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DESCRIPTION OF THE DATA CLEANING PROCESS AND DESCRIPTIVE ANALYSIS OF THE ENTIRE DATASET AND THE ABNORMALITIES FOUND IN A MULTI-SITE BREAST CANCER STUDY CONDUCTED BY MICHIGAN STATE UNIVERSITY.

presented by

NAGESH NARAYAN BORSE

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Major Professor's Signature

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By

Nagesh Narayan Borse

A THESIS

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ABSTRACT

DESCRIPTION OF THE DATA CLEANING PROCESS AND DESCRIPTIVE ANALYSIS OF THE ENTIRE DATASET AND THE ABNORMALITIES FOUND IN A MULTI-SITE BREAST CANCER STUDY CONDUCTED BY MICHIGAN STATE UNIVERSITY

By Nagesh Narayan Borse

Data for the analytic portion of my thesis came from a study supported by the Department of Defense (DOD), Dorothy Pathak, PI, entitled "Improved Follow-up of Breast Abnormalities through Comprehensive Breast Care in Women 40 to 70 Years of Age". This was a community-based randomized controlled trial whose aim was to enhance primary care physicians' skills in secondary prevention, diagnosis and follow-up of abnormal findings in the control of breast cancer for woman 40 to 70 years of age. Data from all breast-related encounters were abstracted for visits between August 1, 1998 and July 31, 2000 in Microsoft Access software using four forms. Data cleaning was done using SAS Version 8 and was done primarily to identify any duplicate information and recoding required. For analysis purpose subsets were created based on intervention and control sites, age of the patient, normal and abnormal findings etc. In the final step, frequency analysis was carried out on main variables in the study. Screening rates were calculated using three methods for overall study, intervention sites and control sites.

The total number of patients in the final database is 10,101 for Year 1 and 12,816 with almost 30,000 breast care entries. Two year patient based screening rate was 68% for CBE done, 42% for mammogram ordered and done and 74% for mammogram either ordered or done. The combined (CBE and Mammogram done) screening rate was 54% based on patient based screening rate, 59% based on physician based screening rate and 46% based on practice based/public health screening rate.

DEDICATION

To my aunt *'Akka-aatya'* and all those other women in developing world who could not seek any type of care and died due to undetected breast cancer.

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My thesis project at the Michigan State University has contributed a lot to my knowledge and skills. Firstly, thanks to my parents Mr. Narayan Borse and Mrs. Laxmi Borse who supported my decision to come to the USA and attend my master's degree program at the Michigan State University. My parents deserve a special thank for being so accommodating with my plans. I also want to thank my American parents Mr. and Mrs. York for their contribution and endless support during my master's degree studies.

Thanks to Dr. Gardiner for his continuous support and for signing a research contract with MDCH to provide me necessary financial support for my master's degree studies. I owe a great debt to many people who provided me the necessary support to complete my thesis. Special thanks go to my advisor Dr. Dorothy Pathak for her guidance during my studies at Michigan State University. I also want to thank Dr. Henry Barry for his guidance during my project.

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Last but not least, I want to thank everyone who directly and indirectly helped me during my studies at Michigan State University.

Faith, Hope, Love

you need all of the above.

If you want to live, then you have got to be positive.

There is a rumor I have a tumor.

I used to be a dancer, then I got cancer.

I used to have hair all down my back,

but now it's shorter than Kojak.

But that is all right,

Cuz I am gonna win the fight.

Kristine Kirsten

Poem written by a breast cancer survivor

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LIST OF ABBREVIATIONS

For Variable names Please refer Appendix B – Data Dictionary for DOD Dataset

ACS: American Cancer Society

BCT: Breast Conserving Therapy

BRFS: Behavioral Risk Factor Survey

BSE: Breast Self Examination

CBE: Clinical Breast Exam

CDC: Center for Disease Control and Prevention

Cum. Freq.: Cumulative Frequency

DOD study: Department of Defense Study

DK: Don't Know

FNA: Fine Needle Aspiration

FNAB: Mass – Fine Needle Aspiration Biopsy

E-code: Eligibility Code

FPs: Family Physicians

OB/GYN: Obstetrician and Gynecologist

NCI: National Cancer Institute

NVSS: National Vital Statistic Systems

SEER: Surveillance, Epidemiology, and End Results

StudyID: Study Identification Number

US: United States of America

Undoc: Undocumented

Introduction

Breast cancer is the second leading cause of cancer deaths in women after lung cancer and is the most common cancer among women, excluding non-melanoma skin cancers. According to the World Health Organization, more than one million cases of breast cancer occur worldwide annually, with some 580,000 cases occurring in developed countries (>300/100,000 population per year) and the remainder in developing countries (usually <1500/100,000 population per year), despite their much higher overall population and younger age. (1) In 2000, the last year for which global data exists, some 400,000 women died from breast cancer, representing 1.6 per cent of all female deaths. (1)

For United States, the American Cancer Society (ACS) estimates that in 2005, 269,730 new cases of breast cancer will be diagnosed: 211,240 invasive breast cancers and 58,490 cases of in situ breast cancer, of which, 85% will be ductal carcinoma in *situ* (DCIS). (2) According to the ACS, the chance that breast cancer will be responsible for a woman's death is about 1 in 33 (3%). The incidence rate of breast cancer (number of new breast cancers per 100,000 women) increased by approximately 4% during the 1980s but leveled off to 100.6 cases per 100,000 women in the 1990s. (2) (Figure 1)

Breast Cancer Screening in the United States

Population statistics indicate that age-adjusted breast-cancer mortality rates began to decline during the early 1990s in many developed countries. For several decades before 1990, breast-cancer mortality rates in these countries had been either stable or increasing. (3) In the US, the death rates from breast cancer also declined significantly between 1992 and 1996, with the largest decreases among younger women. Medical experts attribute the decline in breast cancer deaths to earlier detection by screening and more effective

treatments. (Figure 2)

The Behavioral Risk Factor Survey (BRFS) 2000 presented a map with the age adjusted percentage of women aged GT 40 who reported receiving a mammogram within the past two years by States. (Figure 3) Age adjusted percentage of women aged 40 and more who reported receiving a mammogram within the past 2 years was 77%, over the target set by Healthy People 2010 of 70%. (4) The BRFS map also demonstrates a mammography utilization rate in Michigan of 82%, in excess of the Healthy People 2010 target. However, one has to be careful when interpreting self reported rates used in the BRFS study. Possible limitations of the BRFS survey is that one it excluded women living in households without a telephone another is that self-reported information about cancer screening practices may differ from information obtained from the records of healthcare providers. Persons tend to over report their use of screening and to underreport the time since their last screen. (5)

In 1999, the National Vital Statistic Systems (NVSS) reported an age-adjusted death rate due to breast cancer in the US of 27.0 per 100,000 females. Individual age-adjusted death rates by State ranged from 20.5 to 30.0 per 100,000 females. Michigan is among highest breast cancer death rate states (28 per 100,000 females). The Healthy People 2010 target for death rate due to breast cancer is 22. With the exception of Utah and Alaska, no other state is near to the target set by Healthy People 2010. (Figure 4)

Incidence and Survival Rate by Age

Each woman's breast cancer risk may be higher or lower, depending upon several factors, including family history, genetics, age of onset of menstruation, and other factors, many of which have not yet been identified. According to the National Cancer Institute (NCI),

the chance of getting breast cancer goes up as a woman gets older. The risk of breast cancer is greatest for women over age 60. (6) (Table 1) While breast cancer is less common at a young age, some studies have shown that breast carcinoma in young women is more aggressive biologically, which may explain why survival rates are lower among younger women. (7, 8) This can be supported by the ACS's five year survival rate by age which is lower in younger women and higher in older women. (Table 2)

Treatment Cost

It is critical to screen for and diagnose breast cancer as early as possible. If the cancer is detected and treated at an early stage survival rates are highest and recurrence and treatment costs are lowest. Screening mammograms generally cost between $100 and $150. Most states now have laws requiring health insurance companies to reimburse all or part of the cost of screening mammograms. The overall 5-year survival for breast cancer is 85%. However, 5-year survival for women diagnosed at Stage 0 is 100% and for those with Stage I, 98%. Therefore, if all Americans participated in regular cancer screenings the overall survival rate could increase to more than 95% (9)

For example a mammogram and diagnostic workup will not cost more than $200 and $2000 respectively. However, cost differences between early stage treatment and late stage treatment can range anywhere from $10,000 to $150,000. (Table 3)

According to Barlow study with SEER data, at 6 months after diagnosis, the adjusted mean costs were $12,987, $14,309, $14,963, and $15,779 for mastectomy alone, mastectomy with adjuvant therapy, Breast Conserving Therapy (BCT) plus radiation therapy, and BCT plus radiation therapy with adjuvant therapy, respectively. The 1-year adjusted mean costs were $16,704, $18,856, $17,344, and $19,081, respectively, for the

four groups. By 5 years, BCT was less expensive than mastectomy (P :< .001), with 5-year adjusted mean costs of $41,930, $45,670, $35,787, and $39,926, respectively. (10)

Recommended Guidelines for Breast Cancer Screening:

All major US medical/cancer research organizations recommend screening mammography for women aged 40 years and older. However, there is no one single recommended guideline for breast cancer screening that consists of the clinical breast examination (CBE) and mammogram. Each organization in the US has its own guidelines. (Table 4) CDC displays a US map on its website with state specific annual CBE guidelines which is an additional concern to the variations in mammography guidelines. (Figure 5) This is especially true for women living in Michigan who live in warm places like Florida for the winter. Whereas Michigan recommends annual CBE, in Florida it is recommended every two years for ages 40 – 50 years and annually exam for women aged 50 and above. Additionally these guidelines need adjustment based on women's family history and risk factors.

Chapter 1

Literature Review

Clinical Preventive Medicine in Primary Care:

Clinical evidence supports the value of preventive medicine, defined as the maintenance and promotion of health and the reduction of risk factors that result in injury and disease. Primary prevention activities deter the occurrence of a disease or adverse event, e.g., smoking cessation. Secondary prevention (screening) is early detection of a disease or condition in an asymptomatic stage so treatment delays or blocks occurrence of symptoms, e.g., mammographic detection of breast cancer. Tertiary prevention attempts to decrease adverse consequences of existing clinical disease, e.g., cardiac rehabilitation to prevent the recurrence of a myocardial infarction. (11)

Preventive services have decreased morbidity and mortality from both acute and chronic conditions. However, these services are underutilized for numerous reasons. Barriers to their use include physician, patient, and health system factors. (11)

Cancer Screening

Screening makes it possible to detect cancer before the disease gives rise to symptoms. A more effective treatment could thus be offered, and patients would then have a better prognosis. (12) Early detection of malignant tumors, preferably before symptoms present, is important because the earlier the stage at diagnosis, the less chance that the cancer will spread to distant organs, the major reason for mortality from malignancy.

Triad of Breast Cancer Screening

Three breast cancer screening methods are commonly employed in combination: mammography, breast self examination (BSE), and Clinical Breast Examination by trained personnel (CBE). (Figure 6) Breast cancer screening by a combination of BSE, CBE and mammography is recommended by the American Cancer Society as effective in

detecting abnormalities in all age groups for years 40 and above. (13) Figure 7 was created to illustrate the continuum of breast care.

The key to surviving breast cancer is early detection and treatment. According to the ACS, when breast cancer is confined to the breast, the five-year survival rate is close to 100%. The early detection of breast cancer helps reduce the need for aggressive treatment and minimizes pain and suffering, allowing women to continue leading happy, productive lives. Results from large clinical trials also indicate that adjuvant systemic therapy, adjuvant radiotherapy, and screening can reduce breast cancer mortality. (14, 15)

For a screening test to be effective, that test must be capable of diagnosing disease prior to it becoming symptomatic. That is, it must be capable of disease detection during the latent phase. Mammography is capable of detecting breast cancer in asymptomatic women and therefore meets the criteria for a screening test. (Figure 8) As shown by the middle portion of the graph, the portion of the latent phase during which breast cancer is detectable by mammography is termed the pre-clinical phase. Mammography is the single most effective method in obtaining the mortality reductions from screening. The overall results of the randomized controlled trials indicate that mammographic screening in women 50 and over can reduce breast cancer mortality by about 25%. (16)

The CBE can be done safely by both physicians and other health professionals properly trained in the CBE technique. Screening clinical breast examination adds information at times not apparent on mammography and has been shown to detect some cancers missed by mammography. However, its sensitivity reported in randomized trials is low compared to mammography, about 54%. (17) Breast self-examination (BSE) is useful in detecting breast abnormalities in early stages.

Controversies in Mammography:

All randomized breast cancer screening trials have shown a reduction in breast cancer mortality in the 'invited for mammography' screening arm compared with the 'control arm' for women aged 50 years and older at randomization (overall 25%). (18) Annual screening mammography can decrease breast cancer mortality by 45% in women over fifty and 23% in women between forty and fifty years of age. (19) However, concerns about screening mammography are raised and those include questions of efficacy, high recall rates, false positives, and age at which to institute annual screening. Approximately 95% of women with abnormalities on screening mammograms do not have breast cancer with variability based on such factors as age of the woman and assessment category assigned by the radiologist. (17)

Younger women (40-49 years) have lower mammographic sensitivity (i.e., greater proportion of cancers detected after a negative mammogram) than older women (> or =50 years). (20-22) Greater breast density explained 67.6% of the decreased mammographic sensitivity in younger women at 12 months, whereas at 24 months breast density explained 37.6% and rapid tumor growth explained 30.6% of the decreased sensitivity in younger women. (23)

Breast density largely explained decreased mammographic sensitivity at 12 months, whereas rapid tumor growth contributed to decreased mammographic sensitivity at 24 months. A 12-month versus a 24-month mammography screening interval may therefore reduce the adverse impact of faster growing tumors on mammographic sensitivity in younger women. (23)

Staging and Survival Rates

Staging is the process physicians use to assess the size and spread of location of a patient's cancer at diagnosis. This information helps determine the most optimal form of treatment. Breast cancer stages range from Stage 0 (in-situ) to Stage IV (advanced, metastatic breast cancer). Breast cancer survival continues to decline after five years post-diagnosis. (Table 5 & 6)

Mortality and Breast Cancer Screening

A study by Aubard in 2002 observed that more widespread use of mammography screening for breast cancer led to smaller tumors being discovered during the second screening period, with less lymph node involvement and less initial metastasis. It has been shown that, at least for patients aged 50 to 70, properly organized mass screening for breast cancer led to a reduction in mortality rate. (24)

Annual screening mammography can decrease breast cancer mortality by 45% in women above age 50 and 23% in women between 40 and 50 years of age. (19)

Screening mammography reduces breast cancer mortality by about 20% to 35% in women aged 50 to 69 years and slightly less in women aged 40 to 49 years at 14 years of follow-up. (17) The mammography service screening programme in Copenhagen, Denmark showed reduction in breast cancer mortality in the screening period by 25% (relative risk 0.75, 95% confidence interval 0.63 to 0.89). For women actually participating in screening, breast cancer mortality was reduced by 37%. (25)

In Switzerland, breast cancer mortality rates for Swiss national females aged 50-79 years fell between 1990 and 2000 by 25% in all regions. It has been suggested that the decrease in breast cancer mortality in Switzerland is not solely due to mammography screening but

also partly due to treatment developments and changes in cause-of-death coding (26)

The Swedish study on the long-term effects of a screening program in women aged 40-64 years found a significant 20% reduction of breast cancer excess mortality. (27) In another Swedish Two-County Trial of mammographic screening for breast cancer, invitation to screening was associated with a reduction in deaths from all causes among breast cancer cases, consistent with high participation rates in screening. (28)

Seven out of eight published randomized controlled trials found a significant decrease in breast cancer mortality among women who underwent screening mammography. The data indicated that screening mammography does indeed assist in early diagnosis, and most published studies show a significant reduction in breast cancer-related mortality in the screened population. (29)

A combined analysis of data from five major screening studies indicates that annual screening of all women aged 40 and over by means of state-of-the-art mammography, with two views per breast and physical examination, could reduce breast cancer mortality by at least 40% and possibly as much as 50%. (30)

In England and Wales, both screening and improvements in treatment have resulted in substantial reductions in mortality from breast cancer. Many deaths in the 1990s will reflect women diagnosed in the 1980s and early 1990s, before invitation to screening was instituted. Further major effects from screening and treatment are expected, which together with cohort effects will result in further substantial reductions in mortality from breast cancer, particularly for women aged 55-69, over the next 10 years. (31)

Treatment of breast abnormalities

The most common breast abnormality other than benign breast pain is a new lump or mass, although, even with this symptom, most breast lumps are benign. Other physical signs include a generalized swelling of part of a breast (even if no distinct lump is felt), skin irritation or dimpling, nipple pain or retraction (turning inward), redness or scaliness of the nipple or breast skin, or a discharge other than breast milk. Treatment is most successful when it is detected early, depending on the situation and the patient's choices; treatment may involve breast conservation surgery (surgical removal of only the tumor and surrounding tissue) or mastectomy (surgical removal of the breast).

Cost – Benefit Analysis

When balancing the benefits of screening women for breast cancer against the harms and costs of screening, the relative reduction in the risk that will result from screening women in different age groups are important considerations. Seven randomized controlled trials provide evidence of the relative risk reduction that results from screening women in different age groups; other studies estimate the harms and costs of screening. These studies indicate that the benefit of screening, expressed as the absolute number of lives extended per 1000 women screened, increases with age and that the harm of screening, expressed as the number of follow-up procedures per cancer detected, decreases with age. Thus, the tradeoff between the benefits and the harms and costs of screening is better for older than for younger women. (32)

Barriers to Screening:

Many published studies on breast cancer screening have identified specific barriers to screening. (11) Some of those barriers are listed as follows:

Patient Factors: Young women, particularly if married or women of color have shown poor compliance with screening. Low socio-economic status, lack of education or awareness, lack of insurance coverage or embarrassment are some other factors which have cause poor patient compliance for breast cancer screening. (Table 7)

Physician Factors: Physician gender, specialty group, and age category were significant predictors of breast cancer screening rate. Male physicians in young and middle age have shown poor rates of breast cancer screening.(33) For CBE screening, male physicians reported a greater barrier due to inadequate reimbursement for CBE than female physicians. (34) This may be due to issues of embarrassment. Lack of knowledge and belief in the importance of screening are other factors.

Health System Factors: As shown in table 4, there is poor consensus on screening guidelines by various organizations and institutes working in this field. Hospitals with lack of screening strategies, poor utilization of reminders and poor training of physicians are factors affecting poor implementation of breast care and screening programs.

Disincentives of Mammography: Poor reimbursement for mammography and high prevalence of breast cancer-related litigation are disincentives for radiologists to provide mammography services. (19) The public must be educated so that reasonable expectations on the benefits and limitations of mammography will develop. Concerns about screening mammography include questions of efficacy, high recall rates, false positives, and age at which to institute annual screening.

