Findings From 752 081 Clinical Breast Examinations Reported to a National Screening Program From 1995 Through 1998

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Background and Methods: **Mammography programs have received extensive study, but little is known about the outcome of clinical breast examinations (CBEs) performed in community settings. Consequently, we analyzed data from the National Breast and Cervical Cancer Early Detection Program on CBEs provided to low-income women from 1995 through 1998 and determined the percentage of CBEs considered to be abnormal, suspicious for cancer; the rates of cancer detection; and the sensitivity, specificity, and positive predictive value of CBEs.** ***Results:*** **We analyzed data from 752 081 CBEs and found that 6.9% of all CBEs were coded abnormal, suspicious for cancer, and that 5.0 cancers were detected per 1000 examinations (95% confidence interval [CI] = 4.9–5.2). The values observed for sensitivity (58.8%) and specificity (93.4%) were comparable to those reported for the CBE component of clinical trials. The observed positive predictive value was 4.3%. About 74% of all records also reported mammography results. The cancer-detection rate among records reporting an abnormal CBE and normal mammography was 7.4 cancers per 1000 records (95% CI = 6.3–8.4). When the CBE was normal but the mammography was abnormal, the rate was 42.0 cancers per 1000 records (95% CI = 39.9–44.1). When both CBE and mammography results were abnormal, the rate was 170.3 cancers per 1000 records (95% CI = 162.7–177.9). Cancer detection could not be attributed entirely to CBE or mammography on 38% of the records in the latter subset because the tests were performed on the same day.** ***Conclusion:*** **CBEs performed in community-based screening programs can detect breast cancers as effectively as CBEs performed in clinical trials and may modestly improve early-detection campaigns. [J Natl Cancer Inst 2000;92:971–6]**

Breast cancer screening in the United States relies jointly on mammography and clinical breast examination (CBE) *(1)*. Data from the 1997 Behavioral Risk Factor Surveillance System *(2)* suggest that 65% of the women 40 years of age or older had received both mammography and a CBE in the past 2 years. A considerable body of literature exists on mammography *(3–8)*, but relatively little is known about CBEs conducted in community settings.

Current data on breast and cervical cancer screening for low-income women in the United States can be derived from the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) data files. By late 1998, the NBCCEDP had funded more than 960 000 screening examinations for breast cancer and more than 1 million screening examinations for cervical cancer. Previous papers have summarized mammography *(7)* and cervical cytology *(9)* data. This article presents CBE data from 1995 through 1998, including percentages of CBEs judged to be "abnormal, suspicious for cancer"; breast cancer-detection rates; and estimates of sensitivity, specificity, and positive predictive value.

Patients and Methods

Structure of the NBCCEDP

The NBCCEDP was established in 1990 with passage of The Breast and Cervical Cancer Mortality Prevention Act *(10)* to provide routine cancer screening to uninsured or underinsured low-income women. In 1991, eight states received funds from the Centers for Disease Control and Prevention (CDC). By 1996, all 50 states, the District of Columbia, 15 Native American/Alaska Native tribes, and four territories were providing screening services to women meeting income and age criteria. NBCCEDP funds cover screening tests and most of the diagnostic tests that women may need after an abnormal screening result, including biopsy, additional mammographic views, breast ultrasound, fine-needle aspiration of the breast, and cervical colposcopy. Treatment costs for screen-detected cancers are not covered by the national program. However, to receive NBCCEDP funds, participating programs must ensure that women with abnormal screening results receive timely and appropriate treatment.

Low-income women who meet NBCCEDP age criteria are eligible to receive free cancer screening. Routine breast cancer screening for women under the age of 40 years is not encouraged, but women in this age range are eligible for cervical cancer screening, and many receive a CBE in conjunction with a Pap smear. Diagnostic mammographies are provided if they have had an abnormal CBE. Women 40 years or older are eligible for annual breast cancer screening with both CBE and mammography. To balance issues of screening efficacy and funding limitations, programs direct the majority of their breast-screening resources to women 50 years of age or older. Screening services are provided in thousands of facilities across a wide range of settings (e.g., university and community-based hospitals and clinics, health department clinics, mobile mammography units, and private-practice offices).

