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To address inconsistencies among health care providers in breast cancer screening and management of abnormal findings, we randomized eight Family Practice residencies into control and intervention groups. The intervention has multiple components addressing skill, knowledge and management of breast cancer related issues. Additionally, a chart reminder system assists physicians in daily breast care management. Physician performance in clinical settings is assessed through chart audits.

We have successfully completed the training and baseline assessment of cognitive and clinical skills and implemented the chart reminder system for the intervention sites. Chart audits are 95% complete. The analysis of the immediate effect of the training session found that in the short term the curriculum significantly improved cognitive and clinical skills. Assessment of the long-term effect of the curriculum is planned for May and June 2000. The curriculum will be provided to the control sites in August and September 2000. One unexpected outcome is that we have been asked to provide this curriculum to other health care professionals (Nurse Practitioners, OB/Gyn residents, etc.).

Over all we are on target for the successful completion of the project according to the scope of work statement in the original grant.

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Dorothy R. Pathak 3/31/2000

PI – Signature Date

Dorothy R. Pathak, Ph.D., M.S.

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# *Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age*

## INTRODUCTION

### I. SUBJECT OF GRANT

Improvement of primary care physicians at screening for breast cancer and at detecting and following-up on breast abnormalities.

### II. PURPOSE OF GRANT

This study is to address the problem of primary care physicians achieving sub-optimal levels of screening for breast cancer and sub-optimal levels of detection of breast lumps and follow-up of breast abnormalities for their female patients. The purpose of this study is 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. It is directed at the population of physicians (residents in training) in which a pilot study has shown sub-optimal management of breast problems. We are hoping to institutionalize a standard-based approach to breast cancer screening and management of abnormal findings, which should lead to the earliest diagnosis of breast cancer, which in turn will improve prognosis.

### III. SCOPE OF RESEARCH

Since practicing physicians do not have access to techniques for primary prevention of breast cancer, this study is testing an innovative educational intervention designed to optimize secondary prevention, diagnosis and follow-up of abnormal findings. It is directed at a population of physicians (residents and faculty) in which a pilot study has shown sub-optimal management of breast problems. We will implement a standard-based approach to breast cancer screening and management of abnormal findings leading to earlier diagnosis of breast cancer and improved prognosis while simultaneously optimizing the current standard of care. Since this project is implemented in active practice settings of community based family practice residencies, this intervention should easily be translatable to practicing physicians as well as residency programs.

At the end of this study, our goal is to train family practice faculty from other family practice residencies to conduct our intervention, allowing it to be translated into their respective curricula and practices. Residents tend to carry their experiences from residency to their own private practice and future colleagues. The experience we will provide them will allow the various innovative elements of our intervention to be disseminated to their own and other private practice sites.

**The technical objectives of the study are to:**

Specific Aim 1: To determine the effect of a three-component intervention consisting of: 1) Educational material on comprehensive breast care; 2) CBE Skills Course; and 3) Chart Reminder/Guideline System (CRGS) on rates of CBE and mammography, documentation of findings, and timeliness and appropriateness of follow-up of abnormal findings.

Hypothesis 1: When compared with the control sites, where no significant change from Year 1 to Year 2 is expected, practices receiving the intervention will demonstrate a significant increase in rates from baseline to post intervention, for breast cancer screening, follow-up of breast abnormalities and compliance with guidelines as expressed by an:

a) increase in proportion of eligible women receiving the combined screening modality of CBE and mammography, from the current rate of 35% to 60%;
b) increase in adequate documentation of findings from CBE on the breast history/exam form; the baseline rate of documentation will be established at pre-intervention chart audit;
c) increase in documentation of findings from the mammogram, of subsequent follow-up and results obtained, form the current level of 30% to at least 70%;.
d) decrease in the mean length of time from the identification of the abnormality to the appropriate follow-up step as defined by the protocol; the baseline mean length of time to follow-up will be established at pre-intervention audit;
e) increase among patients with abnormalities of the proportion in whom proper follow-up occurs by 3 month, from the current estimated 75% to 95%;
f) increase in the level of appropriate follow-up as measured by percent of abnormalities that were followed according to the protocols provided in the guidelines (**Appendix4**); baseline levels will need to be assessed at the time of initial audit.

Specific Aim 2: To determine the immediate effect of:

1) Educational Session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected; and
2) Clinical Skills Course on the confidence and competence with which family practice physicians and residents perform CBE.

Hypothesis 2: As a result of the training sessions, we will observe immediate

a) increase in post-session scores compared to pre-test scores on: knowledge, attitudes and beliefs about breast cancer screening and early detection;
b) increase in the percentage of lumps detected from an expected baseline of 40% to 60% immediately post-training;
c) increase in the proportion of the correctly conducted components of the CBE technique from baseline. The baseline proportion will be established at the pre-training evaluation.

Specific Aim 3: To describe the long term effect of:

1) Educational Session on knowledge, attitudes and beliefs about breast cancer screening, early detection and follow-up of abnormalities detected; and Clinical Skills Course on the confidence and competence with which family practice physicians and residents perform CBE.

# *Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age*

## BODY

## I. STATEMENT OF WORK

The following table outlines the tasks and timeframe as described in the original proposal. We have added the actual time (when the task was actually completed) and current status for a quick review of our progress. Text following the table describes the details of the task.

| Task | Proposed Time Frame | Actual Time Frame | Status |
|---|---|---|---|
| **Task 1**. Develop, pilot test and refine chart audit and fact/documentation forms. | March – May, 1999 | March – June, 1999 | Completed |
| **Task 2**. Develop materials on risk management principles and guidelines for follow-up of abnormal findings for the Educational Session course pack. | March-June 1999 | March-June '99 | Completed |
| **Task 3**. Preparation of sites<br>• Each residency site generates a list of female patients 40 to 70 years of age<br>• Randomize residency sites to intervention and control arms | March-April 1999 | March – July, 1999<br><br>March, 1999 | Completed |
| **Task 4**. Assemble Chart Reminder/Guideline kits for all patients identified in Task 3 for the intervention sites. | May-June 1999 | July – August, 1999 | Completed |
| **Task 5**. Train nurse abstractors<br>• Hire 2 nurse abstractors at each site (8 sites). Bring all 16 nurse abstractors to MSU for a two day training workshop. Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women. | June 1999 | August, 1999 | Completed |
| **Task 6**. Develop data management system for chart audit data | June-July1999 | | Completed |
| **Task 7**. Training of evaluators for workshop (month 4)<br>• hire and train patient instructors in evaluation of clinical breast examination technique<br>• train faculty in evaluation of clinical breast examination technique | June 1999 | June - July 1999 | Completed |

| Task | Proposed Time Frame | Actual Time Frame | Status |
|---|---|---|---|
| **Task 8.** Workshop on 'Screening and Diagnosis of Breast Cancer for Primary Care Physicians'.<br>• Collect baseline data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza.<br>• Collect baseline data on skills in CBE performance.<br>• Conduct the one day Workshop consisting of the Educational Session and Clinical Skill Course.<br>• Repeat all measurements from the pre-test at the end of the Workshop. | July 1999 | July-August 1999 | Completed |
| **Task 9.** Data entry and analysis of data collected at time of intervention:<br>• pre-post outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis;<br>• pre-post outcome measures on CBE skills | July-August 1999 | December 1999 – January 2000 | Completed |
| **Task 10.** Baseline chart audit (for the baseline year 8/1/98-7/31/99) | July -Sept 1999 | September, 1999 –March, 2000 | Completed at 6 sites<br>In process at 2 sites |
| **Task 11.** Quality control assessments of baseline chart audits at each practice site | July and August 1999 | October – December, 1999 | Completed |
| **Task 12.** Data entry and analysis of baseline chart audit:<br>• Data entry<br><br>• Data analysis of baseline outcome measures | July-December, 1999<br><br>December, 1999 – June, 2000 | September, 1999 – March, 2000<br><br>February – July, 2000 | Completed at time of chart audit. Data entered directly on laptop.<br><br>In process |
| **Task 13.** Assessment of retention of training effect<br>• Train evaluators<br>  • hire and train patient instructors in evaluation of clinical breast examination technique<br>  • train faculty in evaluation of clinical breast examination technique<br>• Collect follow up data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza.<br>• Re-evaluate skills in CBE performance<br>• Repeat all measurements from the original pre-test | Train evaluators - May, 2000<br><br>Collect follow-up data and re-evaluate skills – June, 2000 | | • Scheduled - April 26, 2000<br><br>• Scheduled for May 4th, 18th, 19th, June 8th, and 9th 2000 |

| Task | Proposed Time Frame | Actual Time Frame | Status |
|---|---|---|---|
| **Task 14**. Data entry and analysis of data collected for the evaluation of training retention<br>• data entry of outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis<br>• data entry of outcome measures on CBE skills<br>• data analysis of knowledge, attitudes and beliefs about breast cancer screening and early diagnosis<br>• data analysis of outcome measures on CBE skills<br>• compare data from Task 16 (retention of training effect) to data from Task 8 (pre-training and immediate post-training) | July – August, 2000 | | Scheduled for July-August 2000 |
| **Task 15**. Assess implementation of CRGS<br>• convene focus groups at each site<br>• identify local implementation issues<br>• identify global implementation issues<br>• compare and contrast themes across sites | June, 2000 | | Scheduled for May and June 2000 |
| **Task 16**. Hire and train nurse auditors for the post-intervention chart audit. | May-June, 2000 | | Scheduled for August 2000 |
| **Task 17**. Post-intervention chart audit (8/1/99-7/31/2000) | July- Sept, 2000 | | Scheduled for August-November 2000 |
| **Task 18**. Quality control of the post-intervention chart audit at each practice site. | July-August, 2000 | | Scheduled for September-October ,2000 |
| **Task 19**. Data entry and analysis of the post-intervention chart audit<br>• data entry<br>• data analysis of pre-post intervention changes in the outcome measures defined in hypotheses 1a-1f | July – October, 2000 | | This occurs at the time of chart audit since data are entered directly on the laptop |
| **Task 20**. Manuscript preparation . | August 2000-February, 2001 | | Nov.2000 through February 2001 |

## II. WORK ACCOMPLISHED

**Task 1: Develop, pilot test and refine chart audit and fact/documentation forms.**

The chart review form originally submitted for the grant was developed by Drs. Janet Osuch M.D. and Dorothy Pathak, Ph.D., specifically for that purpose with the understanding that it would need to be peer-reviewed and field tested. The research team spent many sessions revising the form and it was then tested on a number of charts and modified further. The research team decided that given the complexity of the information that needed to be abstracted, it was more efficient to develop a chart-audit form where data could be entered directly onto a laptop computer. A detailed description of the development of the chart audit form/database is provided in the description of **Task 6.** Feedback from the nurse abstractors was incorporated into the final version of the abstracting form/database. A hard copy of the chart audit form/database can be found in **Appendix1.** Data were entered on this form via direct computer entry.

**Task 2: Develop materials on risk management principles and guidelines for follow-up of abnormal findings for the Educational Session course pack.**

This task was accomplished in concert with a major curriculum revision. It was originally intended that the breast care curriculum written by Janet Rose Osuch MD for the American Medical Women's Association be used. This curriculum, first published in 1994, had been revised and expanded twice since originally written. It was decided that another major revision was necessary to accomplish the goals of the grant and to design the optimal learning experience for the participants. This was accomplished during the summer of 1999. A copy of the final curriculum, which included 256 images, can be found in **Appendix 2**. It incorporates principles of risk management into the didactic elements of the curriculum.

To illuminate the importance of these principles, additional elements of the curriculum were added. Developed by Drs. Osuch and Pathak, they serve as summaries in the form of tables and algorithms for each category of screening depending on risk and for work-up of each of the breast abnormalities. They can be found in Appendices 1, 3 , 4, 5a, 5b. 5c, 6, and 7 of the curriculum manual **(Appendix 2)**. A summary of common allegations for failure to diagnose breast cancer, included recommendations for risk management, was published in an article by Osuch and Bonham in Cancer in 1994. This was revised by Dr. Osuch for purposes of the grant and can be found in Appendix 9 of the curriculum manual. Guidelines on what attorneys expect from a chart that has been properly documented had been published on-line at the web site Medscape by Osuch and Bonham in 1998. This was summarized by Dr. Pathak for inclusion in the curriculum and can be found as **Appendix 3**.

**Task 3: Preparation of sites:**

- **Each residency site generates a list of female patients 40 to 70 years of age;**
- **Randomize residency sites to intervention and control arms.**

**List of female patients 40 to 70 years of age;** Jodi Holtrop, Project Manager and Director of the MSU Network contacted each of the residency program directors for the name and the number of a contact person for each site. This person was either the nurse manager or practice manager. Dr. Holtrop arranged an initial meeting with the contact person at each site. During the meetings, Dr. Holtrop introduced the site contact person to the overall plan and process for the study. The tasks that needed to be accomplished at each site are outlined below:

- Determination of patients eligible for the study:
  Site contacts were to generate a list of patients who met the following criteria for inclusion in the study:
  - Female
  - Active patients in the practice. This was defined as having at least one visit in the past three years (or since 8/1/96).
  - Between the ages of 40-70 for the baseline year, i.e.born after August 1, 1928 and before July 31, 1959.

- Orientation and assistance of nurse abstractors to be working at the site:
  This list of generated names was then provided to the nurse abstractors at their orientation session at the residency program site. The orientation meetings were held in August of 1999.

- Insertion of Chart Reminder Guideline System in the records of eligible patients (Intervention sites only):
  The organization of charts at each site was reviewed. The contact person and Dr. Holtrop agreed on what would be the best place in the chart at each site, for insertion of the Chart Reminder Guideline System.

**Randomize residency sites to intervention and control arms:** Dr. Dorothy Pathak completed a random assignment of sites to the Intervention and Control Arm. The Grand Rapids Family Practice Residency site could not participate in this project as in the meantime they have agreed to participate in a breast cancer screening project that was funded prior to this grant. Consequently we have solicited participation of Providence Hospital in Southfield, Michigan which the research team felt would resemble the patient characteristics of the population in Grand Rapids. Dr. Dickson, Residency Director of FP residency program at Providence Hospital was very interested in participating in this intervention trial and agreed to take part in it. The following sites were designated as Intervention and Control. The residency program sites were notified of their intervention or control status at the April, 1999 meeting of Residency Program Directors for the MSU Network.

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

**Task 4: Assemble Chart Reminder/Guideline kits for all patients identified in Task 3 for the intervention sites.**

The Chart Reminder Guideline System (CRGS) consisted of three components:
1. Breast Care Summary
2. Abnormality Flow Sheet
3. Reminder Sticker

**Development:**
The CRGS was developed using modifications of previous management algorithms published by Janet Osuch MD in the 1994 AMWA curriculum and in a book chapter from the 1996 edition of Harris, Diseases of the Breast. The other algorithms were modified from the 1998 AMWA curriculum of Morris and Osuch. Drs. Pathak and Osuch developed the modifications to reflect the content of the curriculum and to provide the uniform end-points of screening, work-up, or referral. One algorithm had not been previously published and was developed by Drs. Pathak and Osuch specifically for this grant. In total, seven algorithms were developed and printed on a single bright pink-colored sheet to be inserted into the chart to serve as a management reminder. The Breast Care Summary Sheet was developed to include the dates and type of breast care provided during the 15 months that the activities in the patient's chart were eligible to be abstracted for the appropriateness of breast care delivered. The Reminder Sticker was also bright pink-colored and is a graphic representation of a women of any ethnic origin performing breast self-examination. A copy of the CRGS is provided in **Appendix 4**..

**Implementation:**

Supplies were ordered for use in the intervention sites. These supplies were distributed to nurses as they began auditing. At the initial meeting, Dr. Holtrop discussed and determined the placement of the CRGS in the medical record for each site with each site contact. The placement of the CRGS in the medical record for each intervention site was as follows:

| Site | Sticker Placement | Guideline/Breast Care Summary Placement |
|---|---|---|
| Kalamazoo | Outer front top section of chart | Top under divider section "Family Practice" |
| Midland | Outer front top section of chart | Top under section "Problem List" |
| Saginaw | Outer front top section of chart | Top under divider section "Physical Exams and Questionnaires" |
| St. Lawrence site of Sparrow/MSU Residency | Outer front top section of chart | Summary – Top under section "Problem List"<br>Guidelines – Top under section "Health Maintenance" |
| Sparrow site of Sparrow/MSU Residency | Top of pink data sheet inside chart *(site preferred this location as this section seen by provider at every visit)* | Top under divider section "Health Maintenance" |

Actual results of the number of women who meet the study criteria of being 1) female, 2) active patients (having at least one visit in the past three years), and 3) between the ages of 40-70 revealed the following approximate numbers at each site:

| Intervention sites: | # Eligible: |
|---|---|
| Kalamazoo Center for Medical Studies | 1100 |
| MidMichigan Regional Medical Center, Midland | 2000 |
| Saginaw Cooperative Hospitals, Inc. | 1660 |
| Sparrow/MSU – St. Lawrence site | 1140 |
| Sparrow/MSU – Sparrow and Mason site | 1600 |

| Control sites: | # Eligible: |
|---|---|
| Genesys Health Systems, Flint | 1035 |
| McLaren Regional Medical Center, Flint | 975 |
| Munson Medical Center, Traverse City | 1000 |
| Providence Hospital, Southfield | 2100 + |

**Task 5: Train nurse abstractors:**

- Hire 2 nurse abstractors at each site (8 sites).
- Bring all 16 nurse abstractors to MSU for a two day training workshop.
- Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women.

**Hire 2 nurse abstractors at each site (8 sites):** For each residency program site, we recruited and hired two nurses not affiliated with the residency programs to conduct the audits of the medical records in their respective programs. All individuals hired were at least an R.N., with many being bachelor and master prepared. We also employed one M.D. Many had experience in chart audits.

**Bring all 16 nurse abstractors to MSU for a two day training workshop:** On August 9 and 10, 1999, a nurse abstractor training was held on the campus of Michigan State University. Seventeen nurses were trained to abstract data related to breast care at the nine residency program sites (one program site – Saginaw – began with just one nurse abstractor) and to insert the CRGS in the medical records of eligible patients (intervention sites). The training was led by Barbara Given, Ph.D., R.N., with assistance from Ping He, M.D., Dorothy Pathak, Ph.D., M.S., Prinicipal Investigator, Suiying Huang, Data Coordinator, and Jodi Holtrop, Ph.D., Project Manager. Please see **Appendix 5** for the agenda and instruction manual for this two day training. The training included education on:

- Overview of the purpose of the study
- Lectures and examples on breast care documentation and follow-up.
- How to evaluate evidence of CBE being completed, findings of CBE recorded, referrals for mammogram, evidence that responses were made to abnormalities, and possible options for follow-up of these abnormalities.
- Chart audit content was reviewed in detail for each form that needed data entry. Examples were provided to show both process and content of the audit.

  Sample cases were identified representing a variety of breast care concerns from the Clinical Practice Site at the Michigan State University Family Practice Center and Kalamazoo Center for Medical Studies. Names and all identifiers were blacked-out and these were used as sample cases. The auditors were paired for each site and given 10 practice cases to complete and successfully electronically transfer to the Data Coordinator. Investigators at MSU created the gold standard for the completed audits and Barbara Given, Ph.D., R.N. reviewed each of the practice cases from each of the auditors and completed the Kappa statistical test. Each pair entered several cases as a part of this practice session on the second day of training. Auditors went to their practice site and practiced on the 10 cases. Auditors were to revise these practice cases until he/she achieved a Kappa of 90% or higher as a measure of inter-rater agreement for the various components of the chart audit. Auditors were brought back to MSU for an additional day of training to ensure understanding of audit guidelines. This educational process and quality control assessment took additional time and delayed the beginning of the auditing process by approximately four to six weeks.

Once implemented, the auditors provided weekly reports on their progress. Email and telephone were used to deal with problems daily as they arose.

**Distribute to the nurse abstractors the required number of chart audit forms and CRGS kits to be inserted at the time of the audit into the charts of all age eligible women:**
After the auditors passed the quality control assessment, packages with at least 500 kits of CRGS were sent to each Intervention site. The kits included the guidelines that needed to be inserted into the eligible charts, the summary of breast care activity sheets and the stickers (**see Appendix 4**).

**Task 6: Develop data management system for chart audit data.**

The database was created in Access 97 using four forms. The 4 forms are included in **Appendix 1.**

"**Form I-Front End**" The first form is called "Form I-Front End", and contains general information about the patient. The information collected includes: the patient's full name, medical record number, date of birth, and abstractor's ID (all seventeen abstractors in nine sites were given unique abstractor ID's.). One of the first steps on this form was to determine each patient's eligibility code (Ecode). The five criteria to determine the Ecode; were as follows:

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 Doctor (FPC)?
5. Has the patient been in contact with the physician for breast care between 8/1/98 and 7/31/99?

There are three values for the Ecode: 1, 2, or 3.
An Ecode of 1 means that patient has satisfied all 5 of the above criteria and is eligible for having their chart abstracted. Additionally at the intervention sites these patients were eligible for insertion into their charts of Chart Reminder Guideline System (CRGS described in Task 4 and included in **Appendix 4**).
An Ecode of 2 means the patient 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) and thus the chart is not eligible to be abstracted. At Intervention sites, these patients were still eligible for insertion into their charts of CRGS.
An Ecode of 3 means this patient is ineligible for this study because she did not satisfy one of the first 4 criteria.