Chapter 2

Department of Defense Study in Nine Sites in Michigan

Purpose of the Department of Defense (DOD) Study

The purpose of this study was to test a three-component intervention designed to enhance primary care physicians' skills in secondary prevention, diagnosis and follow-up of abnormal findings in the control of breast cancer.

The study was carried out to test an innovative educational intervention designed to optimize secondary prevention, diagnosis and follow-up of abnormal findings. It was directed at a population of physicians (residents and faculty) in which a pilot study has shown sub-optimal management of breast problems. It implemented education about breast cancer screening and management of abnormal findings. The study had three specific aims as follows:

Specific Aim 1 To determine the effect of a three-component intervention consisting of educational material on comprehensive breast care; a CBE skills course, and a Chart Reminder/Guideline System on rates of CBE and mammography, documentation of findings, and timeliness and appropriateness of follow-up of abnormal findings.

Specific Aim 2 To determine the immediate effect of the educational session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected. In addition, the effect of the Clinical Skills Course on the confidence and competence with which family physicians (FPs) and residents perform CBE will be measured.

Specific Aim 3 To describe the long term effect of the educational session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected, as well as the long-term effect of the Clinical Skills Course on the confidence and competence with which FPs and residents perform CBE.

Type of Study

A randomized controlled trial (with randomization based on the location of the residency) was designed to measure the impact of breast care training provided to physicians. During Year 1 of the study, sites were selected and randomly assigned to the intervention and control arms. The sites designated as Intervention and Control is listed in Table 8.

Study Period

Data was collected through chart audit during the baseline year which was from 08/01/1998 to 07/31/1999. Year 2, the post-intervention year, audited charts from 08/01/1999 to 07/31/2000. For each woman 40-70 years of age, each breast care-related encounter was abstracted. In addition, total number of office visits, irrespective of the reason, during the given time period was abstracted since each office visits can be viewed as an opportunity for the FPs to review the current status of breast cancer screening for the patient.

It was determined that the relevant time period to abstract breast care activity for calculation of annual screening rate should include the 15 months prior to the last visit to the office in a given year. The auto-calculated fifteen-month intervals from the last office visit in Year 1 and Year 2 were then audited for the occurrence of breast care activity.

Database Development

Initially databases were created in Microsoft Access and exported in Microsoft Excel. There were 9 sites in total for this study. Data was exported in four separate sheets into a Microsoft Excel file, representing the four forms created in the Access database. The forms used for chart abstraction are included in Appendix 1. Figure 9a and 9b explains

how the study attempts to collect all aspects of breast care information, using all four forms for a particular patient in the study.

1. Form I - Front End Form
2. Form II - Visit Entry Form
3. Form III - Test Result Entry Form
4. Form IV - Follow-up Form

Database development started with assigning unique identification number by site to subjects whose charts were abstracted for the study.

StudyID Structure

StudyID	Site Number	Ecode	Subject Number
123456	1	2	3456

It was anticipated that the dataset created at the end of study will be large; hence it was necessary to have a unique variable to follow the subject throughout the study period. Each patient was assigned a unique study identification number (StudyID) consisting of six digits. The first digit of the identification number matches with the number that was assigned to each study site. The nines sites in this study were assigned a unique number and those numbers were used as the first digit of the StudyID. Table 9 lists the assigned unique site number. The second digit represents the eligibility code (E-code ranging from 1 to 3) numeral, which is discussed below. The remaining four digits are consecutive numbers starting with 0001.

Eligibility Code (E-code)

The second digit of the StudyID represented the eligibility code that identified the type of patient abstracted in year 1. The E-code had three possible values; 1, 2 or 3. For the first year, the E-code was defined based on following five criteria:

1. Is the patient a female?
2. Has the patient been seen in the last three years?
3. Was the patient's date of birth between 8/1/1928 and 7/1/1959?
4. Has breast care been provided by a Family Practice Physician (FPs)?
5. Has the patient had any visit to FP between 8/1/98 and 7/31/99?

E-code 1

To be assigned this code, the patient had to have satisfied all 5 of the above criteria. This made her eligible for having her chart abstracted. Additionally, at the intervention sites, these patients were eligible for insertion of the Chart Reminder Guideline System (CRGS) into their charts.

E-code 2

Patients who did not satisfy criteria 5, i.e. there was no visit by the patient to the given Health Care Facility during the time period 8/1/98-7/31/99 (baseline year), were thus not eligible to be abstracted. At intervention sites, these patients were still eligible for insertion of CRGS into their charts.

E-code 3

An E-code of 3 was assigned when the patient did not satisfy at least one of the first 4 criteria listed above. This made her chart ineligible for abstraction.

In Year 2, a new variable, current year eligibility code (E-code), was created which allowed for specification of the eligibility code during Year 2. Thus it was possible to identify all patients whose eligibility code changed between Year1 and Year2 (designated E-code old to E-code). Otherwise, E-code was similar to E-code old for all patients. Only patients that turned 40 during Year 2 and new patients to the practice had a new StudyID assigned in year 2 and added to our study.

If the patient had an E-code of 2 or 3, after the patient identification number was assigned, the Microsoft Access program prompted the abstractor to discontinue chart audit, and go to the next patient.

Form I - Front End Form

This form contains general information about the patient and includes approximately 60 different descriptive variables such as the patient's first and last name, medical record number, date of birth, abstractor's ID, abstraction eligibility code (E-code) and date of most recent visit (DMRVis) etc. Form I Front End was changed in Year 2, the post intervention year, to gather new information and update previously entered information. The new questions which were added are as follows:

a) Date of the very first visit to the FP and

b) Any documentation that patient left practice before 7/31/00.

The reason for this was to ensure that if there was an abnormality that needed to be followed there was documentation that FP physician did not have the opportunity to follow-up this abnormality since the patient left practice.

Criteria for the E-code were changed as follows

1. Was the patient's date of birth between 8/1/1928 and 7/31/1960?

(The limit on date of birth was changed to 7/31/1960 to ensure that the new group of patients who were turning 40 prior to August 1, 2000 were included in the study).

2. Has the patient had any visit to FP between 8/1/99 and 7/31/2000?

Form II - Visit Entry Form

Form II - Visit Entry was used to enter each breast care encounter the patient received during the 15 month interval. This form had important variables such as 'Texttel' and 'Purpose' which provided information about the type of contact and purpose of contact made.

Type of Contact (Texttel)

The abstractor recorded the date of each breast care activity and the type of contact made: 1 = Office visit, 2 = Office initiated phone consultation, 14 = Office response phone consultation, 3 = Patient initiated phone consultation, 4 = Screening/routine/regular mammogram, 5 = Regular Diagnostic Mammogram, 6 = Diagnostic/cone-compression/magnification mammogram, 7 = Ultrasound result, 8 = Fine needle aspiration (FNA) for cyst result; 9 = Fine needle aspiration biopsy (FNAB) result, 10 = Pathology report for radiological/image guided biopsy, 11 = Pathology report for open biopsy; 12 = Surgeon's letter, or 13 = Other.

Purpose of this visit/call (Purpose)

The variable "purpose of this visit/call" contained the following options: 1 = Screening/well women exam/annual exam, 2 = Presenting symptom(s), 3 = Follow-up of

a previous abnormality, 4 = Prompted by results of screening mammogram, 5 = Prompted by results of other test(s), 6 = Routine care/other health problems, and 8 = Other.

The rest of Form II contains specifics of for any symptoms with which the patient presented, and the findings of CBE, entered by left and right breast.

Form III - Test Result Entry Form

Form III - test result entry form was created to note the breast care related test results. It includes the results of mammography, Cyst – Fine Needle Aspiration (FNA), Solid Mass – Fine Needle Aspiration Biopsy (FNAB), Ultrasound, and Image-guided biopsy/Open biopsy results. For each test performed, options were provided to enter the results obtained from that test. For all of the tests, documentation of test dates was tracked very carefully using date of order, date of test performed, date of results obtained and reviewed and date when the results were given to the patient.

Form IV - Follow-up Entry Form

Form IV - follow-up entry is intended to record the follow-up that occurred or was recommended by the physician associated with each breast care encounter. It is divided into follow-up for normal test results, specific abnormalities, follow-up common to any abnormality, and surgeon's letter.

Chapter 3

Data Construction and Data Cleaning

Data Construction

In the dataset for each patient in the study the following numbers of forms are expected to be completed. Each patient should have an exclusive and individual "Form I" which provides unique information about that particular patient. If the patient is eligible for the study and breast care was provided during the 15 month interval of interest, then the patient should have "Form II" filled out for each breast encounter that was made. The number of times "Form II" is filled out for a given patient, equals the number of times breast care occurred ("encounters") during the fifteen-month interval of interest. Additionally patients will have "Form III" filled out for every time "Form II" records the type of visit as a "test result". Lastly, for every "Form II" there will be a "Form IV" recording the follow-up recommended by the health care provider for that breast care "encounter". Overall a patient will have

1. One "Form I".
2. If the patient is eligible and breast care is provided, at least one or more copies of "Form II" will be filled out, each recording a specific type of breast care "encounter"
3. If "Form II" describes the breast care encounter as ordering a "test result" or actual findings on a test result, then a "Form III" describing the test result will be filled out.
4. For every "Form II" or "Form II and III" combined, there should be "Form IV" describing the follow-up recommended.

If information was provided in the medical chart that breast care was performed at an outside facility or by another physician such as OB/GYN, the patient was not eligible for chart abstraction, and was assigned E-code 3, but also received a special code of "6" for

criteria 4 "Has breast care been provided by a FP?". Before the data cleaning process began, the number of subjects per site is shown in Table 10.

Data Cleaning

In general, the academic community focuses more on quantitative results of studies, especially if statistical analysis is involved. In addition, we believe in the accuracy of the computerized statistical analysis performed by the various programs that are in common use. Data processing errors can be very subtle and difficult to trace for those doing the research. The larger the study, the more difficult it is for procedures to be kept under control—thus the close supervision of the data gathering process and data cleaning is a must.

Form 1 (Front End) in Excel for all sites were imported in SAS 8.0 Version to identify any duplicate entries or Study Identification Number (StudyID) duplicates.

Types of Duplicates

Mainly there were four types of duplicates found in the datasets.

(1) Those StudyIDs with the exact same information entered more than once. We called them Exact Duplicates. This may be because on same day, the chart was abstracted more than once by the abstractor.

(2) Those StudyIDs with same information entered on different date of abstraction. We called them Duplicate Entry with different dates.

(3) Same StudyIDs were assigned to different people. This might have occurred due to data entry error or the same StudyIDs having been used by different abstractors to abstract the data within the same site.

(4) There were some subjects who were abstracted more than once who had the same Date of Birth, but a different Last Name. All information was the same for a given visit. This occurred because of a name change after marriage or divorce etc.

Search for Duplicates in the Front End Forms (Form 1)

Search for duplicate was carried out using SAS. Four subsets were created and printed out for the above mentioned description of duplicates. There were unique variables in the dataset which were used to identify the duplicates. These unique variables were Medical Record Number (MRNum), Date of Birth, First Name and Last Name.

Treatment of Duplicates

For the four different types of duplicates, a different method of treatment was applied.

(1) Exact Duplicate

This type of duplicate was the easiest one to identify and treat. Exact duplicates were identified based on Last Name, First Name, Date of Birth and Medical Record Number. The latest form was kept as a final record and duplicate information was deleted.

(2) Subjects entered more than once with different dates of abstraction

Based on unique variables such as medical record number these duplicates were identified. Other than the date of abstraction (Variable Label – Date), the Last Name, First Name, Date of Birth and Medical Record Number was the same. Front End information that was missing from the latest abstraction form but present on the earliest entry was appended onto the latest form. Only the latest abstracted information form was retained.

(3) Same StudyID assigned to different people

There were a few StudyIDs which were used for more than one subject. This was the most difficult type of duplicate to handle as the same StudyID was used in the other forms for two different people as well.

Before joining data from three separate files at one of the sites, we used the original files to understand any reason why abstractors used a given StudyID for different subjects. We then created a NewStudyID for these duplicates, one for each unique patient in the dataset, which would be present on all four forms.

(4) Same subjects with different StudyIDs

Based on Last Name, First Name, Date of Birth and Medical Record Number, duplicate entries for the same person with different StudyIDs were identified. The reason for this duplicate entry were: 1) a typographical error in last name or first name which created new StudyID, 2) the subject changed her first name and or last name, 3) for the site with two clinics a given subject could have separate files thus was abstracted twice. Only one entry per person was kept in the Front End form. However, necessary changes were made in the other forms to join the visits to same person's record, if appropriate.

Except Site 1 where there were two different clinics for a site where more than one abstractor abstracted charts at these clinics, other datasets had fewer numbers of duplicates. A list of the number of patients in the new data sets created after cleaning duplicates, along with the number of duplicate entries found per site, are presented in Table 11.

Chapter 4:

Recoding of variables in Text

Recoding of variables in Text

Initially to separate normal findings from abnormal findings, selected variables were used. However after doing this separation of normal and abnormal we found that when variables named as "Other" for a given section were coded (yes) there was additional information contained in the next variable that prompted abstractors to "specify". This data structure was put in place to ensure that if abstractor was not able to interpret the results/findings of exam or test result in order to enter it as a normal or abnormal finding they had an option to provide a description of the finding. There were four variable/tests (two subcategories to categorize left and right breast) which had this text information entered. This information needed to be coded back into numeric data. These variables are as follows (Please refer attached Appendix A and B for variable names and details)

1. For Symptoms: If Symfinol and/or Symfinor were coded '1' (Yes = 1), then SYMOTHER and SYMOTHERR were recoded.
2. For CBE Test results: If LCBEfino and/or RCBEfino were coded '1' (Yes = 1), then LOTHERA and ROTHERA were recoded.
3. For Mammogram Test results
    a. If Mamfinol and/or Mamfinor were coded '1' (Yes = 1), then MAMFINLS and MAMFINRS were recoded.
    b. If MamDesol and/or MamDesor were coded '1' (Yes = 1), then MamDesLS and MamDesRS were recoded.

Using SAS version8, text which was entered for these variables was exported into Microsoft Excel sheets. New codes for numerical coding of this text were created.

New codes created for these variables are as follows:

1. For Symptoms two new codes were created.
    a. One code was created as CODEL and CODER to identify normal and abnormal results for symptoms based on text entered in SYMOTHER and SYMOTHERR variables. This code had two values '0' and '1'. If the symptom was abnormal, then a code of '1' was used for CODEL or CODER.
    b. CODESYML and CODESYMR was another code created to identify the exact type of symptom. This was useful to identify abnormalities by type of symptom. The major codes for this variable are as follows: LUMP = 1, NIPPLE DISCHARGE = 2, SKIN CHANGE = 3, PAIN = 4 and OCCULT = 5. If the symptom had no abnormal presentation in the text, then no code was assigned. However this code was also extended to add other descriptions found in the text. Refer Table 12 for details of the codes and its description.
2. For CBE

    LCBE-CODE and RCBE-CODE were the new codes created for text entered in variables LOTHERA and ROTHERA. LCBE-CODE and RCBE-CODE were coded as '0' for normal CBE and '1' for abnormal CBE.
3. For Mammogram
    a. Based on Mammogram impression, MAMFINLS and MAMFINRS were recoded into ML_Code and MR_Code.

i. ML_CODE and MR_CODE

- ✓ 0 is further work needed
- ✓ 1 is Category I – Normal or No Finding
- ✓ 2 is Category II – Normal/Benign Appearing
- ✓ 3 is Category III – Probably Benign/ Possibly Malignant
- ✓ 4 is Category IV – Suspicious for Malignancy
- ✓ 5 is Category V – Malignant until proven otherwise
- ✓ 1111 was used for findings that were missing
- ✓ 999 was used when a mastectomy was done (and mammography therefore impossible).

b. Mammogram Finding Description had text variables MAMDESLS and MAMDESRS which were coded into CODE_DESLS and CODE_DESRS.

- 0 is further work needed/from GComment
- 1 is Category I – Normal or No Finding
- 2 is Category II – Normal/Benign Appearing
- 3 is Category III – Probably Benign/ Possibly Malignant
- 4 is Category IV – Suspicious for Malignancy
- 5 is Category V – Malignant until proven otherwise

Abnormalities found from Follow-up Form

There were some patients who were not confirmed as having abnormality based on clinical visits but the physician recommended a follow-up that he/she considered appropriate for resolution of this abnormality. Therefore we also looked at the recommended follow-up to identify additional patients with potential abnormalities. This

included patients that had in their follow-up recommendation for an immediate work up such as Extra Mammography views, (Cone compression and Magnification views), there was an interval follow-up for a Mammogram or CBE, or the patient was asked to undergo Ultrasonography or had a surgical referral letter. The General Comment which was in the Form IV Follow-up form (GComment) was another useful text variable which was used to understand why there was any additional work up or any other abnormal finding not coded in the appropriate sections. A new code was entered in CODE_DESLS and CODE_DESRS (In the Test Results form variables) as appropriate, when abnormal findings were listed in GComment.

Merging New Codes with Datasets

Data sets with names FINALDOD.DOD_YR1_ALLOTH and FINALDOD.DOD_YR1_ALLOTH were created for the additional coded abnormalities. Table below specifies which data sets were joined together

STRATEGY USED TO ADD CODED VARIABLES TO EXISTING DATASETS

FOR YEAR 1:

FINALDOD.DOD_Y1 + SHEET="YR1" (MAMFINOLMAMFINOR CODING.xls + CBEFINOLCBEFINOR CODING.xls + SYMFINOLSYMFINOR CODING.xls + DESOTHER CODING.xls) = FINALDOD.DOD_YR1_ALLOTH

FOR YEAR 2:

FINALDOD.DOD_Y2 + SHEET="YR2" (MAMFINOLMAMFINOR CODING.xls + CBEFINOLCBEFINOR CODING.xls + SYMFINOLSYMFINOR CODING.xls + DESOTHER CODING.xls) = FINALDOD.DOD_YR2_ALLOTH

Based on StudyID and Date of Visit, recoded variables and new codes were added to the original dataset. For identification of all the abnormal findings, this was necessary in order to separate normal and abnormal findings. Using the SAS PROC SQL 'Right Join' function, these codes were added to existing datasets using the above described process.

Creating Subsets and SAS Permanent Files

In the end, final dataset had approximately 12,900 patients with almost 30,000 breast care entries.

1. Form I - Front End Form – 12,816 patients
2. Form II - Visit Entry Form – 29,623 visit entries
3. Form III - Test Result Entry Form – 21,147 visit entries
4. Form IV - Follow-up Form – 29,297 visit entries

At the end of this process there were 45 permanent files and 405 subsets created from the original dataset. These subsets were created mainly for analysis purpose. Refer to figure 10 for the explanation of the sub-setting strategy.

Creating Year One and Year Two Subsets

Subsets were created based on study period. Data collected during the time period from 08/01/1998 up to 07/31/1999 was considered Year One data. Year Two data, representing the post-intervention year, was considered from 08/01/1999 up to 07/31/2000. The study also had extra periods of chart abstraction. All visits prior to 8/1/98 and 3 months post 7/31/2000 (to capture up to 3 month follow-up of abnormalities detected at the end of Year Two) were categorized in file labeled "DODothers".