Data Accrual

All programs electronically submit standardized data semiannually to the CDC on all screening examinations supported by the NBCCEDP. Data submissions are cumulative and include all NBCCEDP cancer screenings ever provided by that program. The analysis file used herein was derived from datasets submitted in January 1999 (Fig. 1). Each electronic record contains information on a single round of cancer screening. Most records report CBE and mammography data, but some report only one or the other. Records without CBE data were excluded from our analyses to reduce computer processing time. All CBEs

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See "Notes" following "References."

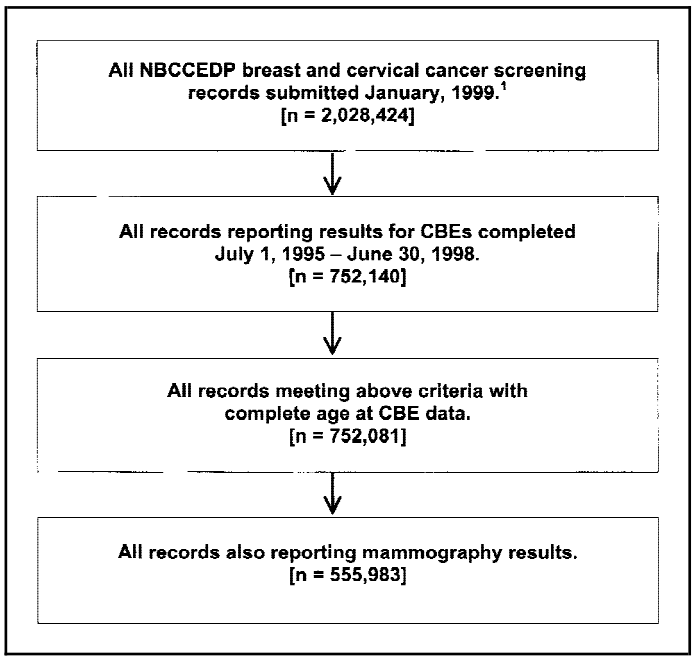

Fig. 1. Development of dataset from clinical breast examination (CBE) records submitted to the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in January 1999.

[1]Data submissions are cumulative and include all NBCCEDP cancer-screening reports submitted to the Centers for Disease Control and Prevention from October 1992 through January 1999.

performed from July 1, 1995, through June 30, 1998, were included. CBEs provided before the start of this interval were excluded because of coding problems with earlier versions of the CBE variable. The end of the study interval was set to allow the programs at least 6 months to report the results of diagnostic work-ups associated with abnormal CBE findings.

CBE results are reported as either 1) normal/benign findings—schedule for routine CBE in 1 year (normal) or 2) abnormality suspicious for cancer—diagnostic evaluation needed (abnormal). Detailed guidelines provided to all programs define benign findings as fibrocystic changes, diffuse lumpiness, or nodularity. Abnormal findings include discrete palpable mass, bloody or serous nipple discharge, nipple or areolar scaliness, or skin dimpling or retraction. Some programs record the finding that prompted a "suspicious for cancer" diagnosis, but those data are not forwarded to the CDC.

Mammography results are reported via the Breast Imaging Reporting and Data System lexicon developed by the American College of Radiology *(11).* Breast-screening records that report a mammography coded negative, benign, or probably benign (benign) and a CBE result of normal are considered to be complete. Records reporting either an abnormal CBE or an abnormal mammogram (coded assessment incomplete, suspicious abnormality, or highly suggestive of malignancy) must also report a final breast cancer-screening diagnosis variable using one of the following three codes: 1) breast cancer *in situ;* 2) breast cancer, invasive; or 3) breast cancer not diagnosed. Programs are instructed to consult with local tumor registry staff to distinguish new from recurrent breast cancers among women with a previously detected cancer and to report only new, non-recurrent cancers.

