Program sites to examine a limited number of feasibility issues, then subsequently funded three other sites in 1994 on the basis of a request for applications issued in 1993. Because data on mammography screening in the potentially underserved minority and rural populations is a priority for NCI, a second request for applications was issued in 1995 that expanded the geographic, rural, and minority representation within the surveillance consortium. Currently the surveillance consortium is comprised of nine sites (Table 1). Eight sites are funded by NCI; of these eight, two sites are funded jointly by NCI and the Department of Defense, and one is funded jointly by NCI and the Centers for Disease Control. One additional site is funded solely by the Department of Defense. Sites are located in most of the major regions of the United States. The first meeting of the surveillance consortium was held in June 1994. Meetings are held every 6 months, and all sites have been participating since October 1995.

This research effort requires a thorough understanding of population-based research and of diverse types and sources of data, including the clinical practice of breast cancer screening, radiology and pathology, and the structure of cancer registries. Because of the diversity of research and clinical expertise required, surveillance consortium investigators include epidemiologists, nurses, internists, family physicians, radiologists, pathologists, statisticians, health educators, health service researchers, economists, and data managers. The scope and depth of the research expertise within the surveillance consortium is substantial and has led to impressive progress in both defining a standard set of variables and prioritizing the research plan.

Data Definitions and Collection

By 2000, the database will contain information on nearly 3.2 million mammographic examinations and over 24,000 cases of breast cancer. The estimated racial and ethnic distribution of women receiving mammography reflects that of the geographic catchment areas for the nine sites (Table 2). The age distribution of women currently receiving mammography within the database is 8%, 31%, 26%, 19%, and 16% for ages less than 40 years, 40–49, 50–59, 60–69, and 70 years and older, respectively. Before beginning data collection, the surveillance consortium identified the critical data elements for evaluating screening performance in diverse community settings, which necessitated consensus on a standard set of major or core data variables (Appendixes 2–4), definitions for analysis, and a standard definition of a screening mammographic examination. Second, standardized codes for each core variable were established. Data from all sites are being evaluated to determine whether similar core data collected from different sources will, in fact, be sufficiently comparable for use in pooled analyses. Third, standard definitions were created for complex outcomes, particularly measures of accuracy such as sensitivity, specificity, and

TABLE 1 Breast Cancer Surveillance Consortium Sites

Site	Metropolitan Status	Yrs of Funding	Funding Source	Women 40 Yrs Old and Older[a]	Estimated Annual Mammograms[b]	Estimated Total Mammograms[c]
University of California, San Francisco	U	1994–2000	NCI	160,916	61,400	200,000
Washington State	U, S, R			528,626		
Group Health Cooperative (and Statistical Coordinating Center)		1994–1999	NCI		41,400	135,000
Fred Hutchinson Cancer Research Center		1994–1999	NCI, DOD		100,000	500,000
Colorado Department of Public Health and Environment	U, S	1994–1999	NCI, CDC	350,641	125,500	643,000
University of New Mexico	S, R	1994–2000	NCI	286,674	100,000	550,000
University of Iowa	S, R	1994–1998	NCI	30,408	10,000	30,000[d]
University of North Carolina at Chapel Hill	S, R	1994–2000	NCI, DOD	366,476	175,000	600,000
University of Vermont	R	1995–2000	NCI	113,700	50,000	230,000
New Hampshire Mammography Network	S, R	1994–1999	DOD	321,277	160,000	275,000
Total				2,055,503	823,300	3,163,000

Note.—U = urban, S = suburban, R = rural, NCI = National Cancer Institute, DOD = Department of Defense, CDC = Centers for Disease Control.
[a] 1990 census.
[b] Estimated annual number of mammograms when sites are fully operational.