Creating Intervention and Control Subsets

Based on StudyID numbers, the entire dataset was categorized into Intervention and Control. StudyIDs with less than 600000 are from the intervention arm and StudyIDs with more than 600000 are from the control arm.

Creating Normal and Abnormal subsets

The dataset with all of the recoding attached was used to create patients with normal and abnormal findings. The criteria used to separate abnormalities from the entire dataset follows. Please refer to the attached Data Dictionary in the appendix IV for the variable details. In short, any patient with any symptom or abnormal CBE finding or abnormal Mammogram finding was categorized as a patient with an abnormal finding.

By the end of this process, there were three datasets which were categorized based on study year (Year 1, Year 2 and DoDOther). These were further categorized as intervention and control and in the end were categorized as normal and abnormal findings. There were 21 subsets created from the original dataset.

Criterion used to extract abnormal was as follows:

If any visit had any of following abnormal findings by symptom or CBE or Mammogram, it was abstracted as an abnormal finding. As mentioned above, new codes were created which were also used to create abnormal.

Abnormal Symptom: (Please refer appendix A and B for the variable name and details)

SYMLUMP = Yes OR SYMDIS= Yes OR SYMCHA= Yes OR SYMPAIN= Yes OR SYMOCC= Yes OR SYMLUMPR= Yes OR SYMDISR= Yes OR SYMCHAR= Yes OR SYMPAINR= Yes OR SYMOCCR= Yes

Recoded Symptom:

CODEL = Yes OR CODER = Yes

Abnormal CBE:

LCBEFLU= Yes OR RCBEFLU= Yes OR LCBEFDIS = Yes OR LCBEFOBS = Yes OR LCBEFP = Yes OR RCBEFDIS = Yes OR RCBEFOBS = Yes OR RCBEFP = Yes

Recoded CBE:

LCBE-CODE = Yes OR RCBE-CODE= Yes

Abnormal Mammogram:

MAMFINSL = Yes OR MAMFINML =Yes OR MAMFINPL= Yes OR MAMFINPR= Yes OR MAMFINSR= Yes OR MAMFINMR= Yes

Recoded Mammogram:

ML_CODE = Category 3 OR ML_CODE = Category 4 OR ML_CODE = Category 5 OR ML_CODE = Category 0 OR MR_CODE = Category 3 OR MR_CODE = Category 4 OR MR_CODE = Category 5 OR MR_CODE = Category 0

Recoded Mammogram Finding:

CODE_DESLS= Category 3 OR CODE_DESLS = Category 4 OR CODE_DESLS = Category 5 OR CODE_DESLS= Category 0 OR CODE_DESRS= Category 3 OR CODE_DESRS = Category 4 OR CODE_DESRS = Category 5 OR CODE_DESRS= Category 0

Other types of subsets created were as follows: The dataset was subdivided into three categories based on the patient's age. This was calculated using each woman's date of birth from the medical record. Ages were categorized into less than 50 years of age, 50 to 59 years of age and 60 to 70 years of age.

For individual site comparison, subsets were created based on site from which data was abstracted. A new variable was created named as 'Place' which was used to categorize data by site. The abnormal subset was further classified based on the abnormality detected by type. Abnormal subsets were categorized into three nonexclusive groups: Abnormality presenting as a Symptom, an abnormal finding from the CBE, and an abnormal finding from the Mammogram (the same person could be present in all three subsets).

List of FINAL DATASETS:

Based on Forms:

FINALDOD.DODFRONTEND
FINALDOD.DODVISIT1
FINALDOD.DODVISIT2
FINALDOD.DODFOLLOWUP

Based on study period year 1 and Year 2:

FINALDOD.DODFRONTEND
FINALDOD.DODFRONTEND_YR1
FINALDOD.YR1_ALL
FINALDOD.YR2_ALL
FINALDOD.DOD_YR1_ALLOTH
FINALDOD.DOD_YR2_ALLOTH

Based on intervention and control Sites:

FINALDOD.INV_FE_Y1
FINALDOD.CNTRL_FE_Y1
FINALDOD.INV_FE_Y2
FINALDOD.CNTRL_FE_Y2
FINALDOD.INVY1_ALL
FINALDOD.CNTRLY1_ALL
FINALDOD.INVY2_ALL
FINALDOD.CNTRLY2_ALL
FINALDOD.INV_VISIT_Y1
FINALDOD.CNTRL_VISIT_Y1
FINALDOD.INV_VISIT_Y2
FINALDOD.CNTRL_VISIT_Y2

Based on age of patient and intervention and control site:

FINALDOD.INV_YR1_LT50
FINALDOD.INV_YR1_GT50
FINALDOD.INV_YR2_LT50
FINALDOD.INV_YR2_GT50
FINALDOD.CNTRL_YR1_LT50
FINALDOD.CNTRL_YR1_GT50
FINALDOD.CNTRL_YR2_LT50
FINALDOD.CNTRL_YR2_GT50

Based on age of patients:

FINALDOD.FE_YR1_LT50
FINALDOD.FE_YR1_GT50
FINALDOD.FE_YR2_LT50
FINALDOD.FE_YR2_GT50

Based on study period and forms:

FINALDOD.DOD_VISIT1_YR1
FINALDOD.DOD_VISIT2_YR1
FINALDOD.DOD_FUP_YR1
FINALDOD.DOD_VISIT1_YR2
FINALDOD.DOD_VISIT2_YR2
FINALDOD.DOD_FUP_YR2
FINALDOD.DOD_VISIT1_OTHER
FINALDOD.DOD_VISIT2_OTHER
FINALDOD.DOD_FUP_OTHER

Chapter 5:

Scoring Technique for Abnormalities

Descriptive Analysis of Abnormal

A scoring technique was used to identify type of abnormality represented during the visit or test finding. Scores were assigned to each type of abnormality based on the severity of abnormality. This was done to get a score that summarized all of the abnormalities that were observed during a given visit. Frequency of each score was obtained using SAS Proc Freq function.

Scoring used for Symptom

For patient who presented with a given symptom, a '1' was recorded in the dataset for the variable that represented presence of that symptom on the given side of the breast. The most common symptoms that presented were Lump, Pain or Tenderness, Nipple Discharge, Skin or Nipple Change and Occult Mammographic abnormality. Coding was separate for left and right breast. For example for symptom of lump, the variable names are: SYMLUMP and SYMLUMPR for left and right breast respectively.

Scoring was done as follows:

- Lump was assigned 10000: SYMLUMP and SYMLUMPR
- Pain was assigned 1000: SYMPAIN and SYMPAINR
- Nipple Discharge was assigned 100: SYMDIS and SYMDISR
- Skin Change was assigned 10: SYMCHA and SYMCHAR
- Occult Mammogram was assigned 1: SYMOCC and SYMOCCR

Then the total score was calculated to obtain the total abnormal finding for that visit for that patient.

SYML=SYMLUMP+SYMLUMPR

SYMP=SYMPAIN+SYMPAINR

SYMD=SYMDIS+SYMDISR

SYMC=SYMCHA+SYMCHAR

SYMO=SYMOCC+SYMOCCR

Tot_SYMP=SYML+SYMP+SYMD+SYMC+SYMO;

For example, a lump that presented as a symptom during a visit was given a score of 10000. If a patient presented with a lump as a symptom in both breasts, she would be given a score of SymLump * 10000 and SymLumpR * 10000; therefore the total for that patient for that particular visit will be 20000.

By this method we could calculate the total symptom presenting during that visit for each patient. Scoring was useful as it could easily identify the combinations of symptoms with which the patient presented. For example: If the total row score is 21200: That means for that particular visit there were lump on both sides, pain in the breast on one side and nipple discharge from both breasts. The same technique was used to score CBE and Mammogram.

For CBE, scoring was done as follows

```
LCBEFLU1=LCBEFLU*10000;
RCBEFLU1=RCBEFLU*10000;
LCBEFP1=LCBEFP*1000;
RCBEFP1=RCBEFP*1000;
LCBEFDIS1=LCBEFDIS*100;
RCBEFDIS1=RCBEFDIS*100;
LCBEFOBS1=LCBEFOBS*10;
RCBEFOBS1=RCBEFOBS*10;

CBEFL=LCBEFLU1+RCBEFLU1;
CBEFD=LCBEFDIS1+RCBEFDIS1;
CBEFO=LCBEFOBS1+RCBEFOBS1;
CBEFP=LCBEFP1+RCBEFP1;

Tot_CBE=CBEFL+CBEFD+CBEFP+CBEFO;
```

For Mammogram, scoring was done as follows

(Please refer Appendix A and B for variable names and other details)

```
MAMFINML1=MAMFINML*100000;
MAMFINMR1=MAMFINMR*100000;
MAMFINSL1=MAMFINSL*10000;
MAMFINSR1=MAMFINSR*10000;
MAMFINPL1=MAMFINPL*1000;
MAMFINPR1=MAMFINPR*1000;
MAMFINBL1= MAMFINBL*100;
MAMFINBR1= MAMFINBR*100;
MAMFINNL1= MAMFINNL*10;
MAMFINNR1= MAMFINNR*10;

MAMFINM=MAMFINML1+MAMFINMR1;
MAMFINS=MAMFINSL1+MAMFINSR1;
MAMFINP=MAMFINPL1+MAMFINPR1 ;
MAMFINB=MAMFINBL1+MAMFINBR1;
MAMFINN=MAMFINNL1+MAMFINNR1;

MAM=MAMFINN+MAMFINB+MAMFINP+MAMFINS+MAMFINM;
```

The total score for abnormalities for a given visit were calculated by adding the row totals.

Scoring method was also applied to calculate total abnormality during that visit SAS program is as follows:

```
SYML=SYMLUMP+SYMLUMPR
SYMD=SYMDIS+SYMDISR
SYMC=SYMCHA+SYMCHAR
SYMP=SYMPAIN+SYMPAINR
SYMO=SYMOCC+SYMOCCR

CBEFL=LCBEFLU+RCBEFLU;
CBEFD=LCBEFDIS+RCBEFDIS;
CBEFO=LCBEFOBS+RCBEFOBS;
CBEFP=LCBEFP+RCBEFP;
CBEFIN=LCBEFINO+RCBEFINO;

MAMFINO=MAMFINOL+MAMFINOR;
MAMFINS=MAMFINSL+MAMFINSR;
MAMFINM=MAMFINML+MAMFINMR;
MAMFINP=MAMFINPL+MAMFINPR ;
MAMFINL=MAMFINL+MAMFINL;
MAMFINB=MAMFINBL+MAMFINBR;

MAM=MAMFINO+MAMFINS+MAMFINM+MAMFINP;
CBE=CBEFL+CBEFD+CBEFO+CBEFP+CBEFIN;
Tot_SYMP=SYML+SYMD+SYMC+SYMP+SYMO;

ABNORMAL=MAM+CBE+SYMP;
```

Chapter 6:

Screening Rate Calculation

Screening Rate Calculation

Screening rate calculations were done using three different methods and were calculated for two year study period 8/1/1998-7/31/200 for all sites combined. These methods distinguish themselves based on the denominator used for the calculation of the screening rate. (Figure 11) These three methods are as follows

- **Patient Based Screening Rate:**

In this method the denominator used for the screening rate calculation uses only active patients in the practice. For the purpose of two year screening rate calculation, active patients are those with E-code 1, which means that the patient is a female, has been seen in the last three years, date of birth was between 8/1/1928 and 7/1/1960, breast care has been provided by a FPP and the patient had a visit to FP between 8/1/98 and 7/31/2000.

- **Physician Based Screening Rate:**

In this method, in addition to all active patients, those who were provided breast care by other specialties such as gynecologists, obstetricians or surgeons were also added to the denominator.

From the eligible for screening dataset, E-code 3 (Ineligible for abstraction) and Care 6 (care provided by others) were counted and added to numerator and denominator due to this it will always be little higher than patient screening rate.

- **Public Health or Practice Based Screening Rate:**

In this method of the screening rate calculation, patients with E-code 2 who did not satisfy criteria 5, i.e. there was no visit by the patient to the given Health Care Facility during the time period 8/1/98-7/31/2000 were included in the denominator.

Denominator for this screening rate includes denominator of physician based screening rate and in addition to that it includes patients with E-code 2. However numerator remains same as physician based screening rate.

Interpretation of different methods of screening rates

Different methods for calculating screening rates lead to different rates and different interpretations. The patient-based screening rate is liberal method (yields high screening rate values) of calculation as it takes only those patients in the denominator who had a visit to the clinic in the time period of interest and in whom there was a potential for FPs to screen that women for breast care. The public health or practice based screening rate is more conservative (giving lowest values for screening rate). However the practice based screening rate which is also called Physician based screening rate provides highest screening rate values and considered as a most liberal method of calculation. In this method we also include patients who had breast care from someone other than Family physician because of this it is always higher than patient based screening rate.

In the physician based approach, the main consideration is that the responsibility of physicians in practice is not only to screen those who visit the clinic, but also those active patients who do not, by reminding them of the importance of regular screening. The active patients who had no visit in the last year to the clinic would then be enticed to visit. The public health screening rate yields lowest screening rate values hence believed as a very conservative way of calculating the screening rate and it is likely that physicians will not accept these numbers readily. (Figure 12)

Usefulness of different methods of screening rate calculations:

- **Patient Based Screening Rate:**

This method is useful in determining the physician's potential to screen patients who visit the clinic. If all women who are active patients (seen within last three years) make a visit to the clinic once a year, then the physician has a potential to have 100% screening rate. This can be reinforced to physicians by providing proper training on breast care and by stressing the importance of screening to the physicians in the practice.

- **Physician Based Screening Rate:**

Some patients get breast care by doctors other than FPs such as Obstetricians, Gynecologists, or Surgeons. Under those circumstances, the FP physician only needs to note in the patient's chart when and what type of breast care the patient is receiving. Therefore, when calculating this rate, the additional patients screened outside of the FP office are included both in the denominator and numerator of this rate.

- **Public Health or Practice Based Screening Rate:**

This rate is very useful in determining a local, regional, or national screening rate. This rate reflects the actual potential to screen any eligible patient in the practice. This rate can be increased by applying different screening strategies, reminder letters and awareness campaigns.

Types of Screening Rates:

There are three different types of screening rates that can be calculated.

- **Clinical Breast Examination (CBE) Rate**

  In this type of screening rate calculation, patients who had annual clinical breast examination are evaluated.

- **Mammogram Screening Rate**

  There are four subtypes of screening rates calculated in a mammogram screening rate.

  - **Mammogram Ordered**
  - **Mammogram Done**
  - **Mammogram Ordered and Done**
  - **Mammogram either Ordered or Done**

- **Combined CBE Done and Mammogram Done Rate**

Process of screening rate calculation:

A screening test is a test applied to an asymptomatic individual with no clinical manifestations of the disease. (35)

The above definition states two main criteria which were used to calculate CBE and mammography screening rate. The first criterion was to use only asymptomatic patients for screening rate calculations, and remove individuals who presented with any breast symptom 30 days prior to the documented CBE or Mammogram. The second criterion was to remove those who had abnormal finding in CBE for screening mammogram or abnormal finding in mammogram for screening CBE. The total number of patients who are eligible for screening will be asymptomatic patients with no abnormal finding. This

became the denominator for the screening rate. For the schematic representation of this calculation please refer to Figure 13 in the appendix.

To calculate the numerator for the screening rate, all the patients in the denominator were analyzed to identify how many of them had a documented screening CBE or screening mammogram. This number was used as a numerator for the screening rate calculations.

CBE Screening Rate:

The final data set with all recoding was used for the calculation of CBE screening rate. The first step was to identify all of the visits in which patients presented with symptoms and the date at which symptoms first presented to the clinic.

In order to be eligible for CBE screening, any patient with no presentation of a symptom 30 days prior the first CBE documented were included. All other CBEs done after presentation of a symptom were ineligible in the screening CBE calculations.

The next step was to identify abnormal mammograms in asymptomatic patients prior to screening CBE. Using the file of asymptomatic patients, identification of patients with any finding with category 3 or more on a mammogram was carried out.

In short, the following four important numbers were required for the CBE screening rate calculation:

1) All active people with breast care
2) All those who had a symptom within 30 days of CBE
3) All those who had an abnormal mammogram anytime before CBE
4) CBE Documentation for all eligible people for screening

Where 1, 2 and 3 are used for the denominator [(1 – 2) – 3] and number 4 is a numerator for the CBE screening rate calculation. (Table 13)

Mammogram Screening Rate:

For the Mammography screening rate, four different types of screening rates were calculated. Each has its own importance and explains different dynamics in the mammography screening process. (Figure 14)

- **Mammogram Ordered**

  In this type of calculation of mammography screening rate, the total number of mammograms ordered by the physician was taken into consideration. No effort was made to identify of those ordered, how many were actually performed. This is liberal method of screening rate calculation.

- **Mammogram Done**

  In this type of mammography screening rate, the actual numbers of mammograms performed in the pertinent year are calculated. This rate shows patient compliance to a physician's call for a mammogram. It is relatively conservative approach of screening rate calculation, as a physician may have no control over a women's wish to get a mammogram or not.

- **Mammogram Ordered and Done**

  This type of mammography screening rate is a very conservative way of a screening rate calculation, as those patients who had a mammogram ordered, and done, are only taken into the numerator.

- **Mammogram either Ordered or Done**

  This is very liberal way to calculate a mammogram screening rate. The calculation includes a numerator which counts all mammograms either ordered or done.

The four types of mammogram screening rates were calculated and the formulas for the calculations are as follows:

1. The entire dataset was used to calculate the mammogram screening rate. In the first step we identified office visits and screening or regular mammogram visits which were coded as texttel='1' or texttel='4'.

2. In the second step, identification of a screening or well women exam, routine care, or other reasons for the purpose of the visit were identified. This was done by adding following SAS part to existing code. [AND (PURPOSE='1' OR PURPOSE = '6' OR PURPOSE = '8' OR PURPOSE=' ')]

3. In the third step, any visits with symptoms 30 days prior to the mammogram were identified and the visit was excluded from the screening rate calculation.

There were a few visits with abnormal mammographic findings reported that represented diagnostic rather than screening mammograms. These cases were deleted from the analysis of screening rates. Also deleted were the few mammograms that had no documented dates. (Table 14 – 17)

Combined CBE Done and Mammogram Done Rate

In this type of screening rate, complete breast care which includes annual CBE and mammography is calculated. Those patients who had both a CBE documented and a Mammogram done are the only patients included in numerator.

The entire dataset was used to calculate the combined screening rate. (Table 18)

1. In the first step, we identified office visits and screening or regular mammogram visits which were coded as texttel='1' or texttel='4'.