To limit data collection and reporting burdens, the list of additional required variables is restricted to items deemed to be essential for program monitoring. Required data include characteristics of the woman screened: birthdate (month and year only), race, ethnicity (Hispanic/non-Hispanic), presence of breast symptoms, and history of mammography. Characteristics of the breast-screening round include CBE and mammography results and the dates and locations of the screening examinations. Additional data are required when abnormal findings are recorded, including tumor size and stage for invasive cancers, but our analyses of these variables will be reported elsewhere. For this article, screening site-location data are grouped by National Health Interview Survey codes (Midwest, Northeast, South, and West) *(12).* Tribal sites and territories were coded as "other." To protect confidentiality, NBCCEDP data files do not contain names. Unique code numbers are assigned to all enrolled women at the local level and are reported to the CDC to allow aggregation of data on a per woman basis.

Statistical Analysis

Herein, we report cancer rates per 1000 women screened and per 1000 CBEs. Rate precision was determined with 95% confidence intervals (CIs), which were derived by using the normal-theory method for binomial parameters *(13).* Some rates are reported separately for first and subsequent screening rounds completed during the study interval. All statistical significance tests were two-sided.

Detection of interval cancers in our dataset is possible only among the subset of women with more than one breast-screening record during the study interval. Interval cancers were defined as those detected within 1 year of a normal CBE that did not have a final diagnosis of cancer *in situ* or invasive cancer.

Sensitivity, specificity, and positive predictive value have been estimated in many ways in the cancer-screening literature. To be consistent with the structure of our dataset and the absence of multiple screening records for most women, we relied entirely on data contained within each individual record. Sensitivity was calculated as the number of true-positive results divided by the sum of true-positive and false-negative results *(14–16).* True-positive and false-negative results were determined by the final breast cancer-screening diagnosis variable.

Specificity was defined as the total number of negative test results divided by the sum of all negative and all false-positive test results *(7,14,15).* Negative and false-positive test results were also determined by the breast cancer diagnosis variable. When the CBE result was normal and a final diagnosis was missing, the CBE was considered to be a negative test. Abnormal CBEs with a missing final diagnosis code were considered false-positive results. The positive predictive value was calculated as the percent of records with an abnormal CBE diagnosis that had a final diagnosis of cancer *in situ* or invasive cancer.

After deriving sensitivity, specificity, and positive predictive value estimates for all records in the file, five additional analyses were completed. First, these measures were recalculated within a dataset restricted to the first, or only, CBE reported for each woman. Next, because specificity has been shown to depend heavily on how a positive screening result is defined *(3),* all negative test results were divided by the sum of all negative and false-positive test results established by biopsy examination or fine-needle aspiration. A similar approach was used to estimate the positive predictive value of CBEs confirmed by biopsy or fine-needle aspiration. Then, to parallel a recently reported meta-analysis of CBE sensitivity and specificity *(17),* estimates were derived for the subset of records that had at least 12 months of follow-up between the CBE date and time of submission of the data files to the CDC. Finally, we obtained separate estimates among the groups of records defined by the presence or absence of reported breast symptoms at the time of examination.

RESULTS

After excluding 59 records with missing age data, the analysis file contained 752 081 CBE reports (Fig. 1). About 12% of these were performed in 1995, 32% in 1996, 38% in 1997, and 18% in 1998. The 752 081 CBEs were provided to 564 708 women (Table 1). Most women (73.8%) had one record in the file, 19.7% had two, and 6.5% had three or more (mean = 1.3 records). The mean age at CBE was 52.5 years (standard deviation = 12.1 years). About 10% of the CBEs were provided to women under the age of 40 years; 9% were performed on women 70 years or older.