After the Ecode was assigned, each patient was given a unique study identification number. The study identification number consists of six digits. The first digit of the identification number corresponds to the site number (there are nine site one number 1-9 assigned to each site). The second digit is the previously determined Ecode numeral. The remaining four digits are consecutive numbers starting with 0001. If the patient had an E-code of 2 or 3, after the patient identification number was assigned, the computer prompted the abstractor to discontinue chart audit, and go to a next patient. At the intervention sites, the abstractors proceeded with insertion of guidelines and breast activity form, for patients with Ecode2. For those patients with an Ecode of 1, the remaining pertinent information of the patient's chart was abstracted and data entered on the laptop. At the intervention sites CRGS were than inserted into the chart.

The next important step that had to occur on Form I, was the calculation of the time period for which the chart was to be abstracted. It was determined by the research team, that if we are to calculate yearly screening rates, the relevant time period to abstract the breast care activity had to extend for 15 months prior to the last visit to the office. Every visit to the office, irrespective of the reason, was viewed as an opportunity for the family practice provider to review the current status of breast cancer screening for the patient. If there was no breast care activity during the proceeding 15 months of the given visit, the provider was expected to note this in the chart and make appropriate recommendations for breast cancer screening. Thus, when the abstractor entered the information located in the field labeled "Date of most recent office visit" (during the baseline year), the database automatically performed the calculation to determine the date fifteen months prior to patient's most recent office visit. This fifteen-month interval was than audited for the occurrence of breast care activity The final portion of Form I includes; total number of visits, and personal/family history of breast cancer (see **Appendix 1** Form I for details).

**"Form II-Visit Entry"** The next form is called "Form II-Visit Entry". This form records each breast care encounter the patient has received during the 15 months interval. The abstractor is required to record each date of breast care activity, and what type of contact was made.

On Form II the field labeled "type of contact" (breast care encounter) has the following options: office visit, doctor initiated phone consultation, patient initiated phone consultation, screening/routine/regular mammogram, diagnostic (regular) mammogram, diagnostic/cone compression/magnification mammogram, ultrasound result, fine needle aspiration (FNA) for cyst result; fine needle aspiration biopsy (FNAB) result, pathology report for radiological/image guided biopsy, pathology report for open biopsy; surgeon's letter, or Other.

If the option chosen is one of the following: Office visit, Doctor initiated phone consultation, patient-initiated phone consultation, or other, the rest of the form II is entered. If another type of contact was made, then abstractor goes directly to "Form III", which is the test result form.

On form II another field labeled "purpose of this visit/call" has the following options: screening/well women exam/annual exam, presenting symptom(s), follow-up of a previous abnormality, prompted by results of screening mammogram, prompted by results of other test(s), routine care/Other health problems, and Other. Only visits with some breast care activity are entered onto Form II. Based on this field we know why the patient was there and what was done during that visit with regard to breast care. From this point based on the information in the chart the abstractor identifies the person who performed the breast care/phone consultation, if patient presented with symptoms/signs, clinical breast exam (CBE) findings and quality of CBE documentation. The field of CBE findings is subcategorized into two headings of normal and abnormal. If an abnormal finding is recorded, the abstractor is required to record all the details of the abnormality (See **Appendix 1** Form-II). Quality of CBE documentation is divided into five subgroups of drawings, inspection, palpation, lymph node examination, and other. For more specific details of data collection in "Form-II Visit entry" please see **Appendix1** Form-II.

**"Form III-test result entry form"** The third form is called "Form III-test result entry form". It consists of the breast care related test results that are found in the patient chart of a family practice doctor. It includes the results of mammogram, FNA, FNAB, ultrasound, and image-guided biopsy/open biopsy results. For each test performed options are provided as to the results obtained from that test (**see Appendix 1** Form III for more details).

**"Form IV-follow-up entry".** The last form is "Form IV-follow-up entry". This form 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 and abnormal findings, and Surgeon's letter. For normal findings the recommended follow-up can be: no follow-up, routine screening, time for twelve-month CBE, time for twelve-month mammogram, following ACS guideline, or the abstractor can type in alternative follow-up(s) if none of the fore mentioned applies. The recommendation can be done by the family practice doctor only (FPD), Radiologist only, both FPD and radiologist, surgeon, other, or undocumented. One of these options is given and recorded in the field named "recommended by" under the normal finding subcategory (see **Appendix 1** Form-IV).

The follow-up for abnormal findings was subdivided as follow-up for "specific abnormalities" and follow-up "common to any abnormalities" (see **Appendix 1** Form-IV). The follow-up headings relative to "specific abnormal findings" were: breast mass/asymmetry initial approach, known breast cyst, known solid mass, nipple discharge, skin/nipple changes on observation, breast pain. The options that were specific for these major categories were those discussed in the curriculum and provided in the guidelines that were inserted into the charts. Some options were common to all abnormalities and consequently were included under the column "follow-up common to any abnormalities" These options included: call if problem worsens, routine screening, immediate mammogram work-up, interval follow-up, ultrasound, surgical referral, and undocumented. For additional recommendations relative to the follow-up procedure of an abnormal finding, the abstractor could type in the documentation in the comment box provided on the form.

Since a surgeon's letter would occasionally be found in a patient's chart, particularly those patients who had a biopsy of some sort, recommended follow-up by the surgeon was also recorded. The surgeon's letter documentation allowed for recording of information regarding surgeon's assessment of abnormality, additional tests performed, and subsequent recommended follow-up (see **Appendix 1** last page of Form-IV).

## Physician Breast Care Database Mechanics:

The information collected in the four forms has been explained in the previous section and can be seen in **Appendix 1.** This portion of the report describes how these database "Forms I-IV" function for the data collection process.

Form one is the "Front-end" form. It describes the characteristics of interest and determines the eligibility of the patient. Each patient has a "Form one" assigned to their chart. If a patient is deemed ineligible, i.e. assigned an eligibility code of 2 or 3, the data collection process is stopped after the study I.D. is assigned. If they are assigned an eligibility code of one, the remaining "Front-end" information is collected. The question that associates a patient with the remaining "forms" is whether breast care was performed during the fifteen-month interval of interest (Question 4 on Form 1, see **Appendix 1**). If the answer to this question is "yes", the chart auditor will be prompted to continue onto "Form II" and describe the type of care given.

On "Form II" the type of breast care encounter found in the chart is described. If the patient is in contact with the doctor for an office visit, patient initiated phone call, physician initiated phone call, or a less specific reason, i.e. other, the various relevant parts of "Form II" are completed. If the type of breast care encounter were the results of a test, then the abstractor would be prompted to "Form III – Test Results". Lastly if the type of breast care encounter described in the charts is a surgeon's letter, then the abstractor is prompted to go to "Form IV".

For each "Form II" and/ or "Form III" entered, the auditor was expected to fill out a "Form IV". "Form IV" describes the follow-up recommended by the health care provider. Since an assessment plan is part of the physician's routine procedures for any type of breast care, "Form IV" was to capture this data and record it as follow-up.

For each patient the following numbers of forms are expected. Each patient should have an exclusive and individual "Form I". If the patient is eligible for the study and breast care was provided during the fifteen-month interval of interest, then the patient should have "Form II" filled out. The number of times "Form II" is filled out for a given patient, equals to the number of times breast care encounters occurred 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 different type of breast care encounter.
3. If "Form II" describes the breast care encounter as a "test result", then a "Form III" describing the test result will be filled out.

For every "Form II" or "Form II and III" combined, there will be a "Form IV" describing the follow-up recommended.

**Task 7: . Training of evaluators for workshop:**

- **Hire and train patient instructors in evaluation of clinical breast examination technique**
- **Train faculty in evaluation of clinical breast examination (CBE) technique**

**Training of patient instructors**:

In April of 1999 we began recruiting patient instructors for the evaluation of CBE technique to be completed at the workshops at the five intervention sites. In July of 1999, nine patient instructors were trained for this purpose. Most of the patient instructors recruited were experienced patient models employed by the MSU College of Human Medicine for training of medical students.

The training was conducted by Henry Barry, M.D., M.S. and consisted of the following components:

- Brief orientation to the project and its goals
- Completion of breast examination and health history by Dr. Barry to determine the patient model had no existing breast health problems or conditions
- Instruction and demonstration of proper CBE technique and components
- Instruction on CBE examination evaluation form including what the component meant and how to properly complete the form

Patient instructors were then shown a 10 minute video "The Essentials of Clinical Breast Examination" California Department of Health Services, 1996. The video reinforced the concepts and instruction provided by Dr. Barry. The manual for patient instructor responsibilities is included in **Appendix 6**. Dr. Holtrop then completed employment paperwork and instructed patient instructors as to the location, time and date for workshops.

**Training of faculty**:

Since the decision was made to utilize patient model trained in evaluating breast examination technique, faculty evaluators were not needed. Thus, no training occurred.

**Task 8: . Workshop on 'Screening and Diagnosis of Breast Cancer for Primary Care Physicians':**

- **Collect baseline data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the 'Knowledge, Attitudes and Beliefs' Survey developed and used by Costanza.**
- **Collect baseline data on skills in CBE performance.**
- **Conduct the one day Workshop consisting of the Educational Session and Clinical Skill Course.**
- **Repeat all measurements from the pre-test at the end of the Workshop.**

A three component intervention was utilized. These three components included:

1. Educational Session (ES) which included material on epidemiology of breast cancer, benefits of screening, guidelines for screening and follow up of abnormal findings, and principles of risk management.
2. Clinical Skills Course (CSC) which trained the physicians how to perform CBE and to interpret the findings. The education was then reinforced by the third component of the intervention which is the:
3. Chart Reminder/Guideline System (CRGS). The CRGS was placed in the charts of all eligible women at the four/five intervention sites, and included: a) a form summarizing breast care activity during the previous year; b) guidelines for follow-up of abnormal findings, and c) identifying sticker to remind physicians that this patient is eligible for breast care.

## Workshops:

The first two components of the intervention (ES and CSC) were organized into a one day, eight hour workshop. The title of this workshop was changed to "Comprehensive Breast Care for Primary Care Physicians" to better reflect the revised content of the curriculum. Although it was originally planned for the workshops to be held on weekends, the programs requested to close their clinics and hold the workshops on week-days. The Lansing program was a new residency program as of July 1, 1999. It formerly consisted of two programs: Sparrow Hospital Program and St. Lawrence/MSU Program. It is now (as of July 1, 1999) the Sparrow/MSU Program. However, this program still has two locations for clinics: Sparrow site and St. Lawrence site. The total number of residents and faculty at this program was double the other programs. Therefore, there were five workshops held instead of four to accommodate this large number in Lansing. The following is a schedule of the workshops, when and where they occurred, and the number attending.

**Summary of Breast Care Workshops**

| Date | Program | Total Participation N | Faculty* N | Resident N |
|---|---|---|---|---|
| July 15 | Sparrow Hospital - St. Lawrence site | 18 | 4 Physician | 14 |
| July 22 | Saginaw Cooperative Hospitals, Inc. | 28 | 3 Physician<br>1 NP | 24 |
| July 23 | Kalamazoo Center for Medical Studies | 22 | 5 Physician | 17 |
| July 27 | MidMichigan Regional Medical Center - Midland | 26 | 6 Physician<br>3 PA-C | 17 |
| August 5 | Sparrow Hospital – Sparrow Professional building site | 35 | 8 Physician<br>2 PA-C<br>1 NP | 24 |

*Faculty includes physician faculty as well as Physician Assistants (PA-C) and Nurse Practitioners (NP).

As mentioned, the Educational Session and Clinical Skills Course were organized into a one day, eight hour workshop. The first four hours were designated as the Educational portion and the last four as the Clinical Skills Portion. Please see **Appendix 7** for an outline of the day for the workshop. The participant manual developed for use with the workshop can be found in **Appendix 2.** Instructors for the sessions included two of the following three instructors: Janet Osuch, M.D., Henry Barry, M.D., M.S., and Thomas Zuber, M.D. Laura Morris, M.D., who was initially designated as an instructor, declined participation.

Upon registration, the participants were assigned a name and color code for the purposes of identification and confidentiality. The color codes were useful in organizing the participants into rotating twice to three stations for evaluation at the second half of the day. Participants were then welcomed and given the pre-test for the knowledge, attitude and beliefs (KAB) scale (development of the KAB scale is described in the paragraph below). The remainder of the first four hours of the workshop was largely didactic and devoted to the Educational Session portion of the intervention. It was originally intended that the breast care curriculum written by Janet Rose Osuch MD for the American Medical Women's Association be used. This curriculum, first published in 1994, had been revised and expanded twice since originally written. It was decided that another major revision was necessary to accomplish the goals of the grant and to design the optimal learning experience for the participants. The revisions to the previously published curriculum are described in Task 2. A copy of the final curriculum can be found in **Appendix 2.** It incorporates principles of risk management into the didactic elements of the curriculum.

Instruction during this time covered:

1. Anatomy and Physiology
2. Epidemiology, Genetics, Risk Factor Counseling and Tamoxifen
4. Breast Cancer Screening and Evidence Based Medicine
3. Breast Pain and Work-up of Occult Mammographic Abnormalities
4. Work-up of Abnormal Findings on Clinical Breast Examination
5. Risk Management

After a lunch break, participants rotated through three stations (20 minutes each):

1) One station included a pre-test of their CBE skills utilizing trained patient instructors. Patient instructors evaluated the technique and completeness of the examination provided by the physician. See **Appendix 8** for a sample evaluation form that was completed by the patient instructors.
2) Another station was a pre-test of the physician's accuracy in locating breast lumps. This was assessed utilizing silicone breast models. See **Appendix 9** for the forms used by the physicians to record their responses with regard to the location, size, depth and hardness of breast lumps they identified.
3) A third station was to evaluate the knowledge, attitudes and behaviors (KAB) regarding breast care by having the physicians complete a post-test of the KAB scale **(Appendix 10)**. The physician completed the pre-test prior to the Educational Workshop. Originally we intended to use the survey instrument developed by Constanza et al.[1] in their multidimensional intervention designed to alter physician breast cancer screening practices. However, upon careful review of that instrument and the content of our curriculum, the research team realized that we need to develop our own evaluation tool that would be based on the goals of the curriculum and the goals specified in the grant. Thus we looked at the survey developed by Constanza as well as two additional evaluation surveys, one developed by Dr. Osuch and the other by Dr. Zuber. Dr. Osuch submitted questions that she had formerly developed with Laura Morris, MD that they used in the Breast Cancer Education for DoD primary Care Mangers. That curriculum was delivered to military personnel throughout the world in 1997 and was sponsored by the American Medical women's Association in conjunction with the DoD(HA) Breast Cancer prevention, Education and Diagnosis Initiative Work Group. Dr. Zuber submitted questions that he has formerly developed to evaluate the curriculum on Breast Cancer Detection, that he developed and teaches nationally to Primary Care Providers. Dr. Barry and Dr. Pathak looked at three evaluation tools, and identified from each instrument those questions that would derive from our educational goals and objectives and eliminated those that were not consistent with the goals and objectives of the curriculum. We needed to balance the questions for all the areas that we discussed in the curriculum. The areas were: Knowledge of risk factors/epidemiology, screening, abnormalities, appropriateness of follow-up, attitudes and beliefs, barriers and behaviors. For each instrument we identified which questions fall into the various domains. The next task was to ensure that within each of the domains we had a balance of the key content areas. After the questions were chosen, questions 1-19 were randomly permuted. Questions 20-24, which measured attitudes, beliefs and behaviors, were included at the end of the survey **(Appendix 10).**

After rotating through these stations, participants received the Clinical Skills Course portion of the intervention. During this time, we trained the physicians in the performance of CBE and in documenting and interpreting the findings. This educational approach is based on the work of Fletcher et al., and Pennypacker et al.[2-4] We taught CBE using the "Lump Discrimination Teaching Model-TM-LD-T", a hemispherical model developed by Pennypacker with transparent skin and lumps of varying size, hardness and mobility embedded against normal nodularity. Lump sizes ranged from 3mm to 1.0 cm in diameter. The participants were taught the six components of the CBE technique performance which included using: 1) their finger pads; (2) middle three fingers; (3) circular motion; (4) systematic pattern; (5) sequence of varied superficial, moderate, and firm pressures; and (6) thoroughly covering the total area of the breast model. This part of the program included reinforcement of the Clinical Breast Examination (CBE) training using professionally produced videotape. The California Department of Health Services made the instructional video with Janet Osuch, M.D. as a consultant.

After this training, participants then rotated through three stations again in the later afternoon to assess any improvements in CBE skills (patient models station) or accuracy in finding lumps (silicone model station). The third station allowed participants to practice using the **GAIL** model for risk assessment. Six practice cases were adapted by Dr. Osuch from the Breast cancer risk assessment and counseling kit, an educational resource provided by Astro-Zeneca Pharmaceuticals, manufacturers of Tamoxifen citrate, a drug used to reduce the risk of breast cancer in women determine to be at high risk **(Appendix 11).**

Throughout the day, risk management principles and guidelines for follow-up of abnormal findings were emphasized. Participants were also trained in the use CRGS.

***RESULTS from Evaluation of the Workshop***

At the end of the Workshop participants were asked to fill out a written evaluation of the Workshop **(Appendix 12)**. Overall, 77% of the participants rated the Workshop as "Excellent", 20% rated it as "Good" and 3% rated it as "Satisfactory". No one rated it as "Poor". Additionally the participants were asked for comments and suggestions on how to improve the Workshop. All comments are listed in **Appendix 12**.

**Chart Reminder/Guideline System (CRGS):**

A third component to our intervention was to implement a CRGS. The CRGS was placed in the charts of all eligible patients at the intervention sites in the four months proceeding the workshop as part of a permanent record. Please see **Appendix 4** for the CRGS. The CRGS includes:

a) Fact/documentation form which we re-titled a Breast Care Summary. (Appendix 4). The documentation form summarizes the breast care activity during the baseline year as abstracted from the existing medical records and will serve to establish the time when a women becomes eligible for screening or diagnostic follow-up in the post intervention year.
b) Guidelines for follow-up of abnormal findings-Please see the description of the process of development of the Guidelines in Task 4. The Guidelines are included in Appendix 4.
c) Sticker placed on the outside of the chart to identify the patients who may be eligible for breast care. This serves as a reminder for the provider to check that patient's screening record for need for recommendation of CBE and/or mammogram.

In our proposal, we discussed also including the following:

a) Breast history/physical exam form-currently in use at the Comprehensive Breast Health Clinic; it documents skin changes, nipple discharge, lumps, puckering, pain, scars, palpable mass, breast consistency in terms of smoothness and nodularity, axillary nodes information and provides additional space for summary of impression and overall plan of action.
**b)** Mammogram requisition form and sample letter for patient notification about results.

These were not included in the CRGS because individual sites have their own forms for documenting breast history/physical exam and mammogram requisition. Therefore they did not want to change from the current forms that they are using.

Because the audit period overlapped with the first three months of when the CRGS should be present in the chart, nurse auditors at intervention sites checked on a daily basis with the receptionist to establish if any of the women on their list had a scheduled appointment. Charts of women who had an appointment scheduled during that day had their CRGS inserted at that time. Thus, the CRGS forms were inserted into the women's chart prior to her first visit during the intervention year. Because of the delay in getting the auditing completed, a decision was made in late November to have the auditors stop abstracting and finish inserting the CRGS. This was completed in early to mid-December by all sites. A one-page reminder notice was placed in the mailbox of providers in November, 1999 to notify them that insertion of the CRGS was complete.

**Task 9: Data entry and analysis of data collected at time of intervention:**

- **pre-post outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis;**
- **pre-post outcome measures on CBE skills**

**Assessment of immediate training effect:**

1. **To assess the immediate effect of the educational session on knowledge attitudes and beliefs of breast cancer screening and early detection**:
The survey instrument **(Appendix 10)** was completed before and after the educational session to assess physicians predisposing attitudes toward, and level of knowledge of, screening, early detection of breast cancer, and appropriateness of follow-up for specific abnormalities detected either by CBE or mammogram. This survey will document potential barriers and facilitator to breast cancer screening and early detection. Outcome measures evaluated were the individual questions on the survey.

2. **To assess CBE competence, we used two approaches**:

a) Assessment of ability to detect lumps by CBE (pre-post CSC): For evaluation of CBE competence in detecting lumps, we used 6 silicone models known as the "UNC Series", developed by Pennypacker and colleagues at the University of Florida, Gainesville and the Mammatech Corporation. Each silicone model has a volume of 250 mL, simulates the breast of a 50-year-old woman, and contains simulated background fibroadenomatous tissue. Across the 6 models (A, B, C, D, E, F), there are 18 lumps which vary in size (1.0, 0.5, and 0.3 cm in diameter), hardness (60, 40, and 20 durometers), and depth of placement (medium and deep). Five models contain between one and five lumps each and one model contains no lumps. We had 6 sets of 6 silicone models each. Each set was assigned a color. Forms with two breast models were printed on 6 different colors of paper. These forms together with the models were placed on three separate tables with 2 models from each color present on each table (Table I, Table II, Table III). The order of models within a given color was randomly chosen so that adjacent colors on the table did not have the same models. Colored forms were placed by the models and participants were asked to mark on them the location, size, depth and hardness of the lumps detected. During the post-test participants were instructed to choose a different color set than the pre-past. This ensured that the order in which they examined the 6 breast models was different on the pre and post-test. Participants were asked to assume the breasts are those of a 50-year-old asymptomatic women with no personal or family history of breast disease. Using these models we evaluated physicians' ability to detect lumps and properly document them on the form. These forms were subsequently coded and for each physician, we calculated their sensitivity and specificity of lump detection (Hypothesis 2b).

b) Assessment of CBE technique (pre-post CSC): We utilized patient models to assess the technical quality of CBE technique used by participants. We trained the live models in evaluating the technical quality of CBE techniques using the evaluation scheme described below. The live models rated the participants before and after training using an existing 6 point evaluation instrument **(Appendix 8).** This instrument assesses the six components of the CBE technique performance which includes using: 1) their finger pads; (2) middle three fingers; (3) circular motion; (4) systematic pattern; (5) sequence of varied superficial, moderate, and firm pressures; and (6) thoroughly covering the total area of the breast. Outcome measures to be evaluated are the proportion of correctly conducted components of the CBE and the area of the breast covered during the CBE.