2. In the second step, identification of a screening or well women exam, routine care, other reasons for the visit were identified. This was done by adding the following SAS part to existing code. [AND (PURPOSE='1' OR PURPOSE = '6' OR PURPOSE = '8' OR PURPOSE=' ')] Steps one and two provided the denominator for the calculation.
3. In the third step, any patients who had symptoms that presented 30 days prior to the CBE or mammogram were removed.
4. In the fourth step, the numerator was calculated. Using the same data as was used for the denominator, the number of patients with documented CBEs and Mammograms were counted.
5. In the last step we removed all those visits with no mammogram or CBE documented and ran a PROC FREQ.

Chapter 7:

Results:

Descriptive Analysis and Screening Rates

Descriptive Analysis:

With the development of large data sets it is important to run initial descriptive analysis to detect any particular pattern shown in the collected data in terms of patients by site, age, eligibility codes and care providers.

Eligibility and New Patients in Year 2:

The total number of patients abstracted into the database is 10,101 for Year 1 and 12,816 for Year 2. An increase of 2,715 patients in Year 2 included 1,436 patients joining as active patients; 296 patients who did not make any visit in year 2; and, 983 patients who did not satisfy eligibility criteria for chart abstraction.

Table of E-code by E-code Old:

E-Code	E-Code Old				Total
	1 Active	2 Not Active	3 Ineligible	New Patients in Yr 2	
1 = Active	5344	284	261	1436	7325
2 = Not Active	941	958	46	296	2241
3 = Ineligible	115	113	2039	983	3250
Total	6400	1355	2346	2715	12816

E-code was the eligibility code for Year 2 and E-code old was the eligibility code assigned for baseline year. Only 42% patients were active throughout the study period. Eleven percent (1,436 patients) became active in year two. However, 941 patients did not make any visit in year two and became inactive (E-code 2) in the second year. Sixteen percent of the patients were not eligible for chart abstraction for both years and 8% of patients did not make any visit for breast care in either study years.

Eligibility code (E-code) for Year 2:

E-Code	#	%	Cum. Freq.
1 = Active	7325	57.16	7325
2 = Not Active	2241	17.49	9566
3 = Ineligible	3250	25.36	12816

Overall, 57% of patients were active in Year 2, 25% patients were ineligible for abstraction either because of age or not meeting eligibility criteria, and 17% patients did not have any visit in second year for breast care.

Patient's Age:

Age Range	#	%
31 TO 40	463	3.61
41 TO 50	6455	50.37
51 TO 60	3590	28.01
61 TO 70	1970	15.37

In order to be eligible for chart abstraction, the patient's age had to be in between 40 to 70 years. Overall, 96% patients were eligible for chart abstraction based on age. (Figure 15) However, 338 2.6%) patients had either their date of birth missing or entered incorrectly. Later on it was found out that due to different versions of Microsoft Access birth years were automatically modified from 1928 to 2028. For the purpose of this analysis, these were treated as missing.

Table of Age Range by Eligibility code:

Age Range # %	E-code 1 Active	 2 Not Active	 3 Ineligible	Total
31 TO 40	246 1.92	69 0.54	148 1.15	463 3.61
41 TO 50	3498 27.29	1226 9.57	1731 13.51	6455 50.37
51 TO 60	2156 16.82	595 4.64	839 6.55	3590 28.01
61 TO 70	1241 9.68	301 2.35	428 3.34	1970 15.37
Missing	184 1.44	50 0.39	104 0.81	338 2.64
Total	7325 57.16	2241 17.49	3250 25.36	12816 100.00

Overall, 50% patients in the study were in the age range 41 to 50 years. Of the total active patients 47% patients were in the age range of 41 to 50 years followed by 29% who were between 51 and 60 years of age.

Who provided Breast Care?

Care	#	%
Missing	10	0.08
1 = FPC	9974	77.82
6 = Other	894	6.98
9 = DK	1938	15.12

Family physicians delivered breast care for 78% of the patients the Family Physician. Gynecologist or Obstetrician or Surgeon assumed responsibility for breast care in 7% of patients.

Personal or Family History of Breast Cancer:

Table of History by ActY:

History	ActY			Total
	No = 0	Yes = 1	Missing	
0 = None	148 1.15	3560 27.78	23 0.18	3731 29.11
1 = Yes	39 0.30	1685 13.15	11 0.09	1735 13.54
8 = Undoc	130 1.01	1775 13.85	8 0.06	1913 14.93
9 = DK	9 0.07	76 0.59	1 0.01	86 0.67
Missing	942 7.35	24 0.19	4385 34.22	5351 41.75
Total	1268 9.89	7120 55.56	4428 34.55	12816 100.00

A personal or family history of Breast Cancer was documented for 13% of the active patients who received breast care. For 57% of cases, the family or personal history was either missing or undocumented.

Breast Cancer History in Self:

YSelf	#	%	Cum. Freq.
0 = None	12559	98.06	12559
1 = Yes	238	1.86	12797
8 = Undoc	1	0.01	12798
9 = DK	10	0.08	12808

About 238 patients (2%) had a personal history of breast cancer documented in medical chart.

Age distribution of patients with self-history of Breast Cancer:

Analysis Variable : AGE				
Mean	**Median**	**25th Pctl**	**50th Pctl**	**75th Pctl**
52.71	57.00	51.00	57.00	64.00

SAS code (Proc means) was used to understand age distribution of patients with self-history of breast cancer. These patients had a mean age of 52.7 years and median age of 57 years. Ages 51 to 64 years covered 50% of patients with self-history of breast cancer. (Figure 16)

Time Interval between Mammogram ordered and done:

For patients who had mammogram ordered and done documented in medical charts, time interval was calculated. Overall, Mammogram were ordered and done within a month for 58% for overall study and 2 to 6 month was found in 29% of mammogram. (Figure 17)

	Overall	
Time Interval	**#**	**%**
Same Day	1183	25.0
Within 1 Months	1547	32.7
2 to 6 Months	1380	29.1
7 to 12 Months	233	4.9
13 to 24 Months	394	8.3
	4737	100.0

Screening rates for the two year study period:

As explained in chapter 6 on the screening rate calculation, three different methods were applied to calculate two year screening rates. Screening rates were calculated for overall study, intervention sites and control sites. (Table 19)

Overall two year CBE screening rate was 68% based on patient screening rate, 72% based on physician screening rate and 55% based on public health screening rate. As mentioned before in chapter 6, Physician based screening rate includes patients who get screened by other than FPC. Physician based rates are always higher than other methods of screening rate calculation.

Two year screening rates were found higher in Intervention sites than control sites. However, for screening rates involving mammogram ordered numbers had higher rates for control sites. Later it was found out that there was a simultaneous study carried out during DOD study by the department of Family Practice at one site which was a part of control arm for DOD study. This study was focused on telephone intervention to improve mammogram screening rate at that particular site which was published in 1999 in Family Medicine. (36) This is one possible reason why these screening rates where mammogram order data included are higher in control sites.

Mammogram either ordered or done screening rates for the two year study period provides highest screening rate values. Overall patient based screening rate for either ordered or done screening rate was 74%, 77% for physician based and 61% for public health or practice based screening rate. The lowest values were found for the mammogram done and ordered screening rate which were 42% Patient based, 49% Physician based and 39% Practice based respectively.

Chapter 8

Discussion

Discussion:

Breast cancer is the most common malignancy among American women. (37) The American Cancer Society (ACS) estimates that in 2005, 269,730 new cases of breast cancer will be diagnosed among women in the United States: 211,240 invasive breast cancers and 58,490 cases of in situ breast cancer, of which, 85% will be ductal carcinoma in *situ* (DCIS). (2) Cancers of the breast will be the most frequently diagnosed cancers in American women, followed by lung cancers. (38)

Due to increased screening, the majority of patients in the US present with early-stage breast cancer. Therefore it is essential to identify epidemiological and clinical issues important in breast care early detection. It is fruitless to screen for breast abnormalities if appropriate actions following detection are not followed. In the DOD study more than 450 variables related to epidemiological and clinical factors for breast care were collected. DOD data collected through medical chart abstraction provides a wealth of information about breast care and captures every aspect of it.

Descriptive Analysis:

The process of data cleaning in SAS version 8 was a very laborious and time consuming process as it included four different forms linked to each other with StudyIDs for more than 30,000 breast care visits. In the end, the total number of patients in the database is 10,101 for Year 1 and 12,816 for Year 2 with almost 30,000 breast care entries. At the end of the data cleaning process, there were 45 permanent files and 405 subsets created from the original dataset. Overall, 46% of patients in the study were in the age range 41 to 50 years. During the study period, only 42% of patients had breast care visits documented. Of total active patients, 25% patients were in the age range of 41 to 50

years. For age 41 to 70 years, about 58% patients were active and had some kind of breast care in that year. About 78% patients received breast care from the Family Physicians. Out of total visits recorded for purpose, 46% of those were Well Woman Exams and 24% was routine care visits.

Family History of Breast Cancer:

To date, the etiology of breast cancer is poorly understood with known breast cancer risk factors explaining only a small proportion of cases. (39) Family history has always traditionally been used to identify persons at high cancer risk and to target appropriate preventive and therapeutic measures. Claus et al in his study in 2003 concluded that a family history of breast cancer is associated with an increased risk of DCIS and LCIS, particularly among women with multiple relatives affected at early ages. (40) Study by Webers et al, showed that the first-degree female relatives of women with breast cancer were at increased risk for breast cancer (RR: 1.7, 95% CI: 1.4-1.9). (41)

In the DOD study about 23% of the patients had either a personal or family history of breast cancer.. A study published in Lancet conducted collaborative reanalysis of 52 epidemiological studies and found that 12.9% women with breast cancer and 7.3% controls reported that one or more first-degree relatives had a history of breast cancer: 12% of women with breast cancer had one affected relative and 1% had 2 or more. (42)

Time interval between Mammogram ordered and done:

For patients who had a mammogram ordered and done documented in the medical charts, time interval was calculated. Overall, mammograms were ordered and done within a month for 58% for overall study and 2 to 6 month interval was found in 29% for overall study.

Breast Cancer Screening Guidelines:

Most physicians agree that screening mammograms help detect breast cancer in its earliest stages, often several years before a lump can be felt. However, the debate over when women should begin receiving annual screening mammograms has been ongoing. Most physicians and cancer organizations believe that all women 50 years of age and older should have annual mammograms to help detect breast cancer. However, organizations including the American Cancer Society (ACS), the American College of Radiology (ACR), the American College of Surgeons, and the American Medical Association (AMA), recommend that women should begin receiving annual mammograms at age 40. However, National Cancer Institute (NCI) recommends annual screening beginning at age 50, while suggesting that women in their 40s have screenings every one or two years, depending on individual risk factors.

In the DOD study, when recommending mammograms, physicians noted other guidelines in 17% of visits while only 5% of visits followed ACS guidelines.

Screening rates for the two year study period:

Overall two year CBE screening rate was 68% based on patient screening rate, 72% based on a physician screening rate and 55% based on public health screening rate. As mentioned before in chapter 6, Physician based screening rate includes patients who get screened by other than FPC. Physician based rates are always higher than other methods of screening rate calculations.

Screening rates were found higher in intervention sites than control sites. However, for screening rates involving mammogram ordered numbers had higher rates for control sites. Later it was found that there was a simultaneous study carried out during the DOD

study by the department of Family Practice at that site. This study was focused on telephone intervention to improve mammogram screening rate at that particular site which was published in 1999 in Family Medicine. (36) This is one possible reason why the screening rates where mammogram order data included are higher in control sites.

Having a mammogram either ordered or done screening rates for the two year period provide the highest screening rate values. Overall, the two year patient based screening rate for either ordered or done screening was 74%, 77% for physician based and 61% for public health or practice based screening rate. The lowest values were found for the two year mammogram done and ordered screening rate which were 42% Patient based, 49% Physician based and 39% Practice based respectively.

Implications:

Beginning at the age of 20, every woman should practice monthly breast self-exams and begin a routine program of breast health, including scheduling physician performed clinical breast exams at least every three years. As a woman ages, her risk of breast cancer also increases. Beginning at the age of 40, all women should have annual screening mammograms, receive clinical breast exams each year, and practice breast self-exams every month.

Limitations:

Results presented in the thesis are preliminary findings from the data cleaning process carried out on the DOD dataset. These results should not be quoted or used as the final results. Further data cleaning is necessary and is in progress. Final results for the DOD study will be published in future.

Appendix A

Chart Abstraction Forms Used for DOD Study

Form I- Front-End Form

Add New Patient

Patient Name (Last): Lname
(First): Fname
Medical Record Number: 111111
Date Of Birth: 1/1/1900
Abstractor's ID: 11

Data Transfer

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

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

Click to Determine Eligibility Code: 1

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

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: 100000 **Today's Date:** 11/11/2000

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 =
For eligibility code =
For eligibility code =

Click here To Continue

Add New Patient

Chart Review Form (Only For Eligible Patient)

Study ID: 100000

1. **Date of Most Recent Office Visit (MM/DD/YY):** 11/11/1911
2. *Autocalculated Date For the Last Eligibile Visit Within the Last 15 months (MM/DD/YY):* 8/11/1910
3. **Total Number of Visits Within 15 Months, Including The Most Recent Visit:** 1
4. **Was A Breast Care Performed During Any of The Visits Within The 15 Months Period:** Yes

5. Personal/Family History Of Breast Cancer? Add New Patient

None

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 Implant
- ☐ Autologous Reconstitution
- ☐ Other, specif
- ☐ Undocumented

Treatments (check all that apply)

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

Countinue to record visit info.

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

Study ID: #Name?

Go Back to Front-End

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

6. Date of Breast Care Activity Was Recor #Name?

Type of Cont

7. Purpose of this Visit/

Spe #Name?

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

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

☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ **Undocumented**

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:

☐ **None** ☐ **Undocumented/Don't know**

☐ Lump(s)/Mass(es)/Asymmetrical thickening

☐ Nipple Discharge

☐ Skin/Nipple change (check all that apply)

☐ Skin Dimpling ☐ Erythema/Skin thickening

☐ Nipple Retraction ☐ Nipple Scaling

☐ Pain/Tenderness

☐ Occult Mammographic Abnormality

☐ Density(Nodule or Asymmetry)

☐ Microcalcifications

☐ Other, specify: #Name?

Right Breast:

☐ **None** ☐ **Undocumented/Don't know**

☐ Lump(s)/Mass(es)/Asymmetrical thickening

☐ Nipple Discharge

☐ Skin/Nipple change (check all that apply)

☐ Skin Dimpling ☐ Erythema/Skin thickening

☐ Nipple Retraction ☐ Nipple Scaling

☐ Pain/Tenderne

☐ Occult Mammographic Abnormality

☐ Density(Nodule or Asymmetry)

☐ Microcalcifications

☐ Other, specify: #Name?

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	Breast Size/Shape
	Scar	Skin Change
☒ Palpation, specify:	Fibrocystic Breast	Nodularity
	Mass(es)	Pain/tenderness

☒ Lymph node examination Adenopathy/Axillary Nodes

☒ **No specific documentation besides normal**

☒ Other, Specify: #Name?

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: #Name?	Location: #Name?
☒ Lump(s)/Mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic	☒ Lump(s)/mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic
Lump size: #Name?	Lump size: #Name?
Depth:	Depth:
Hardness:	Hardness:
Mobility:	Mobility:
Shape:	Shape:
Texture:	Texture:
Additional Findings With Lumps (check all that apply):	Additional Findings With Lumps (check all that apply):
Skin Dimpling/Retraction	Skin Dimpling/Retraction
Skin Erythema	Skin Erythema
Skin Peau d'orange or Skin Thickening	Skin Peau d'orange or Skin Thickening
Nipple Retraction	Nipple Retraction
Nipple Scaling	Nipple Scaling
Pain/Tenderness	Pain/Tenderness
Fibrocystic Breast(s)	Fibrocystic Breast(s)
Nipple Discharge	Nipple Discharge
☒ Other, Specify: #Name?	☒ Other, Specify: #Name?
☒ Nipple Discharge With No Lump	☒ Nipple Discharge With No Lump
Spontaneous?	Spontaneous?
Color	Color
Unilateral or bilateral?	Unilateral or bilateral?
Single or multiple ducts?	Single or multiple ducts?
☒ Observational Findings With No Lump	☒ 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: #Name?

☒ Skin dimpling/retraction
☒ Skin Erythema
☒ Skin Peau d'orange/Skin Thickening
☒ Nipple retraction
☒ Nipple scaling

☒ Pain
☒ Breast pain
☒ Chest wall pain
☒ Unspecified

☒ Other, specify: #Name?

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

☒ Drawing of abnormal findings

☒ Inspection, specify: Nipple Change, Breast Size/Shape, Scar, Skin Change

☒ Palpation, specify: Fibrocystic Breast, Nodularity, Mass(es), Pain/tenderness

☒ Lymph node examination

Adenopathy/Axillary Nodes

Lymph Node Enlarged?

☒ Other, Specify: #Name?

Go To Followup Form

Go To Test Result Form

Form III-Test Result Entry

Study ID: #Name? **Date of the Visit:** #Name?

12. Mammogram Documentation:

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

13a. Mammogram Findings: Final Impressions Which Breast?

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

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

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 breas	
☐ 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 fibroadenom	☐ Rounded densities, most likely cyst or fibroaden
☐ Irregular Density(ies)	☐ Irregular Density(ies
☐ Benign Appearing Calcifications	☐ Benign Appearing Calcifications
☐ Suspicious Calcification	☐ Suspicious Calcification
☐ Calcified Fibroadenoma	☐ Calcified Fibroadenoma
☐ Axillary Lymph Node	☐ Axillary Lymph Node
☐ Other, specify: #Name?	☐ Other, specify: #Name?

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 Quadra

☐ Upper Inner Quadrant ☐ Lower Inner Quadrant ☐ Upper Inner Quadrant ☐ Lower Inner Quadra

☐ 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:#Name? ☐ Other, specify: #Name?

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

15.Cyst-Fine Needle Aspiration (FNA)

Done by: **Date done:** #Name?

☐ Mass resolved/fluid not bloody ☐ Fluid blood

☐ Residual Mass

☐ Other, specify: #Name?

☐ **Sent Fluid to Cytology**

Results Obtained Stamped/Documented? Date: #Name?

Results Reviewed By FPCP Signed/Documented? Date: #Name?

Cytology Results:

☐ Insufficient/Hypocellular/Apocrine Cells ☐ Malignant

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

☐ Other, specify: #Name?

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

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

Done by: **Date done:** #Name?

☐ **Specimen Submitted For Analysis**

Results Obtained Stamped/Documented? Date: #Name?

Results Reviewed By FPCP Signed/Documented? Date: #Name?

Pathology Results:

☐ Insufficient/Hypocellular ☐ Benign/Fibrocystic ☐ Atypical cells

☐ Suspicious for malignancy ☐ Malignant

☐ Other, specify: #Name?

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

19. Ultrasound Findings:

Ordered by: **Date done:** #Name?

Results Obtained Stamped/Documented? Date: #Name?

Results Reviewed By FPCP Signed/Documented? Date: #Name?

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

☐ Other, specify: #Name?

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

21. Image-Guided Biopsy/Open Biopsy Results: **Date done:** #Name?

Results Received Stamped/Documented? Date: #Name?

