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By

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ABSTRACT

BREAST CANCER SCREENING IN THREE MICHIGAN FAMILY PRACTICE CLINICS

By

Suiying Huang

As part of a research project supported by the Department of Defense on training physicians for proper follow-up of breast abnormalities, we calculated the breast cancer (BC) screening rate for women 40-70 years old in three Michigan Family Practice Clinics (FPC) between 5/1/98 and 7/31/99. Breast care related office visits and phone calls for all eligible women in the clinics were abstracted. Symptomatic women were eliminated from the calculation. The screening rates for CBE performed alone were 56.5%, 50.3%, and 27%. The rates for mammography were 55.4%, 36.0%, and 28%, and 94% of women had the mammogram done within 3 months of recommendation. The percentages of women who had both CBE and mammography were 35.8%, 22.8%, and 16.7%. Among them, 90% had both tests done within 3 months. For women >=50, the mammography screening rates were consistently higher than for women < 50, for all three clinics. CBE screening rates varied between the two age groups. These results underline two important points: (1) the current BC screening rates for CBE and mammography individually or combined are unacceptably low (2) when screening is recommended, it is accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at FPC will be urgently needed.

To Mom and Dad

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BC - Breast Cancer

CBE - Clinical Breast Exam

ACS - American Cancer Society

CHAPTER 1 INTRODUCTION

Breast cancer (BC) is the most common cancer among women, and it is the second leading cause of cancer death in women, next to lung cancer. The American Cancer Society (ACS) estimated that there will be 182,800 new cases of invasive BC among women and about 40,800 deaths in the United States during 2000 [1]. Based on current incidence rates, ACS estimates that one out of every nine women in the United States will develop BC at some time during her life.

One effective strategy in reducing mortality from cancer is early detection by screening. Early detection of cancer can result in treatment before the tumor metastasizes and can lead to reduction in mortality from the disease. For a screening test to be effective, that test must be capable of diagnosing disease prior to it becoming symptomatic [2].

The main screening methods for BC have been mammography and clinical breast examination (CBE) performed by trained health professionals. Mammography can generally detect smaller tumors than those found by CBE (1.5cm versus 1.8cm) [3].

Recommendations for screening in normal-risk women in the US vary by cancer research organizations. Every major professional cancer organization

recommends screening in women 50-69 at intervals of 1-2 years [3]. Recommendations are inconsistent for women aged 40-49 and 70 and over. The American Cancer Society and the American College of Radiology recommend annual mammography and CBE for women 40 to 49 years, while the National Cancer Institute (NCI) recommends screening mammography every 1 to 2 years for women of the same age group [3] [4]. All of these recommendations apply only to asymptomatic women. The frequency and type of examination for symptomatic and high-risk women will vary individually and should be determined by the responsible physician.

Further, it is recognized that in order to eliminate the false negative rates of either CBE or mammography alone, the two tests should be done as close in time as possible [5]. Hicks et al found that the individual sensitivities of mammography and CBE for detecting BC were 62% and 24%, respectively. However the sensitivity of the two methods combined was 75% [5].

Historically, CBE has been a neglected part of the annual physical examination. Many physicians attribute this to lack of adequate training of CBE in medical school and also to the unrealistic amount of time that is required for doing a proper exam [6]. In addition, several investigators have recently reported that as the use of mammography increases, CBE usage has decreased [3] [7] [8].

I. Breast Cancer Screening Evaluation

A. Efficacy of screening

Efficacy, as defined by Last, is the extent to which a specific intervention produces a beneficial result under ideal conditions [2]. Efficacy of screening can be determined through randomized clinical trials, and there have been several randomized clinical trials testing the value of BC screening (Table 1).

Randomized Trials

The first of these, and the only one conducted in the US, was the Health Insurance Plan of Greater New York (HIP) study, which began in 1963 and ended in 1986. The primary objective of the study was "to determine whether periodic breast cancer screening utilizing mammography and clinical examination holds substantial promise for a long-term reduction in mortality from breast cancer in the female population" [9] [10]. Women aged 40-64 years were enrolled and were randomized individually. The screened group numbered 30,131, compared to a control group of 30,565. Each woman in the intervention group was invited for an initial mammogram and three 12-month interval two-view follow-up mammograms, plus clinical examinations. Women in the control group followed their usual patterns of care. After 10 years, the cumulative mortality from BC was reduced 29% (RR = 0.71, CI 0.55 – 0.92) in the study group compared to the control group. However, the reduction in mortality differed by woman's age of entry to the study. For women younger than 50 years, the RR

was 0.81 (CI 0.53 – 1.24). Among women older than 50 years, the RR was 0.65 (CI 0.46 – 0.92).

Two randomized mammography screening trials were initiated in Sweden in the mid-1970's. The Malmo trial was initiated in 1976. Women enrolled were aged 45-69 years. Subjects were randomized for an 18-24 months interval, one-view, mammographic screening as part of their usual medical care. Women in the control group did not receive screening. After 9 years of follow-up, the RR for all women in the screened group was 0.96 (CI 0.68 – 1.35). Among women aged 50 years and older at entry, the RR was 0.79 (CI 0.51 – 1.24). Among women aged less than 50 years at entry, the RR was 1.29 (CI 0.74 – 2.25). However, in an analysis done in women 40-49 after 12 years of follow-up, the RR became 0.64 (CI 0.45 – 0.89) [11]. The results showed that mammograghic screening may lead to reduced mortality from BC after long-term follow-up.

In 1977, the Swedish National Board of Health and Welfare started another randomized controlled trial in two counties (Kopparberg and Ostergotland counties) to determine the effect of screening with a 24-33 month interval, one-view, mammogram on reducing mortality from BC [12]. Women in the control group followed their usual patterns of care. With an average of 13 years of follow-up, the cumulative mortality from breast cancer was 30% lower in the study group than it was in the control group (RR = 0.7, CI 0.55 – 0.87). The effect of screening was almost entirely concentrated among older women. In

Kopparberg county, the RR was 0.73 (CI 0.31 – 1.4) in women < 50 years, and 0.58 (CI 0.43 – 0.78) in women older than 50. In Ostergotland county, among women < 50 years old, the RR was 1.02 (CI 0.52 – 1.99), and for women 50 years and older, the RR was 0.73 (CI 0.56 – 0.97).

In another randomized clinical trial conducted in Edinburgh, 46,000 women aged 45-64 years were recruited during the period of 1978-1981. The screening methods included an annual two-view mammogram and CBE. Women in the control group received routine health care. After 7 years of follow-up, a non-significant mortality reduction was observed among women < 50 years of age at entry (RR = 0.98, CI 0.45 – 2.1). Among women >= 50 years at entry, the RR was 0.80 (CI 0.54 – 1.17) [13]. In an analysis performed in women less than 50 after 12 years of follow-up, there was a non-significant mortality reduction of 15% (RR = 0.85, CI 0.55 – 1.41) [14].

Another Swedish trial, the Stockholm trial, was initiated in 1981 [17] [18]. The number of women aged 40 to 64 in the intervention arm was 40,000, while the number in the control group was 20,000. The screening method used was a one-view, 28-month interval mammography. Women in the control group did not receive screening. After follow-up of 11.4 years, a non-significant 26% mortality reduction was observed in all women in the intervention group (RR = 0.74, CI 0.5 – 1.1). Beneficial effects were observed in women older than 50 years (RR =

0.62, CI 0.38 – 1.0). For women aged 40-49 years, no effect on mortality was found (RR = 1.08, CI 0.5 – 1.7).

The Canadian National Breast Screening study enrolled 90,000 women 40-59 years of age, starting from 1981. These women were randomly distributed into an intervention group receiving both annual two-view mammography and CBE or into a control group receiving only annual CBE [15, 16]. After 10.5 years of follow-up, among those women aged younger than 50 at entry, the RR of mortality from BC for those in the intervention group was 1.14 (CI 0.83 – 1.56), compared to controls. Among women aged 50 years and above, the RR was 0.97 (CI 0.62 – 1.52). Their results showed that screening with yearly two-view mammography and CBE had no impact on the rate of death from breast cancer for up to 10 years of follow-up from entry in this trial.

The Gothenburg breast cancer screening trial started in 1982 in Sweden. The trial randomized 52,000 women aged 40 - 64 into two groups: one received mammographic screening every 18 months, and one control group, who was not invited to screening until the fifth screen of the intervention group [19] [20]. After 7 years of follow-up, no significant reduction in mortality in all women in the screened group was observed. However, after 12 years, there was a significant 44% reduction in mortality from BC in the screened group of women < 50 years at entry compared to the control group (RR = 0.56, CI 0.32 – 0.98) Their data

suggested that at least 10-12 years of follow-up is needed for the reduction in mortality to be seen among women under the age of 50.

Meta-analysis

Hendrick et al conducted a meta-analysis of eight randomized controlled trials of screening mammography involving women aged 40-49 at entry [21]. The average follow-up time was 12.7 years. The meta-analysis was performed using a Mentel-Haenszel estimator method. After combining the most recent follow-up data, a statistically significant 18% mortality reduction among women who were randomized to screening mammography was observed (RR = 0.82, CI 0.71 – 0.95). This meta-analysis showed, by combining all eight randomized clinical trials involving women younger than 50 years at entry, a statistically significant mortality reduction due to regular screening mammography was observed. This analysis overcame many of the power limitations in the younger age groups that challenged the accuracy of the previous trials, due to the lower prevalence of BC in this age group.

B. Effectiveness of screening

Effectiveness, as defined by Last, is a measurement of the extent to which a specific intervention, when deployed in the field in routine circumstances, does what it is intended to do for a specified population [2].

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One of the largest tests of BC screening effectiveness was the Breast Cancer Detection Demonstration Project (BCDDP), sponsored by the American Cancer Society and the National Cancer institute. Between 1973 and 1981, a total of 283,222 women aged 35-74 years participated in the BCDDP program. The program provided annual two-view screening mammography and CBE for five years, in 29 centers throughout the US. This project was a screening demonstration project that did not include a comparison group of women who did not receive mammographic screening, and so could not measure mortality reduction. However, after 20 years of follow-up, results showed that 50-59% of the cancers diagnosed were stage 0 or I [22]. The results demonstrated that BC can be detected at an earlier stage among women of all ages when screening modalities are used.

A second large-scale non-randomized trial was initiated in the United Kingdom in 1979 to evaluate the effectiveness of mammography and CBE in women aged 45 to 64 years. Subjects were not individually randomized and instead screening eligibility depended on their area of residence. Women in the screened population (n=45,841) were offered annual physical exam and biennial mammography for 7 years. Women in the control population (n = 127,117) were not offered screening services. After 16 years of follow-up, breast cancer mortality was 27% lower in the study group, compared to the control group (RR = 0.73, CI 0.63 – 0.84) [23]. There was no evidence of less benefit in women aged 45-46 years at entry, the effect of screening in this age group begins to emerge

after 3-4 years. After 16 years, a 30% (RR = 0.7, CI 0.57 – 0.86) reduction is seen in women aged 45-46 years at entry. However, this trial is subject to criticism since it is not individually randomized. Possible confounding factors, such as inherent risk across the counties and differences in social-economic status, should be considered when interpreting the results.