CBE Results

Overall, 51 520 CBEs (6.9%) were coded abnormal, suspicious for cancer (Table 1). Abnormal CBEs were recorded for 48 637 women (8.6%); some received two or more abnormal reports. The mean age of the women with abnormal CBEs was statistically significantly less than that of the women with normal findings (47.6 versus 52.9 years, respectively; $P<.001$). A statistically significant variation was also detected across racial and ethnic groups ($P<.001$) and regions of the country ($P<.001$). Abnormal results were more common among women with than among women without breast symptoms (28.2% versus 3.9%, respectively).

Table 1. Results of 752 081 clinical breast examinations (CBEs) provided to 564 708 women by characteristics of the woman screened

			Cancer rate, No. per 1000 CBEs (95% confidence interval)			
	No. CBEs	No. abnormal CBEs (%)	All rounds, all data	All rounds, limited data*	First screening round, all data	Subsequent rounds, all data
Overall	752 081	51 520 (6.9)	5.0 (4.9–5.2)	5.1 (5.0–5.3)	5.8 (5.6–6.0)	2.7 (2.4–2.9)
Age, y†						
<40	79 399	11 218 (14.1)	2.3 (2.0–2.6)	2.4 (2.1–2.8)	2.7 (2.3–3.1)	0.3 (0.06–0.6)
40–49	220 658	19 117 (8.7)	4.3 (4.0–4.6)	4.4 (4.2–4.7)	4.9 (4.6–5.3)	2.0 (1.6–2.4)
50–59	246 876	12 835 (5.2)	5.5 (5.2–5.8)	5.6 (5.3–5.9)	6.5 (6.2–6.9)	2.7 (2.3–3.1)
60–69	140 886	6118 (4.3)	6.2 (5.8–6.7)	6.3 (5.9–6.7)	7.5 (6.9–8.0)	3.4 (2.8–3.9)
⩾70	64 262	2232 (3.5)	6.4 (5.8–7.0)	6.5 (5.9–7.1)	7.2 (6.5–8.0)	4.4 (3.4–5.3)
Race/ethnicity, No.‡						
African-American	101 663	5905 (5.8)	5.6 (5.1–6.0)	5.7 (5.2–6.1)	6.2 (5.7–6.8)	3.2 (2.5–3.9)
American Indian, Alaska Native	29 357	1564 (5.3)	3.1 (2.5–3.8)	3.2 (2.5–3.8)	3.5 (2.7–4.2)	2.0 (0.9–3.1)
Asian, Pacific Islander	25 145	1038 (4.1)	3.9 (3.2–4.7)	4.0 (3.2–4.8)	4.4 (3.5–5.3)	2.0 (0.8–3.3)
Hispanic	153 902	11 236 (7.3)	3.8 (3.5–4.1)	3.8 (3.5–4.2)	4.3 (3.9–4.7)	2.0 (1.6–2.5)
White	428 224	30 679 (7.2)	5.5 (5.3–5.7)	5.7 (5.5–5.9)	6.5 (6.2–6.8)	2.8 (2.5–3.1)
Other, unknown	13 790	1098 (8.0)	5.8 (4.5–7.1)	5.9 (4.6–7.2)	5.9 (4.5–7.3)	5.2 (2.3–8.2)
Region, No.§						
Midwest	173 755	11 333 (6.5)	5.2 (4.9–5.5)	5.3 (5.0–5.6)	6.2 (5.7–6.6)	2.8 (2.3–3.2)
Northeast	165 178	7798 (4.7)	5.0 (4.6–5.3)	5.0 (4.7–5.4)	5.7 (5.2–6.0)	2.5 (2.0–3.0)
South	231 279	20 227 (8.8)	5.5 (5.2–5.9)	5.8 (5.5–6.1)	6.5 (6.1–6.9)	3.0 (2.6–3.4)
West	173 030	11 718 (6.8)	4.3 (4.0–4.6)	4.3 (4.0–4.7)	4.9 (4.5–5.2)	2.2 (1.7–2.7)
Other‖	8839	444 (5.0)	3.3 (2.1–4.5)	3.4 (2.2–4.6)	3.4 (2.0–4.8)	2.7 (0.3–5.1)
Breast symptoms†						
Yes	87 815	24 777 (28.2)	18.7 (17.8–19.6)	20.6 (19.6–21.6)	22.2 (21.2–23.3)	6.0 (4.9–7.1)
No	589 048	23 088 (3.9)	3.1 (3.0–3.3)	3.2 (3.0–3.3)	3.3 (3.2–3.6)	2.3 (2.0–2.5)
Unknown/missing	75 218	3655 (4.9)	4.1 (3.6–4.6)	4.1 (3.7–4.6)	4.8 (4.2–5.3)	2.4 (1.8–3.1)