Results Reviewed By FPCP Signed/Documented? Date: #Name?

Open Biopsy Findings(check all that apply):

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

☐ 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: #Name? **Date of Visit:** #Name?

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: #Name?

Recommended by: Comments: #Name?

Follow-up for Specific 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

#Name? (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? #Name?

☒ Reassurance and CBE within 3-6 months if pain persists

☒ Supportive Brassiere

☒ Over-the-counter Analgesics

☒ Danazol, Bromocriptine

Follow-up Common To Any Abnormali

☒ 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:

an (How many) month mammo

an (How many) month CBE

Recom

☒ Ultrasound

Recom. by:

☒ **Surgical Referral**

Recom. by:

☒ Undocumented

Other Recommendations Or Comments Concerning Abnormality(ies):

#Name?

For Occult Mammographic Abnormality:

☒ Radiologic Biopsy/Image-Guided Biopsy

Recommended by:

General Comments About This Visit:

#Name?

Assessment/Recommended Follow-up From Surgeon's Letter

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

Assessment

☒ Referral Diagnosis Not Confirmed

☒ Referral Diagnosis Confirmed

☒ Additional/New findings

☒ Further Tests Recommended/Done By Surgeon, check all that apply

- ☒ Immediate Mammogram
- ☒ Interval Mammogram, how long? #Name?
- ☒ Interval CBE, how long? #Name?
- ☒ Ultrasound
- ☒ FNA
- ☒ FNAB
- ☒ Radiological/Image Guided Biopsy
- ☒ Open Biopsy

Evidence of Malignancy?

☒ Previous Abnormality Resolved

☒ Current Abnormality Resolved

☒ Other Comments From Surgeon's Letter

#Name?

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 B

Data Dictionary used for DOD Datasets

Variable Name	Label	Type	Value Labels /Valid Values	Note
Front-End				
Lname	Patient Last Name	Char		
Fname	Patient First Name	Char		
MRNum	Medical Record Number	Num		
DOB	Patient DOB	Date		DOB stands for Date of Birth
AbsID	Abstractor's ID	Num		
Gender	1. Patient Gender is	Char	1=Female 2= Male 9 = Undoc	
Active	2. Patient has been seen in last 3 years	Char	1=Yes 0 = No 9 = Undoc	
FirstVis	2a.Date of the very first visit to the FPC provider	Date		Very first visit to the FPC provider
Age70	3 Patient birthday is between August 1, 1928 and July 31, 1960	Char	1=Yes 0 = No 9 = Undoc	Patient birthday must be between 8/01/1928 and 7/01/1959
Care	4. Breast health care provided by	Char	1=FPC Provider 6 = Other 9 = Undoc	Breast Care Health Provider
Active1	5. Active patient between 8/1/99 - 7/31/00	Char	1=Yes 0 = No 9 = Undoc	Set dates are 08/01/98 – 07/31/99
E5a	5a. If there is documentation patient left practice before 7/31/00	Char	1=N/A 2=Death 3=Transferred 4=Move out of town 8=Other, specify	if inactive patient
E5aspe	Other, specify	Char		specify
E5adate	Date of Documentation:	Date		date of inactivity
ECode	Eligibility Code	Char	1=Eligible 2 = Guide;ine Insertion 3 = Ineligible	
ECodeOld	The old ECoded assigned last year	Char	1=Eligible 2 = Guide;ine Insertion 3 = Ineligible	
StudyIDOld	Study ID	Num		Old Study ID
Dateold	Date the form was filled out	Num		Date the form was filled out old

Variable Name	Label	Type	Value Labels /Valid Values	Note
Front-End				
Date	Today's Date: Date the form was filled out	Num		Date the form was filled out year 2000
NewGuide1	Guideline Inserted	Char	Yes/No	
NewGuide2	Guideline Not Found	Char	Yes/No	
NewGuide3	Summary Sheet Inserted	Char	Yes/No	
NewGuide4	Summary Sheet Not Found	Char	Yes/No	
NewGuide5	Additional Information on Summary Sheet	Char	Yes/No	
NewGuide6	No Additional Information on Summary Sheet	Char	Yes/No	
Stamp	Are documents stamped?	Char	1=Guideline Stamped 2=Summary Sheet Stamped 3=Both Stamped 4=Not Applicable	
StudyID	Study ID	Num		StudyID year 2000
DMRVis	1. Date of most recent visit	Char		Date of most recent visit (MM/DD/YY)
dclevis	2. Autocalculated Date For the Last Eligibile Visit Within the Last 15 months (MM/DD/YY):	Char		Calculated Last Eligibility Visit
DateAdd	2a Overlap Period	Num		
DCLEVisold	2b. Last Year's Autocalculated Date For the Last Eligibile Visit Within the Last 15 months:	Num		Calculated Last Eligibility Visit
TNum	3. Total Number of Visits Within 15 Months, Including The Most Recent Visit	Num		
ActY	4. Was A Breast Care Performed During Any of The Visits Within The 15 Months Period	Char	0=No 1 = Yes	
History	5. Personal/Family History Of Breast Cancer?	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Front-End				
YSelf	In Self?	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	History of breast cancer in self
AgeS	Age	Num		Age of self
SelfFul	Complete Breast Removal	Char	Yes/No	In self Complete Breast Removal
SelfPar	Partial Breast Removal/Lumpectomy	Char	Yes/No	In self Partial Breast Removal/Lumpectomy
SelfProl	Prophylactic Implants	Char	Yes/No	In self Prophylactic implants
SelfAut	Autologous Reconstitution	Char	Yes/No	In self Autologous Reconstitution
SelfsOth	Other	Char	Yes/No	In self Other
SelfsOts	Other, specify	Char		In self other specify
SelfU	Undocumented	Char	Yes/No	In self Undocumented
SelfTChe	Chemotherapy	Char	Yes/No	In self Chemotherapy
SelfTRad	Radiation	Char	Yes/No	In self Radiation
SelfTTam	Tamoxifen/Nolvadex	Char	Yes/No	In self Tamoxifen Nolvadex
SelfTAlt	Alternative medicine(s),	Char	Yes/No	In self Alternative medicine
SelfTAlS	Alternative medicine(s), specify	Char		In self specify
SelfTOth	Other	Char	Yes/No	In self Other
SelfTOts	Other, specify	Char		In self Specify
SelfTUn	Undocumented	Char	Yes/No	In self Undocumented
YMother	In Mother?	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	
AgeM	Age	Num		Age of the Mother
Ysister	In Sister	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	
YSister1	Sister1	Char	Yes/No	
AgeS1	Age	Num		age of sister1
YSister2	Sister2	Char	Yes/No	
AgeS2	Age	Num		age of sister2
YDaugh	In Daughter	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	
YDaugh1	Daughter1	Char	Yes/No	
AgeD1	Age	Num		age of daughter1
YDaugh2	Daugher2	Char	Yes/No	
AgeD2	Age	Num		age of daughter2

Variable Name	Label	Type	Value Labels /Valid Values	Note
Front-End				
YOther	In Other Relatives	Char	0=None, 1=Yes 8 = Not Applc 9 = Undoc	
SYOther	specify:	Char		
BOX-A	Record information for patient's each visit when a breast care was performed.	Char		

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
DMRVis	Last Eligible Visit	Num		Date of most recent visit (MM/DD/YY), carried over
DVisit	6.Date of Breast Care Activity Was Recorded	Num		Date of visit
texttel	Type of Contact	Char	1=Office Visit 2=Office Initiated Phone Consultation 14=Office Response Phone Consultation 3=Patient Initiated Phone Consultation 4=Screening/Routine/Regular Mammogram 5=Diagnostic(Regular) Mammogram 6=Diagnostic/Cone Compression/Magnification Mammogram 7=Ultrasound Result 8=FNA for Cyst Result 9=FNAB Result 10=Pathology Report for Radiological/Image Guided Biopsy 11=Pathology Report for Open Biopsy 12=Surgeon's Letter 13=Other	
purpose	7.Purpose of this Visit/Call	Char	1=Screening/Well Women Exam/Annual Exam 2=Presenting symptom(s) 3=Follow-up of a previous abnormality 4=Prompted by results of screening mammogram 5=Prompted by results of other test(s) 6=Routine care/Other health problems 8=Other	
text	Specify	Char		Describe
YRPN	8.Resident Physician	Char	Yes / No	Who Performed Breast Care/Phone Consultation?

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
YFPN	8.Faculty Physician	Char	Yes / No	~ do ~
YPAN	8.Physician Assistant	Char	Yes / No	~ do ~
YNPN	8.Nurse Practitioner	Char	Yes / No	~ do ~
UndocN	8.Undocumented	Char	Yes / No	undocumented
Provider1	8.Breast Care Provider1	Char	Yes / No	~ do ~
Provider2	8.Breast Care Provider2	Char	Yes / No	~ do ~
WbrePre	9.Which breast(s) has presenting symptom	Char	1=Left 2=Right 3=Both 9=Don't Know	
PreNone	None	Char	Yes / No	Presenting symptoms, left breast
SymUndo	Undocumented/Don't know	Char	Yes / No	~ do ~
SymLump	Lump/masses	Char	Yes / No	~ do ~
SymDis	Nipple Discharge	Char	Yes / No	~ do ~
SpoonDis	Nipple Discharge specify	Char	1=Spontaneous 0=Non-Spontaneous 9=Undocumented	~ do ~
SymCha	Skin/Nipple change	Char	Yes / No	Presenting symptoms, left breast
SkinDim	Skin Dimpling	Char	Yes / No	~ do ~
Eryth	Erythema/Skin Thickening	Char	Yes / No	~ do ~
NipRet	Nipple Retraction	Char	Yes / No	~ do ~
NipSca	Nipple Scaling	Char	Yes / No	~ do ~
SymPain	Pain/Tenderness	Char	Yes / No	~ do ~
SymWPain	Pain/Tenderness specify	Char	1=Premenstrual/Menstrual 2 = Persistent 8 = Not Specified	~ do ~
SymOcc	Occult Mammographic Abnormality	Char	Yes / No	Presenting symptoms, left breast
symOcc1	Density(Nodule or Asymmetry)	Char	Yes / No	~ do ~
symOcc2	Microcalcifications	Char	Yes / No	~ do ~
SymOth	Other	Char	Yes / No	~ do ~
Other	Other, specify	Char		~ do ~
PreNoneR	None	Char	Yes / No	~ do ~
SymUndoR	Undocumented/Don't know	Char	Yes / No	~ do ~
SymLumpR	Lump(s)/Mass(es)/Asymmetrical thickening	Char	Yes / No	~ do ~
SymDisR	Nipple Discharge	Char	Yes / No	~ do ~

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
SponDisR	Nipple Discharge specify	Char	1=Spontaneous 2 = Non-Spontaneous 9 = Undoc	~ do ~
SymChaR	Skin/Nipple change	Char	Yes / No	Presenting symptoms, right breast
SkinDimR	Skin Dimpling	Char	Yes / No	~ do ~
ErythR	Erythema/Skin thickening	Char	Yes / No	~ do ~
NipRetR	Nipple Retraction	Char	Yes / No	~ do ~
NipScaR	Nipple Scaling	Char	Yes / No	~ do ~
SymPainR	Pain/Tenderness	Char	Yes / No	~ do ~
SymWR	Pain/Tenderness	Char	1=Premenstrual/Menstrual 2 = Persistent 8 = Not Specified	~ do ~
SymOccR	Occult Mammographic Abnormality	Char	Yes / No	~ do ~
symOcc1R	Density(Nodule or Asymmetry)	Char	Yes / No	~ do ~
symOcc2R	Microcalcifications	Char	Yes / No	~ do ~
SymOthR	Other	Char	Yes / No	~ do ~
OtherR	Other, specify	Char		~ do ~
CbeDoc	10. CBE Documentation	Char	1=Documented 0 = Not Done Undoc	
BP	11. Bilateral Implants	Char	Yes / No	11. CBE Findings (Check All That Apply):
Mas	11. Mastectomy, which breast?	Char	Yes / No	~ do ~
MasWhich	11. Mastectomy, which breast?	Char	1=Left 2=Right 3=Both 9=Don't Know	~ do ~
AbnRes	11. Previous abnormality resolved	Char	Yes / No	~ do ~
LGone	Lump/mass resolved	Char	Yes / No	~ do ~
OFGone	Observational finding resolved	Char	Yes / No	~ do ~
NDGone	Nipple discharge resolved	Char	Yes / No	~ do ~
PGone	Pain gone	Char	Yes / No	~ do ~
CBEFN	11.Normal/Symmetrical nodularity/Symmetrical fibrocystic	Char	Yes / No	Quality of Written Description of CBE Documentation
Insn	Inspection, specify	Char	Yes / No	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
CBEInsNC	Nipple Change	Char	1=Yes 0 = No 9 = Undoc	
CBEInsSc	Scar	Char	1=Yes 0 = No 9 = Undoc	
CBEInsBs	Breast Size/Shape	Char	1=Mentioned 0 = Not mentioned 9 = Undoc	
CBEInsS	Skin Change	Char	1=Yes 0 = No 9 = Undoc	
PaIn	Palpation, specify	Char	Yes / No	
CBEPalFC	Fibrocystic Breast	Char	1=Yes 0 = No 9 = Undoc	
CBEInsMa	Mass(es)	Char	1=Yes 0 = No 9 = Undoc	
CBEPalND	Nodularity	Char	1=Yes 0 = No 9 = Undoc	
CBEPalPa	Pain/tenderness	Char	1=Yes 0 = No 9 = Undoc	Pain gone
CBEPALMAS	Masectomy site(s) free of masses	Char	1=Yes 0 = No 9 = Undoc	
NodeN	Lymph node examination	Char	Yes / No	
AdenoN	Adenopathy/Axillary Nodes	Char	1=Yes 0 = No 9 = Undoc	
UndocNR	Undocumented			
NoDoc1	No specific documentation besides normal	Char	Yes / No	
CBEFinO1	Other	Char	Yes / No	
OtherA1	Other, Specify	Char		
Wbre	Which breast(s) has abnormal finding?	Char	1=Left 2=Right 3=Both 9=Don't Know	Abnormal
LClock	Location	Char		Left Breast 0-12 for clock position
LCBEFLu	Lump(s)/Mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic	Char	Yes / No	CBE finding: lump/masses
LLumSize	Lump size	Char		Left breast lump size
LLumDept	Depth	Char	1=Superficial, 2=Medium, 3=Deep	
LLumHard	Hardness:	Char	1=Hard, 2=Firm, 3=Soft	
LLumMobi	Mobility	Char	1=Mobile, 2=Fixed	
LLumShap	Shape	Char	1=Round, 2=Oblong 3 = Irregular	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
LLumText	Texture:	Char	1=Regular, 2=Irregular, 3=Smooth	
LLumSkiD	Skin Dimpling/Retraction	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumEry	Skin Erythema	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LlumPeau	Skin Peau d'orange or Skin Thickening	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumNip	Nipple Retraction	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumSca	Nipple Scaling	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumpPa	Pain/Tenderness	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumpFi	Fibrocystic Breast(s)	Char	1=Yes, 0=No 9 = Undoc	~ do ~
LLumpND	Nipple Discharge	Char	1=Yes, 0=No 9 = Undoc	~ do ~
llumoth	Other	Char		Additional Findings With Lumps- left
llumoths	Other, Specify	Char		~ do ~
LCBEFDis	Nipple Discharge With No Lump	Char	Yes / No	CBE finding: nipple discharge - no lump
LSpon	Spontaneous?	Char	1=Yes, 0=No, 9=Undocumented	CBE finding: nipple discharge
LColor	Color	Char	1=Milky, 2=Green/Brown/Yellow 3=Watery/Serous/Blood y	~ do ~
LLate	Unilateral or bilateral?	Char	2=Bilateral, 1=Unilateral 9 = Undoc	~ do ~
LDuct	Single or multiple ducts?	Char	1=Single duct, 2=Multiple ducts 9 = Undoc	~ do ~
LCBEFObs	Observational Findings With No Lump	Char	Yes / No	CBE finding: observational finding
LSkiDim	Skin dimpling/retraction	Char	Yes / No	~ do ~
LEry	Skin Erythema	Char	Yes / No	~ do ~
LPeau	Skin Peau d'orange/Skin Thickening	Char	Yes / No	~ do ~
LNipRet	Nipple retraction	Char	Yes / No	~ do ~
LNipSca	Nipple scaling	Char	Yes / No	~ do ~
LCBEFP	Pain	Char	Yes / No	CBE finding: pain
LBreast	Breast pain	Char	Yes / No	Pain: breast pain
LCyclic	Breast pain	Char	1=Cyclic, 0=Noncyclic 9 = Undoc	Pain: breast pain

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
LChest	Chest wall pain	Char	Yes / No	Pain: chest pain
LUnspe	Unspecified	Char	Yes / No	Pain: unspecified
LCBEFinO	Other	Char	Yes / No	CBE finding other
LOtherA	Other, specify:	Char		CBE finding other, specify
RClock	Location	Char		Location Right Breast 0-12 for clock position
RCBEFLu	Lump(s)/mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic	Char	Yes / No	CBE finding: lump/masses right breast
RLumSize	Lump size	Char		Lump size right breast
RLumDept	Depth	Char	1=Superficial, 2=Medium, 3=Deep	Depth lump right breast
RLumHard	Hardness	Char	1=Hard, 2=Firm, 3=Soft	Hardness lump right breast
RLumMobi	Mobility	Char	1=Mobile, 2=Fixed	Mobility lump right breast
RLumShap	Shape	Char	1=Round, 2=Oblong, 3=Irregular	Shape lump right breast
RLumText	Texture:	Char	1=Regular, 2=Irregular, 3=Smooth	Texture right breast
RLumSkiD	Skin Dimpling/Retraction	Char	1=Yes, 0=No, 9=Undocumented	Additional Findings With Lumps- right breast
RLumEry	Skin Erythema	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumPeau	Skin Peau d'orange or Skin Thickening	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumNip	Nipple Retraction	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumSca	Nipple Scaling	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumPa	Pain/Tenderness	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumFi	Fibrocystic Breast(s)	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
RLumpPa	Nipple Discharge	Char	1=Yes, 0=No, 9=Undocumented	~ do ~
rlimoth	Other	Char	Yes / No	~ do ~
rlimoths	Other, Specify:	Char		~ do ~
RCBEFDis	Nipple Discharge With No Lump	Char		CBE finding: nipple discharge right breast
RLSpon	Spontaneous?	Char	1=Yes, 0=No, 9=Undocumented	CBE finding: nipple discharge right breast