C. Efficiency of screening

In addition to efficacy and effectiveness, BC screening efficiencies must also be considered. Efficiency, as defined by Last, is the effects or end results achieved in relation to the effort expended in terms of money, resources, and time [2].

Cost

The cost of screening is usually measured by the cost per year of life saved. In 1995, it was estimated that cost/year of life saved by screening mammography ranged from $6,000 - $13,000, with a median of $8,900 [24]. In comparison, the median cost per year of life saved in the appropriate age groups for other interventions were: $6,000 for cholesterol, $12,000 for cervical cancer, and $42,000 for hormone replacement therapy. This demonstrated that annual mammography compares favorably with other public health interventions.

Risks

However, there are existing potential hazards associated with BC screening as well, especially with mammographic screening [25]. First, if earlier

time of diagnosis doesn't translate into a reduction in breast cancer mortality for an individual woman, then some women are given advanced notice of a cancer diagnosis without tangible gain [26]. This can, of course, have an adverse effect on the quality of life. Second, mammographic screening results in exposure to low-dose radiation, and this may induce breast cancer, especially for women with the inherited gene for ataxia-telangiectasia [3]. Third, false positive results can lead to unnecessary breast biopsies and anxiety [26]. These patients have to face the financial/emotional burden of being falsely identified as a potential cancer patient. Finally, mammography has a false negative rate in screening settings of 10-15% [26]. This can lead to false reassurance that cancer is absent and mislead women and their providers.

D. Summary

Despite the potential risks involved, data from clinical trials support on average a 30% mortality reduction in BC resulting from annual or bi-annual mammography and CBE among asymptomatic women between the ages of 50 and 69 years [27]. A meta-analysis of the randomized trials demonstrated a 18% reduction in BC mortality from mammography screening among asymptomatic women between the ages of 40 and 49 years. The lower mortality reduction demonstrated in women 40-49 as compared with women 50 and over is likely due to lack of power to demonstrate a difference based on low prevalence of BC in this age group, the need for longer follow-up time, and the demonstrated need

for shorter screening intervals in younger women, due to shorter cancer sojourn times in this population [28].

Table 1: Summary of Randomized Clinical Trials Testing the Effectiveness of Screening

Location	Time period	Age	# in study group	# in control group	Yrs of F/UP	Types of Screening	Interval (mo)	Relative Risk (95% CI)	
USA	1963-1986	40-64	30,131	30,565	10	2 V MM[1] and CBE	12	<50 >50	0.81 (0.53-1.24) **0.65 (0.46-0.92)**
Malmo, Sweden	1976-	45-69	21,088	21,195	12	2 V MM[1]	18-24	After 9 years	
								<50 >50	1.29 (0.74-2.25) 0.79 (0.51-1.24)
								After 12 years	
								<50	**0.64 (0.45-0.89)**
Kopparberg, Sweden	1977-1984	40-74	38,589	18,582	13	1 V MM[2]	24	<50 >50	0.73 (0.31-1.4) **0.58 (0.43-0.78)**
Ostergotland, Sweden	1977-1984	40-74	38,491	37,403	13	1 V MM[2]	24	<50 >50	1.02 (0.52-1.99) **0.73 (0.56-0.97)**
Edinburgh, UK	1978 - 1985	45-64	23,000	23,000	12	2 V MM[1] and CBE	12	After 7 years	
								<50 >50	0.98 (0.45-2.1) 0.80 (0.54-1.17)
								After 12 years	
								<50	0.85 (0.55-1.41)
Canada	1980	40-49	25,000	25,000	10.5	2 V MM[1] and CBE	12	1.14 (CI 0.83 – 1.56)	
Canada	1980	50-59	20,000	20,000	8.3	2 V MM[1] and CBE	12	0.97 (CI 0.62 – 1.52)	

Location	Time period	Age	# in study group	# in control group	Yrs of F/UP	Types of Screening	Interval (mo)	Relative Risk (95% CI)	
Stockholm, Sweden	1981-1986	40-64	40,000	20,000	11	1 V MM[2]	28	<50 >50	1.08 (0.54-1.7) **0.62 (0.38-1.0)**
Gothernburg, Sweden	1982-1994	40-59	22,000	30,000	12	2 V MM[1]	18	After 7 years	
								<50 >50	0.73 (0.3-1.97) 0.91 (0.5-1.55)
								After 12 years	
								<50	**0.56 (0.3-0.98)**

1 = 2-view mammography

2 = 1-view mammography

Table 2: Summary of Other Studies Testing the Effectiveness of Screening

Location	Time period	Age	# in study group	# in control group	Yrs of F/UP	Types of Screening	Interval (mo)	Relative Risk (95% CI) Or Other Findings	
Meta-analysis		40-49			12.7			**0.82 (0.71-0.95)**	
UK Trial	1979-	45-64	45,841	127,117	16	1 V MM[2] and CBE	12	<50 50-54 55-59 60-64	**0.7 (0.57-0.86)** 0.79 (0.62-1.0) **0.71 (0.56-0.9)** **0.7 (0.56-0.92)**
BCDDP	1973-1980	35-74	283,222		20	2 V MM[1] and CBE	12	50-59% of cancer were diagnosed at stage 0 or 1	

1 = 2-view mammography

2 = 1-view mammography

II. Current breast cancer screening rates

A. Patient Self-Reported BC Screening Rates

Anderson et al described the use of breast cancer screening within the US population in 1987 and 1992 as reported in the National Health Interview Survey [29]. In 1987, a total of 5,052 women aged 50 years or older were interviewed and asked whether or not they had had mammography and CBE in the past year (Table 3). In 1992, the corresponding women interviewed were 2,709. The percentage of women who self-reported having received a mammogram in 1987 was 16.5%. In 1992, the percentage increased to 35.3%. The percentage of women who self-reported receiving CBE increased from 41.6% in 1987 to 46% in 1992. These figures showed that the usage of BC screening modalities increased between 1987 and 1992 but that levels remained low.

Coleman et al compared annual BC screening rates from a telephone survey conducted in 1988 and again in 1991, among women aged 65 – 74 [8]. Participants were selected from five communities around the country. In 1988, the numbers of women included were 57 in California, 133 in Massachusetts, 124 in North Carolina, 64 in Long Island, and 121 in Philadelphia (Table 3). In 1991, 237 women participated in California, 508 in Massachusetts, 409 in North Carolina, 523 in Long Island, and 479 in Philadelphia. None of the eligible women had a previous history of BC, and all were able to complete the interview or questionnaire. The authors found that mammography use increased from 19-33% in 1988 to 35-59% in 1991. However, among women who received a

mammogram, the percent who also received a CBE decreased from 95% to 85% (P = 0.001). They conclude that even though mammography in older women increased dramatically over the 3 years, the use of CBE may be decreasing.

The Centers for Disease Control's 1997 Behavioral Risk Factor Surveillance System (BRFSS) examined the usage of screening mammography, screening CBE, and both examinations among a multistage probability sample of women aged 50 years and older, in 52 states (including the District of Columbia and Puerto Rico) [30]. They used a standard questionnaire to conduct random-digit-dialing telephone surveys. The questionnaire included questions about CBE and mammography. The report was restricted only to screening examinations, which is defined as an examination that was part of a routine check-up. In 1997, the average percentage of women aged 50 years and older who self-reported receiving a screening mammogram in the previous two years was 73.7%; screening CBE 77.0%; and both examinations 66.4% (Table 3).

B. Physician Self-Reported BC Screening Rates

Albanes et al conducted a survey of physicians in Pennsylvania to ascertain current BC early detection practices in 1988 [31]. They found that over 90% of the physicians self-reported having performed annual breast physical examinations in asymptomatic women age 50 years or older (Table 3). However, for this age group, annual mammograms were self-reported as ordered by only 42% of physicians.

Kripalani et al did a survey of self-reported BC screening rates among 700 randomly chosen Texas primary care physicians in 1996, in order to determine their screening behaviors and compliance with national recommendations [32]. For women between 40 and 49 years of age, 75.5% of physicians reported recommending mammography every 1-2 year(s), and 8.4% suggested screening annually (Table 3). For women 50 years and older, 81.4% reported recommending annual mammography and 16.1% of clinicians recommended screening every 1 to 2 years. The authors concluded that the screening practices reported by this sample of Texas physicians compared very favorably with those reported by other authors.

Slanetz et al conducted questionnaires among 278 physicians in the state of Massachusetts concerning their use of BC screening in 1995 [33]. In women aged less than 50, 144 (52%) of 278 physicians self-reported performing annual CBE combined with screening mammography every two years, whereas 57 (21%) favored annual mammography and CBE (Table 3). In women aged 50 years and older, 232 (83%) physicians reported screening patients annually with CBE and mammography.

C. Chart-Audited BC Screening Rates

Burns et al investigated the prevalence of CBE among women receiving mammography [7]. This retrospective cohort consisted of one hundred women aged 50 years or older who received mammography between 1987 and 1990 in Boston, Mass. Chart review recorded demographic information, severity of illness, and performance of CBE, within 1 year to 18 months after the mammography. They found that 76% of the population studied had mammography and CBE, while the remaining 24% had mammography alone. Socioeconomic factors did not differ for women with and without screening examinations. However, female breast care providers were more likely to perform screening examinations (both mammography and CBE) than male providers. The authors concluded that mammography may be replacing CBE, especially among patients receiving breast care from male providers. Interventions that are targeted to male providers should help to improve the use of both CBE and mammography.

Love et al determined the frequency and determinants of mammography screening in 24 nonacademic primary care group practices, during a 3-year period, 1988 through 1991 [34]. They audited the medical records and obtained questionnaire responses from 1819 women older than 50 and from their 98 physicians in the non-metropolitan Midwest. Medical record abstraction indicated that mammography was performed in all 3 years in 16.7% of women, in at least two of 3 years in 49.8% of women, and in at least one of 3 years in 81.7% of women (Table 3). The significant predictors for receiving mammography included

family history of BC, health insurance coverage for mammography, and greater annual household income. The strongest predictor for greater frequency of mammography was the discussion of the procedure by a clinic staff member. The authors concluded that clinic staff initiatives with screening mammography have a large impact on higher rates of mammography performed, and should be a focus of intervention research designed to increase use of screening mammography.