TABLE 2 Racial and Ethnic Distribution of Women Receiving Mammography in Breast Cancer Surveillance Consortium Database[a]

Racial or Ethnic Group	Estimated Total Mammograms[b]	Percentage in the Nine Consortium Catchment Areas[c]
White, not Hispanic	2,470,000	78.1
Black, not Hispanic	270,000	8.5
Hispanic	170,000	5.4
Asian and Pacific Islanders	168,000	5.3
Native Americans	29,000	0.9
Other	56,000	1.8
Total	3,163,000	100.0

[a] Assuming no differential in screening rates among racial and ethnic groups.
[b] By 2000.
[c] 1990 census.

positive predictive value. Making these definitions operational must address differences in time to reporting of outcomes by regional cancer registries, cutoffs in the American College of Radiology coding system to categorize findings on a screening mammogram as positive or negative, variations in the use of batch reading, and one- versus multiple-step screening mammography interpretations.

Unlike multicenter clinical trials that use a common protocol and common data collection instruments, the research projects within the surveillance consortium must operate within existing health care systems. Variability in practices at diverse sites presents a challenge to the collaborative research effort for which all sites must collect the same core variables. Core variables are being collected to build three databases that can be linked: patient demographic and health history (Appendix 2), radiologic history (Appendix 3), and follow-up (Appendix 4). Data are being collected from a range of health service delivery systems, including traditional fee-for-service, solo and group radiology practices, managed care organizations, free-standing mammography centers, mobile van programs, hospital-based radiology practices, and nonradiology practices. Data relevant to diagnostic follow-up are also being collected from nonradiology practices, such as surgical practices performing breast biopsies and pathology laboratories. The consortium decided to allow flexibility in data collection of some variables (termed "optional" variables) because of the likelihood that these variables are not readily available at most sites. The following optional variables are being collected at some, but not all, sites: place of birth; number and dates of previous breast biopsies; date of last mammogram; date, number, and outcomes of previous clinical breast examinations; type of and age at menopause; height; weight; whether MR imaging was done; results of clinical breast examinations, sonography, MR imaging, fine-needle aspiration, and core and excisional biopsy; type of biopsy guidance (stereotaxic, sonography-guided, needle-localized); procedure date; and pathology report date. Some of the optional variables, such as pathology report date, have been used in the past to allow more rapid and efficient retrieval of pathology reports or tissue specimens; others, such as weight, are being collected to pursue hypotheses of interest at individual sites.

A central requirement for all sites was linkage of data from mammography centers with pathology data on cancer outcomes from population-based cancer registries. This linkage is accomplished by ensuring that unique identifiers are included in data obtained from each source. Linkage occurs at each site. To ensure anonymity, all study identifiers at individual sites are replaced with unique, anonymous surveillance consortium study identifiers. All sites are linked to population-based cancer registries. Five sites (University of California, San Francisco; two Washington State sites; University of New Mexico; and University of Iowa) are linked to cancer registries within the Surveillance, Epidemiology, and End Results Program. Four sites (Colorado Department of Public Health and Environment, University of North Carolina at Chapel Hill, University of Vermont, and the New Hampshire Mammography Network) are linked to their respective statewide cancer registries. More specific details regarding linkages and cancer registries used at some sites are available from publications from individual sites [13–16].

Although measures of screening performance, such as sensitivity, specificity, and positive and negative predictive value, are commonly applied to evaluate screening, establishing consistent measures across diverse

population-based mammography screening programs is complex. For purposes of analysis, operational definitions were necessary for these performance measures. The surveillance consortium considered analytic methods for consistently converting the five-level American College of Radiology interpretation codes [17] into a dichotomous positive and negative interpretation, appropriate lengths of follow-up time after screening examination to assess cancer status, and histologic coding schemes to establish cancer status. Agreement was reached on several analytic approaches to evaluate the accuracy of screening mammography using both 1- and 2-year follow-up intervals, to alternatively consider mammograms with recommendations for short-term follow-up as positive or negative in separate analyses, and to categorize ductal carcinoma in situ as cancer. Lobular carcinoma in situ will not be categorized as cancer for analyses of performance outcomes but will be evaluated separately. The surveillance consortium will take advantage of the full American College of Radiology scale to determine likelihood ratios for various categories of interpretation and to create receiver operating characteristics for analysis [18]. In receiver-operating-characteristics analyses, regressions will allow for simultaneous adjustment for other factors that may influence accuracy [18].