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
RColor	Color	Char	1=Milky, 2=Green/Brown/Yellow 3=Watery/Serous/Blood y	~ do ~
RLate	Unilateral or bilateral?	Char	2=Bilateral, 1=Unilateral 9 = Undoc	~ do ~
RLDuct	Single or multiple ducts?	Char	1=Single duct, 2=Multiple ducts 9 = Undoc	~ do ~
RCBEFObs	Observational Findings With No Lump	Char	Yes / No	CBE finding: observational finding, right breast
RSkiDim	Skin dimpling/retraction	Char	Yes / No	
REry	Skin Erythema	Char	Yes / No	
RLPeau	Skin Peau d'orange/Skin Thickening	Char	Yes / No	
RLNipRet	Nipple retraction	Char	Yes / No	
RNipSca	Nipple scaling	Char	Yes / No	
RCBEFP	Pain	Char	Yes / No	CBE finding: pain
RBreast	Breast pain	Char	Yes / No	Pain: breast pain
RCyclic	Breast pain specify	Char	1=Cyclic, 0=Noncyclic 9 = Undoc	Right breast pain
RChest	Chest wall pain	Char	Yes / No	Pain: chest pain
RUnspe	Unspecified	Char	Yes / No	Pain: unspecified
RCBEFinO	Other	Char	Yes / No	CBE finding other
ROtherA	Other, specify:	Char		
CBEDDra	Drawing of abnormal findings	Char	Yes / No	Quality of Written Description of CBE Documentation For Abnormal Findings
Ins	Inspection, specify:	Char	Yes / No	Written description
CBEInsAC	Nipple Change	Char	1=Yes, 0=No, 9=Undocumented	
CBEInsas	Scar	Char	1=Yes, 0=No, 9=Undocumented	
CBEInsAB	Breast Size/Shape	Char	1=Mentioned 0 = Not mentioned	
CBEInsag	Skin Change	Char	1=Yes, 0=No, 9=Undocumented	
Pal	Palpation, specify:	Char	Yes / No	Palpation
CBEPalaf	Fibrocystic Breast	Char	1=Yes, 0=No, 9=Undocumented	
CBEInsAM	Mass(es)	Char	1=Yes, 0=No, 9=Undocumented	
CBEPalan	Nodularity	Char	1=Yes, 0=No, 9=Undocumented	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form II Visit Entry Form				
CBEPalP1	Pain/tenderness	Char	1=Yes, 0=No, 9=Undocumented	
Node	Lymph node examination	Char	Yes / No	
Adeno	Adenopathy/Axillary Nodes	Char	1=Yes, 0=No, 9=Undocumented	
LNLar	Lymph Node Enlarged?	Char	1=Yes 0 = No	
cbeoth	Other	Char	Yes / No	other quality control
cbeoths	Other, Specify:	Char		
Change	Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the changes	Char	Yes / No	Is this visit changed?
COMMENT	COMMENT	Char		

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
StudyID	Study ID	Num		Carried over study ID
Date	Date of the Visit	Date		Carried over date of visit
DMRVis	Last Eligible Visit	Date		
MamDoc	12. Mammogram Documentation	Char	1=Documented 2=Previously Documented 0=Not Done/Undocumented	
DiaOrd	1. Ordered/Recommended/Encouraged	Char	1=Yes 0=No 9=Don't Know/Undocumented	
DDiaOrd	Date	Date		
DiaMam	2. Mammogram Performed	Char	1=Yes 0=No 9=Don't Know/Undocumented	
DDiaMam	Date	Date		
DiaObtSt	3. Results Obtained Stamped/Documented	Char	1=Yes 2=Yes, but can not read date 0=No	
DDiaObt	Date	Date		
DiaRevSt	4. Results Reviewed By FPCP Signed/Documented?	Char	1=Yes 2=Yes, but can not read date 0=No	
DDiaRev	Date	Date		
bcsideC	13a. Mammogram Findings: Final Impressions Which Breast?	Char	1=Left 2=Right 3=Both 9=Don't Know	
MamFinNL	Left Breast: Normal/No Finding Identified/Category I	Char	Yes / No	
MamFinBL	Left Breast: Normal/Benign-appearing abnormality/Category II	Char	Yes / No	
MamFinPL	Left Breast: Probably benign/possibly malignant, inderterminate /Category III	Char	Yes / No	
MamFinSL	Left Breast: Suspicious for malignancy/Category IV	Char	Yes / No	
MamFinML	Left Breast: Malignant until proven otherwise/Category V	Char	Yes / No	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
MamFinoL	Left Breast: Other:	Char	Yes / No	
MamFinLS	Left Breast: Other: Specify:	Char		
MamFinNR	Right Breast Normal/No Finding Identified/Category I	Char	Yes / No	
MamFinBR	Right Breast Normal/Benign-appearing abnormality/Category II	Char	Yes / No	
MamFinPR	Right Breast Probably benign/possibly malignant, inderterminate /Category III	Char	Yes / No	
MamFinSR	Right Breast Suspicious	Char	Yes / No	
MamFinMR	Right Breast Malignant until proven otherwise/Category V	Char	Yes / No	
MamFinoR	Right Breast, Other	Char	Yes / No	
MamFinRS	Right BreastOther: Specify: Right Breast	Char		
bcsideb	13b. Mammogram Findings: Description Which Breast?	Char	1=Left, 2=Right, 3=Both 9 = DK	
MamDesA	Asymmetric Breast: in Breast Location	Char	Yes / No	
MamDesAw	Asymmetric Breast: more in which breast:	Char	1=Right, 2=Left	
MamDesBL	Left Breast Bilateral Implants	Char	Yes / No	
MamDesRL	Left Breast Radiolucent Breasts	Char	Yes / No	
MamDesDL	Left Breast Dense Breasts/Dense Nodular Breasts	Char	Yes / No	
MamDesL	Left Breast Rounded density(ies), most likely cyst or fibroadenoma	Char	Yes / No	
MamDesIL	Left Breast Irregular Density(ies)	Char	Yes / No	
MamDescL	Left Breast Benign Appearing Calcifications	Char	Yes / No	
MamDesSL	Left Breast Suspicious Calcification	Char	Yes / No	
MAMDECFL	Left Breast Calcified Fibroadenomas	Char	Yes / No	
MamDesAR	Left Breast Axillary Lymph Nodes	Char	Yes / No	
MamDesOL	Left Breast Other	Char	Yes / No	
MamDesLS	Left Breast Other, specify:	Char		
MamDesBR	Right Breast Bilateral Implants	Char	Yes / No	
MamDesRR	Right Breast Radiolucent Breasts	Char	Yes / No	

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
MamDesDR	Right Breast Dense Breasts/Dense Nodular Breasts	Char	Yes / No	
MamDesr	Right Breast Rounded densities, most likely cyst or fibroadenoma	Char	Yes / No	
MamDesIR	Right Breast Irregular Density(ies)	Char	Yes / No	
MamDesCR	Right Breast Benign Appearing Calcifications	Char	Yes / No	
MamDesR1	Right Breast Suspicious Calcification	Char	Yes / No	
MamDecFR	Right Breast Calcified Fibroadenomas	Char	Yes / No	
MamDesAI	Right Breast Axillary Lymph Nodes	Char	Yes / No	
MamDesOR	Right Breast Other	Left Breast Locatio n: /No		
MamDesRS	Right Breast Other, specify:	Char		
bcsideA	13c. Mammogram Findings: Location For Category II and Up Which Breast?	Char	1=Left, 2=Right, 3=Both 9 = DK	
MamLUppO	Upper Outer Quadrant	Char	Yes / No	Left Breast Location
MamLLowO	Lower Outer Quadrant	Char	Yes / No	~ do ~
MamLUppI	Upper Inner Quadrant	Char	Yes / No	~ do ~
MamLLowI	Lower Inner Quadrant	Char	Yes / No	~ do ~
LmamLb	Lateral Breast	Char	Yes / No	~ do ~
LMamMb	Medial Breast	Char	Yes / No	~ do ~
MamLRetr	Areolar/Nipple Area	Char	Yes / No	~ do ~
MamLDeep	Deep Against Chest Wall	Char	Yes / No	~ do ~
MamLSca	Scattered/Throughout Breast	Char	Yes / No	~ do ~
MamLPosO	Other	Char	Yes / No	~ do ~
MamLPosS	Other, specify:	Char		~ do ~
MamRUppO	Upper Outer Quadrant	Char	Yes / No	Right Breast Location
MamRLowO	Lower Outer Quadrant	Char	Yes / No	~ do ~
MamRUppI	Upper Inner Quadrant	Char	Yes / No	~ do ~
MamRLowI	Lower Inner Quadrant	Char	Yes / No	~ do ~
Rmamlb	Lateral Breast	Char	Yes / No	~ do ~
RMamMb	Medial Breast	Char	Yes / No	~ do ~
MamRRetr	Areolar/Nipple Area	Char	Yes / No	~ do ~
MamRDeep	Deep Against Chest Wall	Char	Yes / No	~ do ~
MamRSca	Scattered/Throughout Breast	Char	Yes / No	~ do ~
MamRPosO	Other	Char	Yes / No	~ do ~
MamRPosS	Other, specify:	Char		~ do ~

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
PM	14. Patient Notified of the Mammogram Findings?	Char	1=Yes, 0=No 9 = Undoc / DK	
DPM	Date of Notification:	Char		Date patient was notified
WHoFNA	15.Cyst-Fine Needle Aspiration (FNA) Done by:	Char	1=FPCP, 2=Surgeon, 8=Other 9 = Undoc / DK	
FNAD	Date done:	Date		Date FNA was performed
FnaFinM	Mass resolved/fluid not bloody	Char	Yes / No	Fine Needle Aspiration mass resolved/fluid not bloody
FnaFinF	Fluid bloody	Char	Yes / No	Fine Needle Aspiration fluid bloody
FnaFinR	Residual Mass	Char	Yes / No	Fine Needle Aspiration residual mass
FnaFinO	Other	Char	Yes / No	Fine Needle Aspiration other
Other2	Other, specify:	Char		
FNACyto	Sent Fluid to Cytology	Char	Yes / No	
DiaObtStf	Results Obtained Stamped/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaObtf	Date:	Date		
DiaRevStf	Results Reviewed By FPCP	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaRevf	Date:	Date		
Insuf1	Cytology Results: Insufficient/Hypocellular/Apocrine Cells	Char	Yes / No	Insufficient
Benign1	Cytology Results: Benign/Fibrocystic/Apocrine Cells	Char	Yes / No	Benign
Acell1	Atypical cells	Char	Yes / No	
Sus1	Suspicious for malignancy	Char	Yes / No	
Malig1	Malignant	Char	Yes / No	
FnaRFinO	Other	Char	Yes / No	~ do ~
ROtherB	Other, specify:	Char		
PF	16. Patient Notified of the FNA Findings From Cytology?	Char	1=Yes, 0=No 9 = Undoc / DK	
DPF	Date of Notification:	Date		Date patient was notified

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
WHoFNAB	17. Solid Mass-Fine Needle Aspiration Biopsy (FNAB) Done by:	Char	1=FPCP, 2=Surgeon, 8=Other 9 = Undoc / DK	
FNABD	Date done:	Date		Date FNA was performed
FNABPath	Specimen Submitted For Analysis	Char	Yes / No	
DiaObtStfb	Results Obtained Stamped/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaObtfb	Date:	Date		
DiaRevStfb	Results Reviewed By FPCP Signed/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaRevfb	Date:	Date		
Insuf	Pathology Results: Insufficient/Hypocellular	Char	Yes / No	Insufficient
Benign	Pathology Results: Benign/Fibrocystic	Char	Yes / No	
Acell	Pathology Results: Atypical cells	Char	Yes / No	
Sus	Pathology Results: Suspicious for malignancy	Char	Yes / No	
Malig	Pathology Results: Malignant	Char	Yes / No	
FnabFinO	Other	Char	Yes / No	~ do ~
OtherB	Other, specify:	Char		
PFB	18. Patient Notified of the FNAB Findings From Path Report?	Char	1=Yes, 0=No 9 = Undoc / DK	
DPFB	Date of Notification:	Date		Date patient was notified
WhoOrdUl	19. Ultrasound Findings: Ordered by:	Char	1=FPCP 2=Surgeon 3=Radiologist 8=Other 9=Undocumented/Don't Know	Date ultrasound was performed
UltD	Date done:	Date		
DiaObtStul	Results Obtained Stamped/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaObtul	Date:	Date		
DiaRevStul	Results Reviewed By FPCP Signed/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
DDiaRevul	Date:	Date		
UltFinNe	Negative finding	Char	Yes / No	ultrasound negative finding
UltFinS	Simple cyst(s)	Char	Yes / No	ultrasound simple cyst

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form III -Test Result Entry				
UltFinC	Solid mass(es) or complex cyst(s)	Char	Yes / No	ultrasound solid or complex cyst
UltFinO	Other	Char	Yes / No	ultrasound other
Other3	Other, specify:	Char		
PU	20. Patient Notified of the Ultrasound Findings?	Char	1=Yes 0 = No 9 = DK/ Undoc	
DPU	Date of Notification:	Date		Date patient was notified
OBRD	21. Image-Guided Biopsy/Open Biopsy Results: Date done:	Date		
OBRRecS	Results Received Stamped/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
OBRRecD	Date:	Date		
OBRRevS	Results Reviewed By FPCP Signed/Documented?	Char	1=Yes 2 = Yes, but can not read 0 = No	
OBRRevD	Date:	Date		
OBRB	Benign/No Evidence of Malignancy	Char	Yes / No	Open Biopsy Findings
OBRFC	Benign/Fibrocystic Changes	Char	Yes / No	~ do ~
OBRBenFi	Benign/Fat Necrosis	Char	Yes / No	~ do ~
OBRBenLi	Benign/Lipoma	Char	Yes / No	~ do ~
OBRBenFb	Benign/Fibroadenoma	Char	Yes / No	~ do ~
OBRDC	Ductal Carcinoma in situ	Char	Yes / No	~ do ~
OBRIDS	Lobular Carcinoma in situ	Char	Yes / No	~ do ~
OBRAH	Atypical Hyperplasia	Char	Yes / No	~ do ~
OBRID	Invasive Ductal Carcinoma	Char	Yes / No	~ do ~
OBRLC	Invasive Lobular Carcinoma	Char	Yes / No	~ do ~
OBRO	Other	Char	Yes / No	~ do ~
OBROS	Other, specify:	Char		
Change	Click here if you changed anything about this visit entry, compared to last year's entry and briefly specify the changes	Char		Is this visit changed?
COMMENT		Char		What kind of change?

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form IV - Follow-Up Form				
StudyID	StudyID:	Num		Carried over study ID
Date	Date of Visit:	Date		Carried over date of visit
DMRVis	Last Eligible Visit:	Date		
Undoc	23. Recommended Follow-Up(s) (Check All That Apply) Undocumented	char	Yes / No	
Rou	Routine Screening	char	Yes / No	Follow-up for Normal CBE and Mammogram (or One of Them Undocumented):
CBE12	12 Month CBE	char	Yes / No	~ do ~
Mam12	12 Month Mammogram	char	Yes / No	~ do ~
ACS	Following ACS Guidelines	char	Yes / No	~ do ~
OthGui	Following Other Guidelines	char	Yes / No	~ do ~
OthGuiS	specify:	Char	Yes / No	
WhoRou	Recommended by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	
ncomment	Comments:	Char	Yes / No	
CBEbet	Breast Mass/Asymetry Initial Approach:CBE at better phase cycle (3-10 days)	Char	Yes / No	Follow-up for Specific Abnormalities:
FNAC	Breast Mass/Asymetry Initial Approach:Fine Needle Aspiration for Cyst	Char	Yes / No	~ do ~
cytology	If Known Breast Cyst:Send Fluid to Cytology	Char	Yes / No	~ do ~
Reasp	If Known Breast Cyst:Reaspiration	Char	Yes / No	~ do ~
MInterC	If Known Breast Cyst: (How many) month CBE	Char	Yes / No	~ do ~
FNAB1	If Known Solid Mass: Fine Needle Aspiration Biopsy	Char	Yes / No	~ do ~
SendSpe	If Known Solid Mass: Specimen Submitted for Analysis	Char	Yes / No	~ do ~
rasp3	If Known Solid Mass: Repeat aspiration	Char	Yes / No	~ do ~

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form IV - Follow-Up Form				
CF	If Known Solid Mass: Clinical Followup Every 3 Months for 1 Year	Char	Yes / No	~ do ~
Endo	For Nipple Discharge: Endocrine work-up	Char	Yes / No	~ do ~
Antibio	For Skin/Nipple Changes on Observation: 2 weeks antibiotics	Char	Yes / No	~ do ~
cortis	For Skin/Nipple Changes on Observation: 2 weeks topical hydrocortisone	Char	Yes / No	~ do ~
SB	For Skin/Nipple Changes on Observation: Skin Biopsy	Char	Yes / No	~ do ~
Caff	For Breast pain: Eliminate Caffeine	Char	Yes / No	~ do ~
Estro	For Breast pain: Adjust Estrogen Dose	Char	Yes / No	~ do ~
anes	For Breast pain: Local Anesthetic Injection	Char	Yes / No	~ do ~
Oil	For Breast pain: Primrose Oill,	Char	Yes / No	~ do ~
Oilday	For Breast pain: How Many Months Oil?	Char		~ do ~
Reass	For Breast pain: Reassurance and CBE within 3-6 months if pain persists	Char	Yes / No	~ do ~
Brass	For Breast pain: Supportive Brassiere	Char	Yes / No	~ do ~
Analg	For Breast pain: Over-the-counter Analgesics	Char	Yes / No	~ do ~
dabrom	For Breast pain: Danazol, Bromocriptine	Char	Yes / No	~ do ~
RB	For Occult Mammographic Abnomality: Radiologic Biopsy/Image-Guided Biopsy	Char	Yes / No	~ do ~
WhoRB	For Occult Mammographic Abnomality: Recommended by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	~ do ~
Call	Call if Problem Worsens	Char	Yes / No	Follow-up Common To Any Abnor:

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form IV - Follow-Up Form				
Rou1	Routine Screening	Char	Yes / No	Follow-up Common To Any Abnor:
WHORS	Recom. by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	~ do ~
RegMam	Immediate Mammo Workup Regular Mammo	Char	Yes / No	Follow-up Common To Any Abnor:
EV	Immediate Mammogram Workup: Extra Mammogram Views	Char	Yes / No	Follow-up Common To Any Abnor:
CC	Immediate Mammogram Workup: Cone or Spot Compression	Char	Yes / No	~ do ~
MV	Immediate Mammogram Workup: Magnification Views	Char	Yes / No	~ do ~
WhoEV	Recom. by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	~ do ~
MInterM	Interval Followup How many month mammo	Char	Yes / No	Follow-up Common To Any Abnor:
MInterC1	Interval Followup: (How many) month CBE	Char	Yes / No	~ do ~
WhoInt	Recom. by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	Follow-up Common To Any Abnormalities:

Variable Name	Label	Type	Value Labels /Valid Values	Note
Form IV - Follow-Up Form				
ultra	Ultrasound	Char	Yes / No	Follow-up Common To Any Abnor:
WhoUlt	Recom. by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	Follow-up Common To Any Abnor:
SR	Surgical Referral	Char	Yes / No	Follow-up Common To Any Abnor:
WhoSR	Recom. by:	Char	1=Family Practice Doctor only(FPD) 2=Radiologist only 3=Both FPD and Radiologist 4=Surgeon 5=Nurse Practitioner 8=Other 9=Undocumented	Follow-up Common To Any Abnor:
undoc1	Undocumented	Char	Yes / No	Follow-up Common To Any Abnor:
Comments	Other Recommendations Or Comments Concerning Abnormality(ies):	Char		Comments for follow-up
Gcomment	General Comments About This Visit:	Char		General comments about this case

Appendix C

Tables

Table 1: A Woman's Chances of Breast Cancer Increases with Age

Age	Incidence Rate
By age 30	1 out of 2,212
By age 40	1 out of 235
By age 50	1 out of 54
By age 60	1 out of 23
By age 70	1 out of 14
By age 80	1 out of 10
Ever	1 out of 8

Source: Feuer EJ, Wun LM. DEVCAN: Probability of Developing or Dying of Cancer. Version 4.0. Bethesda MD: National Cancer Institute. 1999.