*Limited dataset excludes all abnormal CBE records that lacked a final breast diagnosis code.

†Statistically significant differences ($P<.001$) were observed for percent of abnormal CBEs and cancer-detection rates.

‡The P values for the percent of CBEs considered to be abnormal, the cancer rate based on all data, the rate based on limited data, and the rate based on initial-round data were all <.001. The P value for the subsequent round rate was .007. These P values are from two-sided tests.

§The P values for the percent of CBEs considered to be abnormal, the cancer rate based on all data, the rate based on limited data, and the rate based on the first screening round were all <.001. These P values are from two-sided tests.

‖Includes data from territories and American Indian/Alaska Native tribal organizations.

Cancers Detected

Breast cancers were detected in 3753 women, for a rate of 6.6 cancers per 1000 women (95% CI = 6.4–6.9). Twenty-seven women had two new primary cancers detected. Among the 3780 cancers, 2852 were diagnosed as invasive cancer and 928 were diagnosed as cancer *in situ.* The diagnostic yield was, thus, 5.0 cancers per 1000 examinations (95% CI = 4.9–5.2). Invasive and cancer *in situ* rates were 3.8 (95% CI = 3.6–3.9) and 1.2 (95% CI = 1.1–1.3), respectively.

The final breast cancer diagnosis code was missing on 17 501 abnormal CBE records (2.3% of all CBEs in the dataset). Excluding these records had little effect on the observed rates (Table 1). Higher cancer-detection rates were observed for first-round screens than for subsequent rounds. When the set of initial CBEs was further restricted by excluding CBEs provided to women who had received an NBCCEDP breast screen before our study interval, the rate was 6.9 cancers per 1000 CBE records (95% CI = 6.6–7.2).

Cancer rates varied statistically significantly by age, breast symptoms, and race/ethnicity (Table 1). Cancer rates were positively associated with age and were higher among women reporting breast problems. Lower rates were observed among American Indians/Alaska Natives. Rates were substantially higher among screening rounds reporting an abnormal CBE than among those reporting a normal examination (Table 2).

Because 555 983 records (74%) also reported mammography results, we determined overall rates (cancer *in situ* plus invasive) for three additional subsets. The detection rate among records reporting an abnormal CBE and a benign mammography was 7.4 cancers per 1000 records (95% CI = 6.3–8.4). When the CBE was normal, but the mammography was abnormal, the rate was 42.0 cancers per 1000 records (95% CI = 39.9–44.1). When both CBE and mammography results were abnormal, the rate was 170.3 cancers per 1000 records (95% CI = 162.7–177.9). Cancer detection could not be attributed entirely to CBE or mammography on 38% of the records in the latter subset because the tests were performed on the same day.

Only 83 of the cancers (2% of all detected cancers) met our definition of an interval cancer. In five instances, the record reporting no diagnosis of cancer preceded the record with a cancer diagnosis by less than 90 days, suggesting a data-reporting error rather than a missed cancer. For 78 cancers, the mean number of days between a normal CBE with no diagnosis of cancer and a subsequent CBE with a cancer diagnosis was 233 days.