A second complex issue addressed was the differentiation of screening from diagnostic mammography. Because of incomplete and nonuniform definitions of symptoms, the validity and reliability of data used to classify mammograms as screening or diagnostic have been questioned [13]. The surveillance consortium sought to define data elements that would allow making operational the analytic definition independent of billing codes. Two data elements are used to classify a mammographic examination consistently across sites: symptoms reported by a woman, and whether concern regarding those symptoms was the reason for scheduling a mammographic examination. Mammography performed in asymptomatic women in the absence of concern about a symptom will be classified as a screening examination. When symptoms are reported and mammography is scheduled because of concern for symptoms, the examination will be classified as diagnostic. Finally, in some cases, symptoms may be present but neither the physician nor patient is concerned about these symptoms (as might be the case for a previously evaluated benign breast mass of long-standing duration without recent change in characteristics). In these cases the mammography will be classified as screening in one set of analyses and as diagnostic in another. Analyses by the surveillance consortium based on these definitions should help clarify whether this approach to classifying mammograms as screening or diagnostic alters the assessment of the performance of screening mammograms.

Statistical Coordinating Center

Comparability of variables collected from different sources and with different formats is an important concern. In the fall of 1995, a statistical coordinating center (SCC) was funded as a supplement to the Puget Sound site to assist the surveillance consortium in analyzing data using core variables and to permit comparison of results across all sites. In addition to serving as the repository of data from all sites for pooled data analyses, the SCC serves two major functions for the surveillance consortium: It establishes and evaluates data collection procedures that create comparable definitions and codes for the surveillance consortium's core and optional variables; and it works with sites to develop quality control procedures for data collection, storage, and transmission to the SCC. The SCC will assist in quantifying the short-term outcomes of screening and associated procedures for the surveillance consortium overall and across sites. The SCC is currently evaluating data collection procedures at each site. An immediate result of the evaluation has been a more centralized understanding of which variables can be collected at each site; this understanding has led to a shorter list of primary (core) variables that will be used in pooled data analysis.

Confidentiality

The absence of adequate legislative protection of the data in transit to and while at the SCC was a major issue influencing the ability of the surveillance consortium to perform pooled data analyses. The concern was raised because data contributed to the SCC are exceedingly sensitive. Data from health care providers represent their practice and accuracy in performing mammography; and data from patients pertain to their cancer status, which payers might have interest in obtaining. Although state legislative statutes, institutional quality assurance statutes, or both may (depending on state laws or institutional policies) protect research databases and quality assurance data from either litigation or access, once the data cross state lines or institutional borders they may not be protected. The surveillance consortium addressed this concern by applying for and receiving federal certificates of confidentiality for each member site, including the NCI and the SCC, in accordance with the provisions of section 301(d) of the Public Health Service Act (42 United States Code 241 (d)). The certificate [19] is issued to protect the privacy of research subjects by withholding their identities from all persons not connected with the research. This federal level of protection of surveillance consortium and SCC databases is the highest level of protection available in the United States, and this application of the federal certificate is precedent-setting in that it is the first Public Health Service certificate of confidentiality that has included health care providers as research subjects. The certificates provide protection to research data irrespective of location—whether at the originating site, in transit to the SCC, or at the SCC. Such protection may become increasingly important to the conduct of research involving community practice and patients.

To protect data confidentiality further, common confidentiality procedures are followed. For example, no identifying information is included in the surveillance consortium's shared databases. Under no circumstances will identifiers such as name, address, or Social Security number of specific patients, radiologists, or practices be included in a transferred data set. The identifiers assigned to cases in the database are encrypted. Furthermore, data returned to health care providers regarding accuracy of mammographic interpretation include coded identifiers known only to the individual health care provider. The surveillance consortium is surveying all sites to collect information on quality control practices for maintaining confidentiality of data.