The data collected for each resident physician was a pre and post form for each of the following components: a survey, a live model CBE, and silicone model breast exam **(see Appendices 8,9,10).** Databases were created using Microsoft Access 97 for each of the three components, and then dichotomized into pre and post portion of information, totaling 6 databases (i.e. pre and post survey, pre and post live model CBE, and pre and post silicone model breast exam). All data collection questions and items remained the same for both pre and post observations. The data were analyzed using the SAS program to determine whether statistically significant improvements could be observed for the various outcomes of interest.

***Survey:***

The pre and post survey form created in the database consisted of physician identification number, site of intervention, date intervention was performed, the 24 questions of the survey, and a comment box for the data entry person to write any additional physician comments (**See Appendix 13**). The physicians' answers to the survey were entered directly from the survey to the computer.

***Assessment of CBE Technique (Patient Instructor):***

Another form was created for the Patient Instructor CBE data entry. The intricacy of this form is a result of the mapped area located on the top right corner of each Patient Instructor CBE form (**see Appendix 14**). Each of the form sections, Communication, Positions, Perimeter, Pattern of Search, Palpation, Pressure, and Patient education were collected and entered from the original to the computer as checks marks. Additional information such as which breast was being examined, date of exam, physician identification, patient instructor, total time of exam, time per breast, and site were also entered into this database form

The mapped breast area in the upper right corner of the live model CBE form needs further explanation. The live models were instructed by the investigators of the grant to mark an "x" in concordance with the area on the form where the physician did **NOT** palpate them. The heavy lined boundaries were explained to the women, so that it would be known if the physician had palpated the entire area. This mapped area was later sectioned into five segments. The segments were labeled and described as the areola, upper inner quadrant (UIQ), lower inner quadrant (LIQ), upper outer quadrant (UOQ), and lower outer quadrant (LOQ). These areas remained constant for both right and left breast exams (**see Appendix 15**). The number of boxes comprising each segment was summed and is displayed in the table below. The area **MISSED** for each section of the breast was calculated as follows: the numerator was defined as the number of boxes marked "x" in that area of the breast and a denominator was the total number of boxes comprising that area of the breast. Using Access 97 to calculate and report these percentages, the pre and post exams for each physician were compared using SAS to see if their technique improved after intervention.

| Area of breast | Number of squares in each area |
|---|---|
| Areola | 4 |
| Upper Inner Quadrant | 9 |
| Lower Inner Quadrant | 32 |
| Upper Outer Quadrant | 32 |
| Lower Outer Quadrant | 32 |

***Lump Detection Assessment (Silicone Breast Models):***

Information regarding the physicians ability to detect lumps in the silicone breast models was collected. Each physician evaluated six silicon model breasts for lumps. For each breast the number of lumps detected, location, depth, size and hardness of the lumps was known. Each physician was asked to report this information on the silicone breast model form (**see Appendix 9**). Each form was composed of two breasts divided into quadrants, and the circumference for each breast was directly proportional to the actual model. In addition to the physician description of the quantity detected, location, depth, size and hardness of the lumps in each individual breast, the physician code, date of workshop, and site of workshop were also collected.

A key coding sheet was developed by Drs Barry and Pathak with regard to the location and number of actual lumps in each model. This allowed us to quantify the total number of lumps correctly detected and number of

false positive lumps specified for all six breasts for each physician. Thus we were able to calculate sensitivity and specificity of lump detection for each physician and an average for site. For a lump to be considered properly detected by a physician, the lump recorded by the physician must have been within a 4-cm diameter circle. The location of the 4-cm diameter circle was determined as having an origin defined by the center of the actual lump located in the silicone model. This process is currently being repeated using a 2-cm diameter circle, and the specificity and sensitivity will be recalculated for these more stringent criteria of a true and false positives (**see Appendix 16**).

False positives were determined with the unit of analysis being breasts. A breast was considered to be false positive if the physician had reported a lump that did not exist, or did not properly place the lump within the 4cm circle. For this calculation, the numerator was the number of breasts with at least one nonexistent or incorrectly marked lump, and the denominator was the total number of silicone breast models, which was six.

Using the summation of the number of correctly detected lumps and the number of false positives, sensitivity and specificity could be calculated respectively. Sensitivity was defined as the percentage of the 18 lumps a physician correctly detected in all six silicone breast models. This was determined by the dividing the number of lumps that a physician properly detected by 18, the total number of lumps. Specificity equaled one minus the percentage of the six breasts examined with at least one false positive. False positive is defined as the number of breasts with at least one nonexistent or incorrectly marked lump, divided by the number of breast models, which was six.

***RESULTS of the Pre-Post Training Evaluation. Abstract Submitted for Era of Hope Meetings to be held in Atlanta, June 8-12, 2000 (Appendix 17).***

One hundred twenty two physicians, five physician assistants and two nurse practitioners participated in the one-day workshops in July 1999. The proportion of correct answers to the 19 knowledge questions changed from a mean of 53% (range 12% to 86%) before to 80% (range 50% to 98%) after the training ($p<0.001$). The proportion of physicians correctly using all five components of palpation technique rose from 36% to 71% after the training ($p<0.001$). The mean percent of the total area missed during CBE decreased from 11.4% (range 0% to 72%) before to 1.1% (range 0% to 41%) after the training ($p<0.001$). The sensitivity for location of the breast lump, defined as the proportion of 18 lumps correctly detected (within 2 cm radius), increased from 67% at baseline to 71% after the training ($p<0.05$). The specificity defined as percent of models without a false-positive, rose from 28% before to 42% after the training. Paired t-test was used to assess the significance of improvement from pre to post values for each outcome of interest. One way analysis of variance was used to assess if there were differences for a given variable of interest between the various residencies. For all variables under consideration, except for specificity, the residencies did not differ with regard to the level of improvement. For specificity there was a significant difference between residencies. Therefore for all outcomes other than specificity, the results from all intervention residencies were combined and paired t-test was used for the final analysis. For specificity we will report our results specific for each residency.

Thus, this study shows that a comprehensive approach to training was effective in improving short-term knowledge, technique, sensitivity and specificity of CBE, which should translate into improved detection of breast cancer. We will be re-testing participants in May and June to determine their retention of knowledge and CBE skills gained during the training.

**Task 10: Baseline chart audit (for the baseline year 8/1/98-7/31/99).**

**Chart Audit Process:**

It was initially proposed that auditors would enter data on a paper audit form and send via Federal Express on a weekly basis. Then, a student would enter data. A decision was made early in the project to handle the data electronically. Thus, the data entry forms were created in the Access database program and placed on laptop computers. Each site was provided one laptop computer in which to enter and transmit data. Each abstractor was provided an MSU email account and encouraged to utilize this account for communication with project staff. Thus, the nurse abstractor training also included instruction on using the laptop computer, entering data on the computer, using the email account, and electronically transferring data.

A list of names of patients whose charts were eligible for audit were generated in July and August, 1999. Auditors began abstracting data in September and October, 1999. The table below lists the residency program sites, number of records to be audited and progress with completion.

| Intervention sites: | # Eligible | Date completed | # of charts abstracted |
|---|---|---|---|
| Kalamazoo Center for Medical Studies | 1100 | Completed | 905 |
| MidMichigan Regional Medical Center, Midland | 2000 | Completed | 1735 |
| Saginaw Cooperative Hospitals, Inc. | 1660 | 300 more | 1319 |
| Sparrow/MSU – St. Lawrence site | 1140 | Completed | 946 |
| Sparrow/MSU – Sparrow and Mason site | 1600 | 400 more | 1106 |

| Control sites: | # Eligible: | Date completed | # of charts abstracted |
|---|---|---|---|
| Genesys Health Systems, Flint | 1035 | Completed | 990 |
| McLaren Regional Medical Center, Flint | 975 | Completed | 563 |
| Munson Medical Center, Traverse City | 1000 | Completed | 941 |
| Providence Hospital, Southfield | 2100 | Completed | 2036 |

For Intervention sites, the information obtained on the baseline chart audit form is summarized using the Breast Care Summary Form in the CRGS. This is readily accessible to the physician for determination of time when each patient becomes eligible for annual CBE and mammogram during post-intervention year.

**Task 11: Quality control assessments of baseline chart audits at each practice site.**

**Quality control audit process:**

Two graduate students in Epidemiology were hired for the purpose of visiting the participating residency program sites and conducting the quality assurance audits. The students were trained in a one-day intensive training by Barbara Given, Ph.D., R.N. on October 5th, 1999. The training manual provided to the nurse abstractors was used as a reference for this training (see **Appendix 5** for training manual). The graduate students were also required just as the nurses were, to complete the same 10 practice cases and review their abstracting with Dr. Given. Dr. Given completed the Kappa test for each to determine accuracy of their auditing. A 100% Kappa was required from the graduate students since they were to serve as gold standard for the abstractors.

Quality assurance checks for the nine sites were completed during November 1999 through January 2000, according to the following schedule:
November 9, 1999 - St. Lawrence, Lansing
November 12, 1999 – Kalamazoo

November 16, 1999 – McLaren, Flint
November 19, 1999 – Saginaw
November 23, 1999 – Traverse City
December 02, 1999 – Providence, Southfield
December 10, 1999 – Genesys, Flint
December 16,1999 – Midland
January 17, 2000 – Sparrow, Lansing

During these quality assurance checks, 12 records were randomly selected from each auditor's patient eligibility list. Charts were first sorted on their eligibility code 1, 2, or 3. Within the eligibility code of 1, charts were sorted on the number of breast care encounters. The distribution of the 12 charts chosen for quality control audit was as follows: 2 with Ecode=3; 2 with Ecode=2, and 8 with Ecode=1; Within the 8 charts with Ecode=1, 2 charts had 1 encounter, 2 had 2 encounters, 2 had 3 encounters, 1 had 4 encounters and 1 had 5 encounters or more

The graduate students audited the same selected records as had been completed by each auditor. Suiying Huang, Data Manager, then completed Kappa tests for the charts audited by both the nurse abstractor and graduate student **(Appendix 18).**

**Kappa Calculation for Quality Control:**

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

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

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

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

Examples of Kappa calculation:

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

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

After this table is made, the data is input into SAS for Kappa calculation. The reason that there are only 8 patients is that 4 charts had either Ecode 2 or 3 and consequently this portion of Form I was not filled out. The following output was obtained.

| Statistic | Value | ASE | 95% Confidence Bounds | |
|---|---|---|---|---|
| **Simple Kappa** | **0.8431** | **0.1430** | **0.5628** | **1.1234** |
| **Weighted Kappa** | **0.9500** | **0.0501** | **0.8517** | **1.0483** |

2. **For fields labeled 0 or 1**:

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

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

After this table is made, the data is transferred into SAS for Kappa calculation. For the 8 patients there were 9 office visits where CBE was performed. For six of them there was no documentation of lymph node examination, while for 3 of them it was documented. The abstractor missed one documentation record.

| | |
|---|---|
| **Kappa** | **0.7273** |
| **ASE** | **0.2474** |
| **95% Lower Conf Bound** | **0.2424** |
| **95% Upper Conf Bound** | **1.2121** |

3. **Situations where Kappa is calculated to be 0%:**

There are some fields where the calculated Kappa value equals 0%. Often this happens when the marginal totals are very unbalanced i.e, if we have 10 charts , for example 9 provide answer 'yes' and only one provides answer 'no'. In those situations the Kappa statistics is not the best way to represent the data and in those situations the percent agreement is more appropriate. When such situations arose in our data, we have included in parenthesis the percent agreement

An example is included for bilateral mammogram findings. For a bilateral mammogram, the abstractor is required to record mammogram findings for both breasts. However, sometimes the abstractors would forget to record the bilateral mammograms findings for one of the breasts. Within this group of 12 patients only 4 had bilateral mammograms. The following table is the summary of bilateral mammogram documentation results for the 4 patients with mammogram reports in their charts. In this case "1" signifies mammogram documentation and "0" signifies no mammogram documentation. In this scenario the abstractor missed recording the mammogram documentation compared to the quality control for patient 4.

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

| | |
|---|---|
| Kappa | 0.0000 |
| ASE | 0.0000 |
| 95% Lower Conf Bound | 0.0000 |
| 95% Upper Conf Bound | 0.0000 |

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

$(4 - 1) / 4 = 75\%$

***RESULTS from Quality Control:***

Tables 1-5 in Appendix 18 provide Kappa values for each of the 17 abstractors. The fields chosen for Kappa calculations were those that the research team considered critical for dermination of outcome values specified in study hypothesis. Forty three fields were subjected to quality control evaluation:

1) **4 from Form I (General Information)**-Eligibility Code, date of the most recent visit, total number of visits within 15 months, total breast care related encounters;
2) **5 from Form II (Visit Entry form)** - Type of contact, presenting symptoms(lump) in the right or left breast, CBE documentation with regard to inspection, palpation, lymph node examination, and whether there was abnormal finding with regard to lump in the right or left breast.
3) **15 from Form III (Test results entry form)** - For mammogram findings, the 6 categories of mammogram classification for both right and left breast (12 fields) and for 3 outcomes for FNA findings-resolved/not bloody, bloody fluid, residual mass.
4) **12 from Form IV (Follow-up form)** - Follow-up undocumented, routine screening, 12 month CBE, 12 month mammogram, immediate mammogram, extra views, cone compression, magnification views, interval mammogram, interval CBE, ultrasound, surgical referral.
5) **4 from Form IV ( Surgeon's Letter) -** Further tests, evidence of malignancy, follow-up in primary care office, follow-up in surgeon's office.

The "*" in the tables specifies that Kappa value was 100%. Over 90% of Kappa values were 100% and the remaining ones were either excellent (>80%) or Very Good (60-80%) Only 2 kappa values were less then 60% and they were 58% and 59%. We attribute this high quality of abstracting to the intensive training that the abstractors received, the requirements by Dr. Given that for the 10 practice cases their Kappa values be at least 90% prior to being allowed to abstract in the field, and the additional day of training that they received right before going into field after they had the opportunity to practice the 10 cases and ask questions that allowed them to properly enter the data. Although this process has delayed our abstracting by at least six weeks, it guaranteed for us high quality of data. All the abstractors have agreed to continue abstracting during the next year.

**Task 12: Data entry and analysis of baseline chart audit:**

1. **Data entry**
2. **Data analysis of baseline outcome measures**

**1. Data Entry**

It was determined that the data entry would occur at the point of the nurse abstractor rather than by a hired student employee. Therefore, data entry coincided with the chart audit process. As the nurses audited the medical records of the eligible patients, they entered the data directly onto the laptop computer. This was electronically transferred by the FTP (file transfer protocol) process on a weekly basis.

Each week completed chart audits were sent to Suiying Huang, Data Coordinator. A weekly report was also sent to Barbara Given, Ph.D., R.N. relating the number of hours worked, the number of record audited and any other questions/concerns. Items needing clarification or completion were returned to the auditors for action. The number of returned chart audits for each site was tracked for each auditor and reports were generated on the completion rates for each auditor

2. **Data analysis of the baseline outcome measures.**

Data analysis of the chart abstract information for the baseline year has just begun and will continue through the summer of 2000. Drs. Pathak and Osuch will perform the initial screening of any charts identified with an abnormal finding. The follow-up of each abnormality will be judged as appropriate or inappropriate according to the algorithms developed for the curriculum. In all cases where management is judged inappropriate, and in any equivocal cases where judgement could be swayed, the charts will be discussed in a team meeting with all of the investigators involved in clinical care so that a consensus judgment can be made.

The outcome measures of interest for the primary hypothesis (based on chart audits) are changes in pre-post levels of: 1) proportion of women receiving CBE and mammography; 2) rate of documentation of findings; 3) time to follow-up of abnormal findings; and 4) rate of appropriate follow-up for abnormal findings. We will test the null hypothesis that for a given outcome measure, the changes from pre-post intervention are the same for sites in the intervention and control arm of the study, versus the alternative hypothesis that these changes are significantly greater for the intervention arm.

Statistical analyses for this study will take into consideration the cluster randomization of intact physician groups. The primary outcome measures for the intervention effect will be based on comparison of the baseline measures of interest with those for the intervention year.

**<u>Task 13:</u> Assessment of retention of training effect:**

- Train evaluators:
  - Hire and train live models in evaluation of clinical breast examination technique.
  - Train faculty in evaluation of clinical breast examination technique
- Collect follow-up data on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis using the "Knowledge, Attitudes and Beliefs" Survey developed specifically for this study.
- Re-evaluate skills in CBE performance.
- Repeat all measurements from the original pre-test.

Recruitment of patient evaluators for the assessment of retention of training effect has been completed. Training for these patient models is scheduled to occur on April 26th, 2000. The training will encompass the same components as the initial training held in July of 1999 for the initial patient instructors (**see Task 7 and Appendix 6**).

We will collect data on knowledge, attitudes, and beliefs, ability to detect lumps and technique of CBE, during re-evaluations which are scheduled, as described below:

| LOCATION | DATE | TIME |
|---|---|---|
| Lansing<br>Family Practice Center-<br>Sparrow Hospital-St. Lawrence Campus | May 4, 2000 - Thursday | 3 P.M. – 5 P.M. |
| Midland<br>Family Practice Center<br>Mid-Michigan Regional Medical Center | May 18, 2000 - Thursday | 9 A.M. – 11 A.M. |
| Saginaw<br>Family Practice Center<br>Saginaw Cooperative Hospitals, Inc. | May 19, 2000 - Friday | 11 A.M. – 1 P.M. |
| Lansing<br>Family Practice Center<br>Sparrow Hospital-St. Lawrence Campus | June 8, 2000 - Thursday | 3 P.M. – 5P.M. |
| Kalamazoo<br>Family Practice Center | June 9, 2000 - Friday | 9 A.M. – 11 A.M. |

The re-evaluations will have two components. 1) Collection of data for the KAB survey, technique of CBE and lump detection skills, and 2) Focus Groups to asses relevance of the curriculum thought and the resident's ability to utilize the information and skills gained during the workshop, in his/hers daily care of patients. Dr. B. Given has agreed to conduct all five Focus Groups. At each residency site, half of the residents will first participate in the Focus Group, while the other half will rotate during that hour through the 3 stations for re-testing of KAB survey, CBE technique, and ability to detect lumps. During the second hour the two groups will switch their roles.

**Task 14: Data entry and analysis of data collected for the evaluation of training retention:**

- **data entry of outcome measures on knowledge, attitudes, and beliefs about breast cancer screening and early diagnosis**
- **data entry of outcome measures on CBE skills**
- **data analysis of knowledge, attitudes and beliefs about breast cancer screening and early diagnosis**
- **data analysis of outcome measures on CBE skills**
- **compare data from Task 16 (retention of training effect) to data from Task 8 (pre-training and immediate post-training)**

For the re-testing participating physicians will be assigned the same color/number as they had during the original training. The collected data will be entered into the data-bases developed for the assessment of immediate effect of the curriculum on the physicians cognitive (KAB survey) and clinical (CBE technique and lump detection ability) skills. Comparisons will be made between individual's scores on the post-test at the time of training and on the current re-testing.

**Task 15: Assess implementation of CRGS:**

- **Convene focus groups at each site.**
- **Identify local implementation issues.**
- **Identify global implementation issues.**
- **Compare and contrast themes across sites.**

Assessment of these variables is scheduled according to the schedule described in Task 13. Focus groups of 10-15 physicians in each group will be convened to assess the implementation of the CRGS. Dr. Barbara Given, an experienced focus group facilitator has agreed to lead all of the Focus Groups. Questions to be asked during these sessions are outlined below:

## DoD Focus Group Breast Care Questions

1. Relevance of the curriculum to your daily practice
   - How have you used the information on BCS and follow-up workshop to help your patients?
2. Impact on your professional effectiveness in breast cancer screening and follow-up of abnormalities. Related to performing comprehensive breast exams now a year later:
   - What has been your experience in your ability to continue to perform comprehensive breast exams?
   - How have you altered your examination since the training session?
   - How did the teaching workshop help you in the breast cancer-screening component of patient care this past year?
   - How did the teaching workshop assist you in follow-up of breast disorders for your patient care this past year? (Give an example related to direct care).
3. Value of the Clinical Skills Component
   - How has the training assisted you in breast examination? Be specific to:
   - position of patient during exam
   - skin exam
   - lump identification (number & type)
   - communication with the patients
4. Barriers in applying the content learned in daily practice.
   - How do practice realities and time pressure help or interfere with your ability to carry out techniques learned in the workshop?
5. Utilizing the Chart Reminder/Guideline System for screening and follow-up of breast abnormalities
   - How did you utilize the Chart Reminder/Guideline System? How did it help you in your daily practice?
6. Relating to the use of the Gail model:
   - How have you been able to use the Gail model in the actual care of your patients?
   - What would you recommend about training to make Gail model beneficial to your care?
7. Overall, how has your practice for CBE changed due to this training?

8. What was the most valuable component of the course as you review it now, one year later?
9. Additional needs/topics that could be covered during this Workshop or in future educational offerings.
10 Suggestions for improving the workshop

## *Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age*

# CONCLUSIONS

We have successfully developed and implemented a new curriculum entitled "ESSENTIALS OF BREAST CARE." We have evaluated its short-term efficacy and found that cognitive (knowledge, attitudes and behaviors) and clinical (CBE technique, ability to detect lumps in silicone breast models) skills are improved. We have submitted an abstract to the Era of Hope meetings with the results of the immediate effect of the curriculum on cognitive and clinical skills.