Kinsinger et al conducted a randomized controlled trial with primary care practices to evaluate the improvement of performance rates of BC screening through implementation of office systems in 1992 [35]. Physicians in 20 mostly rural counties in North Carolina were assigned to either an intervention group or a control group. The intervention, focusing on BC screening by mammography and CBE, consisted of a series of activities designed to assist primary care practices in developing and implementing individualized office systems for BC screening. To facilitate the implementation of office system plans in the intervention groups, practices were encouraged to use resources for tracking and prompting (e.g., flow sheets, chart prompts and sticker, etc) and for patient education (e.g., brochures listing recommended preventive care for women over 50 years of age). Medical records of women 50 years and older were randomly chosen for data abstraction, both at baseline year (1992) and follow-up year (1995). The numbers of records abstracted were 2,887 and 2,874 for the two years, respectively (Table 3). The chart audits showed an increase from 39% to

51% in the mention of mammography ("mention" of mammography on the visit note in any way) in the intervention practices, compared with increases from 41% to 44% in the control practices (Odds Ratio = 1.5, CI 1.1 – 2.0). However, there was no significant difference between the two groups in the percent of actual mammograms reported in the charts during the two years. In the intervention group, the percentage of women with a mammogram reported in the chart increased from 28% to 32.7%. In the control group, it increased from 30.6% to 34.0%. Regarding CBE, either completion of CBE or mention of a CBE recommendation was considered. The percentage of women having a CBE either performed or recommended improved from 41.1% to 46.4% in the intervention arm, while it dropped from 44.6% to 43.9% in the control group. The percentages of women whose chart indicated that both mammography and CBE were recommended increased from 28.2% to 38.7% in the intervention group, and 30.3% to 32.6% in the control group. These results showed that outreach interventions to increase rates of BC screening through the development of office systems was modestly successful in improving the documentation of recommendation for mammography, but had little impact on the actual performance of BC screening.

McCarthy et al measured the effect of systemic health care delivery factors and patient demographic factors on the use of mammography among a population of women with insurance coverage for screening mammography in 1992 [36]. They studied 8,805 women, age >= 50 years, who were members of a

health maintenance organization in Michigan during 1992. Data were obtained using computerized patient registration and billing systems. In 1992, 47% of the entire study population received a mammogram (Table 3). Not having at least one primary care visit at the time when due for screening was the strongest predictor for not receiving a mammogram. This study suggested that physicians may rely too much on offering mammography during office visits, and that more attention should be focused on a population-based perspective that includes outreach to women who have not visited their health care provider and are overdue for screening. In addition, they also found that the number of visits a patient had was related to obtaining a mammogram. Women who had 2-10 visits had the highest mammography use, compared to those with 1 visit and visits beyond 10.

Tishler et al tried to determine the rates of BC screening for older women cared for in a primary care practice in 1996 [37]. The retrospective cohort consisted of 130 women aged 65 to 80. Data were collected from the hospital's computerized medical record between October 1996 and October 1997. They abstracted all CBE and mammograms performed or recommended during the 2-year study period. They found that among the 130 women, mammography was recommended for 95% of women and completed for 84% (Table 3). CBE was performed on 75% of those women. They reported a very high rate of mammography for women cared for in a hospital-based primary care practice, about twice that reported in most previous studies. The systems in place to

facilitate ordering and tracking of mammograms may have contributed to the unusually high rates of mammography observed. Mammograms were included in a computerized "To Do" list for women aged 50 and older. The clinician received a computer prompt at the time of a patient's visit if it had been more than a year since the women's last mammogram.

D. Comparisons Between Self-report And Chart Audit

Montano et al measured the cancer screening rates of family physicians and compared the measures obtained by physician self-reports, chart audits, and patient surveys in 1988 [38]. Sixty physicians participated in the physician survey, and 326 patients were surveyed for each physician (n = 21,876 patients). Fifty to sixty patients' charts were selected for each participating physician (n = 3,281 patient charts). The chart audit indicated that on average 51% of female patients older than 50 years had had a mammogram within the previous year of the study (between 1988 and 1989), and 57% of women had had a CBE in the past year. Corresponding physicians' self report showed that the rate for mammography was 51% among women aged 50 and older, and 67% for CBE. Patients' self reported survey indicated that 46% of women older than 50 received mammography and 63% received CBE (Table 3).

Whitman et al tried to determine whether chart reviews and patient interviews provide the same information about BC screening [39]. The percentage of women older than 40 who received a breast exam and the

percentage of women older than 50 who received a mammogram at two different public health clinics in Chicago were studied using both chart reviews and telephone interviews. They found that interviews estimated significantly higher proportions of women having received breast exams and mammograms in the previous 12-month interval than were estimated from randomly selected medical records. At center A, the chart review produced an estimate of 6% of women who received CBE, while patient interviews produced an estimate of 55% (Table 3). At center B, the chart review indicated that 36% of the eligible patients had received a CBE in the past year compared to 63% derived from the telephone interview. Regarding mammography, 3% of the eligible patients had mammography recorded in their charts in Center A, while interviews estimated 29%. At Center B, 17% of the women had mammograms recorded in their charts, while interviews produced 38%. This study demonstrated that the BC screening rates in the two clinic centers were low, and there are marked discrepancies between what women report regarding BC screening and what is revealed by reviewing the medical records.

E. Summary of Breast Cancer screening literature review

BC screening rates can be reported by interviewing patients, physicians, or by medical chart auditing. Self-reported BC screening rates are consistently higher than those rates obtained from medical chart auditing. The literature also indicated that since the late 1980's mammography usage had increased steadily. However studies have reported that CBE usage may be decreasing.

Table 3. Literature Review For Breast Cancer Screening Rate

Study	Study Period	Method	N=	Women Age	% CBE done	% Mammogram Done	% Both done
Anderson et al	1987	Women self-report	5052	>= 50	41.6	16.5	
	1992		2709	>= 50	46	35.3	
Coleman et al	1987	Women self-report	499	65-74		19-33%	
	1991		2156	65-74		35-59%	
CDC BRFSS	1996-1997	Women self-report		>= 50	77	73.7	66.4
Albanes et al	1988	Physician self-report	557	>= 50	90	42 (recomm.)[1]	
Slanetz et al	1995	Physician self-report	278	40-49	52	52	52
				>= 50	83	83	83
Kripalani et al	1996	Physician self-report	254	40-49		75.5 (recomm.)[1]	
				>= 50		81.4 (recomm.)[1]	

1 = recommended

Study	Study Period	Method	N=	Women Age	% CBE done	% Mammogram Done	% Both done
Love et al	1988 - 1991	Chart Review	1819	>= 50		16.7 (in all 3 yrs)	
						49.8 (>=2 in 3 yrs)	
						81.7 (>=1 in 3 yrs)	
Kinsinger et al*	1992	Chart Review	2887	>= 50	42.9	29.3	29.3
	1995	Chart Review	2874	>= 50	45.2	33.4	35.7
McCarthy et al	1992	Billing system	8805	>= 50		47	
Tishler et al	1996	Chart Review	130	>= 65	75	84	
Montano et al	1988	Physician Survey	326	>= 50	67	51	
		Patient Survey	11,005	>= 50	63	46	
		Chart Review	3,281	>= 50	57	51	
Whitman et al (Center A)	1989	Chart Review	454	>= 40	6		
			394	>=50		3	
		Phone interview	140	>= 40	55		
			112	>=50		29	
Whitman et al (Center B)	1989	Chart Review	352	>= 40	36		
			144	>=50		17	
		Phone interview	303	>= 40	63		
			115	>=50		38	

* Percentages in the two years were derived from the averages of both intervention and control arms

III. Barriers to screening

Among identified barriers to screening are the discomfort or cost of the procedure, lack of health insurance, lack of transportation or remoteness of the mammography facility [3].

However, the two common reasons women give for not having had a mammogram was that they did not know they needed it and that their physician had not recommended it [40][41]. Fox et al analyzed the reasons provided by 517 women 50 years and older, living in Los Angeles, California, for their underutilization of BC screening [40]. They found that the most important factor that predicted whether a woman ever had a mammogram was whether her physician had talked to her about mammography. Similar results were also found by Grady et al [42]. Their multivariate analyses revealed physician encouragement to be more strongly associated with screening mammography than health status, health care utilization, attitudes, and socio-demographic characteristics. Those women who reported having received a physician recommendation were nearly four times more likely to have ever had a screening mammogram than those not receiving a physician recommendation [42].

These findings further strengthened the critical importance of physician behaviors in the secondary prevention of BC in women.

IV. Overall Study Objective

The current study was conducted to calculate the patient-specific annual screening rates for CBE, mammography, and both, in three Michigan family practice clinics, among women 40-70 years old. For this study, the annual screening rate will be defined as screening occurring during a fifteen-month time frame between 5/1/98 and 7/31/99.

CHAPTER 2 METHOD

I. Data Source:

Data for this analysis were derived from an ongoing large-scale study, funded by the United States Department of Defense. The aim of that study was to enhance primary care physicians' skills in secondary prevention, diagnosis and follow-up of abnormal findings in the control of breast cancer.

II. Study Population:

Three mid-Michigan family practice clinics were included in this analysis. They were designated as sites G, H, and I.

The clinics are members of the Michigan State University Network of Family Practice Residency Programs that serve Michigan by providing family centered care to the citizens of the communities in which they are located. They train resident family physicians to meet primary care needs, and to reach out to the medically underserved and the elderly of these communities. The programs estimated that in 1996 each site saw approximately 10 to 15% of all female patients 40 to 70 years of age. Approximately one-third of the total patients were Medicaid patients.

Each site generated a list of patients who met the following criteria for inclusion in the study:

1. Female
2. Active patients in the practice. This was defined as having at least one visit in the past three years (or since 8/1/96).
3. Between the ages of 40-70 for the baseline year, i.e. born after August 1, 1928 and before July 31, 1959

For each residency program site, two nurses with R.N degrees who were not affiliated with the residency programs were recruited to conduct the audits of the medical records. Each site was provided with one laptop computer in which to enter and transmit data. Nurse abstractor training was held on the campus of Michigan State University. Data entry forms were created in the ACCESS 97 database program and placed on the laptop computers. Sample cases were identified representing a variety of breast care concerns from the Clinical Practice Site at the Michigan State University Family Practice Center and Kalamazoo Center for Medical Studies. Names and all identifiers were blacked-out. Investigators at MSU created the gold standard for the completed audits and each of the practice cases. The nurse auditors abstracted ten sample cases and their entries were reviewed by the investors until the abstractor achieved a Kappa of 90% or higher as a measure of inter-rater agreement. After initial training in August 1999, the auditors were brought back to MSU for an additional

day of training in September, since additional changes were made to the database based on abstractors' feedback. This also allowed the reinforcement of the previously discussed audit guidelines. At the end of the training, each nurse abstractor signed confidentiality agreement forms.