Research Work Groups

In meetings from June 1994 through April 1996, the surveillance consortium delineated three primary areas of research (Table 3) that will use pooled data from all sites. Several secondary areas of research (Table 4) will use data from sites collecting more specific data for particular areas of research. More limited research projects are also occurring at individual sites and include projects focusing on phenotypic and genotypic characteristics of screened breast cancer; mammographic characteristics of benign breast disease; methods to improve the quality of mammographic interpretation; and an assessment of the cost,

TABLE 3 Primary Research Projects in Breast Cancer Surveillance Consortium Using Pooled Data from All Sites

Project	Objective
Accuracy of screening mammography	Examine sensitivity, specificity, and positive and negative predictive values of screening and diagnostic mammography, including variations by region and demographic characteristics
Patterns of care	Examine variations in patterns of care, including follow-up protocols, costs, and the percentage of mammograms with abnormal findings, across facilities by demographic and clinical characteristics and by health care delivery setting
Description of pathologic characteristics in screening-detected cancers	Examine variations in pathologic characteristics of breast tumors (benign and malignant) and in diagnostic breast surgery procedures by demographic and regional characteristics

TABLE 4 Secondary Research Projects in Breast Cancer Surveillance Consortium Using Pooled Data from All Sites

Project	Objective
Effectiveness of feedback mechanisms in enhancing radiologists' performance	Examine feedback to radiologists for quality assurance and medical audits, including how such feedback contributes to standardization
Cost comparisons by region and costs related to diffusion of new technology	Define cost, as opposed to price, data Stratify analyses by different provider and payer settings
Breast density and its relationship to interval cancer risk	Examine the relationship of breast density to mammography performance Compare digitized measures of percent density with radiologist-coded ACR density categories [17]
DCIS risk factors and genetic markers[a]	Examine the accuracy of identifying or coding of DCIS versus invasive breast cancer pathology Compare risk factors for DCIS versus invasive cancer and identify genetic markers for DCIS

Note.—DCIS = ductal carcinoma in situ, ACR = American College of Radiology.
[a] Proposed.

usefulness, and effectiveness of mammography screening. Working groups have been formed to study each of the research areas using pooled data, with mammography accuracy and patterns of care being the focus of initial analyses. In the working group focusing on mammography accuracy, initial analyses will examine regional and demographic variations in accuracy and the effect of changing definitions of measures of accuracy, case status, and duration of follow-up on accuracy parameters. In the working group focusing on patterns of care, initial analyses will examine regional variation in the use of the American College of Radiology lexicon, the usefulness of the short-term follow-up, variation in time to further diagnostic evaluation, and the types of diagnostic evaluations being performed after mammography with abnormal findings.

Summary

The standardized procedures and tools created and tested by the surveillance consortium will be of value to all radiologists in mammography reporting, data collection, and auditing. These tools are particularly important for linking practice data to tumor registry data. Second, because the results and outcomes published by the consortium and its members are based on community practice, they will help establish realistic targets for mammography performance. Finally, these data will give radiologists and referring clinicians more realistic estimates of how mammography will affect their patients.

The surveillance consortium is accomplishing its primary objective of developing standardized data collection and linkage mechanisms for mammography practice and population-based cancer registry data. This database will be a research resource for enhancing understanding of mammography screening practice in the United States and has already fostered substantial collaborative research among its participants. Prospective data collection with the established core variables did not begin at many sites until 1996, and pooled data analysis began in 1997. However, research at individual sites on a range of issues has already been published, is in press, or is under review. Publications have included descriptions of the mechanics of establishing regional and state mammography registries [13–16]; trends in the use of mammography [20, 21]; and evaluation of mammography performance by region and patient characteristics, such as family history and use of hormone replacement therapy [13, 21–24].

In addition to its intended purpose of evaluating population-based screening mammography in the United States, the database will be a valuable resource for future research. With continued collection of data in these populations and follow-up for outcomes, surveillance consortium data will allow assessment of the effect of community mammography screening on the stage distribution of breast cancer. The effectiveness of screening mammograms is hypothesized to vary by biologic characteristics, stage, and rate of growth of breast tumors. Pilot studies within the surveillance consortium are examining this hypothesis and may suggest future research to clarify the associations between biologic characteristics and screening performance. Furthermore, the surveillance consortium database will provide information on demographics, risk factors, and clinical characteristics of and treatment for women who subsequently develop breast cancer. It will provide data on a large population-based sample of women at high risk for breast cancer, including those with family history of breast cancer or benign breast disease. Therefore, this resource may be particularly useful for identifying patients relevant for research into the population prevalence of genetic and other biologic markers for breast cancer risk and for research into the prognosis and potential associations of these markers with other known breast cancer risk

factors. Data from the surveillance consortium will provide estimates of the prevalence of diagnostic follow-up and information relevant to improving the communication of risks and benefits related to screening. The mammography registry may also serve as a resource for intervention trials to study ways to improve screening compliance.