After grouping records with a cancer diagnosis by CBE and mammography data, we found that 5.1% (193 records with a cancer diagnosis) were reported on records where the CBE was abnormal, but the mammography was negative, benign, or probably benign (Table 2). Another 11.2% (423 records with a cancer diagnosis) had an abnormal CBE, but mammography data were missing. Only 1.9% of the records with a cancer diagnosis reported normal results for both the CBE and mammography. On

Table 2. Number of breast cancers detected and cancer-detection rates by clinical breast examination (CBE) result, age at CBE, and associated mammography findings

	All ages	<40 y	40–49 y	50–59 y	60–69 y	⩾70 y
CBE abnormal, suspicious for cancer						
Total CBEs, No.	51 520	11 218	19 117	12 835	6118	2232
Cancers detected, No.	2224	162	679	776	451	156
Among CBEs with abnormal mammogram*	1608	96	472	582	335	123
Among CBEs with benign mammogram	193	17	59	53	46	18
Among CBEs with missing mammogram	423	49	148	141	70	15
Overall cancer rate†	43.1 (41.4–44.9)	14.4 (12.2–16.6)	35.5 (32.9–38.1)	60.4 (56.3–64.6)	73.7 (67.2–80.3)	69.9 (59.3–80.5)
Invasive	35.8 (34.2–37.4)	12.1 (10.0–14.4)	29.4 (27.0–31.8)	50.0 (46.2–53.8)	61.1 (55.1–67.1)	58.2 (48.5–68.0)
Carcinoma *in situ*	7.4 (6.6–8.1)	2.3 (1.4–3.2)	6.1 (5.0–7.2)	10.4 (8.7–12.2)	12.6 (9.8–15.4)	11.6 (7.2–16.1)
CBE negative or benign						
Total CBEs, No.	700 561	68 181	201 541	234 041	134 768	62 030
Cancers detected, No.	1556	21	272	580	428	255
Among CBEs with abnormal mammogram*	1452	18	253	540	398	243
Among CBEs with a benign mammogram	74	2	16	26	22	8
Among CBEs with missing mammogram	30	1	3	14	8	4
Overall cancer rate†	2.2 (2.1–2.3)	0.3 (0.1–0.4)	1.4 (1.2–1.5)	2.5 (2.3–2.7)	3.2 (2.9–3.5)	4.1 (3.6–4.6)
Invasive	1.4 (1.3–1.5)	0.2 (0.1–0.3)	0.8 (0.7–0.9)	1.6 (1.4–1.7)	2.1 (1.8–2.3)	2.8 (2.4–3.2)
Carcinoma *in situ*	0.8 (0.7–0.8)	0.09 (0.02–0.16)	0.5 (0.4–0.6)	0.9 (0.8–1.0)	1.1 (0.9–1.3)	1.3 (1.0–1.6)

*Mammogram with Breast Imaging Reporting and Data System code of assessment incomplete, suspicious abnormality, or highly suggestive of malignancy.

†Rates per 1000 CBEs (95% confidence interval).

71.6% of these 74 records, the mammography code was probably benign (short interval follow-up suggested). On 18.9% of the records, breast symptoms were reported. All records indicated completion of at least one additional breast cancer diagnostic procedure (89.2% reported a breast biopsy or fine-needle aspiration). Tumor staging data were provided for 80% of the invasive cancers.

Sensitivity, Specificity, and Positive Predictive Value

Across all records in the dataset, sensitivity, specificity, and positive predictive value estimates were 58.8%, 93.4%, and 4.3%, respectively (Table 3). Sensitivity decreased with age, but specificity and positive predictive value increased with age. Unstratified and age-specific specificity and positive predictive value estimates were higher when only abnormal CBE records that reported completion of a biopsy examination or fine-needle aspiration were considered. After the dataset was restricted to the initial CBE recorded for each woman, sensitivity increased to 62.0%. Specificity did not change, and positive predictive value increased slightly to 4.9%. A similar effect was observed when the dataset was restricted to records with at least 12 months of follow-up (sensitivity = 59.0%; specificity = 95.3%; positive predictive value = 4.2%). As anticipated, sensitivity was higher and specificity was lower among records reporting the presence of breast symptoms at the time of the examination (85.2% and 72.9%, respectively). Among records reporting an absence of symptoms, the reverse was observed (sensitivity = 36.1% and specificity = 96.2%).