III. Data Collection

The ACCESS database (Appendix 1) captured all patient encounters and phone calls during which breast care activities occurred. Any evidence in the medical record of a mammogram or CBE was recorded, such as a mammogram recommendation or report, comments regarding test refusals and comments regarding the reasons why recommended tests were not performed. We also recorded information regarding screening at outside facilities or by other physicians when documented.

IV. Quality control audit process:

Two trained graduate students in Epidemiology conducted quality assurance audits of the medical records in all three sites. The training manual provided to the nurse abstractors was used as a reference for a one-day training for the students. They were also required to complete the same 10 practice cases as the nurse abstractors. These were reviewed by the investigators as they had been for the nurse abstractors. A 100% Kappa was required from the

graduate students on these cases since they were to serve as the gold standard for the abstractors.

Twelve records were randomly selected from each auditor's list of patients that had already been abstracted by the nurses. The complete Kappa tests for the charts audited were shown in Appendix 2.

The "*" in Appendix 2 specifies that Kappa value was 100%. Over 90% of Kappa values were 100% and the remaining ones were either excellent (>80%) or Very Good (60-80%). Only 3 kappa values were less then 60% and they were 49%, 58% and 59%. This high quality of abstracting was the result of the intensive training that the abstractors received and the requirements that for the 10 practice cases their Kappa (agreement) values be at least 90% prior to being allowed to abstract in the field. The additional day of training that the auditors received prior to entering the field also contributed.

V. Screening Rate Calculations

For the purpose of this analysis, the screening rate calculation is defined as screening that occurred during a fifteen-month time period from 5/1/98 to 7/31/99. If a patient's breast care was provided by other physicians such as an OB/GYN, or if the patient was being followed by an oncologist, this was recorded in the database, and the patient was excluded from our screening rate calculations. Mammograms ordered for diagnostic rather than for screening

purposes, either on the basis of an unresolved mammographic abnormality or an abnormal CBE, were not considered to be a screening mammogram and this patient was also excluded from the mammography screening rate. Similarly, patients with a diagnostic CBE, which is defined as a CBE performed after knowledge of abnormal mammogram results, were also excluded. Comments concerning each breast care related encounter, such as refusal and the reason why the tests were not done, were recorded and were subsequently reviewed.

For this analysis, women were classified as being "screened" if they had received at least one CBE or Mammogram, or both within the 15-month period between 5/1/98 and 7/31/99.

The following screening rates or issues related to screening rates were calculated:

(1) The CBE screening rate defined by an actual CBE performed in asymptomatic women

(2) The mammography screening rate defined by an actual mammogram performed in asymptomatic women

(3) The BC (both CBE and mammography) screening rate defined by both CBE and mammography performed in asymptomatic women.

(4) The rates of CBE recommended, regardless of whether or not they were performed.

(5) The rates of mammography that are ordered, regardless of whether or not they were performed.

(6) The time interval between performance of CBE and mammography for asymptomatic women who had both examinations. The four time periods chosen for evaluation were: 3 month, 3-6 months, 6-9 months, and >9 months.

(7) The time intervals between when a mammogram was ordered and when it was actually done, according to the four intervals described above.

(8) The compliance rate for CBE and mammography: percentages of women who refused mammography or CBE upon recommendation.

(9) The reasons for refusal if documented in charts and other reasons why mammography or CBE was deferred or not performed.

(10) The percentages of women who received an annual well-women exam.

(11) The percentages of CBE performed and mammograms ordered during annual well-women exams.

(12) The BC screening rate among women who did not receive an annual well women exam.

(13) The screening rates broken down by age groups: women 40-49 and women 50-69.

(14) The association between the total numbers of visits to the family practice physicians during the 15-month study period and the BC screening rates. Total numbers of visits were grouped into 1-2 visit(s), 3-4 visits, and beyond 5 visits. Because we collected the total number of visits not only between 5/1/98 to

7/31/99, but also included visits that occurred before 5/1/98, the total number of visits can only serve as a proxy indicator.

VI. Statistical Analysis

Odds ratios (OR) and 95% confidence intervals (CI), derived from logistic regression models, were calculated to ascertain the association between the total numbers of visits to the family practice physicians during the 15-month study period and the BC screening rates.

CHAPTER 3. RESULTS

I. Sample Size

The numbers of patients assessed for eligibility in the three sites were 540, 872, and 896 (Table 4). Among them, the numbers of patients who were ineligible for analysis were: 23 (4.3%), 94 (10.8%), and 25 (2.8%). These are the patients who were male, not active during the last 3 years, outside the stated age range, or whom breast care was not provided by a family practice provider (Figure 1). The numbers of eligible women were 517 (95.7%), 778 (89.2%), and 871 (97.2%) at site G, H and I, respectively. These women presented at least once to the office during the last 3 years and represented the population that should have received a CBE and mammogram.

Two BC screening rates were generated as follows:

1. BC screening rates among GROUP A women (those who had at least one office visit for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99). The numbers of patients who met those criteria were 398 (73.7%), 653 (74.9%), and 505 (56.4%), in site G, H and I, respectively. The percentage of eligible women who were seen between 8/1/98 and 7/31/99 and in whom no breast care was performed

were 87 (16.1%), 205 (23.5%) and 219 (24.5%), in Site G, H and I, respectively (Table 4).

2. BC screening rates among GROUP A and GROUP B women. GROUP B women were those who presented at least once to the office during the last 3 years, but did NOT have one office visit for any reason or have a phone call/reminder that's breast related during 8/1/98 and 7/31/99. The numbers of patients under this description in the three sites were: 119 (22%), 125 (14.3%), and 366 (40.8%) at site G, H and I, respectively. These women were included only in the denominator of our screening rates, because they had no breast care activities during our study period (Table 4).

Figure 1 showed details of the screening rate calculation.

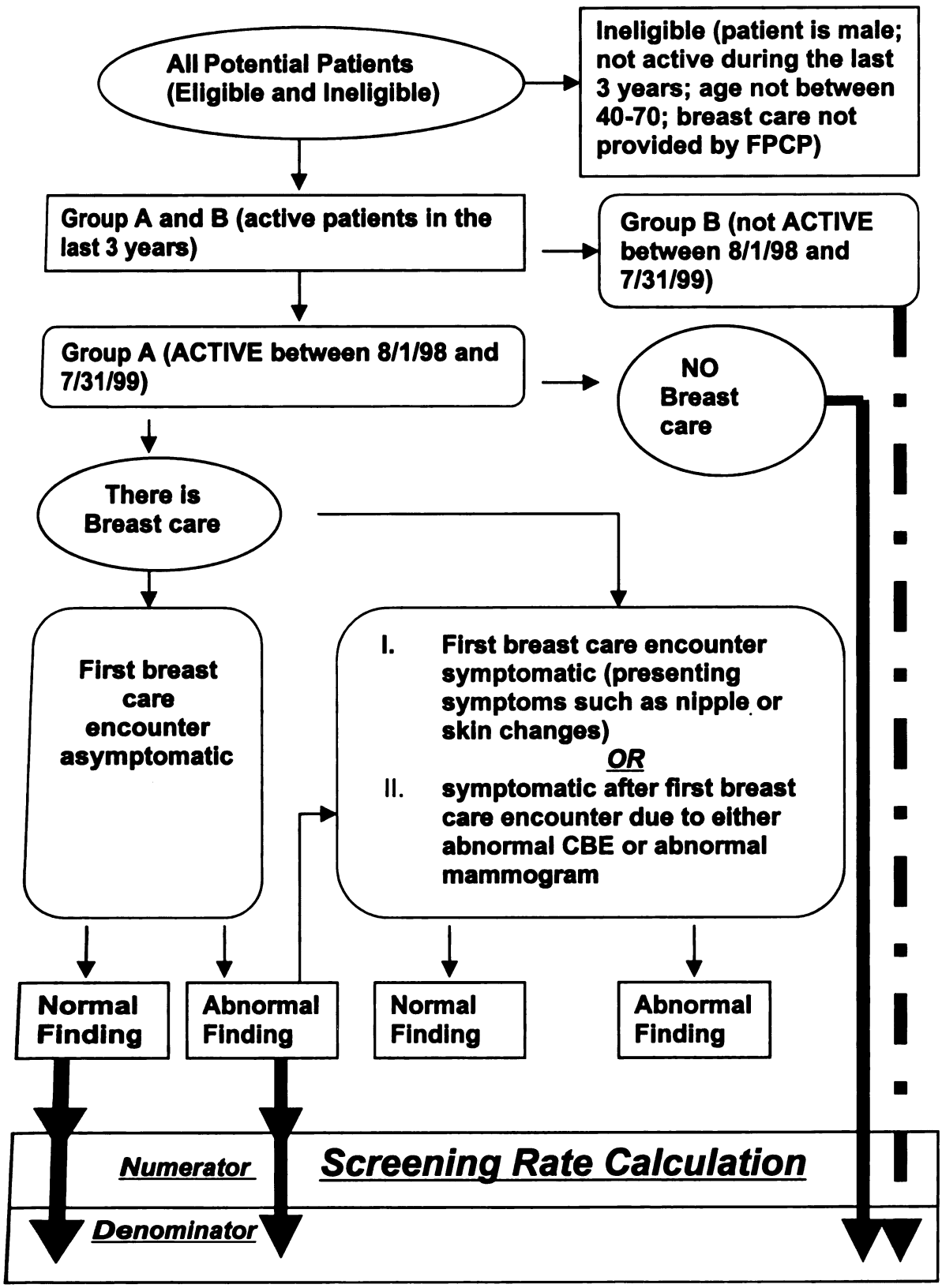
Table 4. Numbers And Percentages of Eligible Women In The Three Clinics, Broken Down By Eligibility Criteria

	Eligible Women			Ineligible Women	Total
	Group A[1]		Group B[2]		
	With Breast Care	Without Breast Care			
Site G	311 (57.6%)	87 (16.1%)	119 (22.0%)	23 (4.3%)	540
Site H	448 (51.4%)	205 (23.5%)	125 (14.3%)	94 (10.8%)	872
Site I	286 (31.9%)	219 (24.5%)	366 (40.8%)	25 (2.8%)	896

1 = Eligible women who have had one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99

2 = Eligible women who did not have one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99

Figure 1: Logistic Flow Chart



II. BC screening rates during the 15-month study period

Table 5 and 6 shows the BC screening rates in women who had at least one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99.

Our results shows that the percentages of CBE and mammography conducted differed between women older than 50 years and younger than 50.