A second use of the database will be to permit the comparison of regional data across the United States. Identifying a uniform set of data to evaluate mammography screening in the population has improved consistency in the process of data collection at the surveillance consortium sites and provides a model for the development of linkages between mammography registries and cancer registries. Other geographic areas, such as states that are establishing mammography registries, have sought information from the surveillance consortium on how to set up comparable systems. Dissemination of such information should foster uniformity in data collection among emerging software packages and at other facilities trying to create linkages between mammography data and cancer registries, thereby further improving the ability to compare the performance of mammography across regions. These efforts should also improve quality of data and, through publication and feedback of the data to radiologists in the community, improve quality of mammography screening. Furthermore, to allow international comparisons, the surveillance consortium is participating in the International Breast Cancer Screening Database project [25], which is seeking to establish a standard set of definitions and classification rules for international comparisons. It is hoped that by developing a common set of data, participants can assess the effectiveness of screening in a variety of practice settings across the United States and internationally.

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APPENDIX 1: Breast Cancer Surveillance Consortium Research Personnel

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APPENDIX 2: Patient Demographic and Health History Data

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, high school graduate, 13–15 years, 16 years, 16+ years)
Health insurance (Medicare, Medicaid, other, none)

Health History

Age at birth of first child (year)
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)

Current Health

Menopausal status at examination (pre-, peri-, postmenopausal)
Hormone use at time of examination (yes, no)
Presence of symptoms in last 3 months (nipple discharge or lump; right or left breast)
Reason mammography scheduled (concern regarding symptoms [yes, no])

APPENDIX 3: Radiologic History Data

Radiologic Site and Interpreting Mammographer Identification

Dates of Current Examination and Comparison Film

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

Indication for Examination

Asymptomatic patient, screening examination, additional views, short interval follow-up, evaluation of breast problem, diagnostic examination

Type of Examination(s) Performed

Standard screening views, additional views, sonography

Breast Density (American College of Radiology lexicon [17] for breast with highest density)

Entirely fat, scattered fibroglandular densities, heterogeneously dense, extremely dense

Assessment per Woman (American College of Radiology lexicon)

Incomplete assessment (for standard screening views only), normal, normal with benign finding, probably benign, suspicious abnormality, highly suggestive for malignancy

Recommendation

Normal interval follow-up, additional views, sonography, short-term follow-up, fine-needle aspiration, consider biopsy or surgical evaluation, clinical evaluation for further diagnostic evaluation

APPENDIX 4: Follow-Up Data

Follow-Up Performed (summarized per woman)

Date and result (include right versus left breast): additional views, short-interval follow-up mammogram

Date and laterality required, result recorded if available: clinical examination, sonography, fine-needle aspiration, core biopsy, excisional biopsy

Pathologic Variables

Carcinoma pathology (as obtained in Surveillance, Epidemiology, and End Results Program registries)

- Type of procedure, reporting source, laterality
- Staging: size, histopathology, grade, tumor size, number of positive nodes, metastasis present (TNM), American Joint Committee on Cancer stage, extension*, nodal involvement* (number examined and positive), tumor sequence*, estrogen and progesterone receptor status*
- Therapy (date first initiated): surgery, radiation, chemotherapy, hormonal, biologic modification, no surgery reason*
- Follow-up status*: date of last follow-up, vital status last follow-up, cause of death

Benign pathology*

- Type of procedure
- Reporting source
- Laterality
- Histopathology (as recorded and also categorized into major groups: atypical hyperplasia, ductal hyperplasia, fibroadenoma, phyllodes tumor, benign, normal, inconclusive)

Note.—Variables with asterisk are optional for sites using non–Surveillance, Epidemiology, and End Results Program registries.