Table 3. Sensitivity, specificity, and positive predictive value of clinical breast examinations (CBEs) overall and by age at examination

	Overall	<40 y	40–49 y	50–59 y	60–69 y	⩾70 y
Sensitivity*	58.8	88.5	71.4	57.2	51.3	38.0
Specificity-A†	93.4	86.0	91.6	95.1	96.0	96.8
Specificity-B‡	95.7	90.6	94.4	96.7	97.4	98.0
Positive predictive value-A§	4.3	1.4	3.6	6.1	7.4	7.0
Positive predictive value-B‖	20.9	7.1	16.7	29.2	38.1	39.4

*Sensitivity = $TP/(TP + FN) \times 100$. *TP* = true-positive results; *FN* = false-negative results.

†Specificity-A = $TN/(TN + FP) \times 100$. *TN* = negative test result; *FP* = false-positive result.

‡Specificity-B = defined above, except that the *FP* value includes only abnormal CBEs referred for biopsy examination or fine-needle aspiration with a final screening code of "breast cancer not diagnosed."

§Positive predictive value-A = true-positive results (cancer *in situ* or invasive cancer diagnosed)/abnormal CBEs × 100.

‖Positive predictive value-B = true-positive results/abnormal CBEs with follow-up via biopsy examination or fine-needle aspiration × 100.

Discussion

Reported herein are CBE results for examinations completed in thousands of medical practices across the United States. The NBCCEDP has standardized reporting procedures to permit data pooling, but the procedural aspects of conducting a CBE are not dictated. Unlike findings from controlled trials, NBCCEDP data thus provide a unique real-world perspective on contemporary CBE practice in diverse community settings. Although our findings cannot be generalized to all CBEs performed in the United States because of the NBCCEDP's restriction of services to low-income women, several of the results have implications for public health efforts to limit breast cancer morbidity and mortality.

About one (6.9%) of every 15 CBEs was coded abnormal, suspicious for cancer. To our knowledge, similar statistics have not been reported previously. An approximation of the frequency of abnormal findings in a research setting can be derived from the Canadian National Breast Screening Study. In a sample of 19 965 women aged 50–59 years who received a CBE from 1980 through 1985 from trained nurse examiners and physicians who followed a standardized protocol, there were 69 true-positive CBEs and 2289 false-positive CBEs, suggesting that about 11.8% of the CBEs were initially judged to be suspicious for cancer *(18)*.

Our cancer-detection rate is similar to that reported by other screening programs that relied on both mammography and CBE *(19–22).* One of every 200 records reporting CBE data also reported a diagnosis of cancer. When first and subsequent CBE records were considered separately, the cancer-detection rates were 5.8 cancers per 1000 first CBE records and 2.7 cancers per 1000 subsequent CBE records. These values are consistent with a report on NBCCEDP-sponsored mammographies performed from July 1991 through June 1995 *(7),* a period entirely preceding the interval considered in our study. In that dataset, the cancer-detection rates were 5.1 cancers per 1000 mammograms (95% CI = 4.8–5.4) for initial mammographies and 2.0 cancers per 1000 mammograms (95% CI = 1.6–2.4) for subsequent mammographies. Cancers detected only by CBEs were not included in the rates reported for that interval.

Several groups recommend annual CBEs as part of routine cancer screening, including the American College of Radiology *(23),* the National Cancer Institute *(24),* the American Cancer Society *(25),* and the Public Health Service authors of *Healthy People 2000 (1).* Foreshadowing these recommendations and in response to public sentiment, the U.S. Congress in 1990 mandated in the Breast and Cervical Cancer Mortality Prevention Act (PL101–354) that agencies receiving NBCCEDP funds provide "both a physical examination of the breasts and the screening procedure known as mammography" to eligible enrollees *(10).* A recent review of the clinical trial literature *(17)* concluded that screening CBEs should be provided to all women older than the age of 40 years who are at risk for breast cancer.