For CBE, women older than 50 had higher, lower, and equal rates at clinic G, H and I, respectively, compared to women younger than 50. Among clinics G, H and I, the overall percentages of women who received at least one CBE were 53.0%, 45.2%, and 27.0%, respectively (Table 5). Among women aged 40-49, the rates were 44.0%, 49.2%, and 25.8%. Among women 50 years and older, the rates were 59.9%, 41.5%, 28.1% (Table 6).

For women aged 50 and older, the mammography screening rates were consistently higher than for women younger than 50, in all three clinics. The percentages of women who had at least one mammogram during the study period were 52.3%, 32.5%, and 28.0%, in the three clinics, respectively (Table 5). Among women aged 40-49, the rates were 41.5%, 24.4%, and 21.7%. Among women 50 years and older, the rates were 60.8%, 40.0%, and 34.0%(Table 6).

The percentages of women who had both CBE and mammogram were 35.8%, 22.8%, and 16.7%, in site G, H and I, respectively (Table 5). Among women aged 40-49, the rates were 26%, 19%, and 14%. Among women 50 years and older, the rates were 45%, 27.3%, and 19.7% (Table 6).

Table 7 shows the BC screening rates among women in GROUP A and GROUP B. It also demonstrate the rates in women who DID NOT have at least one office visit to the family practice clinic for any reason or had a phone call/reminder that's breast related during 8/1/98 and 7/31/99. With the inclusion of this latter group, the screening rates were even lower (Table 7). In site I, <10% of all women received both CBE and mammogram.

III. Time intervals between CBE and mammography

We examined the time interval between performance of CBE and mammography for asymptomatic women who had both examinations. Our results showed that in all three sites, CBE and mammography were performed within three months of one another 90-91% of the time (Table 5).

IV. Time intervals between when mammography was ordered and actually performed

We also evaluated the time interval between when a mammogram was ordered and when it was actually done. Among women who had at least one mammogram, 98.3%, 93.9%, and 96.2% of them had less than 3-month time intervals between the time that mammogram was ordered and when it was actually performed, in site G, H and I, respectively (Table 5).

Table 5. Annual BC Screening Rates Among Group A Women

	Site G	Site H	Site I
CBE ordered	58.7%	54.7%	28.8%
CBE performed	53.0%	45.2%	27.0%
Mammogram ordered	63.5%	42.9%	44.2%
Mammogram performed	52.3%	32.5%	28.0%
BC screening rate (within 3 month)	32.4%	20.7%	15.1%
BC screening rate (both done any time)	**35.8%**	**22.8%**	**16.7%**
Both tests done within 3 month	91.0%	91.0%	90.0%
Mammogram done within 3 month of recommendation	77.3%	60.2%	56.2%
Mammogram done anytime after recommendation	78.6%	64.1%	58.4%
Mammogram done within 3 month of recommendation	98.3%	93.9%	96.2%

Table 6: Annual BC Screening Rates By Age Groups

	SITE G			SITE H			SITE I		
	40-49	>50	Total	40-49	>50	Total	40-49	>50	Total
CBE ordered	50.6%	65.0%		55.0%	54.5%		26.9%	30.6%	
CBE done	44.0%	59.9%		49.2%	41.5%		25.8%	28.1%	
Mammogam ordered	51.8%	72.7%		35.6%	49.5%		33.6%	55.3%	
Mammogram done	41.5%	60.8%		24.4%	40.0%		21.7%	34.0%	
Both done	**25.9%**	**45.1%**		**19.0%**	**27.3%**		**13.7%**	**19.7%**	
Total n = (among group A women only)	173	225	398	315	338	653	259	246	505
Total n = (among all patients)	242	298	540	435	437	872	467	429	896

Table 7: Annual BC Screening Rates By Age Groups Including Women In Group B

	SITE G			SITE H			SITE I		
	40-49	>50	Total	40-49	>50	Total	40-49	>50	Total
CBE ordered	37.6%	50.7%		43.9%	47.7%		15.2%	17.8%	
CBE done	32.7%	46.8%		39.3%	36.3%		14.6%	16.4%	
Mammogram ordered	38.3%	56.3%		28.3%	43.3%		18.8%	32.5%	
Mammogram done	30.6%	47.0%		19.4%	35.0%		12.1%	20.0%	
Both done	**15.7%**	**31.5%**		**13.7%**	**20.8%**		**7.0%**	**9.9%**	
Total n = (among women in group A and group B)	231	286	517	393	385	778	456	415	871
Total n = (among all patients)	242	298	540	435	436	871	467	429	896

V. BC screening rates during an annual well-woman exam

The percentages of women in GROUP A who received an annual well-women exam were 58.0%, 43.5%, and 20.7% in site G, H, and I, respectively, during the period of 5/1/98 and 7/31/99. Among women 40-49, the percentages were 52.0%, 47.6%, and 18.1%. Among women 50 years and older, the percentages were 62.7%, 39.7%, and 20.7% (Table 8).

Table 8 shows the screening rates for women who received a well woman exam. Among women 40-49 years old, the percentages received CBE during a well woman exam were 76.7%, 95.9%, and 87.2%, in the three clinics respectively. For women 50 years and older, the percentages were 83%, 93.1%, and 76.5%. Women 50 years and older consistently received more frequent recommendations for mammography during a well woman exam than those younger than 50. The percentages were 63.5%, 51.9%, and 73.9%, for women 40-49 years old. Among women 50 years and older, the rates were 85.7%, 84%, and 91%.

Table 9 demonstrated that of all of the CBE performed during the study period, most were done during a well woman exam. In site G, among women aged 40-49, 93.2% of CBE was done during a well woman exam; among women age 50 years and older, 90% were done during a well woman exam. In site H, for women aged 40-49, 92.8% of CBE was done during an annual exam, and 89%

for women 50 years and older. In site I, among women aged 40-49, 62.1% of CBE were done during a well woman exam, and 57.4% for women aged 50 years and older. Table 9 further illustrates the percentages of mammograms that were recommended during an annual well-women exam. In site G, for women aged 40-49, the percentage of mammograms that were recommended during a well woman exam was 63.5%, and for women 50 years and older, the percentage was 75%. In site H, among women aged 40-49, the percentage was 63.9%, and for women 50 years and older, the percentage was 56%. In site I, for women aged 40-49, the percentage was 40%, for women 50 years and older, the percentage was 30%.

Table 8: Screening Rates In Women Who Received A Well Woman's Exam (WW) Between 5/1/98 and 7/31/99

	SITE G		SITE H		SITE I	
	40-49	>50	40-49	>50	40-49	>50
CBE ordered	76.7%	83.7%	98.0%	94.7%	87.2%	76.5%
CBE done	76.7%	83.0%	95.9%	93.1%	87.2%	76.5%
Mammoram ordered	63.5%	85.7%	51.9%	84.3%	73.9%	91.0%
Total n	90	141	147	131	47	51
% of women had a WW (among GROUP A women)	52.0%	62.7%	47.6%	39.7%	18.1%	20.7%

Table 9: Percentages of CBE Performed And Mammography Recommended During WW

	SITE G		SITE H		SITE I	
	40-49	>50	40-49	>50	40-49	>50
CBE Done in WW	69	117	141	122	41	39
Total CBE Done	74	130	152	137	66	68
Percentage of CBE Done in WW	93.2%	90.0%	92.8%	89.1%	62.1%	57.4%
Mammogram Ordered in WW	54	114	69	91	34	40
Total Mammogram ordered	85	152	108	162	85	135
Percentage of Mammogram ordered in WW	63.5%	75.0%	63.9%	56.2%	40.0%	30.0%

VI. BC screening rate among women who did not receive an annual well-woman exam between 5/1/98 and 7/31/99

Among women who did not receive an annual exam during our study period, the percentages of women who received CBE (during office visits for other medical reasons) were 6.0%, 6.8%, 11.8% for women 40-49 years, in clinics G, H, and I, respectively. For women 50 years and older, the percentages were 15.5%, 8%, and 14.9% (Table 10).

The percentages of mammograms ordered in patients who were not seen for annual well-women exams (but during other office visits, or as a result of phone or card reminders) were 37.3%, 24.1%, and 24.1% for women 40-49 years, in clinics G, H and I, respectively. Among women 50 years and older, the rates of mammography recommendation were 46.4%, 36%, and 48.7% (Table 10).

Table 10: Screening Rates Among Women Who Did Not Receive a Well Women (WW) Exam During 5/1/98 and 7/31/99

	SITE G		SITE H		SITE I	
	40-49	>= 50	40-49	>= 50	40-49	>= 50
CBE Done	5	13	11	15	25	29
Total n of women without WW	83	84	162	199	212	195
Percentage of CBE Done not in WW	6.0%	15.5%	6.8%	7.5%	11.8%	14.9%
Mammogram Ordered in WW	31	39	39	71	51	95
Total n of women without WW	66	62	125	175	212	195
Percentage of Mammogram ordered not in WW	37.3%	46.4%	24.1%	35.7%	24.1%	48.7%

VII. Compliance rate

Only 0.5-2% of women who had a CBE recommended refused the examination at the time of the office visit. The refusal rates for recommended mammography were 0.8-2% at the time of recommendation by the family practice physician. Table 11 lists the various reasons and total number of patients who refused, if they were recorded in the medical charts.

Table 11: Reasons And Numbers of Refusals When Test Is Recommended

	Reasons	**Numbers**
Site G	Refusal with no explanation	3
	Refused mammogram because it's too painful	1
Total		**4**
Site H	Due to insurance	4
	Refusal with no explanation	5
	Cited physician time restraint	3
	CBE deferred due to menstruating	1
	CBE deferred due to medical reasons / post surgical braces	1
Total		**14**
Site I	Due to insurance	2
	Refusal with no explanation	1
Total		**3**

VIII. The association between the total numbers of visits and the BC screening rates

The association between the total numbers of visits during the 15-month period (proxy indicator), prior to the last office visit during 8/1/98 and 7/31/99, and the BC screening rates was also analyzed. We made the assumption that each office visit represented an equal and independent opportunity for a CBE, and each office visit/phone call consultation represented an equal and independent opportunity for a mammography referral. Therefore, the likelihood of obtaining a CBE or mammogram should increase predictably with each additional visit.

In Site G, the total numbers of visits among ACTIVE patients ranged from 1 to 28. In site H, the numbers ranged from 1 to 29. In site I, the number ranged from 1 to 34. Logistic regression was used to analyze the association between the total visits and the BC screening rates. Table 12 shows that in all three sites, mammography screening rates were significantly higher for those with beyond 5 visits, compared to those with 1-2 visit(s). In site I, CBE ordering and performed were significantly higher for those patients with beyond 3 visits than those with 1-2 visit(s). In addition, the screening rates of BC (both CBE and mammography) in site I were higher for those with beyond 5 visits.