An unforeseen scholarly work from this project has evolved. We are in a process of writing a paper to evaluate the influence of different criteria for defining true and false positives in calculations of sensitivity and specificity of clinical breast examination when a known gold standard exists.

Drs. Osuch and Pathak are currently doing the initial screening of any charts identified with an abnormal finding. For Traverse City, out of the 941 abstracted charts, 98 had some kind of abnormality recorded, i.e, approximately 10%. This percentage agrees with what has been previously reported in the literature for rates of breast abnormalities. For each abnormality reviewed, the follow-up will be judged as appropriate or inappropriate according to the algorithms developed for the curriculum. In all cases where management is judged inappropriate, and in any equivocal cases where judgment could be swayed, the charts will be discussed in a team meeting with all of the investigators involved in clinical care so that a consensus judgment can be made.

One unexpected outcome of this grant, is that we have been asked to provide the "ESSENTIALS OF BREAST CARE" curriculum to other health care professionals (Nurse Practitioners, Ob/Gyn residents, etc.). While this does not directly assess the translatability into private practice, this does identify an important unmet need in other disciplines.

The design of this study did not require that the control sites receive the curriculum, although we have agreed to provide it to each control site if they were interested in it. The informal communication among Residency Directors combined with a perceived need for this training resulted in all of our control sites requesting that we provide them with the curriculum. We plan to teach the curriculum to the control sites in August and September 2000.

Over all we are on target for the successful completion of the project according to the scope of work statement in the original grant.

## *Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age*

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APPENDICES ARE BOUND SEPARATELY

# IMPROVED FOLLOW-UP OF BREAST ABNORMALITIES THROUGH COMPREHENSIVE BREAST CARE IN WOMEN 40 TO 70 YEARS OF AGE

APPENDICES FOR YEAR ONE ANNUAL REPORT
MARCH 1, 1999 TO FEBRUARY 28, 2000

***Funded by:*** Department of Defense # DAMD 17-98-1-8318

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# APPENDIX 1

# Chart Audit Data Collection Forms

# Form I- Front-End Form

Add New Patient

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

Data Transfer

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

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

**Meaning of Eligibility Code:**

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

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

Click to Determine Eligibility Code:

## Rules for Assigning Study ID:

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

Please assign study ID: 1 Today's Date: 3/22/00

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 | 310434 |
| For eligibility code | 320071 |
| For eligibility code | 330137 |

Click here To Continue

Add New Patient

## Chart Review Form (Only For Eligible Patient)

Study ID: 1

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

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

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

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

**5. Personal/Family History Of Breast Cancer?**

Add New Patient

**Rule for filling in the age at diagnosis:**

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

In Self? No Age:

Surgery/Reconstructio

- ☐ Complete Breast Removal
- ☐ Partial Breast Removal/Lumpectomy
- ☐ Prophylactic Implan
- ☐ Autologous Reconstitutio
- ☐ Other, specif
- ☐ Undocumente

Treatments (check all that app

- ☐ Chemotherap
- ☐ Radiation
- ☐ Tamoxifen/Nolvadex
- ☐ Alternative medicine(s), spec
- ☐ Other, specif
- ☐ Undocumente

| | | | | | |
|---|---|---|---|---|---|
| In Mother | No | Age: | | | |
| In Sister? | No | ☐ Sister | Age: | ☐ Sister | Age: |
| In Daughter | No | ☐ Daughter | Age: | ☐ Daughter | 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: 310109

Go Back to Front-End

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

**6. Date of Breast Care Activity Was Recorded:**

**Type of Contact:**

**7. Purpose of this Visit/Call:**

**Specify:**

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

Go Directly to Test Result Form

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

☐ Resident Physician ☐ Faculty Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ **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:** | **Right Breast:** |
|---|---|
| ☐ **None** ☐ **Undocumented/Don't know** | ☐ **None** ☐ **Undocumented/Don't know** |
| ☐ Lump(s)/Mass(es)/Asymmetrical thickening | ☐ Lump(s)/Mass(es)/Asymmetrical thickening |
| ☐ Nipple Discharge | ☐ Nipple Discharge |
| ☐ Skin/Nipple change (check all that ap | ☐ Skin/Nipple change (check all that ap |
| ☐ Skin Dimpling ☐ Erythema/Skin thickeni | ☐ Skin Dimpling ☐ Erythema/Skin thickeni |
| ☐ Nipple Retraction ☐ Nipple Scaling | ☐ Nipple Retraction ☐ Nipple Scaling |
| ☐ Pain/Tendernes | ☐ Pain/Tendernes |
| ☐ Occult Mammographic Abnormality | ☐ Occult Mammographic Abnormality |
| ☐ Density(Nodule or Asymmetry) | ☐ Density(Nodule or Asymmetry) |
| ☐ Microcalcifications | ☐ Microcalcifications |
| ☐ Other, specify: | ☐ Other, specify: |

**10. CBE Documentation:**

**11. CBE Findings (Check All That Apply):**

☐ **Bilateral Implants**

☐ **Previous abnormality resolved**

☐ Lump/mass resolved ☐ Observational finding resolve ☐ 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, specif | Nipple Change | Undocumented | Breast Size/Shap | Undocumented |
| | Scar | Undocumented | Skin Change | Undocumented |
| ☐ Palpation, specif | Fibrocystic Breast | Undocumented | Nodularity | Undocumented |
| | Mass(es) | Undocumented | Pain/tenderness | Undocumented |
| ☐ Lymph node examinatio | Adenopathy/Axillary Node | Undocumented | | |
| ☐ **No specific documentation besides normal** | | | | |
| ☐ Other, Specify: | | | | |

**Abnormal: Which breast(s) has abnormal finding?**

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

| **Left Breast:** | **Right Breast:** |
|---|---|
| Location: | Location: |
| ☐ Lump(s)/Mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic | ☐ Lump(s)/mass(es)/Asymmetric breast thickening/ Asymmetric Fibrocystic |
| ump size: | ump size: |
| Depth: | Depth: |
| Hardness: | Hardness: |
| Mobility: | Mobility: |
| Shape: | Shape: |
| Texture: | Texture: |
| Additional Findings With Lumps (check all that a | Additional Findings With Lumps (check all that a |
| Skin Dimpling/Retractio: Undocumented | Skin Dimpling/Retractio: Undocumented |
| Skin Erythema: Undocumented | Skin Erythema: Undocumented |
| Skin Peau d'orange or Skin Thickening: Undocumented | Skin Peau d'orange or Skin Thickening: Undocumented |
| Nipple Retractio: Undocumented | Nipple Retraction: Undocumented |
| Nipple Scaling: Undocumented | Nipple Scaling: Undocumented |
| Pain/Tenderness: Undocumented | Pain/Tenderness: Undocumented |
| Fibrocystic Breast(s): Undocumented | Fibrocystic Breast(s): Undocumented |
| Nipple Discharge: Undocumented | Nipple Discharge: Undocumented |
| ☐ Other, Specify: | ☐ Other, Specify: |
| ☐ Nipple Discharge With No Lu | ☐ Nipple Discharge With No Lump |
| Spontaneous? | Spontaneous? |
| Color | Color |
| Unilateral or bilateral? | Unilateral or bilateral? |
| Single or multiple duct | Single or multiple duct |
| ☑ Observational Findings With No Lump | ☑ Observational Findings With No Lump |
| ☐ Skin dimpling/retractio | ☐ Skin dimpling/retractio |
| ☐ Skin Erythema | ☐ Skin Erythema |
| ☐ Skin Peau d'orange/Skin Thickeni | ☐ Skin Peau d'orange/Skin Thickeni |
| ☐ Nipple retraction | ☐ Nipple retraction |
| ☐ Nipple scaling | ☐ Nipple scaling |
| ☑ Pain | ☑ Pain |
| ☐ Breast pain | ☐ Breast pain |
| ☐ Chest wall pain | ☐ Chest wall pain |
| ☐ Unspecified | ☐ Unspecified |
| ☐ Other, specify: | ☐ Other, specify: |

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

| | | | | |
|---|---|---|---|---|
| ☐ Drawing of abnormal findin | | | | |
| ☐ Inspection, specif | Nipple Change | Undocumented | Breast Size/Shap | Undocumented |
| | Scar | Undocumented | Skin Change | Undocumented |
| ☐ Palpation, specif | Fibrocystic Breast | Undocumented | Nodularity | Undocumented |
| | Mass(es) | Undocumented | Pain/tenderness | Undocumented |
| ☐ Lymph node examinatio | | | | |
| Adenopathy/Axillary Nod | Undocumented | Lymph Node Enlarged? | | |
| ☐ Other, Specify: | | | | |

Go To Followup Form | Go To Test Result Form

# Form III-Test Result Entry

Study ID: 110005 Date of the Visit: 9/22/98

**12. Mammogram Documentation:**

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

**13a. Mammogram Findings: Final Impressions** Which Breast?

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

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

**13b. Mammogram Findings: Description** Which Breast?

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

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

☐ Asymmetric Breast: more in which br

| | |
|---|---|
| ☐ Bilateral Implant | ☐ Bilateral Implants |
| ☐ Radiolucent Breasts | ☐ Radiolucent Breasts |
| ☐ Dense Breasts/Dense Nodular Breast | ☐ Dense Breasts/Dense Nodular Breasts |
| ☐ Rounded density(ies), most likely cyst or fibroaden | ☐ Rounded densities, most likely cyst or fibroadenom |
| ☐ Irregular Density(ie | ☐ Irregular Density(ie |
| ☐ Benign Appearing Calcification | ☐ Benign Appearing Calcifications |
| ☐ Suspicious Calcification | ☐ Suspicious Calcification |
| ☐ Calcified Fibroadenom | ☐ Calcified Fibroadenom |
| ☐ Axillary Lymph Nod | ☐ Axillary Lymph Nod |
| ☐ Other, specify | ☐ Other, specify |

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

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

☐ AREA NOT SPECIFIED, check SCATTER/THROUGHOUT Breast category

| **Left Breast Location:** | **Right Breast Location:** |
|---|---|
| ☐ Upper Outer Quadrant ☐ Lower Outer Quadrant | ☐ Upper Outer Quadrant ☐ Lower Outer Quadrant |
| ☐ Upper Inner Quadrant ☐ Lower Inner Quadrant | ☐ Upper Inner Quadrant ☐ Lower Inner Quadrant |
| ☐ Lateral Breas | ☐ Lateral Breas |
| ☐ Medial Breas | ☐ Medial Breas |
| ☐ Areolar/Nipple Area | ☐ Areolar/Nipple Area |
| ☐ Deep Against Chest Wall | ☐ Deep Against Chest Wall |
| ☐ Scattered/Throughout Brea | ☐ Scattered/Throughout Brea |
| ☐ Other, specify | ☐ Other, specify |

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

**15.Cyst-Fine Needle Aspiration (FNA)**

**Done by:** **Date done:**

☐ Mass resolved/fluid not bloo ☐ Fluid blood

☐ Residual Mass

☐ Other, specify:

☐ **Sent Fluid to Cytology**

Results Obtained Stamped/Documented Date:

Results Reviewed By FPCP Signed/Documented? Date:

**Cytology Results:**

☐ Insufficient/Hypocellular/Apocrine C ☐ Malignant

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

☐ Other, specify:

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

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

**Done by:** **Date done:**

☐ **Specimen Submitted For Analysis**

Results Obtained Stamped/Documented Date:

Results Reviewed By FPCP Signed/Documented? Date:

**Pathology Results:**

☐ Insufficient/Hypocellul ☐ Benign/Fibrocystic ☐ Atypical cells

☐ Suspicious for malignancy ☐ Malignant

☐ Other, specify:

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

**19. Ultrasound Findings:**

| **Ordered by:** | **Date done:** | |
|---|---|---|
| Results Obtained | Stamped/Documented | Date: |
| Results Reviewed By FPCP | Signed/Documented? | Date: |

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

☐ Other, specify:

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

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

| | | |
|---|---|---|
| Results Received | Stamped/Documented | Date: |
| Results Reviewed By FPCP | Signed/Documented? | Date: |

**Open Biopsy Findings(check all that apply):**

| | |
|---|---|
| ☐ Benign/No Evidence of Malignanc | ☐ Ductal Carcinoma in situ |
| ☐ Benign/Fibrocystic Changes | ☐ Lobular Carcinoma in situ |
| ☐ Benign/Fat Necrosis | ☐ Atypical Hyperplas |
| ☐ Benign/Lipoma | ☐ Invasive Ductal Carcinom |
| ☐ Benign/Fibroadenoma | ☐ Invasive Lobular Carcino |
| ☐ Other, specify | |

Go Back to Visit Form | Go To Followup Form

# Form IV-Follow-up Entry

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

**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 Guideline ☐ Following Other Guidelines specify:

Recommended by: Comments:

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
- ☐ (How many) month CBE

**If Known Solid Mass:**

- ☐ Fine Needle Aspiration Biopsy
- ☐ Specimen Submitted for Analy
- ☐ 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 Biops
- ☐ 2 weeks topical hydrocortisone

**For Breast pain:**

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

**For Occult Mammographic Abnomality:**

- ☐ Radiologic Biopsy/Image-Guided Biopsy

Recommended by:

Follow-up Common To Any Abnormalities:

- ☐ Call if Problem Worsens
- ☐ Routine Screening

Recom. by:

**Immediate Mammogram Workup:**

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

Recom. by:

**Interval Followup:**

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

Recom. by:

- ☐ Ultrasound

Recom. by:

- ☐ **Surgical Referral**

Recom. by:

- ☐ Undocumented

**Other Recommendations Or Comments Concerning Abnormality(ies):**

**General Comments About This Visit:**

## Assessment/Recommended Follow-up From Surgeon's Letter

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

### Assessment

- ☐ Referral Diagnosis Not Confirmed
- ☐ Referral Diagnosis Confirmed
- ☐ Additional/New findings
- ☐ Further Tests Recommended/Done By Surgeon, check all that apply
  - ☐ Immediate Mammogr
  - ☐ Interval Mammogram, how lon
  - ☐ Interval CBE, how long
  - ☐ Ultrasoun
  - ☐ FNA
  - ☐ FNAB
  - ☐ Radiological/Image Guided Biop
  - ☐ Open Biops
- Evidence of Malignancy: No
- ☐ Previous Abnormality Resolved
- ☐ Current Abnormality Resolv
- ☐ Other Comments From Surgeon's Le

### Followup

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

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

# APPENDIX 2

# Essentials of Breast Care Curriculum

# ESSENTIALS OF BREAST CARE


**AUTHORS:**

Janet R. Osuch, MD, Professor, Lead Author
*Department of Surgery*

Henry C. Barry, MD, MS, Assoc. Professor
*Department of Family Practice*

Thomas J. Zuber, MD, Assoc. Professor
*Department of Family Practice*

**PRINCIPAL INVESTIGATOR:**

Dorothy R. Pathak, PhD, MS, Professor
*Departments of Family Practice and Epidemiology*


**GRANT TITLE:**

Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age


**FUNDED BY:**

Department of Defense #DAMD17-98-1-8318


# PARTICIPANT MANUAL


**Michigan State University**
**Departments of Family Practice, Surgery, and Epidemiology**
**College of Human Medicine**
**East Lansing, MI 48824**



**JULY 1999**

# ESSENTIALS OF BREAST CARE

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12. The Use of the Gail Model. Risk Assessment Tools – Practice Session

# HISTORY OF CURRICULUM

**This curriculum has been developed through the efforts of numerous people and over the life of many grants. The current product represents major revisions in curricula and re-focuses on screening, counseling of high-risk women, essentials of clinical breast exam, and identification and work-up of abnormal findings.**

**The concept for the curriculum began when Michigan was named as one of the first states to be funded for grant support for the federally legislated Breast and Cervical Cancer Screening Act administered by the Centers for Disease Control and Prevention in 1992. The then co-chair of the Breast Cancer Task Force at the Michigan Department of Public Health, Janet Rose Osuch, M.D., was asked to prepare a day-long workshop for participants in the project throughout Michigan. Given to physicians and nurse practitioners, this workshop focused on the screening and diagnosis of breast problems and taught a standardized approach to clinical breast exam using the MammaCare® models. The American Medical Women's Association (AMWA) subsequently received grant support from the Centers for Disease Control to formalize the curriculum on breast care and to add a cervical cancer screening component. That project was completed in 1994 and subsequently sent by the Centers for Disease Control to each of the health departments in the country. AMWA had members of its women's health committee deliver the curriculum to the medical staff of several hospitals throughout the country.**

**Subsequently, the California Health Department created its own curriculum on *The Essentials of Clinical Breast Examination.* Janet Rose Osuch, M.D. served as one of the consultants on this project, which resulted, along with other components, in the production of the videotape on CBE that is used in the current curriculum.**

**In response to fiscal year 1996 legislation, the Assistant Secretary of Defense chartered a Tri-Service Interdisciplinary Team called the DoD Breast Cancer Work Group whose purpose was to provide oversight and guidance to the Defense Health Program for breast cancer. The workgroup solicited proposals and AMWA's breast component of the 1994 curriculum was chosen for delivery to physicians and primary care managers in the military system. The 1994 curriculum was expanded by Drs. Laura Morris and Janet Osuch to include genetics, treatment, and psychosocial issues. AMWA members were selected to attend a master training course and to deliver the curriculum to several dozen military sites world-wide in the Army, Navy and Air Force in 1997. The program was continued by military personnel who attended the master training course conducted by Laura Morris, MD, through AMWA in fiscal year 1998.**

**The current project is part of a grant funded by the Department of Defense to evaluate whether physicians who attend the "Essentials of Breast Care" educational workshops will increase their rates of breast cancer screening and improve the appropriateness and timeliness of follow-up for abnormal findings.**

**July, 1999**

# Acknowledgements


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**Secretarial Assistance**

Maria Struck

# BIOSKETCHES

Dorothy R Pathak, PhD, MS, Principal Investigator

Dr. Pathak has been involved in epidemiological and bio-statistical research for the past 25 years, first at the University of New Mexico and now at Michigan State University. In both settings, the principal focus of her work has been in studies of cancer etiology and prevention.

After receiving her doctorate in biostatistics, Dr. Pathak served as a statistical consultant and co-investigator in a variety of research studies. In 1980, she was Co-Principal Investigator, for New Mexico, on a nationwide CDC funded study of "Cancer and Steroid and Hormones". The study evaluated the effect of oral contraceptive use on breast cancer risks in pre-menopausal women. In 1983 Dr. Pathak obtained a Master of Public Health degree in epidemiology from the Harvard School of Public Health. Her research at Harvard led to the publication of paper on the crossover effect of parity on breast cancer risk. Subsequent work includes a paper on the effect of reproductive risk factors on breast cancer incidence in seven countries. Since that time, Dr. Pathak has increasingly concentrated her attention on the problem of breast cancer.

She moved to MSU in 1995 in order to further develop her research on the effects of migration on breast cancer incidence among Polish immigrant women; and therefore, proximity to the large Polish-American populations of Detroit and Chicago is an essential ingredient. The grant "Breast Cancer in Women of Polish Ancestry" was funded by NCI in 1997. At MSU she holds a tenured joint appointment at the Departments of Epidemiology and Family Practice, and thus another principal research interest is the integration of epidemiological and preventive concepts into the practice of family medicine. Through her position in the Department of Family Practice, Dr. Pathak will lead this effort to improve compliance with recommendations for the secondary prevention of breast cancer.

G. Marie Swanson, PhD, MPH, Co-Principal Investigator

Dr. Swanson is currently the Director of the Cancer Center at Michigan State University and has extensive experience providing leadership for the conduct of regional and national studies. Her research has concentrated on occupational cancer, strategies for increasing the use of breast cancer screening, and racial differences in breast cancer risk. Dr. Swanson has researched and written extensively on breast cancer and the barriers to screening. Her expertise in this area, her involvement on the President's Breast Cancer Panel, and her knowledge of what is important in determining barriers to screening and reaching people are essential.

Janet R. Osuch, MD, FACS, Co-Investigator, Lead Author

Dr. Osuch is a board certified surgeon with a fellowship in surgical oncology whose career has been dedicated to breast disease since 1987. She is one of the nation's premier figures in the fields of medical education and public policy on breast cancer and is a co-author of the AHCPR guidelines on the quality assurance of mammography.

Under a cooperative agreement with the CDC in 1994 and with the American Medical Women's Association, Dr. Osuch developed a 200-slide educational module for primary care physicians covering breast cancer screening, clinical breast examination, and work-up of abnormal findings. This education module has been widely distributed by the CDC throughout the nation and was updated and delivered internationally through the Department of Defense in 1997 and 1998.

Dr. Osuch has served as a national spokesperson for breast cancer for the American Cancer Society, published several book chapters and journal articles related to breast disease, and is currently completing a master's degree in Epidemiology at Michigan State University. Her career is dedicated to the advancement of breast cancer knowledge through professional and public education.

Henry C. Barry, MD, MS, Co-Investigator, Author

Dr. Barry is the senior Associate Chair of the Department of Family Practice and a board-certified family physician. He has advanced training in research design and statistics from the University of Michigan School of Public Health.

Additionally, Dr. Barry has completed a faculty development fellowship and will assist in learner evaluation. He will conduct the focus groups to evaluate the Chart Reminder/Guideline System, the third component of this intervention, and will assist with the workshop training and data analysis. He will also work closely with the intervention faculty to develop an advanced program to be offered at the annual meeting of the Society of Teachers of Family Medicine for faculty of the family practice residencies who are interested in adopting the intervention.

Before becoming a pointy-headed academic, Dr. Barry practiced in rural Appalachia for four years and has a great appreciation for real world issues.