Table 2: Five Year Survival Rate by Age

Age	Survival Rate
Younger than 45	81%
Ages 45-64	85%
Ages 65 and older	86%

Source: American Cancer Society

Table 3: Survival vs. Treatment Cost

Stage	Average cost in $
Mammography	90
Diagnostic Workup	500
Biopsy	2,000
Early stage treatment	11,000
Late stage treatment	140,000

Table 4: Guidelines by various organization for Breast Cancer Screening in Women

Organization	Ages 40-49 yr	Ages 50 yr and older
American Cancer Society	Annual mammogram, Annual CBE, Monthly BSE	Annual Mammogram, Annual CBE, Monthly BSE
National Cancer Institute	Mammogram every 1-2 yr	Mammogram every 1-2 yr
US Preventive Services Task Force	Mammogram every 1-2 yr, with or without CBE	Mammogram every 1-2 yr, with or without CBE
American College of Preventive Medicine	Inadequate evidence to recommend or not recommend mammography	Ages 50-69: mammogram every 1-2 year

Table 5: Staging and Survival Rates

Stage	5-year Relative Survival Rate
0	100%
I	98%
IIA	88%
IIB	76%
IIIA	56%
IIIB	49%
IV	16%

Source: American Cancer Society

Table 6: Overall Survival Rate

After 5 years	85%
After 10 years	71%
After 15 years	57%
After 20 years	52%

Source: American Cancer Society

Table 7: American women who have had a Mammogram within past 2 Years

All Women Over 40	66.9%
White, Non-Hispanic Women Over 40	68%
Black, Non-Hispanic Women Over 40	66%
Hispanic Women Over 40	60.2%
Women Over 40 Below Poverty Level	50.5%
Women Over 40 Above Poverty Level	69.3%

1998, Source: National Center for Health Statistics

Table 8: List of intervention and control sites

Intervention Sites:	Control Sites:
Sparrow/MSU	Genesys Health Systems, Flint
St. Lawrance/MSU	McLaren Regional Medical Center, Flint
Kalamazoo Center for Medical Studies	Munson Medical Center, Traverse City
Mid-Michigan Regional Medical Center - Midland	Providence Hospital, Southfield
Saginaw Cooperative Hospitals, Inc.	

Table 9: List of site and assigned site numbers

Site	Site Number
SPARROW	1
STLAWERENCE	2
KALAMAZOO	3
MIDLAND	4
SAGINAW	5
GENESYS	6
MCLAREN	7
TRAVERSE CITY	8
PROVIDENCE	9

Table 10: List of number of subjects per site

Sr. No.	Site	# of Subjects
1	SPARROW	1886
2	STLAWERENCE	953
3	KALAMAZOO	1228
4	MIDLAND	2237
5	SAGINAW	1512
6	GENESYS	1276
7	MCLAREN	781
8	TRAVERSE CITY	1321
9	PROVIDENCE	2036
TOTAL		13230

Table 11: Cleaning of Duplicate Data Entries

Sr. No.	Site	Original Numbers	After Data Cleaning	Number of Duplicate records
1	SPARROW	1886	1624	262
2	STLAWERENCE	953	953	0
3	KALAMAZOO	1228	1222	6
4	MIDLAND	2237	2178	59
5	SAGINAW	1512	1486	26
6	GENESYS	1276	1247	29
7	MCLAREN	781	773	8
8	TRAVERSE CITY	1321	1302	19
9	PROVIDENCE	2036	2032	4
TOTAL		13230	12817	413

Table 12: Symptom Codes

Code Assigned	Description of Abnormality detected by Symptoms presented
1.	Lump
2.	Nipple Discharge
3.	Skin/Nipple Changes
4.	Breast Pain
5.	Occult Mammographic Abnormality
6.	Rash under breasts (intertrigo)
7.	Heavy, full breasts
8.	Boils, pus
9.	Prickly, itchy nipple
10.	Auxiliary lump
11.	Mole, pigmented lesion
12.	Macromastia
13.	Breast swelling on HRT
14.	Increased breast size
15.	Cyclic breast enlargement
16.	Bruising, abrasion
17.	Rash on skin of breast
18.	Nipple bump
19.	Skin bump
20.	Leaky implant
21.	Greenish-yellow nipple discharge
22.	Breast abscess
23.	Pain under arm
24.	Sore on breast
25.	Chemical burn on breast
26.	Auxiliary pain

Table 13: Formula for CBE screening rate calculation

FORMULA	CBE SCREENING RATE
1	SYMPTOM WITHIN 30 DAYS OF CBE
2	ABNORMAL MAMMOGRAM BEFORE CBE
3	CBE DOCUMENTED
4	AVAILABLE SCREENING ELIGIBLE PATIENTS
5	E-CODE ONE AND BREAST CARE
6	E-CODE 1
7	E-CODE 2
8	E-CODE 3 AND CARE 6
NUMERATOR FOR SCREENING	
C1	CBE DOCUMENTED
C2	CBE DOCUMENTED + E-CODE 3 AND CARE 6
DENOMINATOR FOR SCREENING	
D1= 6 - (1+2)	E-CODE 1 - (1+2)
D2= (6 + 8) - (1+2)	(E-CODE 1 & 3*6) - (1+2)
D3= (6 + 7 + 8) - (1+2)	(E-CODE 1, 2 & 3*6) - (1+2)
SCREENING RATE	
PATIENT	C1 / D1
PHYSICIAN	C2 / D2
PUBLIC HEALTH	C2 / D3

Table 14: Formula for Mammogram Ordered

FORMULA	MAMMOGRAM ORDERED
1	DIA ORD
3	E-CODE ONE
4	E-CODE TWO
5	E-CODE THREE CARE SIX
NUMERATOR FOR MAM ORDER SCREENING RATE	
N1 = 1 + 2	DIA ORD + TEXTTEL 13 (REMINDERS)
N2 = 1 + 2 + 5	DIA ORD + TEXTTEL 13 + TEXTTEL 3*6
DENOMINATOR FOR MAM ORDER SCREENING RATE	
D1 = 3 + 2	E-CODE 1 + TEXTTEL 13 (REMINDERS)
D2 = 3 + 5 + 2	E-CODE 1 + 3*6 + TEXTTEL 13
D3 = 3 + 4 + 5 + 2	E-CODE 1 + 2 + 3*6 + TEXTTEL 13
SCREENING RATE	
N1 / D1	BASED ON E-CODE ONE ONLY
N2 / D2	BASED ON E-CODE ONE AND ECODE 3*6
N2 / D3	BASED ON E-CODE ONE, TWO AND 3*6

Table 15: Formula for Mammogram Done

FORMULA	MAMMOGRAM DONE
1	DIA DONE
2	E-CODE ONE
3	E-CODE TWO
4	E-CODE THREE CARE SIX
NUMERATOR FOR MAM DONE SCREENING RATE	
N1 = 1 + 2	DIA DONE
N2 = 1 + 2 + 5	DIA DONE + ECODE 3*6
DENOMINATOR FOR MAM DONE SCREENING RATE	
D1 = 2	E-CODE 1
D2 = 2 + 4	E-CODE 1 + 3*6
D3 = 2 + 3 + 4	E-CODE 1 + 2 + 3*6
SCREENING RATE	
N1 / D1	BASED ON E-CODE ONE ONLY
N2 / D2	BASED ON E-CODE ONE AND ECODE 3*6
N2 / D3	BASED ON E-CODE ONE, TWO AND 3*6

Table 16: Formula for Mammogram Ordered and Done

FORMULA	MAMMOGRAM ORDERED AND DONE
1	DIA DONE & OR ORDERED
2	E-CODE ONE
3	E-CODE TWO
4	E-CODE THREE CARE SIX
NUMERATOR FOR MAM DONE & OR ORDERED SCREENING RATE	
N1 = 1 + 2	DIA DONE & OR ORDERED
N2 = 1 + 2 + 5	DIA DONE + ECODE 3*6
DENOMINATOR FOR MAM ORDER SCREENING RATE	
D1 = 2	E-CODE 1
D2 = 2 + 4	E-CODE 1 + 3*6
D3 = 2 + 3 + 4	E-CODE 1 + 2 + 3*6
SCREENING RATE	
N1 / D1	BASED ON E-CODE ONE ONLY
N2 / D2	BASED ON E-CODE ONE AND ECODE 3*6
N2 / D3	BASED ON E-CODE ONE, TWO AND 3*6

Table 17: Formula for Mammogram either Ordered or Done

FORMULA	MAMMOGRAM EITHER ORDERED OR DONE
NUMERATOR FOR MAM EITHER ORDERED OR DONE	
N1 = 1 + 2	DIA DONE & OR ORDERED
N2 = 1 + 2 + 5	DIA DONE + ECODE 3*6
DENOMINATOR FOR MAM EITHER ORDERED OR DONE	
D1 = 2	E-CODE 1
D2 = 2 + 4	E-CODE 1 + 3*6
D3 = 2 + 3 + 4	E-CODE 1 + 2 + 3*6
SCREENING RATE	
N1 / D1	BASED ON E-CODE ONE ONLY
N2 / D2	BASED ON E-CODE ONE AND ECODE 3*6
N2 / D3	BASED ON E-CODE ONE, TWO AND 3*6

Table 18: Formula for Combined Screening Rate

FORMULA	COMBINED SCREENING RATE
1	CBEDOC AND MAMDOC
2	E-CODE ONE
3	E-CODE TWO
4	E-CODE THREE CARE SIX
NUMERATOR FOR MAM DONE & OR ORDERED SCREENING RATE	
N1 = 1 + 2	DIA DONE & OR ORDERED
N2 = 1 + 2 + 4	DIA DONE + ECODE 3*6
DENOMINATOR FOR MAM DONE & OR ORDER SCREENING RATE	
D1 = 2	E-CODE 1
D2 = 2 + 4	E-CODE 1 + 3*6
D3 = 2 + 3 + 4	E-CODE 1 + 2 + 3*6
SCREENING RATE	
N1 / D1	BASED ON E-CODE ONE ONLY
N2 / D2	BASED ON E-CODE ONE AND ECODE 3*6
N2 / D3	BASED ON E-CODE ONE, TWO AND 3*6

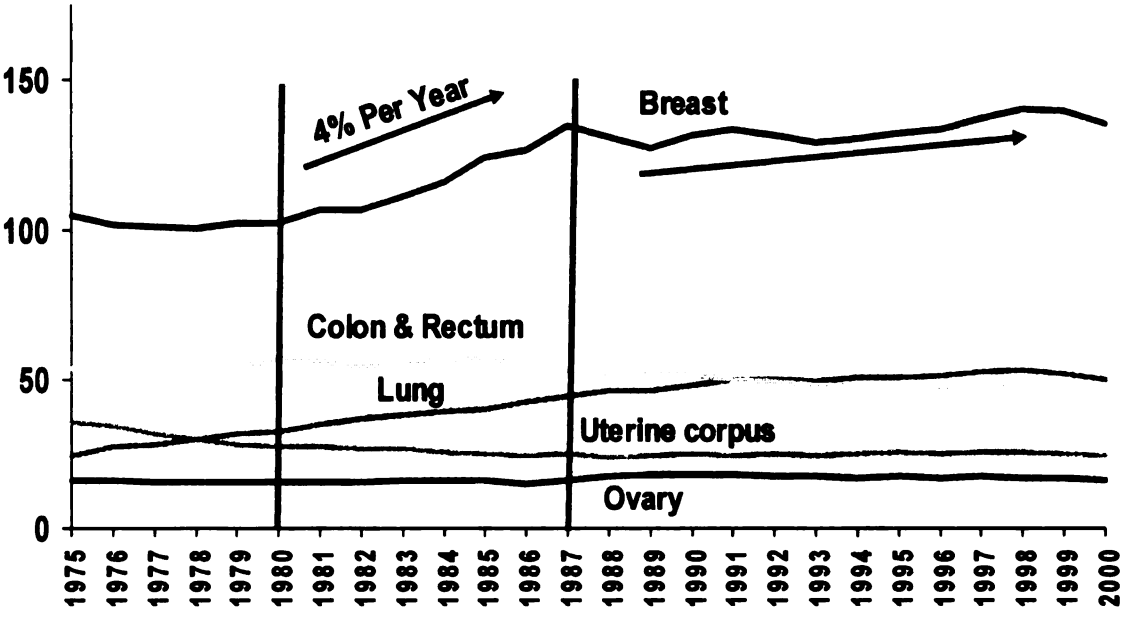
Table 19: Two year screening rates for the DOD study

Screening Rates	Overall	Intervention Sites	Control Sites
CBE Done			
Patient Based	68.4	71.8	63.8
Physician Based	72.2	75.9	66.8
Public Health	55.5	60.5	48.7
Mammogram Ordered			
Patient Based	61.7	57.9	66.9
Physician Based	65.7	63.3	69.3
Public Health	52.0	51.7	52.3
Mammogram Done			
Patient Based	56.8	59.2	53.5
Physician Based	61.5	64.6	57.0
Public Health	48.3	52.5	42.7
Mammogram Ordered and Done			
Patient Based	42.8	43.6	41.6
Physician Based	49.0	51.1	45.9
Public Health	38.5	41.5	34.4
Mammogram either Ordered or Done			
Patient Based	74.3	72.0	77.6
Physician Based	77.1	75.7	79.2
Public Health	60.6	61.5	59.3
CBE and Mammogram Combined Rate			
Patient Based	54.2	52.8	56.3
Physician Based	59.2	59.0	59.5
Public Health	46.5	48.0	44.6

Appendix D

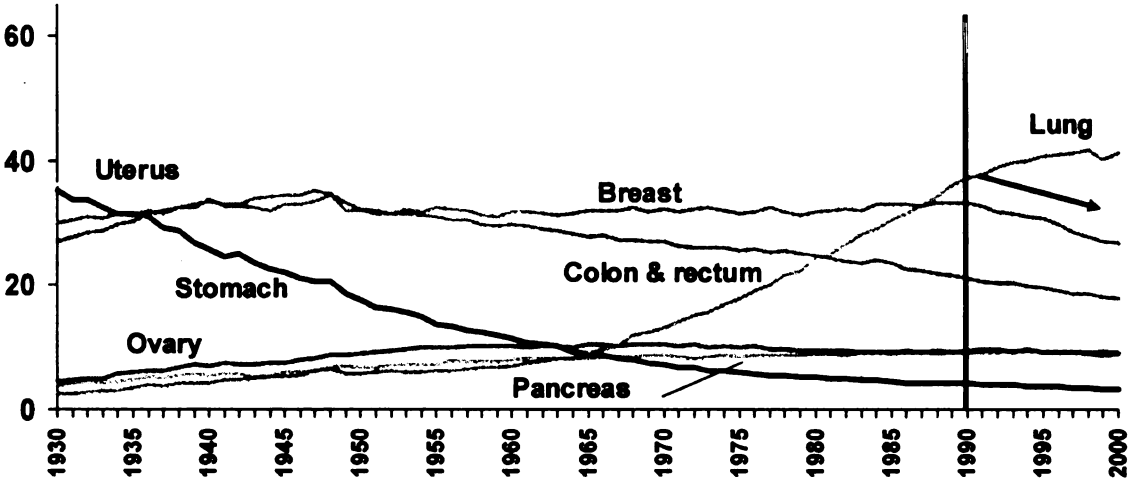
Figures

Figure 1: Cancer Incidence Rates (Age-adjusted rate per 100,000 to the 2000 US standard population) for Women, US, 1975-2000



Source: Surveillance, Epidemiology, and End Results Program, 1975-2000, Division of Cancer Control and Population Sciences, National Cancer Institute, 2003.

Figure 2: Cancer Death Rates (Age-adjusted to the 2000 US standard population) for Women, US, 1930-2000



Source: US Mortality Public Use Data Tapes 1960-2000, US Mortality Volumes 1930-1959, National Center for Health Statistics, CDC, 2003.