Table 12. Odds Ratios and 95% Confidence Intervals For the Association Between Total Number of Visits and BC Screening Rates

Site G	N	CBE ordered	CBE done	Mammo-gram ordered	Mammo-gram done	Both done
Total visit: 1-2	53	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	84	0.96 (0.47-1.95)	1.13 (0.56-2.62)	1.53 (0.76-3.07)	1.52 (0.76-3.06)	1.18 (0.55-2.55)
Total visit: beyond 5	198	0.92 (0.49-1.72)	0.94 (0.51-1.73)	**2.21 (1.19-4.11)**	**2.25 (1.21-4.18)**	1.56 (0.79-3.06)
Site H		**CBE ordered**	**CBE done**	**Mammo-gram ordered**	**Mammo-gram done**	**Both done**
Total visit: 1-2	101	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	120	1.12 (0.65-1.91)	1.25 (0.74-2.13)	1.12 (0.65-1.91)	1.2 (0.66-2.19)	0.97 (0.49-1.91)
Total visit: beyond 5	318	1.13 (0.72-1.78)	1.2 (0.77-1.89)	1.29 (0.82-2.03)	**1.99 (1.2-3.3)**	1.33 (0.76-2.34)
Site I		**CBE ordered**	**CBE done**	**Mammo-gram ordered**	**Mammo-gram done**	**Both done**
Total visit: 1-2	107	1.0	1.0	1.0	1.0	1.0
Total visit: 3-4	88	**2.13 (1.05-4.33)**	1.92 (0.92-4.0)	**4.41 (2.26-8.59)**	2.24 (0.93-5.4)	**3.95 (1.04-15.1)**
Total visit: beyond 5	287	**2.56 (1.42-4.6)**	**2.54 (1.39-4.63)**	**5.33 (3.02-9.4)**	**5.3 (2.57-11.0)**	**7.14 (2.18-23.4)**

CHAPTER 4 DISCUSSION

I. BC screening rates

Our results showed that 25.8 – 59.9% of women in the three clinics received CBE, 21.7 – 60.8% received mammography and 13.7 – 45.1% received both CBE and mammography during our study period. These screening rates are far short of the Healthy People 2000's recommended mammography and CBE combined screening rate of 60%.

In addition, we found that in all three clinics, the mammography screening rates were consistently higher among women 50 years or old, compared to those less than 50. This seemed to be consistent with the current mammography screening guidelines: every major professional organization recommends mammographic screening in women 50-69 at intervals of 1-2 years [3]. However, recommendations are inconsistent for women aged 40-49 and 70 and over.

CBE screening rates varied by site. In Site H, screening rates for CBE were higher among women younger than 50 than those greater than 50, while in Site G, the reverse was true. In site I, women less than 50 and greater than 50 had the same CBE screening rates.

II. Time intervals

Our results showed that over 90% of mammograms and CBEs were done within 3 months. The same applied to the time interval between when mammography was ordered and when it was actually performed.

The potential explanation for why most mammograms were performed within three months was that the impact of a physician's recommendation was most likely to be the strongest close to the time it is made. Longer intervals between the time the test was recommended and actually performed may have diluted the motivation inspired by the physician's recommendation.

III. BC screening during an annual exam

Consistent with Conry's results [43], we found that the percentages of CBEs performed during an annual exam were very high in all three sites. The percentages of women who received mammography recommendations from the family practice physicians were also high during a well woman exam. These results can be confirmed by the fact that extremely low percentages of women with no well woman visit received CBE during our study period. At least in two sites (site G and site H), over 90% of CBE was performed during an annual well-women exam.

The percentages of women with no annual exam who received a mammography recommendation were high. This may reflect the fact that mammograms can be ordered by phone or mammogram reminders, in addition to office visit.

However, we also showed that percentages of women who received an annual well-women exam during our study period are relatively low in all three sites (18.1 – 62.7%). Interventions should be carried out to improve physician and patients' education about the importance of a well woman exam.

IV. Total numbers of office visits and the screening rates

Our results demonstrated that the total number of visits made by a woman during the 15-month period is related to higher screening rates. We found that among all three sites, the mammography performed rates were higher for women with beyond 5 visits, as compared to those with only 1-2 visit(s). In site I, the CBE ordered and performed rates were also higher for this group, as compared to those with only 1-2 visits.

McCarthy et al also found that the mammography rate was related to the number of visits a patient had [36]. Women who had 2-10 visits had the highest mammography use, compared to those with 1 visit or with visits beyond 10. Among women with more than 10 visits, the rate is lower probably due to the fact

that these patients have other severe and more pressing chronic illnesses that focus attention away from preventive health measures.

However, other investigators found that total numbers of visits are not related to the screening rate [31].

V. Chart audit vs. self-reported interviews

It has generally been observed that there may be substantial differences between information obtained from medical records audits and that obtained from patient self-reported interviews. Whitman et al tried to determine whether chart reviews and interviews provide the same information about breast cancer screening [39]. They collected the percentage of women older than 40 who received a breast exam, and the percentages of women aged older than 50 who received a mammogram at two different public health clinics in Chicago. They used both chart reviews and telephone interviews of women participants. They found that interviews significantly estimated higher proportions of women receiving breast exam and mammograms in the previous 12 months interval than were estimated from randomly selected medical records. There are several possible reasons for the discrepancies: first the medical records may be incomplete; second the women being interviewed may incorrectly recall the time when the test was performed, or even which test they obtained; third women could be recalling tests they have done outside the clinics. Their results

suggested that precautions should be taken on the usage of survey data as measures of actual performance. It should be accompanied by comparing these measures with data of actual performance at the medical record level.

VI. Interventions to increase BC screening rates

One strategy for increasing BC screening rates is to enhance physician referrals. A physician's recommendation is one of the most important predictors that a woman will receive a screening mammogram. A better understanding of the factors that influence physician's referral behavior is critical in designing strategies to increase population coverage of BC screening. Enhancing mammography referrals from primary care physicians is of particular public health importance because they see a broad demographic and geographic spectrum of women. Physicians' screening mammography referral rates have been found to vary by physician age, gender, and knowledge or attitudes. Compared with older physicians, younger physicians have a greater tendency to incorporate preventive care into their practice, to disagree less with evidence-based guidelines, and to favor a more frequent screening interval for BC screening [32] [33] [34] [35] [44].

Fletcher et al tested whether a community-wide intervention could increase the usage of mammography screening for BC [45]. They conducted a controlled study from 1/87 to 1/90 in two Eastern North Carolina communities.

During 1989, interventions were developed and aimed at primary care physician and community participating women. Physicians underwent training sessions about CBE skills. To reach community women, they used local media and organizations. They also reviewed medical charts to determine the percentage of women the physicians had referred for mammography. They found that the percentage of women who reported receiving a mammogram increased from 35 to 55% in the experimental community and from 30 to 40% in the control community. The intention to get a mammogram among eligible women was also significantly increased. Physician reports and medical record reviews in the communities showed similar increases in the number of mammograms ordered.

VII. Study strengths

One strength of this study was that we abstracted medical records to calculate BC screening rates in the three Michigan clinics. Summary sheets were made for all breast care related visits that were recorded and reviewed manually. CBE or mammography performed for diagnostic, rather than screening, purposes were identified and excluded. Our sample sizes for clinics G, H and I were 540, 872, and 896, respectively. In addition, we performed a very comprehensive BC screening rate calculation, including the ordered and performed rates of CBE and mammography alone or combined, time interval between CBE and mammography, time interval between when a mammography was ordered and when it was performed, compliance rates for CBE or mammography after

recommendation, BC screening rates during well-woman exams. In addition, the screening rates were broken down to women 40-49 and women 50-69, in order to reflect the different national guidelines for the two age groups.

VIII. Study limitations

In interpreting results from the analysis, some limitations should be considered. First, some CBE or mammography recommendations may have been performed or verbal without being documented in the medical record. Second, the chart audit may not be 100% reliable due to missing information. For example, mammograms could have been performed elsewhere and not documented in the charts.

In addition, though not a limitation of the screening rate calculations reported, it would have been more helpful if we had collected some other potential screening rate predictors, such as social economic status and insurance coverage for all patients in the different clinics. These variables might contribute to the differences in the screening rates among different sites.

CHAPTER 5 CONCLUSION

Our results underline two important points: (1) the current BC screening rates for CBE and mammography individually or combined are unacceptably low in the three family practice clinics we studied and (2) when screening is recommended, compliance with the recommendation is above 98% and accomplished 90% of the time within 3 months. To meet the Healthy People 2000 recommended mammography and CBE combined screening rate of 60%, interventions to improve these findings at family practice clinics is urgently needed.

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Appendices

Appendix 1

Form I- Front-End Form

Add New Patient

Patient Name (Last): testing
(First):
Medical Record Number:
Date Of Birth:
Abstractor's ID:

Data Transfer

Eligibility Criteria:Check One Item For Each Statement (1-5)

1. Patient gender is:
2. Patient has been seen in last three years
3. Patient birthday is between August 1, 1928 and July 1, 1959
4. Breast health care provided by
5. Active patient between 8/1/98-7/31/99

Meaning of Eligibility Code:

For site number 1-5:
1= Eligible for abstract and insertion
2= Eligible for insertion only
3= Ineligible

For site number 6-9:
1= Eligible for abstract
2 or 3= Ineligible

Click to Determine Eligibility Code:

Rules for Assigning Study ID:

Study ID is a 6-digit number. The first digit is your site number. The second digit is the Eligibility code shown in the box above. The rest four digits are consecutive numbers starting 0001.

Please assign study ID: 1 **Today's Date:** 11/11/11

For your reference, please look in the box on the right, find out what was the last number assigned for that specific eligibility category, and use the next consecutive number.

For eligibility code =	110267
For eligibility code =	120133
For eligibility code =	130202

Click here To Continue

Add New Patient

Chart Review Form (Only For Eligible Patient)

Study ID: 1

1. Date of Most Recent Office Visit (MM/DD/YY):

2. Autocalculated Date For the Last Eligibile Visit Within the Last 15 months (MM/DD/YY):

3. Total Number of Visits Within 15 Months, Including The Most Recent Visit:

4. Was A Breast Care Performed During Any of The Visits Within The 15 Months Period:

5. Personal/Family History Of Breast Cancer?

Add New Patient

Rule for filling in the age at diagnosis:

1) Fill in exact age when information is availabe;
2) Fill in '777' if only known Pre-menopausal equal to or less than 50 years ol
3) Fill in '888' if only known Post-menopausal or greater than 50 years old;
4) Fill in '999' if no information is available.