Thomas J. Zuber, MD, Consultant, Author

Dr. Zuber is the residency director for the Saginaw Cooperative Hospitals Family Residency Program. As a board-certified family physician with extensive experience teaching residents and practicing physicians, he is widely recognized as one of the leading educators in family medicine procedural skills training. He serves as faculty for many of the American Academy of Family Physicians (AAFP) Continuing Medical Education courses.

Dr. Zuber recently created a training program for the AAFP on evaluation and management of breast disease. He has taught this program extensively throughout the United States and will participate in the current research study by teaching two of the four training sessions in each year of the study.

Barbara A. Given, RN, PhD, Co-Investigator, Data Collection Coordinator

Dr. Given is a Professor in the College of Nursing and Associate Director, Institute for Managed Care at Michigan State University. Dr. Given has been actively involved in research in long-term care, cancer care, home care, and family involvement in chronic illness care for over 25 years with funding from the National Cancer Institute, National Institute on Mental Health, National Institute for Nursing Research, National Institute on Aging, Walther Cancer Institute, Michigan Department of Community Health, and the American Cancer Society. She has explored these issues with continuous NIH funding since 1978. Dr. Given has continued to explore the unmet needs of the chronically ill and elderly (primarily with cancer) and their family caregivers. Based on the two decades of work a clinical trial is underway to assist the family caregivers to meet patient needs. Dr. Barbara Given testified to the President's Breast Cancer Commission and the President's Cancer Panel for Older Populations in 1997. Dr. Barbara Given has served on the Institute of Medicine's Department of Defense Panel to decide on funding priorities for breast cancer research. Dr. Given participated in a Congressional Breakfast in 1999 to speak to the needs of cancer patients and their caregivers. She has a long standing experience with community based research and data collection in multiple site throughout the State of Michigan and the Midwest.

## Accreditation Statement

### Continuing Medical Education

Michigan State University, College of Human Medicine, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians.

MSU-CHM designates this continuing medical education activity for up to 8 credit hours in Category 1 or the Physician's Recognition Award of the American Medical Association.

# Essentials of Breast Care


***Authors:***

**Janet R. Osuch, M.D.**
**Henry C. Barry, M.D., M.S.**
**Thomas J. Zuber, M.D.**

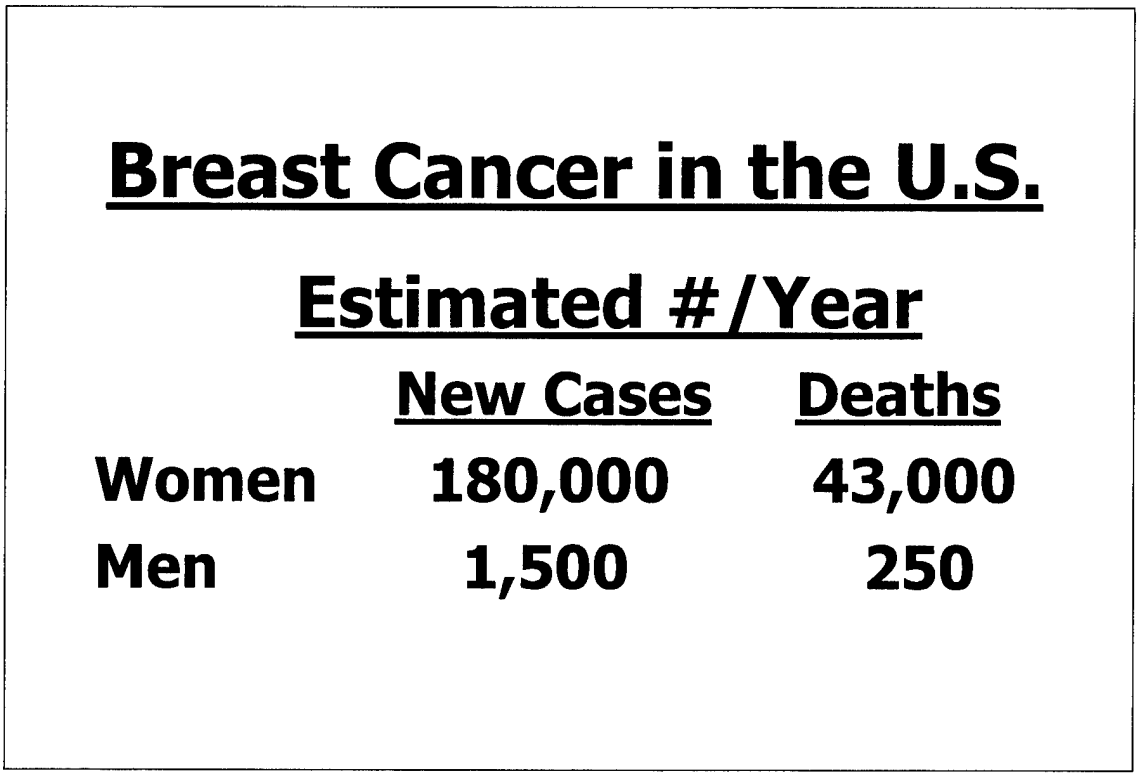
***Principal Investigator:***

**Dorothy R. Pathak, Ph.D., M.S.**



**Funded by Department of Defense #DAMD17-98-1-8318**

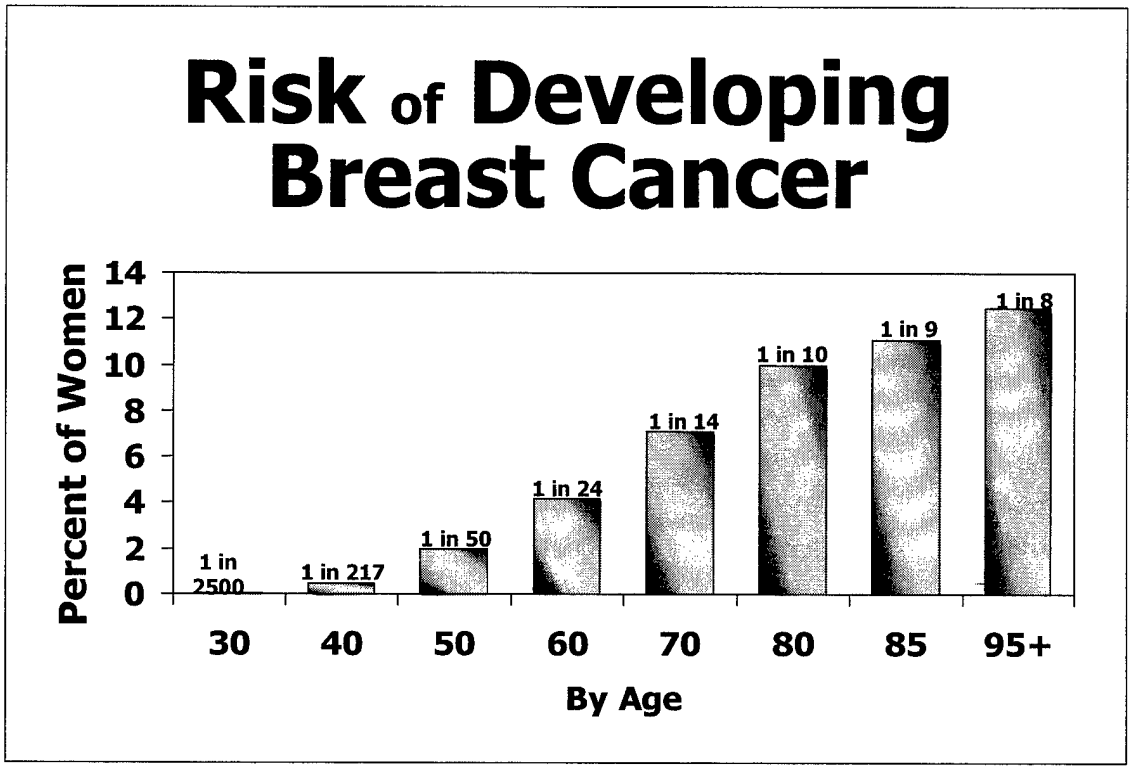

SLIDE 1




SLIDE 2

Breast cancer is a major public health problem. One of every three cancers diagnosed in American women is breast cancer. It affects an estimated 180,000 women each year and causes over 43,000 deaths. It is the leading cause of death in women aged 35-54. Breast cancer can also affect men. As a comparison, approximately 1,500 are diagnosed annually, and 250 men die from breast cancer each year.

**Source:** American Cancer Society. Cancer Statistics 1999, Atlanta, GA. American Cancer Society, 1999, and Vital Statistics of the United States 1999.



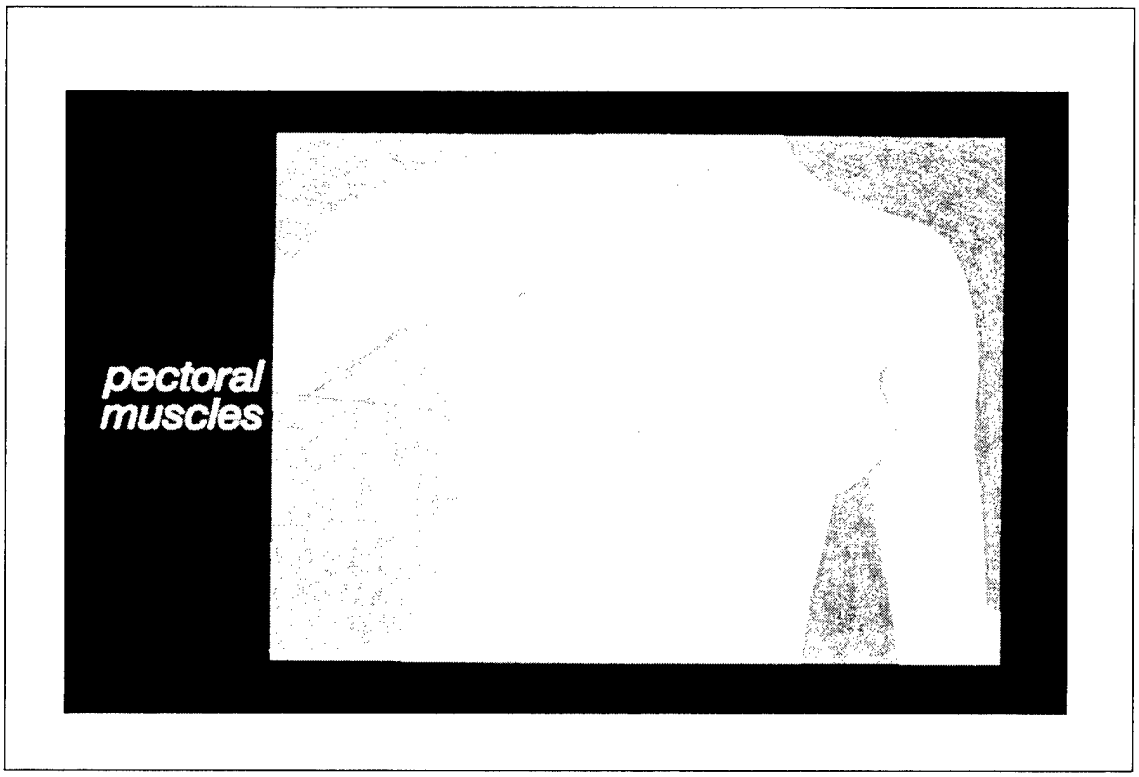

SLIDE 3

This slide shows the risk of developing breast cancer by a given age. One in nine (11.8%) women in a cohort followed from birth to age 85 will be diagnosed with breast carcinoma during her lifetime, and one in eight (12.5%) in a cohort followed from birth to age 95+ years. Women should be told that these risks are calculated starting at birth rather from her current age. Unlike most cancers, breast cancer can strike even young age groups, although the overall incidence is lower than in older women. It is helpful to interpret risk according to age for patients, who often overestimate their actual risk. Do not disregard the risk in premenopausal women, however. Over 44,000 women less than age 50 are diagnosed with breast cancer in the United States annually. This is greater than the incidence of uterine and ovarian cancer combined across a woman's entire lifespan.

**Sources:**

Feuer EJ, Wun LM, Boring CC, et al. The lifetime risk of developing breast cancer. *J Natl Cancer Institute* 1993; 85:892-897.

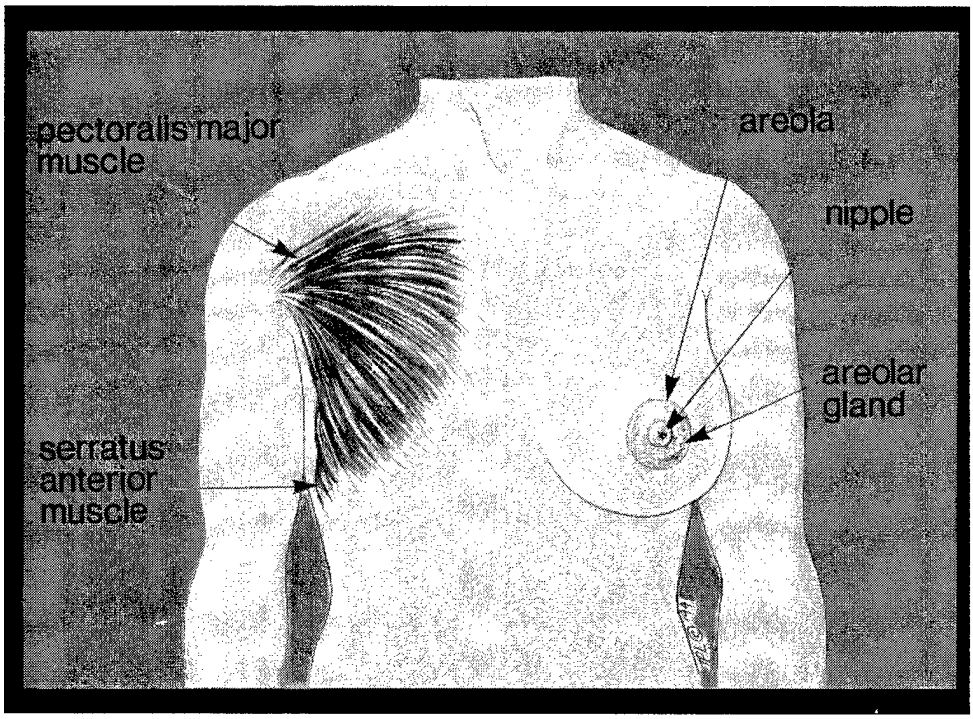
Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.




SLIDE 4

To understand breast cancer, it is useful to review the anatomy of the breast. The breast rests on top of the pectoralis major muscle. Many women believe that there are muscles inside of the breast and attribute a new finding on breast self-exam (BSE) to being muscular in nature. The nipple-areolar complex is the only portion of the breast that has a muscular component. It is circular in nature and assists in lactation. This muscle is not palpable.

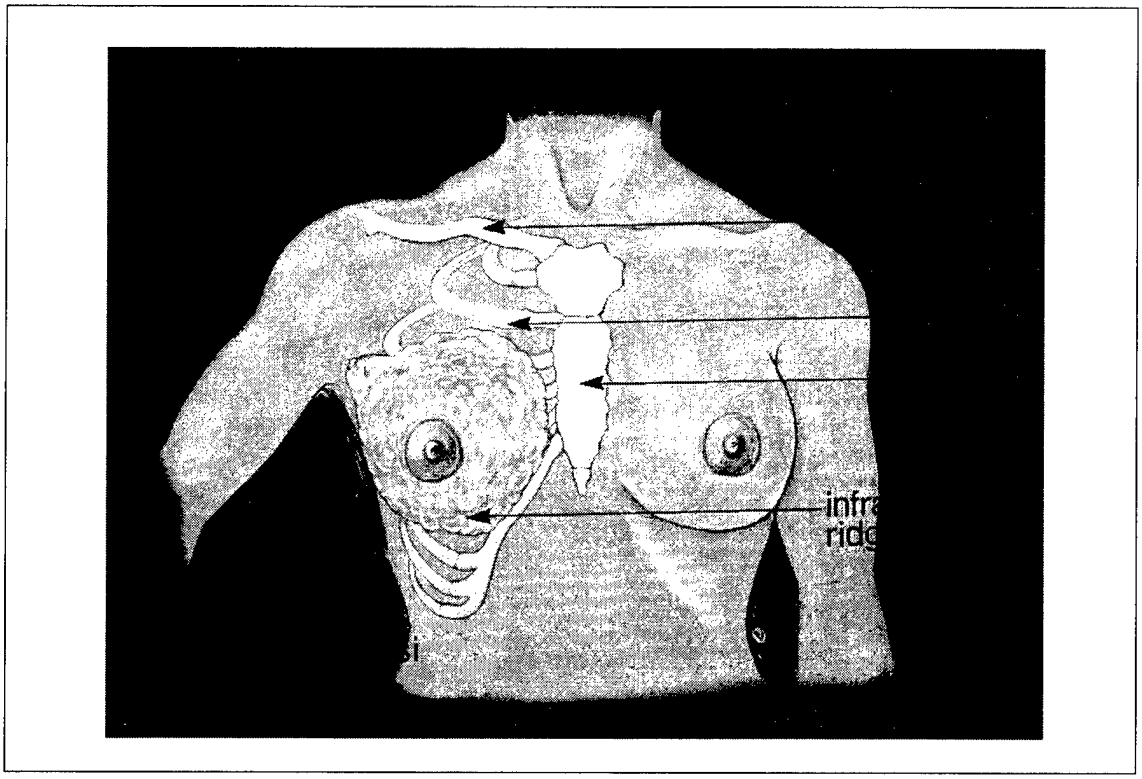
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 5

In most women, and especially in large-breasted women, the breast also covers the anterior portion of the serratus anterior muscle. Many women refer to the nipple-areolar complex as the "nipple". The two structures need to be distinguished when a breast complaint is specific to this region.

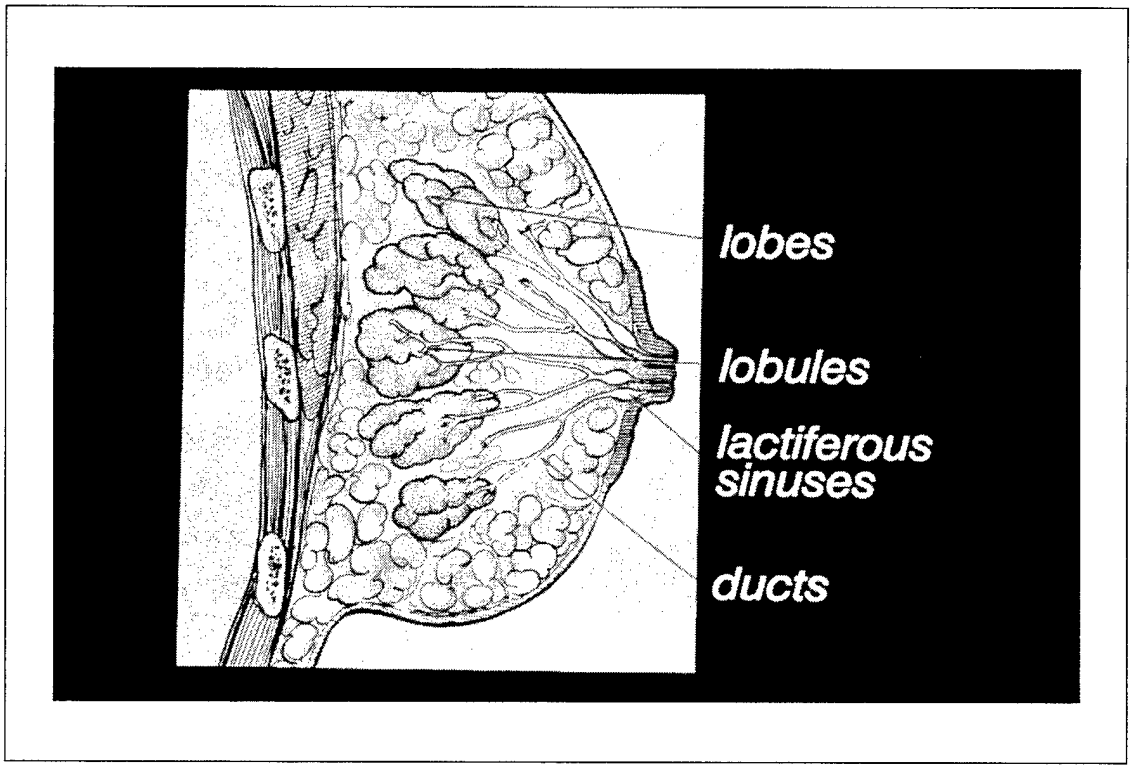
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.



SLIDE 6

Anatomically, breast tissue is enclosed in fascia, which extends to the second rib near the clavicle, and inferiorly to the inframammary ridge near the fifth rib. This ridge is often quite bumpy, and can sometimes be mistaken for a breast mass. However, a similar, symmetrical ridge will be found in a mirror image location in the opposite breast. Medially, breast tissue extends anatomically to the lateral edge of the sternum and laterally, to the latissimus dorsi muscle.