Two influential groups have not recommended routine CBE breast cancer screening. These include the U.S. Preventive Services Task Force *(26)* and the National Committee for Quality Assurance, which developed version 3.0 of the Health Plan Employer Data and Information Set *(27).* Although neither group discourages annual CBEs, some U.S. data suggest a decline in the use of CBE concurrent with increasing use of mammography *(28,29).* In some European countries, routine breast cancer screening relies primarily on mammography *(30–32).*

About 5.1% of the cancers reported in our dataset were not detected by mammography and might have been missed if a CBE had not been performed. An additional 11.2% may have been found only through a CBE because mammography results were not reported. As others have noted *(17),* the importance of cancers detected only through a CBE is uncertain. Without persuasive evidence that breast cancer mortality is reduced by the detection of cancers during CBEs, our findings suggest, but do not establish, the public health benefit of this procedure.

Sensitivity and specificity of CBEs reported to the NBCCEDP were consistent with values published from other screening programs. In our dataset, overall sensitivity was 58.8% and specificity was 93.4%. A review of the literature by Eddy *(31)* concluded that CBE sensitivity was about 50% and specificity was about 98%. A 1999 meta-analysis by Barton et al. *(17)* reported pooled CBE sensitivity and specificity statistics of 54% and 94%, respectively.

As a previous report on NBCCEDP data noted *(7),* enrolled women cannot be linked with cancer-registry data to improve estimates of sensitivity and specificity. However, using negative test results rather than true-negative test results is unlikely to bias results because the proportion who have the disease in the population is very low. Almost all negative test results are also true-negative results *(7,14).*

Age at time of CBE emerged as an important factor in many analyses. Age was negatively associated with the likelihood of having an abnormal CBE but was positively associated with the likelihood of having a cancer detected. We searched the limited available literature on CBE results and were unable to find appropriate comparison data. The positive relationship between age and breast cancer incidence is well documented *(33).*

Our finding of a high rate of abnormal CBEs for women younger than 40 years may be an artifact. The NBCCEDP does not actively encourage routine CBEs for women younger than 40 years, and it restricts payment for mammographies to those needed for diagnostic purposes. Consequently, women with breast symptoms may be over-represented in this group. Also, some providers may be more likely to code questionable CBEs among younger women as abnormal to help them obtain a free mammogram. Such biases could inflate the observed proportion with abnormal CBE results, beyond what would have been observed in a more representative sample of low-income women in that age range. However, only 10% of the CBEs were provided to women in that age range, and most of our analyses were stratified by age.

Race and ethnicity emerged as statistically significant predictors of the likelihood of receiving an abnormal CBE. The importance of this finding is difficult to assess because of likely confounding by screening site location. To illustrate, in Western states (Washington, Oregon, California, Nevada, New Mexico, Arizona, Idaho, Utah, Colorado, Montana, Wyoming, Alaska, and Hawaii), 6.8% of all CBEs were considered to be abnormal. In Southern states (Delaware, Maryland, the District of Columbia, West Virginia, Virginia, Kentucky, Tennessee, North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Oklahoma, Texas, and Arkansas), the corresponding value was 8.8%. Because Western programs provided 53.9% of all CBEs for Asian/Pacific Islanders and 16.0% of all CBEs for white women, whereas Southern programs provided 7.6% of the CBEs for Asian/Pacific Islanders and 31.1% of the CBEs for white women, the higher abnormal rate among white women could be due to racial differences or it could reflect regional differences in CBE methods and coding of CBE findings. NBCCEDP variations in breast cancer detection rates by race and ethnicity are being reported elsewhere.

NBCCEDP cancer surveillance and program-monitoring data collected in conjunction with the provision of screening services have enhanced our understanding of the public health value of CBEs. NBCCEDP data have also identified areas where additional research and education are needed. These include finding ways to improve the sensitivity of CBEs and ensuring that all women with an abnormal CBE result considered suspicious for cancer obtain necessary diagnostic and treatment services. The CDC will continue to work closely with participating programs to advance these objectives.

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NOTES

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