In Self? No Age:

Surgery/Reconstruction:

- ☐ Complete Breast Removal
- ☐ Partial Breast Removal/Lumpectomy
- ☐ Prophylactic Implants
- ☐ Autologous Reconstitution
- ☐ Other, specify
- ☐ Undocumented

Treatments (check all that apply)

- ☐ Chemotherapy
- ☐ Radiation
- ☐ Tamoxifen/Nolvadex
- ☐ Alternative medicine(s), specify
- ☐ Other, specify
- ☐ Undocumented

In Mother? No Age:

In Sister? No ☐ Sister1 Age: ☐ Sister2 Age:

In Daughter? No ☐ Daughter1 Age: ☐ Daughter2 Age:

In Other Relatives? No Please specify:

BOX-A Record information for patient's each visit when a breast care was performed. Start with the first visit when any breast care activity was recorded during that 15 months period. Click the button on the right to continue.

Go To First Patient | Go To Previous Patient | Go To Next Patient | Go To Last Patient

(Click Any of the Buttons Above to Navigate the Record)

Form II- Visit Entry

Add New Visit | Go To First Visit | Go To Previous Visit | Go To Next Visit | Go To Last Visit

Go Back to Front-End

Study ID: 1

Please fill out Question 6 and Question 7 for every visit/call.

6. Date of Breast Care Activity Was Recorded: 11/11/11

Type of Contact:

7. Purpose of this Visit/Call:

Specify:

If this visit is about a test result, you can directly go to Test Result Form, without filling out CBE documentation

Go Directly to Test Result Form

8. Who Performed Breast Care/Phone Consultation? (Check All That Apply)

☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner

9. Patient Presenting Symptoms/Signs (Check All That Apply)

Which breast(s) has presenting symptom?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:	**Right Breast:**
☐ **None** ☐ **Undocumented/Don't know**	☐ **None** ☐ **Undocumented/Don't know**
☐ Lump(s)/Mass(es)/Asymmetrical thickening	☐ Lump(s)/Mass(es)/Asymmetrical thickening
☐ Nipple Discharge	☐ Nipple Discharge
☑ Skin/Nipple change (check all that apply)	☑ Skin/Nipple change (check all that apply)
☐ Skin Dimpling ☐ Erythema/Skin thickening	☐ Skin Dimpling ☐ Erythema/Skin thickening
☐ Nipple Retraction ☐ Nipple Scaling	☐ Nipple Retraction ☐ Nipple Scaling
☐ Pain/Tenderness	☐ Pain/Tenderness
☑ Occult Mammographic Abnormality	☑ Occult Mammographic Abnormality
☐ Density(Nodule or Asymmetry)	☐ Density(Nodule or Asymmetry)
☐ Microcalcifications	☐ Microcalcifications
☐ Other, specify:	☐ Other, specify:

10. CBE Documentation:

11. CBE Findings (Check All That Apply):

☐ **Bilateral Implants**

☑ **Previous abnormality resolved**

☐ Lump/mass resolved ☐ Observational finding resolved ☐ Nipple discharge resolved ☐ Pain gone

☐ **Normal/Symmetrical nodularity/Symmetrical fibrocystic(Fill Out Quality of CBE Documentation)**

Quality of Written Description of CBE Documentation (Check All That Apply):

☐ Inspection, specify:	Nipple Change	Undocumented	Breast Size/Sha	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
☐ Palpation, specify:	Fibrocystic Bre	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
☐ Lymph node examination	Adenopathy/Axillary Nodes	Undocumented		

☐ **No specific documentation besides normal**

☐ Other, Specify:

Abnormal: Which breast(s) has abnormal finding?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:	**Right Breast:**
Location:	Location:

☐ Lump(s)/Mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retractio	Undocumented
Skin Erythema	Undocumented
Skin Peau d'orange or Skin Thickening	Undocumented
Nipple Retracti	Undocumented
Nipple Scaling	Undocumented
Pain/Tenderness	Undocumented
Fibrocystic Breast(s)	Undocumented
Nipple Discharge	Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☑ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☑ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

☐ Lump(s)/mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic

Lump size:

Depth:

Hardness:

Mobility:

Shape:

Texture:

Additional Findings With Lumps (check all that apply):

Skin Dimpling/Retractio	Undocumented
Skin Erythema	Undocumented
Skin Peau d'orange or Skin Thickening	Undocumented
Nipple Retraction	Undocumented
Nipple Scaling	Undocumented
Pain/Tenderness	Undocumented
Fibrocystic Breast(s)	Undocumented
Nipple Discharge	Undocumented

☐ Other, Specify:

☐ Nipple Discharge With No Lump

Spontaneous?

Color

Unilateral or bilateral?

Single or multiple ducts?

☑ Observational Findings With No Lump

☐ Skin dimpling/retraction

☐ Skin Erythema

☐ Skin Peau d'orange/Skin Thickening

☐ Nipple retraction

☐ Nipple scaling

☑ Pain

☐ Breast pain

☐ Chest wall pain

☐ Unspecified

☐ Other, specify:

Quality of Written Description of CBE Documentation For Abnormal Findings (Check All That Apply):

☐ Drawing of abnormal findings				
☐ Inspection, specify:	Nipple Change	Undocumented	Breast Size/Sha	Undocumented
	Scar	Undocumented	Skin Change	Undocumented
☐ Palpation, specify:	Fibrocystic Breast	Undocumented	Nodularity	Undocumented
	Mass(es)	Undocumented	Pain/tenderness	Undocumented
☐ Lymph node examination				
Adenopathy/Axillary Nodes Undocumented			Lymph Node Enlarged?	
☐ Other, Specify:				

Go To Followup Form | Go To Test Result Form

Form III-Test Result Entry

Study ID: 1 **Date of the Visit:** 11/11/11

12. Mammogram Documentation:

1. Ordered/Recommended/Encouraged		Date:
2. Mammogram Performed		Date:
3. Results Obtained	Stamped/Documented?	Date:
4. Results Reviewed By FPCP	Signed/Documented?	Date:

13a. Mammogram Findings: Final Impressions Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast:	**Right Breast:**
☐ **Normal/No Finding Identified/Category I**	☐ **Normal/No Finding Identified/Category I**
☐ **Normal/Benign-appearing abnormality/Categor**	☐ **Normal/Benign-appearing abnormality/Catego**
☐ Probably benign/possibly malignant, inderterminate /Category III	☐ Probably benign/possibly malignant, inderterminate /Category III
☐ Suspicious for malignancy/Category IV	☐ Suspicious for malignancy/Category IV
☐ Malignant until proven otherwise/Category V	☐ Malignant until proven otherwise/Category V
☐ Other: Specify:	☐ Other: Specify:

13b. Mammogram Findings: Description Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

Left Breast: **Right Breast:**

☐ Asymmetric Breast: more in which breast

☐ Bilateral Implants	☐ Bilateral Implants
☐ Radiolucent Breasts	☐ Radiolucent Breasts
☐ Dense Breasts/Dense Nodular Breasts	☐ Dense Breasts/Dense Nodular Breasts
☐ Rounded density(ies), most likely cyst or fibroaden	☐ Rounded densities, most likely cyst or fibroadeno
☐ Irregular Density(ies)	☐ Irregular Density(ies
☐ Benign Appearing Calcifications	☐ Benign Appearing Calcifications
☐ Suspicious Calcification	☐ Suspicious Calcification
☐ Calcified Fibroadenomas	☐ Calcified Fibroadenomas
☐ Axillary Lymph Nodes	☐ Axillary Lymph Nodes
☐ Other, specify:	☐ Other, specify:

13c. Mammogram Findings: Location For Category II and Up Which Breast?

If you don't know which breast, please record information in "Left Breast" category.

IF AREA NOT SPECIFIED, check SCATTER/THROUGHOUT Breast category

Left Breast Location: **Right Breast Location:**

☐ Upper Outer Quadrant ☐ Lower Outer Quadrant	☐ Upper Outer Quadrant ☐ Lower Outer Quadrant
☐ Upper Inner Quadrant ☐ Lower Inner Quadrant	☐ Upper Inner Quadrant ☐ Lower Inner Quadrant
☐ Lateral Breast	☐ Lateral Breast
☐ Medial Breast	☐ Medial Breast
☐ Areolar/Nipple Area	☐ Areolar/Nipple Area
☐ Deep Against Chest Wall	☐ Deep Against Chest Wall
☐ Scattered/Throughout Breast	☐ Scattered/Throughout Breast
☐ Other, specify:	☐ Other, specify:

14. Patient Notified of the Mammogram Findings? ☐ Date of Notification:

15.Cyst-Fine Needle Aspiration (FNA)

Done by: **Date done:**

☐ Mass resolved/fluid not bloody ☐ Fluid bloody

☐ Residual Mass

☐ Other, specify:

☐ **Sent Fluid to Cytology**

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

Cytology Results:

☐ Insufficient/Hypocellular/Apocrine Cells ☐ Malignant

☐ Atypical cells ☐ Suspicious for malignancy ☐ Benign/Fibrocystic/Apocrine Cells

☐ Other, specify:

16. Patient Notified of the FNA Findings From Cytology? Date of Notification:

17. Solid Mass-Fine Needle Aspiration Biopsy (FNAB)

Done by: **Date done:**

☐ **Specimen Submitted For Analysis**

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

Pathology Results:

☐ Insufficient/Hypocellular ☐ Benign/Fibrocystic ☐ Atypical cells

☐ Suspicious for malignancy ☐ Malignant

☐ Other, specify:

18. Patient Notified of the FNAB Findings From Path Report? Date of Notification:

19. Ultrasound Findings:

Ordered by: **Date done:**

Results Obtained Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

☐ Negative finding ☐ Simple cyst(s) ☐ Solid mass(es) or complex cyst(s)

☐ Other, specify:

20. Patient Notified of the Ultrasound Findings? Date of Notification:

21. Image-Guided Biopsy/Open Biopsy Results: Date done:

Results Received Stamped/Documented? Date:

Results Reviewed By FPCP Signed/Documented? Date:

Open Biopsy Findings(check all that apply):

☐ Benign/No Evidence of Malignancy
☐ Benign/Fibrocystic Changes
☐ Benign/Fat Necrosis
☐ Benign/Lipoma
☐ Benign/Fibroadenoma
☐ Other, specify:

☐ Ductal Carcinoma in situ
☐ Lobular Carcinoma in situ
☐ Atypical Hyperplasia
☐ Invasive Ductal Carcinoma
☐ Invasive Lobular Carcinoma

Go Back to Visit Form Go To Followup Form

Form IV-Follow-up Entry

StudyID: [redacted] **Date of Visit:** 11/11/11

23. Recommended Follow-Up(s) (Check All That Apply)

☐ **Undocumented**

Follow-up for Normal CBE and Mammogram (or One of Them Undocumented):

☐ Routine Screening ☐ 12 Month CBE ☐ 12 Month Mammogram

☐ Following ACS Guidelines ☐ Following Other Guidelines specify:

Recommended by: Comments:

Follow-up for Specific Abnormalities: **Follow-up To Any Abnormalities:**

Breast Mass/Asymetry Initial Approach:

- ☐ CBE at better phase cycle (3-10 days)
- ☐ Fine Needle Aspiration for Cyst

If Known Breast Cyst:

- ☐ Send Fluid to Cytology ☐ Reaspiration
- ☐ (How many) month CBE

If Known Solid Mass:

- ☐ Fine Needle Aspiration Biopsy
- ☐ Specimen Submitted for Analysis
- ☐ Repeat aspiration
- ☐ Clinical Followup Every 3 Months for 1 Year

For Nipple Discharge:

- ☐ Endocrine work-up

For Skin/Nipple Changes on Observation:

- ☐ 2 weeks antibiotics ☐ Skin Biopsy
- ☐ 2 weeks topical hydrocortisone

For Breast pain:

- ☐ Eliminate Caffeine
- ☐ Adjust Estrogen Dose
- ☐ Local Anesthetic Injection
- ☐ Primrose Oill, How Many Months? ☐
- ☐ Reassurance and CBE within 3-6 months if pain persists
- ☐ Supportive Brassiere
- ☐ Over-the-counter Analgesics
- ☐ Danazol, Bromocriptine

For Occult Mammographic Abnomality:

- ☐ Radiologic Biopsy/Image-Guided Biopsy

Recommended by:

- ☐ Call if Problem Worsens
- ☐ Routine Screening

Recom. by:

Immediate Mammogram Workup:

- ☐ Regular Mammogram
- ☐ Extra Mammogram Views
- ☐ Cone or Spot Compression
- ☐ Magnification Views

Recom. by:

Interval Followup:

- ☐ (How many) month mammogra
- ☐ (How many) month CBE

Recom. by:

- ☐ Ultrasound

Recom. by:

- ☐ **Surgical Referral**

Recom. by:

- ☐ Undocumented

Other Recommendations Or Comments Concerning Abnormality(ies):

General Comments About This Visit:

Assessment/Recommended Follow-up From Surgeon's Letter

1. Letter Written	Date:	
2. Letter Received	Stamped/Documented?	Date:
3. Letter Reviewed by FPCP	Signed/Documented?	Date:

Assessment

- ☐ Referral Diagnosis Not Confirmed
- ☐ Referral Diagnosis Confirmed
- ☐ Additional/New findings
- ☐ Further Tests Recommended/Done By Surgeon, check all that apply
  - ☐ Immediate Mammogra
  - ☐ Interval Mammogram, how long
  - ☐ Interval CBE, how long?
  - ☐ Ultrasound
  - ☐ FNA
  - ☐ FNAB
  - ☐ Radiological/Image Guided Biopsy
  - ☐ Open Biopsy
- Evidence of Malignancy? No
- ☐ Previous Abnormality Resolved
- ☐ Current Abnormality Resolved
- ☐ Other Comments From Surgeon's Lette

Followup

- ☐ **No Further Workup Required**
- ☐ **Followup In Primary Care Office**
- ☐ **Followup In Surgeon's Office**

Go Back to Form II | Go Back to Form III | Add New Visit | Add New patient

Appendix 2

Kappa Calculation for Quality Control

To perform the quality control we chose the relevant fields in the database for which a kappa value could be calculated. The Kappa value is the ratio of the agreement actually observed minus the agreement expected by chance, divided by 1 (which corresponds to perfect agreement) minus the agreement expected by chance:

$$K = (P_A - P_C)/ (1 - P_C)$$

Kappa statistics were derived using the SAS program. The simple kappa coefficient measures the agreement between the abstractors beyond what could be expected by chance.

Displayed below are three examples of the types of Kappa calculations performed on the data. These examples display the data collected, the SAS code used, and the output produced by SAS.

Examples of Kappa calculation:

1. For fields with numerical value entries:
   The following table is the data entered by both the abstractor and quality control person for the question "Total numbers of visits within 15 months, including the most recent visit" (question #3 on Front End Form). In this case these numerical values were compared. In the table you will notice the discrepancy between the abstractor and quality control for patient number 4.

	Abstractor	Quality Control
Patient 1	6	6
Patient 2	2	2
Patient 3	2	2
Patient 4	5	6
Patient 5	3	3
Patient 6	4	4
Patient 7	6	6
Patient 8	9	9

After this table is made, the data is input into SAS for Kappa calculation. The Kappa results are the followings:

Kappa Statistics

Statistic	Value	ASE	95% Confidence Bounds	
Simple Kappa	0.8431	0.1430	0.5628	1.1234

Sample Size = 8

2. Field labeled 0 or 1:
   For fields with only 0 or 1 value, i.e. unchecked versus checked boxes respectively, in the ACCESS Database, a different method of Kappa calculation was used. An example of a scenario where this occurs is on form II-Visit Entry. In this section the abstractors is asked to record CBE documentation. One portion of the section is to indicate if the lymph node examination is documented. The following table was made comparing the abstractor versus quality control observations of whether during the CBE the doctor documented a lymph node examination. In this example "1" signify lymph node examination was documented and "0" means they it was not.

	Abstractor	Quality Control
Visit 1	0	1
Visit 2	0	0
Visit 3	0	0
Visit 4	0	0
Visit 5	0	0
Visit 6	0	0
Visit 7	1	1
Visit 8	1	1
Visit 9	0	0

   After this table is made, the data is transferred into SAS for Kappa calculation. The Kappa results are the followings:

```
Simple Kappa Coefficient
--------------------------------
Kappa                     0.7273

Sample Size = 9
```

3. Situations where Kappa is calculated to be 0%:
   There are some fields with Kappa value equaling 0%. For these situations included in parenthesis was the percent agreement. It has been documented and determined by our study group that in some situations the Kappa statistics is not the best way to represent the data and that in those situations the percent agreement is more appropriate.

   An example is included for bilateral mammogram findings. For a bilateral mammogram, the abstractor is required to record mammogram findings for both breasts. However, sometimes the abstractors would forget to record the bilateral mammograms findings for one of the breasts.

   The following table is the summary of bilateral mammogram documentation results for several patients comparing quality control to the abstractor. In this case "1" signifies mammogram documentation and "0" signifies no mammogram documentation. In this scenario the abstractor missed recording the mammogram documentation compared to the quality control for patient 4.

	Quality Control	Abstractor
Patient 1	1	1
Patient 2	1	1
Patient 3	1	1
Patient 4	1	0

The Kappa results are the followings:

Simple Kappa Coefficient

Kappa	0.0000

Sample Size = 4

On the other hand, the percent agreement is calculated to be:

(4 – 1) / 4 = 75%

Table 1: Kappa Results From Form-I (General Information Form)

Abstractor ID	Eligibility Code	Date Most Recent Office Visit (Q2)	Total Number of Visits Within 15 Months (Q3)	Total Breast Care Related Encounter(s)
11	*	*	77%	88%
12	*	*	86%	*
21	64%	*	72%	58%
22	69%	*	89%	64%
31	*	*	84%	88%
32	*	*	85%	74%
41	60%	*	74%	70%
42	84%	86%	*	*
51	*	*	*	*
52	85%	*	70%	*
61	84%	*	88%	59%
62	*	89%	*	87%
71	83%	*	*	75%
81	*	86%	74%	*
82	*	*	*	84%
91	*	*	*	77%
92	86%	*	86%	67%

Note: "*" = 100% Kappa Result

Table 2: Kappa Results From Form-II (Visit Entry Form)

Abstractor ID	Type of Contact (Q6)	Symptom Lump R (Q9)	Symptom Lump L (Q9)	CBE Documentation			Abnormal Lump R (Q11)	Abnormal Lump L (Q11)
				Inspection (Q11)	Palpation (Q11)	Lymph Node Exam (Q11)		
11	*	*	*	*	*	78%	*	*
12	*	*	*	*	*	67%	0 (83)%	0 (83)%
21	*	*	*	*	*	*	*	*
22	*	*	*	62%	*	*	*	*
31	*	*	*	*	*	*	*	*
32	91%	*	0 (92)%	*	80%	*	0 (92)%	63%
41	88%	*	*	*	*	75%	*	*
42	*	*	*	*	*	*	*	63%
51	89%	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*
61	*	*	*	71%	*	*	*	*
62	*	*	*	*	*	*	*	*
71	90%	*	*	77%	*	*	*	*
81	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*
91	*	*	*	62%	*	49%	0 (91)%	0 (91)%
92	*	*	*	70%	*	70%	*	*

Note: "*" = 100% Kappa Result
( ) = percent agreement

Table 3: Kappa Results From Form-III (Test Result Entry Form)

	Mammogram Findings											
Abs ID	Cat[1] I Right	Cat II Right	Cat III Right	Cat IV Right	Cat V Right	Cat VI Right	Cat I Left	Cat II Left	Cat III Left	Cat IV Left	Cat V Left	Cat VI Left
11	*	*	*	*	*	*	*	*	*	*	*	*
12	*	*	*	*	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*	*	*
31	*	*	*	*	*	*	*	*	*	*	*	*
32	*	*	*	*	*	*	*	*	*	*	*	*
41	*	*	*	*	*	*	0 (80)%	*	*	*	*	*
42	0 (75)%	*	*	*	*	*	*	*	*	*	*	*
51	*	*	*	*	*	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*	*	*
71	*	*	*	*	*	*	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*	*	*

Note: Cat[1] = Category
"*" = 100% Kappa Result
( ) = percent agreement

Table 4: Kappa Results From Form-IV (Followup Form)

Abs ID	Undocu-mented	Routine Screening	12 month CBE	12 month mammo	Immediate Mammo	Extra Views	Interval Mammo	Interval CBE	Ultra-sound	Surgical Referral
11	83%	87%	*	*	*	*	*	*	*	0 (88)%
12	73%	78%	*	*	*	*	*	*	*	*
21	*	*	*	*	*	*	*	*	*	*
22	*	*	*	*	*	*	*	*	*	*
31	83%	*	0 (95) %	*	*	*	*	0 (95)%	*	*
32	*	*	*	*	*	*	*	*	*	*
41	66%	*	*	81%	*	*	*	*	*	*
42	*	*	*	*	*	*	*	*	63%	*
51	*	*	*	*	*	*	*	*	*	*
52	*	*	*	*	*	*	*	*	*	*
61	*	*	*	*	*	*	*	*	*	*
62	*	*	*	*	*	*	*	*	*	*
71	*	*	*	82%	*	*	*	*	*	*
81	*	*	*	*	*	*	*	*	*	*
82	*	*	*	*	*	*	*	*	*	*
91	*	*	*	*	*	*	*	*	*	*
92	*	*	*	*	*	*	*	*	*	*

Note: "*" = 100% Kappa Result
( ) = percent agreement