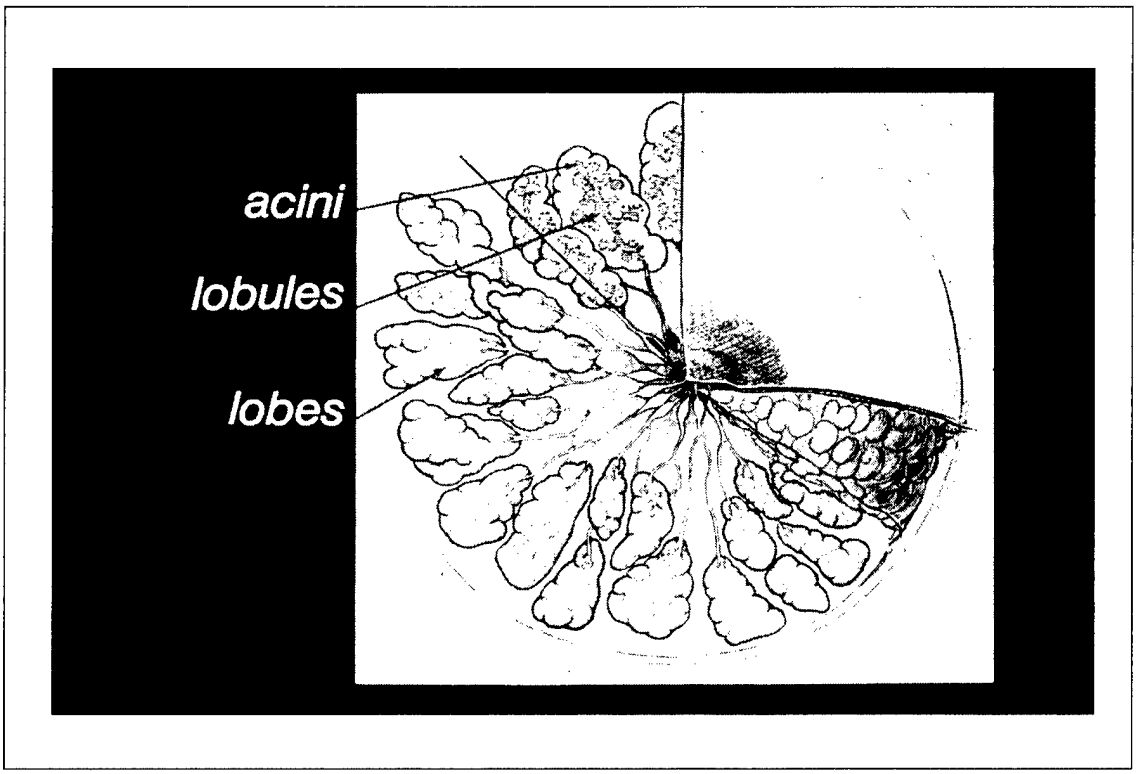
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 7

The internal anatomy of the breast can be viewed as a system of branching tree-like structures embedded in adipose and connective tissue. The parenchymal tissue is composed of two types: the lobes, which secrete milk; and the ducts, which transport the milk to the nipple. Each lobular element is drained by a small duct, which enlarges as it courses towards the nipple and ends as a lactiferous sinus, whose function is to store milk. These structures are located posterior to the areola and often can be palpated as a bumpiness at that location. Circular muscle contraction of the nipple stimulated by suckling empties the lactiferous sinuses to initiate lactation.

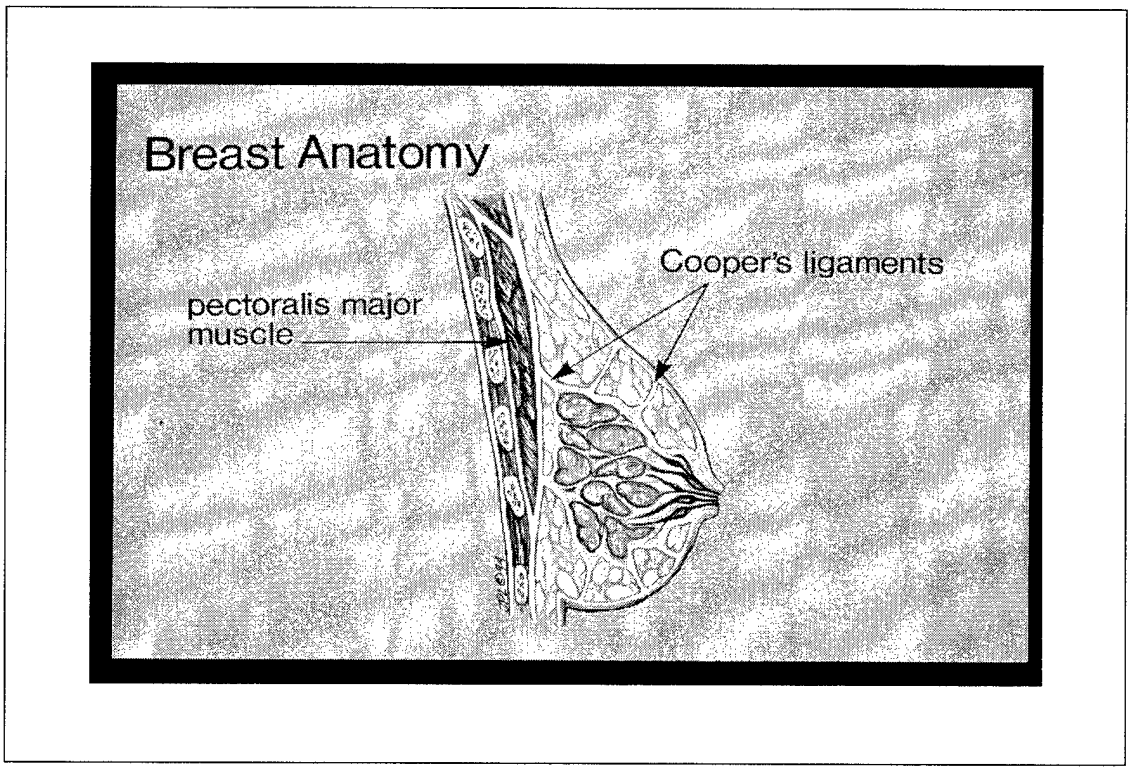
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 8

This frontal view of the breast demonstrates that the lobules divide into acini, the milk-producing structures. During pregnancy or lactation, the acini enlarge. Each lobe is drained by a major duct system, with 12-20 separate major ducts within the breast. Note the lactiferous sinuses in this frontal view just beneath the nipple-areolar complex.

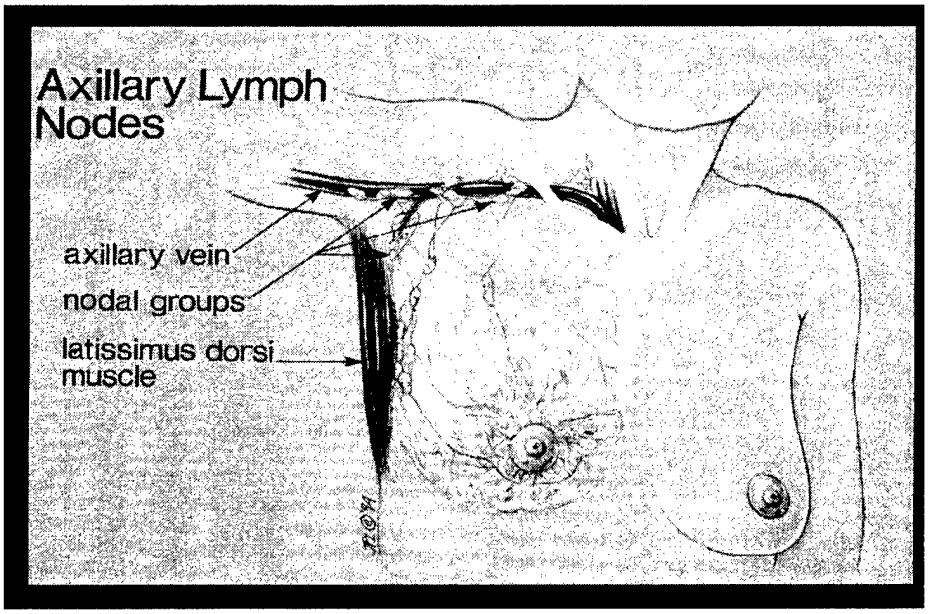
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 9

Cooper's ligaments, composed of connective tissue, are attached to the fascia below the skin, as well as to the fascia of the pectoralis major muscle. These ligaments become important in the physical examination of the breast, as we will discuss later.

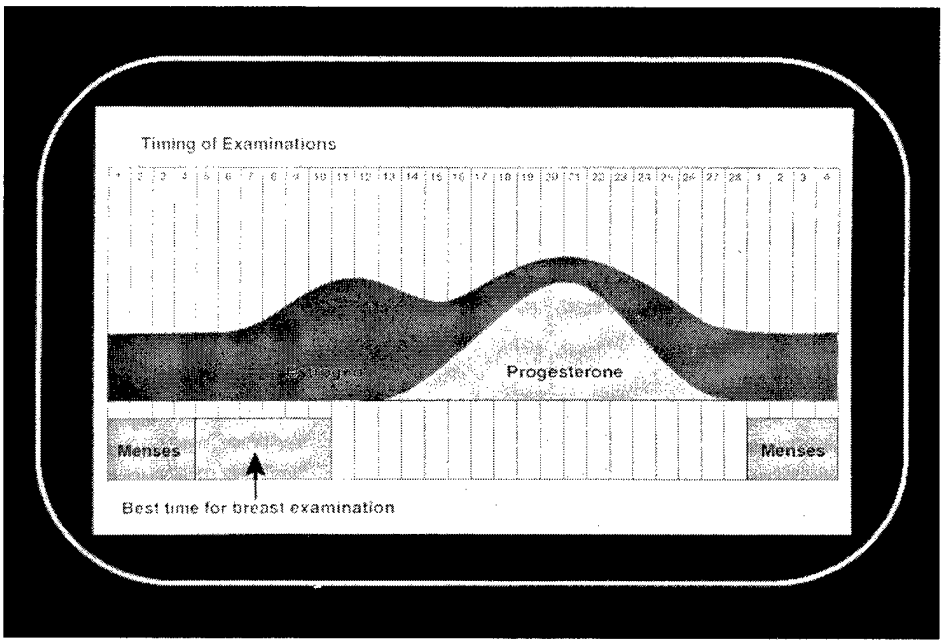
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 10

The majority of breast tissue is drained by axillary lymph nodes, which extend from the axilla along the axillary vein and into the infraclavicular and supraclavicular nodal groups. Some are removed when an axillary dissection is performed to stage breast cancer. This slide also illustrates the anatomical limits of the breast. Note the breast tissue extending into the axilla.

**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.

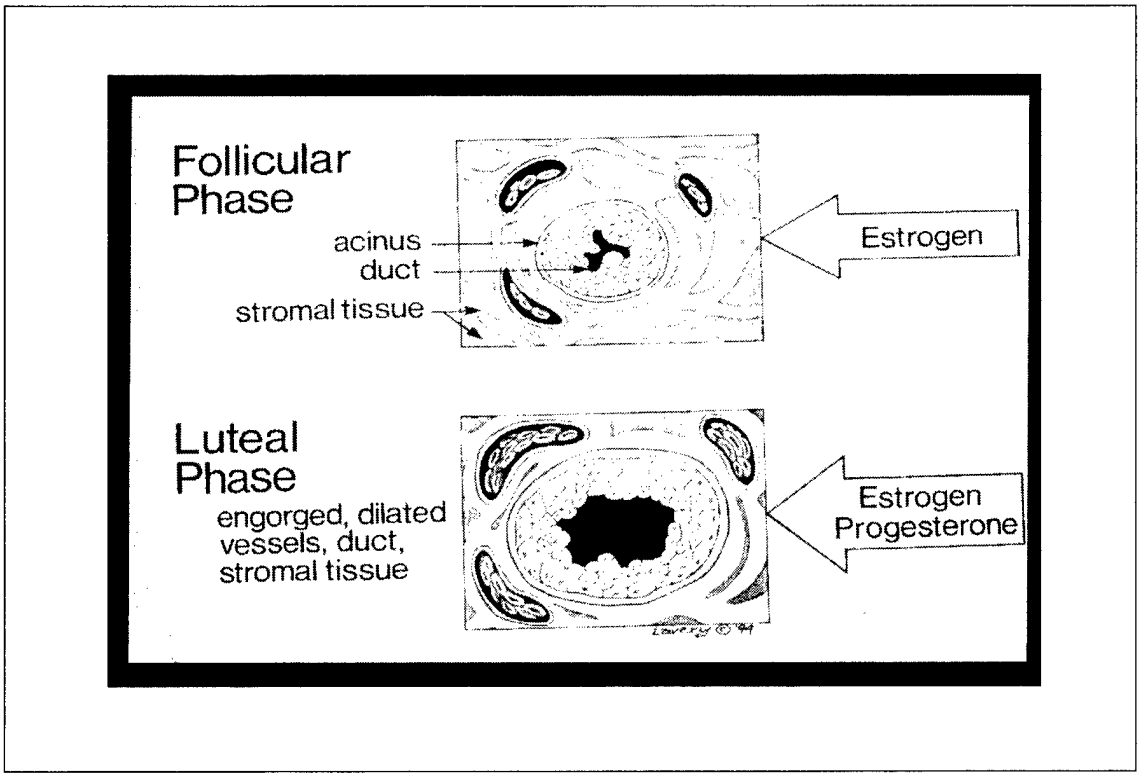



SLIDE 11

The ovarian hormones estrogen and progesterone have a profound physiological effect on breast tissue. This slide illustrates the estrogen and progesterone peaks at the various days of the menstrual cycle. Between days 1 through 7, estrogen levels are at a low point and progesterone is not present. This follicular phase ends at about day 14, when ovulation results in the production of progesterone and the luteal phase begins.

The optimal time for examining the breast is in the follicular phase of the menstrual cycle, preferably between days 3 and 10. The breasts are least tender at this time, least nodular, and the exam easier to interpret than in the luteal phase.

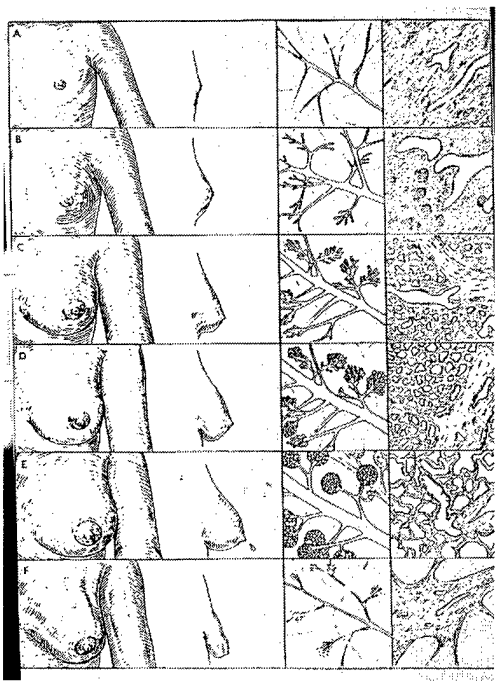
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.




SLIDE 12

The top illustration in this slide demonstrates the appearance of breast tissue in the presence of estrogen alone, whereas the bottom illustration represents the effect of both estrogen and progesterone. Note that in the presence of progesterone, the stromal tissue is engorged and dilated, as is the duct, located in the center of the illustration. The blood vessels also are dilated and engorged with red blood cells. Looking at these illustrations, it is not difficult to understand why many ovulating women have breast pain during the luteal phase of their cycle. The breasts may also be more nodular to palpation during the luteal phase.

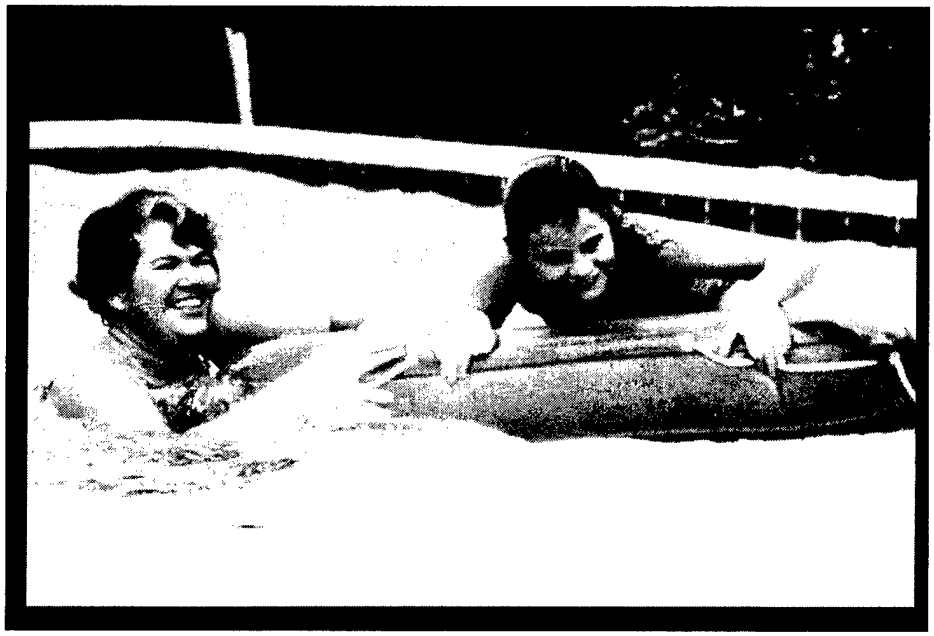
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.



SLIDE 13

An understanding of how the breast changes across a woman's lifecycle can increase an examiner's confidence in his or her findings on breast examination. This slide illustrates the phases of breast development, and correlates the frontal and lateral surface anatomy with the internal and microscopic anatomy. The breasts at birth contain all of the structures needed for development at puberty, and remain dormant until then. In pre-pubertal stages, ducts are present but nonfunctional (A). At the onset of puberty, estrogen stimulates elongation and branching of the ducts and growth of connective tissue within the breast (B). Lobular formation is dependant on progesterone and is absent until the onset of ovulation (C). The full maturation of breast epithelium depends on full-term pregnancy, which stimulates marked proliferation of duct and lobular cells (D). In lactating women, the proliferating lobules remain engorged until weaning (E). The number of breast cells recedes after delivery, but remains elevated above that of nulliparous women. In the perimenopausal woman, the lobules begin to recede, leaving mostly ducts and fibro-connective tissue. Perimenopausal women often develop cysts in the breasts as the lobular elements recede. At menopause, the lobules completely atrophy, leaving ducts, adipose, and connective tissue (F).

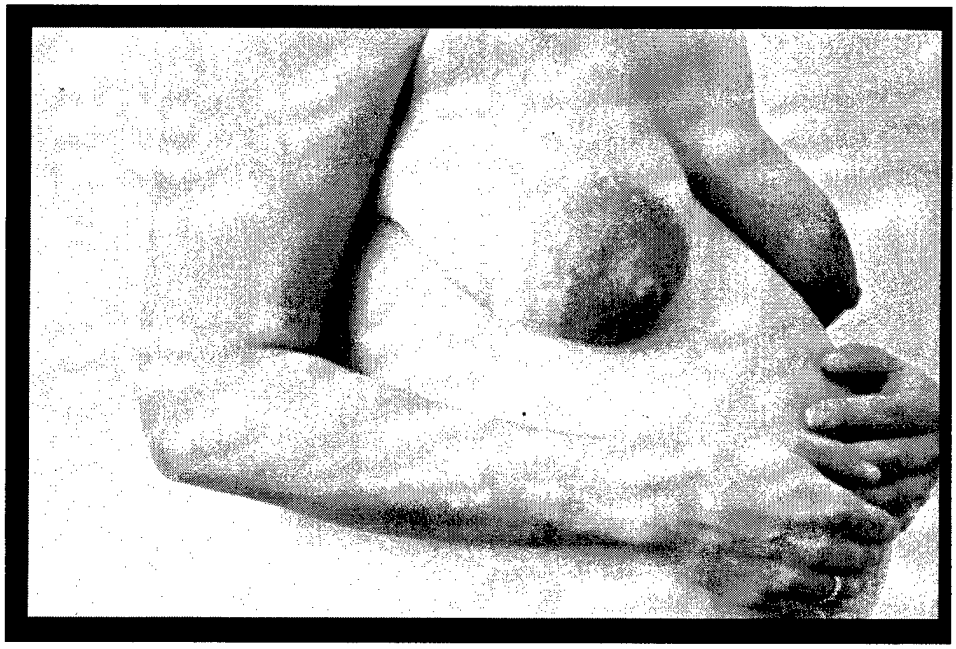
**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds), *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindall, 1989, pp. 5-13.



SLIDE 14

At the onset of puberty, breast buds appear as retroareolar masses. It is important to recognize this as normal. Young girls are sometimes inappropriately referred to surgeons because of a retroareolar breast mass. Removal of the breast bud is a tragic event as all breast tissue is essentially removed, and breast development will not occur.

**Source:** Bland KI and Rommell LJ: Congenital and acquired disturbances of breast development and growth. In: *The Breast: Comprehensive Management of Benign and Malignant Diseases*, Bland KI and Copeland EM (Eds)., 2nd Edition. Philadelphia, PA: W.B. Saunders, 1998.



SLIDE 15

The first prenatal visit should document results of CBE, as examination early in pregnancy is the time when CBE interpretation is the most sensitive and accurate. As pregnancy proceeds, lobular cells become engorged with colostrum and CBE interpretation can be challenging. During pregnancy, the breast increases to about twice its normal weight. The hypervascularity of the breast during pregnancy sometimes results in bloody nipple discharge. Bloody nipple discharge in the second and third trimesters of pregnancy, as well as at the beginning stages of lactation, is normal and almost always regresses spontaneously.

**Source:** Goodson WH, and King EB. Discharges and secretions of the nipple. In: *The Breast: Comprehensive Management of Benign and Malignant Disease*, Bland KI and Copeland EM (Eds), 2nd Edition. Philadelphia, PA: W.B. Saunders, 1998.