Figure 3: Mammography 2000

Source: Behavioral Risk Factor System, CDC

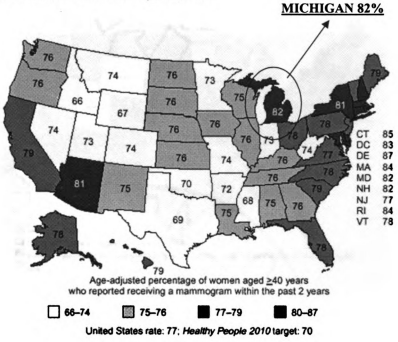


Figure 4: Breast Cancer Deaths 1999

Source: National Vital Statistics System, NCHS, CDC

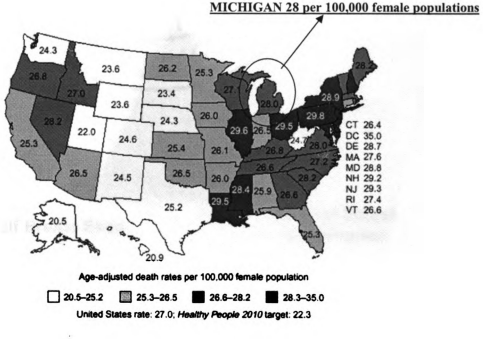


Figure 5: State Specific Annual Breast Exam Guidelines

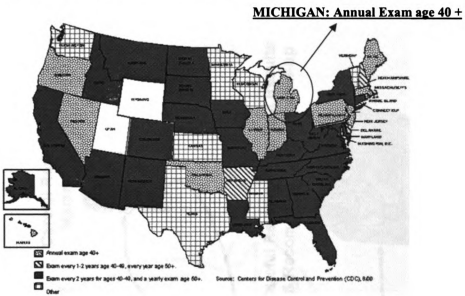


Figure 6: Triad of Breast Cancer Screening:

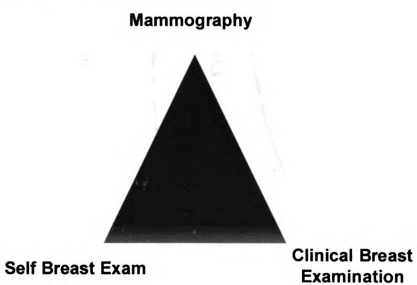


Figure 7: Continuum of Breast Care

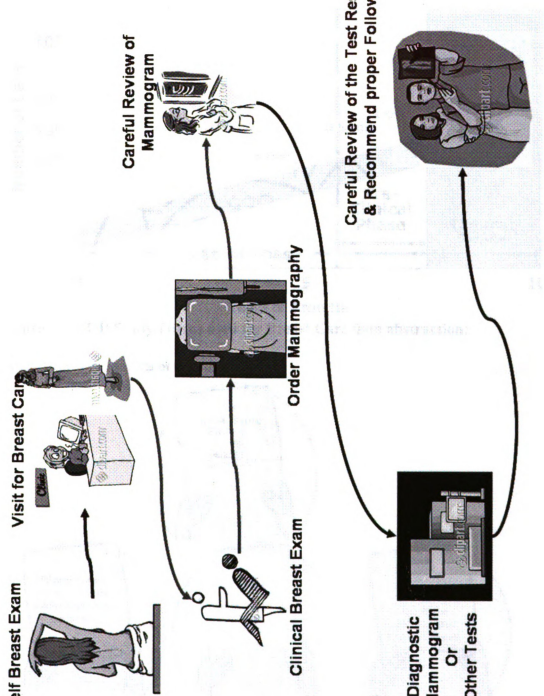


Figure 8: Early Diagnosis by Mammogram
Source: Osuch JR, Pathak DR, Barry HC, Zuber TJ, Slide 66

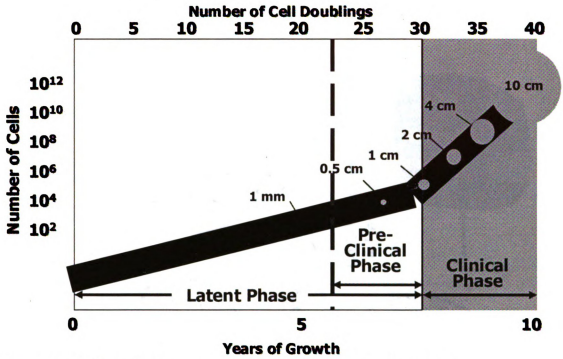


Figure 9a: DOD Study Forms used for Breast Care data abstraction:

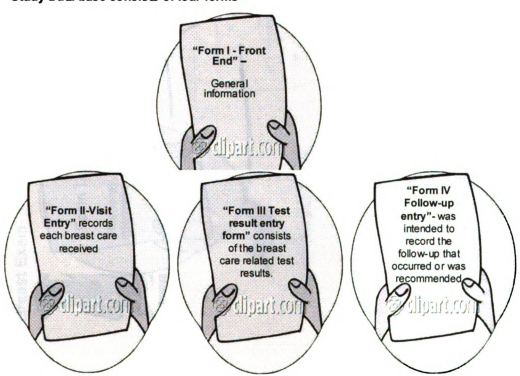


Figure 9b: DOD Study and Breast Care:

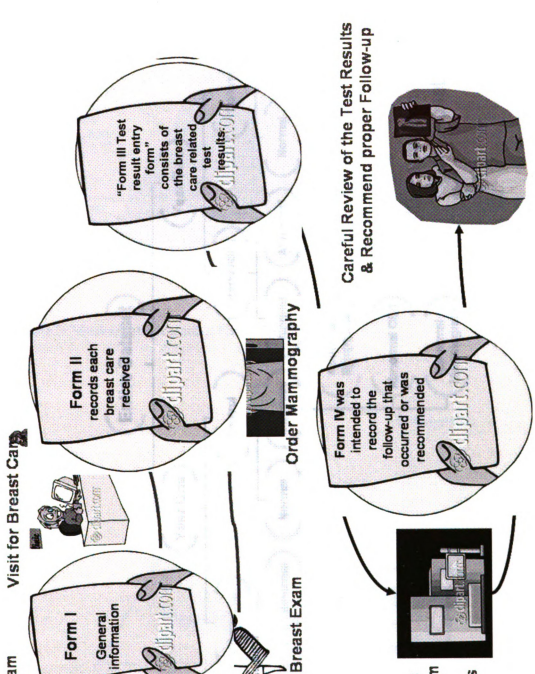


Figure 10: Permanent Dataset Sub Setting Strategy

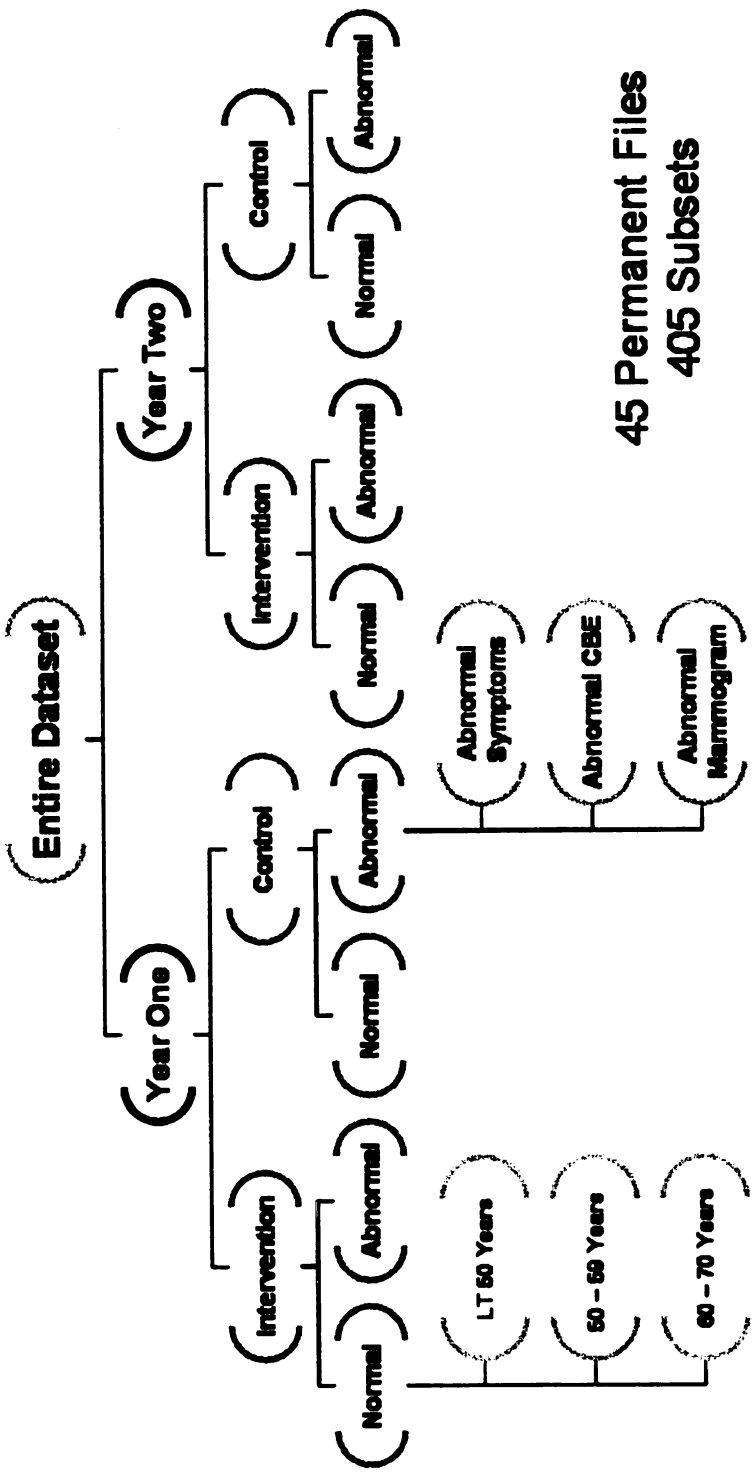


Figure 11: Method of Screening Rate Calculation

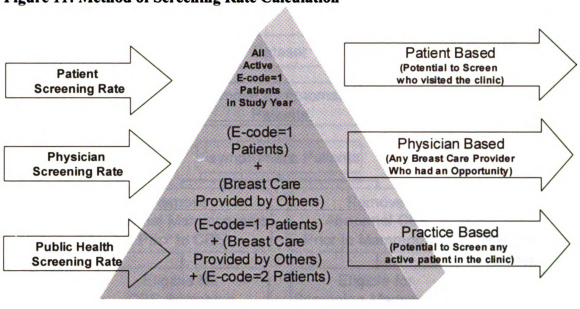


Figure 12: Method of Screening Rate Calculation

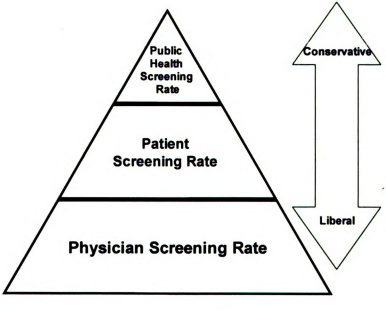


Figure 13: Criteria for Screening Rate Calculation:

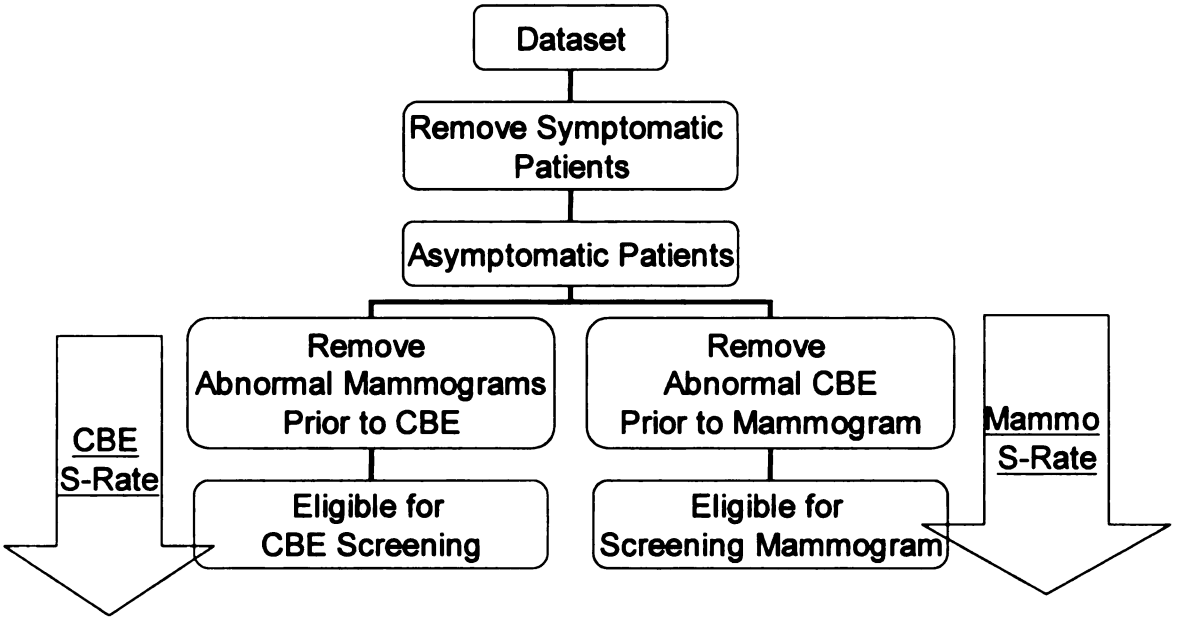


Figure 14: Type of Mammogram Screening Rates:

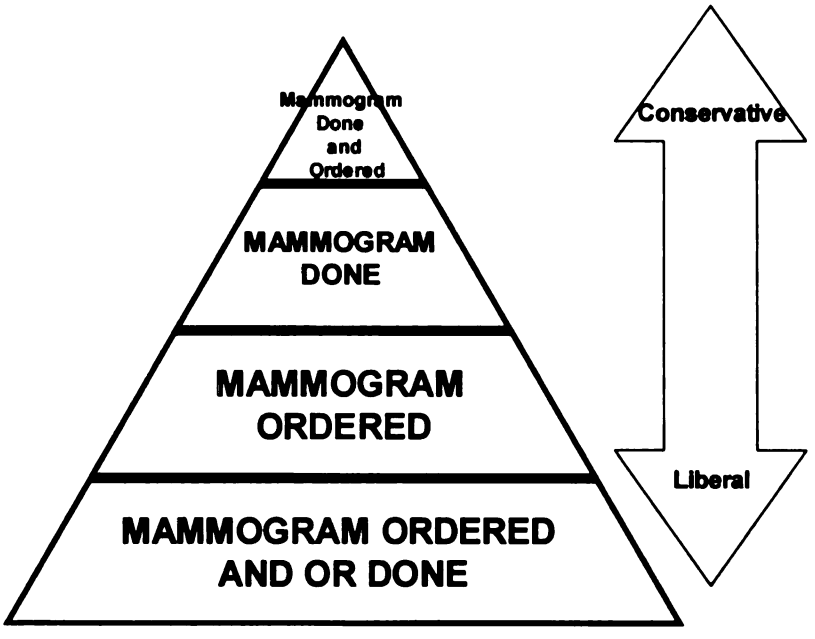


Figure 15: Age Distribution of Eligible Patients in the study

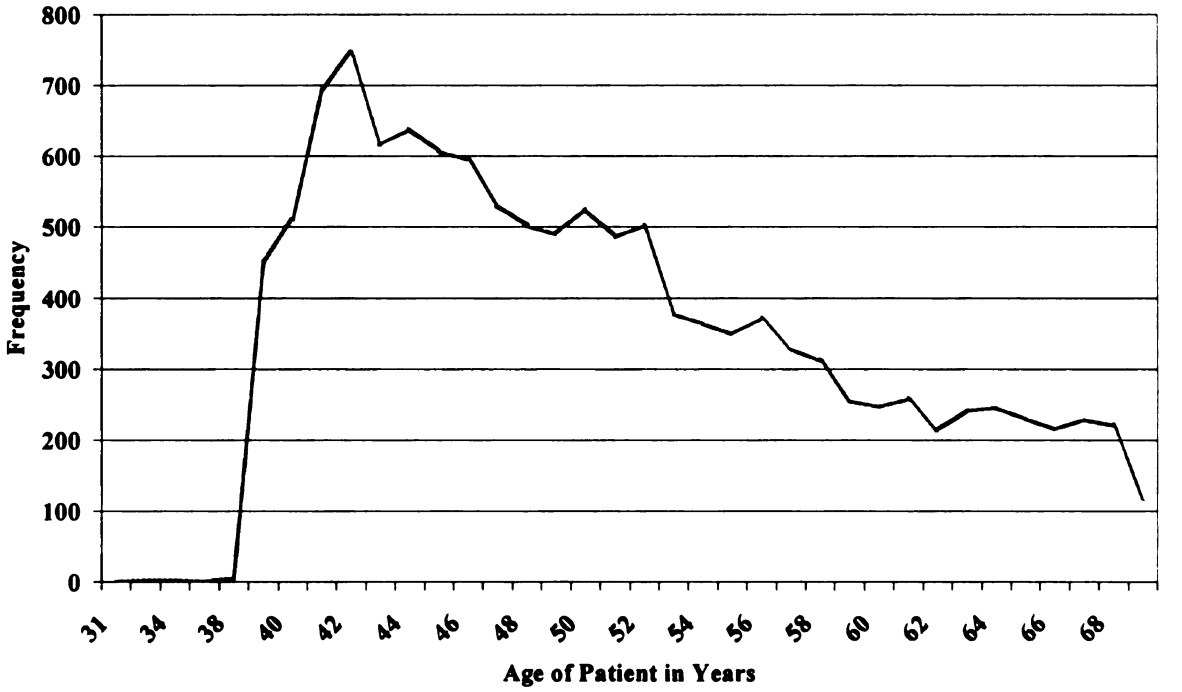


Figure 16: Age distribution of the patients documented with self history of Breast Cancer

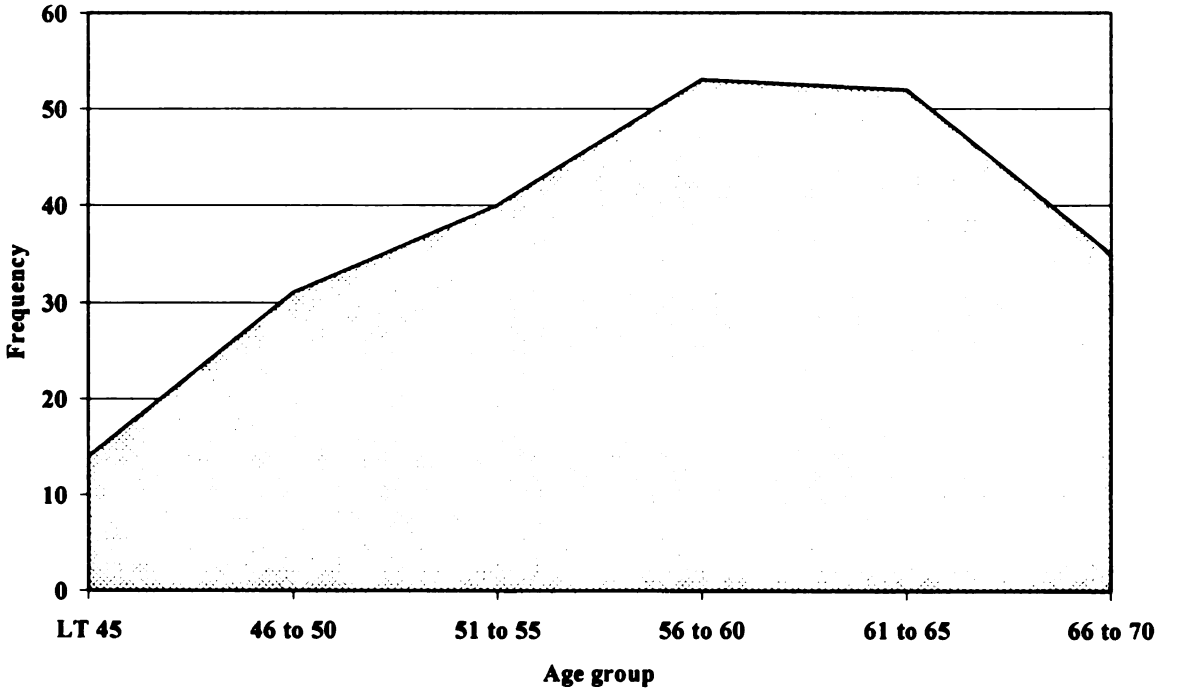
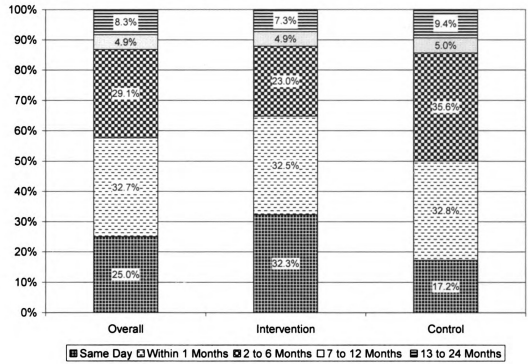


Figure 17: Time Interval between Mammogram Ordered and Mammogram Done



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