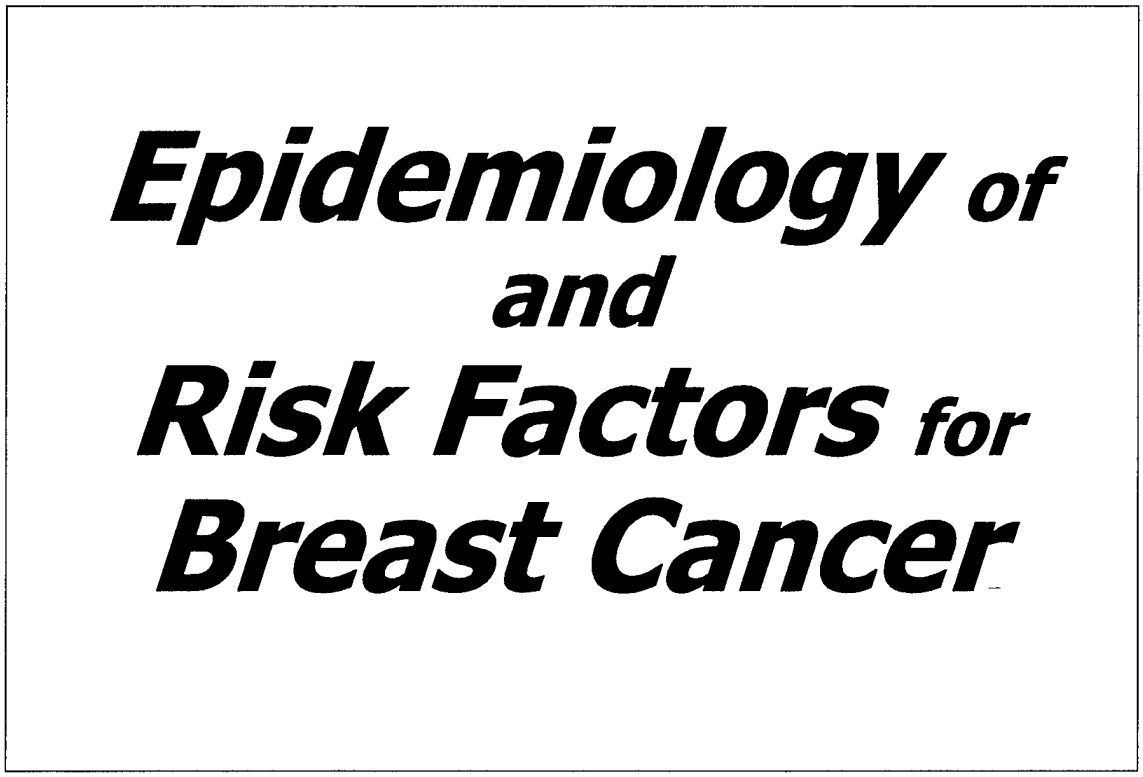
SLIDE 16

Lactation is stimulated within 2-5 days of birth by high prolactin levels and the loss of circulating placental hormones. In lactating women, the breast should be emptied 20 minutes prior to CBE for optimal interpretation.

SLIDE 17

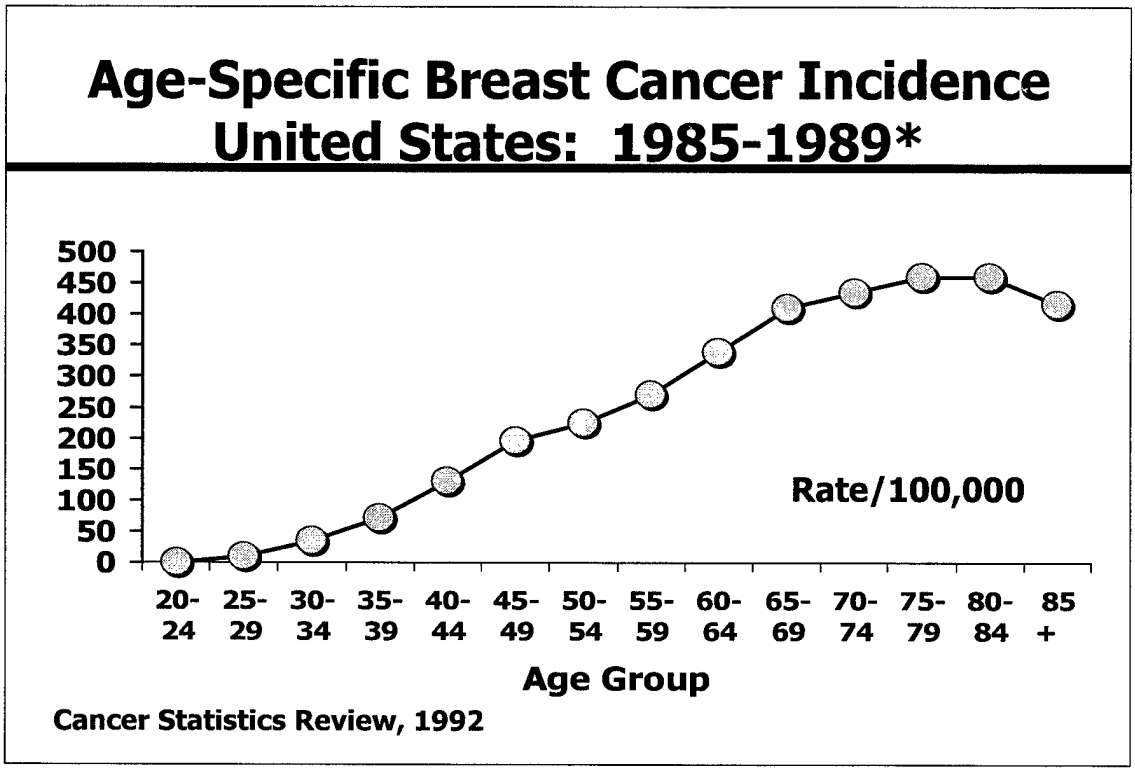
CBE in postmenopausal women is by comparison far easier to interpret than in premenopausal women, due to diminished density and nodularity. However, the breasts of a subset of postmenopausal women who take hormone replacement therapy (HRT) will convert back to the premenopausal state. These changes have been documented by CBE, by mammography, and by histopathology. A physiologic explanation for why this occurs, especially in only a subset of women, is lacking.

**Source:** Powell DE. The normal breast: Structure, function, and epidemiology. In: Powell DE, Stelling CB (eds): *The Diagnosis and Detection of Breast Disease*. St. Louis, MO: Mosby, 1994, pp 3-20.




SLIDE 18

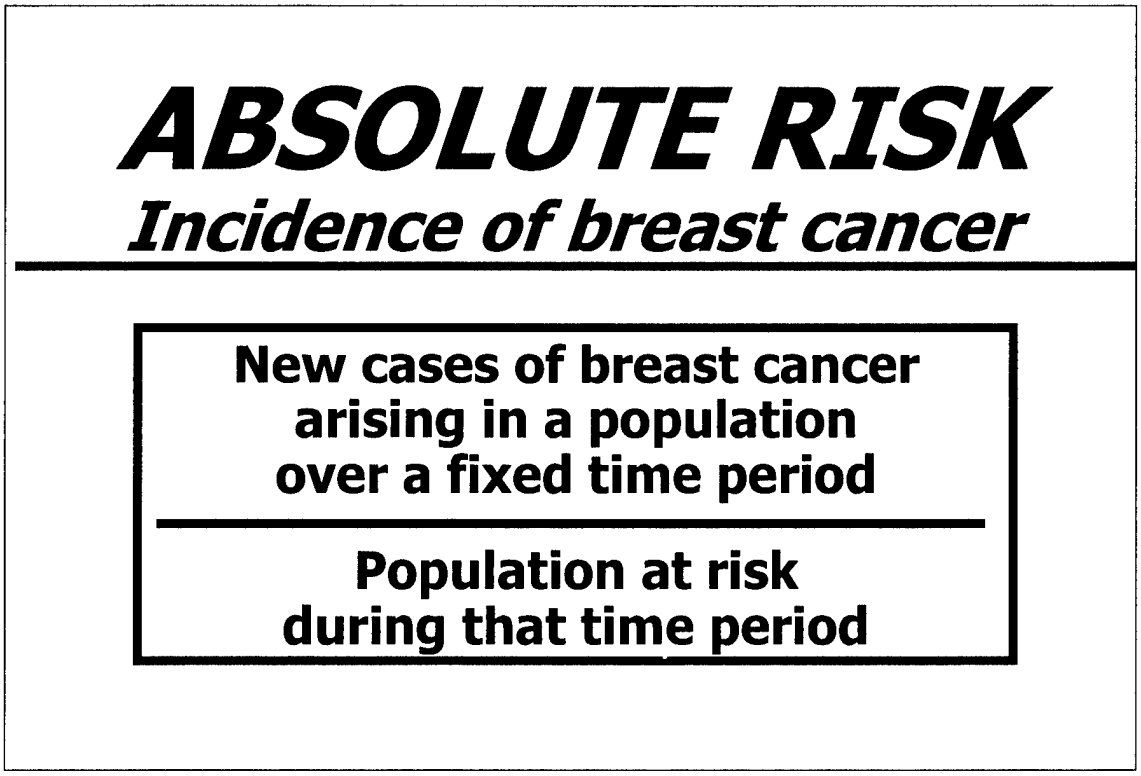
This section is meant to give you practical information regarding risk assessment. To interpret this topic, which often generates fear and confusion, we need to address a few common terms.




SLIDE 19

This slide demonstrates breast cancer incidence expressed as the rate of breast cancer per 100,000 women according to 5-year age groups. It illustrates that starting in age group 20-24, breast cancer incidence rises continuously through age group 80-84, with a slight decrease in the 85+ age group.

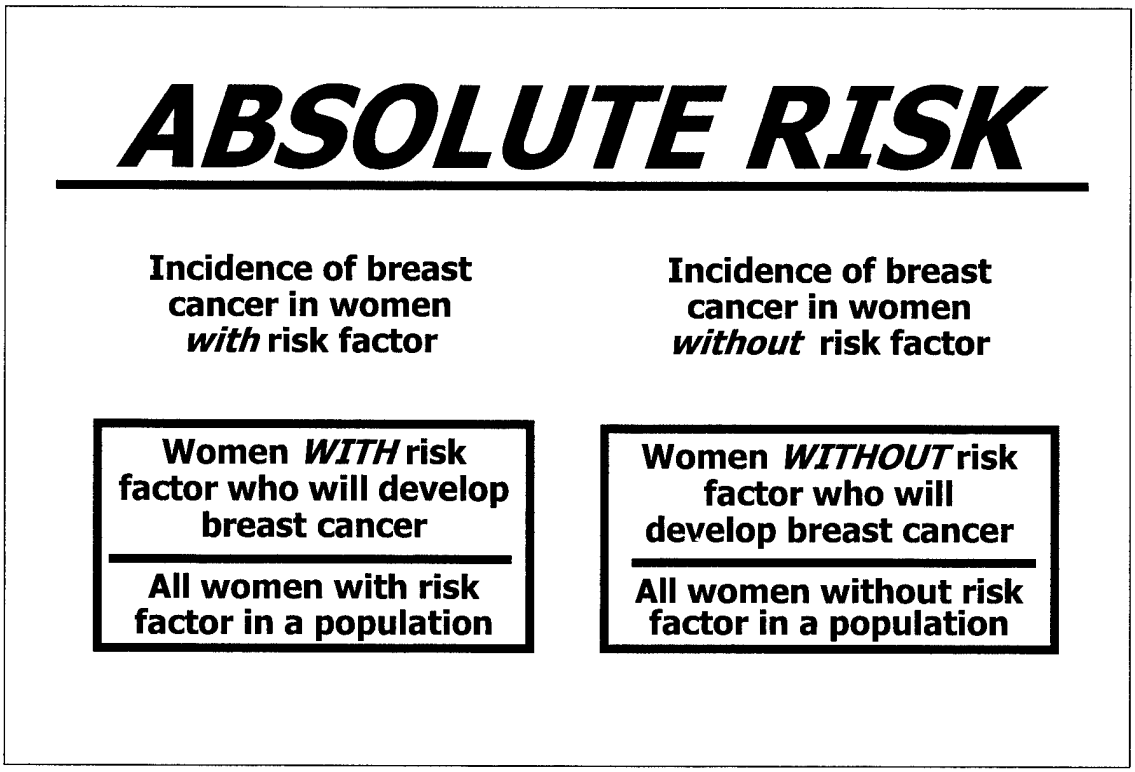
**Source:** Miller BA et al. *Cancer Statistics Review, 1973 - 1989* U.S. Department of Health and Human Services.




SLIDE 20

When interpreting risk factor information for patients, it is important to understand the difference between absolute and relative risk. This slide demonstrates how absolute risk is calculated. It is an expression of incidence of disease and is time dependent. Some commonly used time intervals include 1-year (annual), 5-year, and lifetime expressions of risk. Assuming a life expectancy of 85 years, the lifetime absolute risk of breast cancer is approximately 11%, or one in nine.

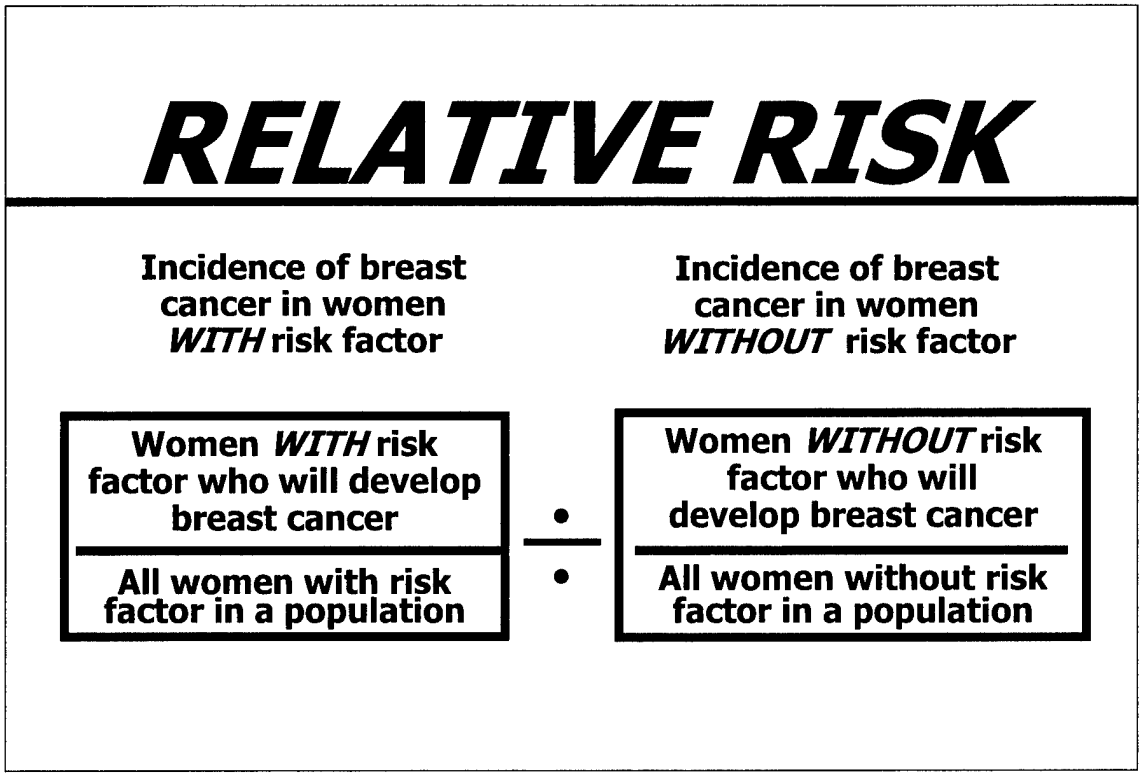
**Source:** Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.




SLIDE 21

Absolute risk calculations can also be applied to specific populations. Two examples of such an application are illustrated on this slide. On the left, the formula for calculating incidence of breast cancer in women with a particular risk factor is shown. On the right, the same calculation is shown for women without the risk factor. Both represent absolute risk calculations. Remember that the calculation is time-dependent.

**Source:** Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.




SLIDE 22

The term RELATIVE RISK is not a rate, like incidence, but instead is expressed as a ratio. It compares the incidence of disease in a group with a particular risk factor to the incidence of disease in a group without that factor. Remember that relative risk is a comparative likelihood of disease development, as compared with absolute risk, which expresses the underlying probability of disease during a specified time period. This slide illustrates this concept. It compares the same two populations for which the previous slide calculated incidence.

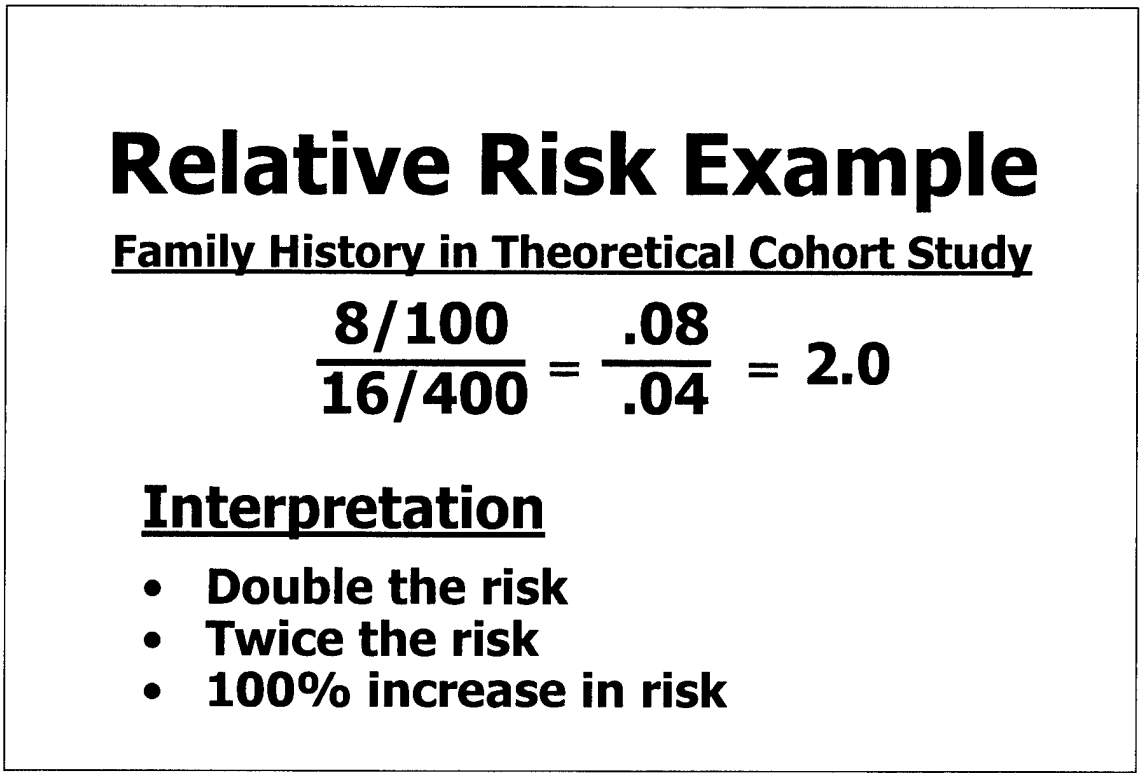
**Source:** Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

# Relative Risk Example

| Family History | New Cases of Breast Cancer in a Fixed Time Period |
|---|---|
| Present N = 100 | 8 |
| Absent N = 400 | 16 |

SLIDE 23

Let us consider a theoretical example of a cohort of 500 women followed for a set period of time. One hundred women have a family history of breast cancer and 400 do not. Eight women are diagnosed with breast cancer in the first group and sixteen in the second. What is the absolute risk for the two groups for the time period of the study? What is the the relative risk in women with a family history of breast cancer versus those without such a history? How are these two types of risk interpreted?




SLIDE 24

The absolute risk in the group with the family history is 0.08 or 8% during the period of observation. In the group without a family history, the absolute risk is 0.04 or 4% during the same period of observation. The relative risk for breast cancer in a woman with a family history of the disease is 2.0. This could be reported as double the risk, twice the risk, or a 100% increase in risk. All expressions mean the same thing and refer to the proportionate increase in risk in the group of women with a family history compared to the group without a family history over the time period investigated in this study.

**Source:** Osuch JR, Bonham VL, Morris LL. *Primary Care Guide to Managing A Breast Mass: Step-by-Step Work Up.* Medscape Women's Health, 1998; Vol 3. No. 5. http://www.medscape.com (See instructions in Appendix 10.)

# Cautions Regarding *Risk Interpretation:*

- **Know the difference between absolute and relative risk**
- **Do not multiply lifetime absolute risk by relative risk**
- **Do not add relative risk values**
- **Remember that both relative and absolute risk can change with time**

SLIDE 25

Several points should be emphasized regarding risk interpretation. Remember that absolute risk is a probability, usually expressed in percentage. Relative risk is a number which represents a comparison, or ratio, between one group and another.

The lifetime absolute risk of the general population cannot be multiplied by the relative risk of an individual woman. As an example, a woman who had a relative risk of 5.0 due to a history of atypical hyperplasia was told that her risk for developing breast cancer was five times the commonly used lifetime risk of 10%, making her risk 50%. She was advised to consider bilateral prophylactic mastectomies based on this information, which she elected to have performed. She successfully sued the physician for unnecessary surgery based on inaccurate informed consent.

It is also not valid to add relative risks. For example, this same woman with a relative risk of 5.0 based on a history of atypical hyperplasia who also had a relative risk of 2.5 due to family history of breast cancer, could have a higher or lower overall relative risk than 7.5.

Whenever interpreting absolute and relative risks, remember that time is an important factor. A 40 year old woman with the same risk profile as a 70 year old will have a higher lifetime risk of breast cancer simply because she will have a greater number of years to live.

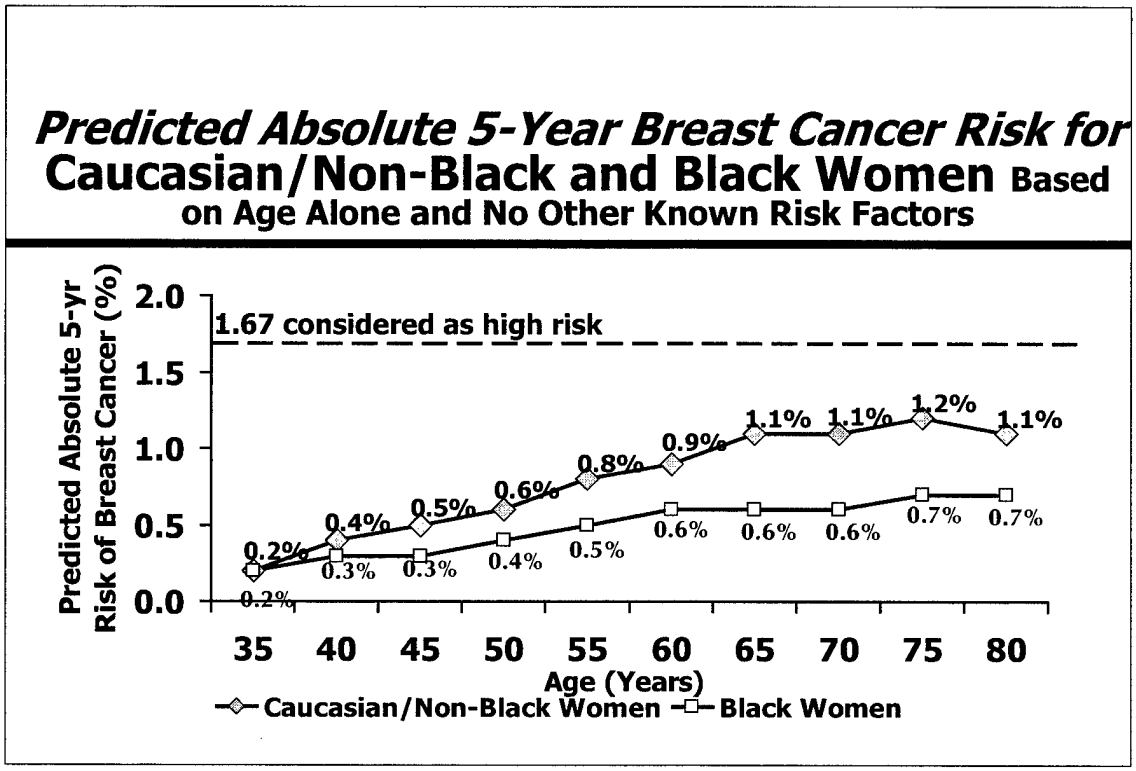
**Source:** Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.

# Practical Breast Cancer Risk Counseling in the Individual Patient

SLIDE 26

A useful device in the interpretation of risk factors for the individual patient is the Gail Model Risk Assessment Tool, developed and validated by the National Cancer Institute and used to assess risk in the most recent breast cancer prevention trial. The data used in predicting individual risk were based on results derived from follow-up of over 280,000 women who participated in the Breast Cancer Detection Demonstration Project (BCDDP). Estimates of relative risks were based on analysis of approximately 3,000 observed cases and an equal number of controls from this study. The calculated risk projections using this model are most reliable for counseling women who have annual examinations.

**Source:** Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.




SLIDE 27

This slide demonstrates the predicted absolute 5-year risk of breast cancer for Caucasian/Non-Black and Black women with menarche at age greater than or equal to 14 years, age at first full-term pregnancy less than 18 years, and no additional risk factors for breast cancer. These women are considered to be at the lowest risk. For women 40 years and older, the risk ranges between 0.3% and 1.2% for the subsequent 5-year period. The risk tends to be lower in Black women, between 0.3% and 0.7%.

**Source:** Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

**Practical Risk Counseling for Breast Cancer**

# The single most important risk factor for breast cancer is the *FEMALE GENDER*

SLIDE 28

Many women believe that because they do not have certain risk factors for breast cancer, that they are not at risk. It is important to educate women so that they know that all women are at risk and that the most important risk is their gender.

**Source:** Osuch JR, Dell D, and Sightler S. *Breast and Cervical Cancer Education for Primary Care Providers.* Alexandra, VA: American Medical Women's Association, 1994.

SLIDE 29

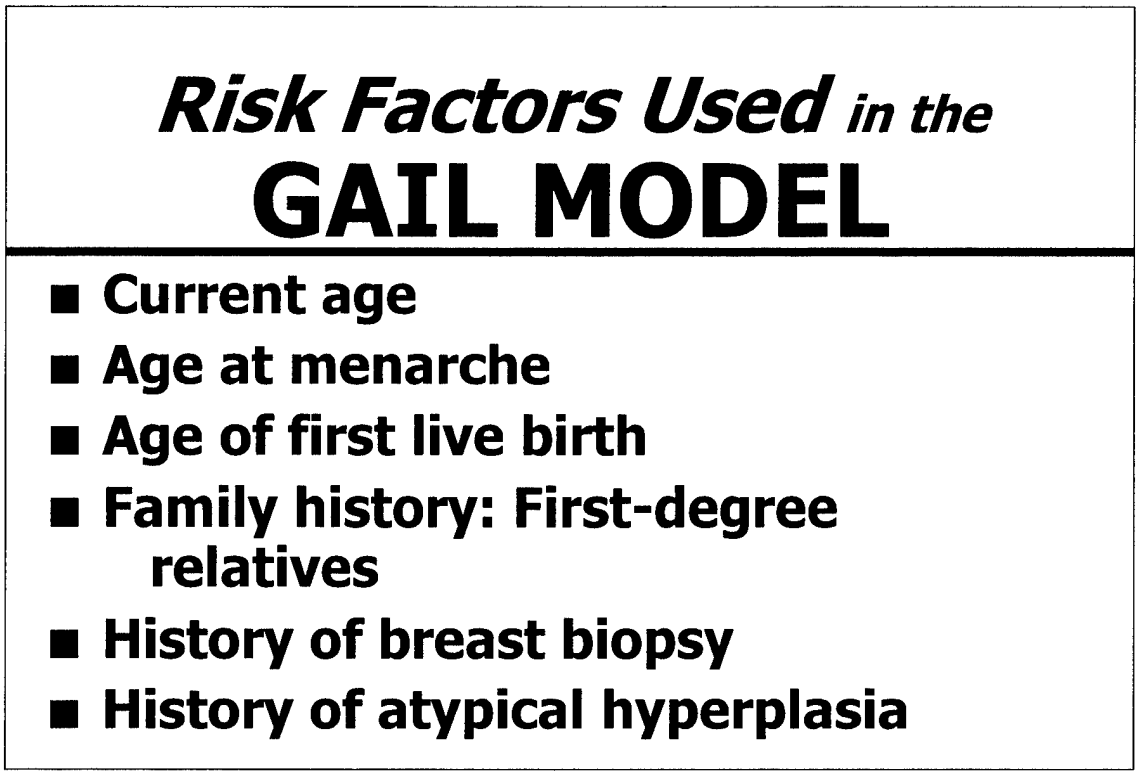
In fact, 75% of women diagnosed with breast cancer have no known risk factors other than gender and age, and 85% have no family history of the disease. The woman at greatest risk for developing breast cancer is elderly, in her seventies and eighties. Unfortunately, this population of women is the least likely to be screened for breast cancer.

**Sources:**

Seidman H, Stellman SD, Mushinski MH. A different perspective on breast cancer risk factors: Some implications of the nonattributable risk. *CA Cancer J Clin* 1982;32(5):301-313.

Thompson WD. Genetic epidemiology of breast cancer. *Cancer* 1994;74:279-287.

Blustein J. Medicare coverage, supplemental insurance, and the use of mammography by older women. *NEJM* 1995;332:1138-1143.




SLIDE 30

Because of the high prevalence of breast cancer, a great deal of research has been performed to understand its etiology. The research generates an abundance of risk factor information which can be misinterpreted. The most practical application to analyze individual risk is the Gail Model, which includes the risk factors of current age, age at menache, age at first live birth, family history in first-degree relatives (mother, sister, daughter), and history of breast biopsies, especially if showing atypical hyperplasia.

**Source:** Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

**Practical Risk Counseling for Breast Cancer**

# *"High Risk"* Definition

# 5-year absolute risk of breast cancer of 1.67% or above based on the Gail Model.

SLIDE 31

The definition of "high risk" is relative. Using the Gail model a 5-year absolute risk of 1.67% or higher is considered high risk. We will now consider each risk factor individually.

**Sources:**

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *J Natl Cancer Inst* 1998;90:1371-1388.

Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, 1999, Wilmington, DE.

# Reproductive Risk Factors Assessed by Gail Model:

| Age at Menarche | RR |
|---|---|
| Age 11 or less | 1.2 |
| Age 12 - 13 | 1.1 |
| Age 14 or more | 1.0 |

SLIDE 32

There is correlation between the length of exposure to endogenous ovarian hormones and the risk of breast cancer. Compared with girls whose onset of menarche is 14 or more, the relative risk of those whose menarche began at age 12-13 is 1.1, and age 11 or less 1.2. These are the age ranges used for onset of menarche in the Gail model calculations.

**Sources:**

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

# Reproductive Risk Factors Assessed by Gail Model:

## AGE AT FIRST BIRTH

| Age | RR MacMahon | RR Gail |
|---|---|---|
| <20 | 1.0 | 1.0 |
| 20 - 24 | 1.2 | 1.2 |
| 25 - 29 | 1.6 | 1.6 |
| 30 - 35 | 1.9 | 1.9 |
| 35+ | 2.4 | 1.9 |
| Nullip | 2.0 | 1.6 |

SLIDE 33

Risk is also influenced by the age at which a woman delivers her first child. Shown here are data from the classic international collaborative case-controlled study by MacMahan, et al., and that from the BCDDP. Using women who deliver their first baby at age 20 years or younger as the reference, or comparison group, nulliparous women have a relative risk of between 1.6 and 2.0, depending on the study. Women who deliver their first full-term baby after age 35 had a relative risk of 2.4 in the MacMahon study, but are assessed to be at the same risk as 30-35 year olds in the Gail model. Patients may inquire about the effect of miscarriages, abortions, and multiple births on risk. Miscarried or aborted pregnancies are not protective. Multiparity may be protective; however, this has not been consistently observed.

**Sources:**

MacMahan B, Cole P, Lin TM, et al. Age at first birth and breast cancer risk. *Bulletin of the World Health Organization*. 1970;43:209-212.

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

# Risk Factors Assessed by Gail Model: *Family History*

| Family Member Affected | Pooled RR | Range |
|---|---|---|
| NONE | 1.0 | |
| One First-Degree Relative (Mother, Sister, Daughter) | 2.1 | (1.2 - 8.8) |
| Two First-Degree Relatives | 3.6 | (2.5 - 13.6) |
| Second-Degree Relative (Grandmother, Aunt, Niece) | 1.5 | (1.2 - 1.9) |

SLIDE 34

A recent meta-analysis of 74 published studies provided pooled estimates of relative risks and the range of the reported risks associated with various family histories. The Gail Model assesses risk only due to family history in first-degree relatives, and includes the number of first-degree relatives affected. First-degree relatives refer to mothers, sisters, or daughters. One affected first-degree relative more than doubles the overall risk, whereas a history in two first-degree relatives could raise the risk to as high as 13.6, which approaches 50% in terms of absolute lifetime risk. Although other family history confers some increased risk, this is not considered in the Gail Model.

**Sources:**

Pahroah PDP, Day NE, Duffy S, et al. Family history and the risk of breast cancer: A systematic review and meta-analysis. *Int J Cancer* 1997;71:800-809.

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

# Family History
## & Breast Cancer Risk

| FIRST DEGREE RELATIVE | RR |
|---|---|
| NO HISTORY | 1.0 |
| Unilateral/Postmenopausal | 1.2 |
| Unilateral/Premenopausal | 1.8 |
| Bilateral/Postmenopausal | 4.0 |
| Bilateral/Premenopausal | 8.8 |

SLIDE 35

The increased risk produced from an affected first-degree relative is influenced by the relative's menstrual status and whether both breasts are involved at the time of diagnosis. The effect of these two factors is not included in the Gail Model, but can signal a genetic predisposition to breast cancer. You will often see patients who report that their mothers had breast cancer. If only one breast was involved, and the mother was postmenopausal at the time of diagnosis, her daughter's relative risk is very close to that of the woman with no such family history--1.2 compared to 1.0. This is reassuring information for your patient.

On the other hand, if the first-degree relative was premenopausal at the time of diagnosis and the disease was bilateral, the woman is at significantly higher risk, with a relative risk of 8.8.

**Sources:**

Anderson DE, Badzioch MD. Risk of familial breast cancer. *Cancer* 1985;56:383-387.

Lynch HT, Albano WA, Danes BS et al. Genetic predisposition to breast cancer. *Cancer* 1984; 53:612-622.

## Risk Factors Assessed by Gail Model:
# *Breast Biopsies*

| Pathologic Result | Frequency | RR |
|---|---|---|
| Atypical hyperplasia | 4% | 5.0 |
| Hyperplasia, no atypia | 15% | 2.0 |
| Non-proliferative breast changes | 80% | 1.0 |

**Dupont WD, et al. *NEJM,* 1985**

SLIDE 36

The Gail Model assesses an increased risk associated with the number of benign breast biopsies performed. The more times a woman needs a biopsy of the breast, the higher the risk, and the more likely proliferative breast changes will be diagnosed. Proliferative changes also predict for increased risk, especially if atypical hyperplasia is diagnosed.

**Source:** Dupont WD, Page DL. Risk factors for breast cancer in women with proliferative breast disease. *N Engl J Med* 1985, 146-151.

Gail MH, Brinton LA, Byar DP, et al. Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989;81:1879-1886.

# Not Assessed by Gail Model:

# Personal History of In-Situ or Invasive Breast Cancer

SLIDE 37

Patients with breast cancer in their medical history are at a increased risk of developing contralateral breast cancer. The 5-year absolute risk is between 2% and 5% for patients with this history and is not evaluated in the Gail Model.

This statistic actually can be reassuring to most patients with breast cancer, because they generally believe that their risk for developing cancer in the other breast is much higher.

**Source:** Hislop TG, Elwood JM, Coldman AJ, et al. Second primary cancers of the breast: Incidence and risk factors. *Br J Cancer* 1985;49:79-85.

SLIDE 38

There are multiple other associations between exposures and breast cancer risk. None of these are considered in the Gail Model. However, listed here are the ones that prompt the most common questions from our patients. Let's look at these individually.

# *Lactation*
# & Breast Cancer Risk

- **May have a small protective effect for premenopausal breast cancer**
- **Study results vary**
- **Largest studies**
  **WHO Multicenter Study - no effect**
  **Nurses Health Study - no effect**

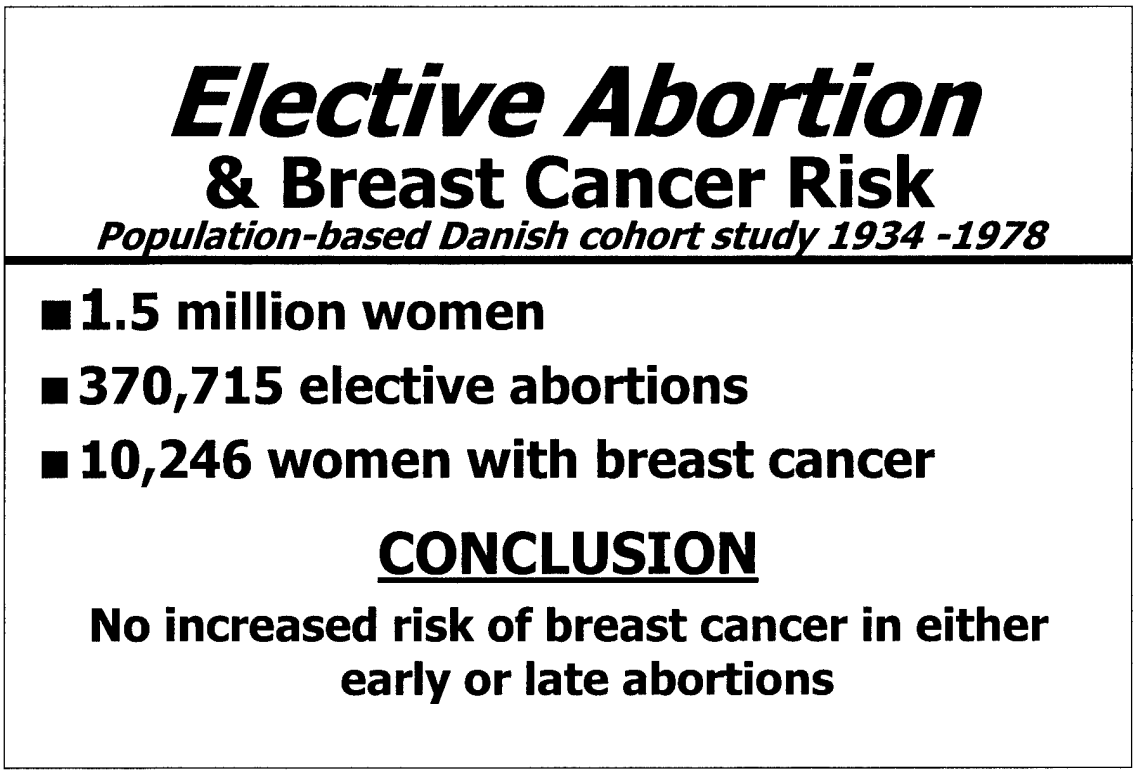
SLIDE 39

A history of lactation has been suggested to be a protective factor for a mother's risk of premenopausal breast cancer in some studies, but the largest studies investigating this association found no effect. Women should be advised to breastfeed because of the nutritional benefits to the infant rather than to impact breast cancer risk.

**Sources:**

Thomas DB, Noonan EA. Breast cancer and prolonged lactation. The WHO Collaborative Study of Neoplasa and Steroid Contraceptives. *Int J Epidemiol* 1993; 22:619-626.

Michels KB, Willett WC, Rosner BA, et al. Prospective assessment of breast feeding and breast cancer incidence among 89,887 women. *Lancet* 1996; 347:431-437.




SLIDE 40

The possible connection between induced abortions and an increased risk of breast cancer has received a great deal of media attention. Some patients may wonder if abortion and breast cancer are linked. The confusion arises from earlier conflicting studies that examined this issue. The largest scientific study analyzed a cohort of 1.5 million women, over 370,000 who had a history of induced abortions and 10,000 who subsequently developed a history of breast cancer. No association between elective abortion and breast cancer risk was found.

**Source:** Melbye M, Wohlfahrt J, Olsen JH, et al. Induced abortion and risk of breast cancer. *JAMA* 1997;336:81-85.

# *Oral Contraceptives(OCP)* & Breast Cancer Risk

## Meta-Analysis 1996

- 54 studies
- 53,297 women with breast cancer
- 100,239 women without breast cancer

## Conclusions:

1. Increased risk in current users - RR 1.24
2. Increased risk returns to baseline after 5 years have elapsed from last use

SLIDE 41

A recent meta-analysis of OCP use and breast cancer risk pooled the data from over 150,000 women in over 50 studies. A 24% increased risk was observed in current users of OCPs, which returned to baseline 5 years after discontinuing use. Women concerned about breast cancer risk and contraceptive choice should be made aware of the slightly increased risk of breast cancer among current and past users within 5 years. Those most concerned are likely to have a family history; this study found no additive effect when women were stratified by family history.

**Source:** Breast cancer and hormonal contraceptives: Collaborative reanalysis of individual data on 53,297 women with breast cancer and 100,239 women without breast cancer from 54 epidemiological studies. Collaborative Group on Hormonal Factors in Breast Cancer. *Lancet* 1996; 347:1713-1727.

## *Hormone Replacement Therapy(HRT)* & Breast Cancer Risk

### Meta-Analysis 1997

- **51 studies**
- **52,705 women with breast cancer**
- **108,411 women without breast cancer**

### Conclusions:

1. **Increased risk in current users for ≥ 5 years - RR 1.35**
2. **Increased risk returns to baseline after 5 years have elapsed from last use**

SLIDE 42

A recent meta-analysis of HRT use and breast cancer risk examined over 50 studies in over 160,000 women. A 35% increased risk was observed in current users of HRT, which returns to baseline 5 years after discontinuing use. Most of the studies examined use of estrogen alone rather than combined therapy with progestins, but early evidence does not suggest a similar effect of progestins on the breast as the uterus; that is, progestins do not counteract the proliferative effects of estrogen on breast tissue.

**Source:** Breast cancer and hormonal replacement therapy. Combined reanalysis of data from 51 epidemiologic studies involving 52,705 women with breast cancer and 108,411 women without breast cancer. Collaborative Group on Hormonal Factors in Breast Cancer. *Lancet* 1997; 350:1047-1059.

# Counseling Women on HRT

| | | No HRT | HRT | |
|---|---|---|---|---|
| | Annual Mortality | | Disease RR | Mortality RR |
| Breast Cancer | 43,000 | Ref* | ↑ | ↓ |
| Heart Disease | 233,000 | Ref* | ↓ | ↓ |
| Osteoporotic hip fracture | 65,000 | Ref* | ↓ | ↓ |

*Reference Group

SLIDE 43

When counseling women about HRT use, one should discuss the disease occurrence and mortality risk data for breast cancer, heart disease and osteoporosis. While the risk of developing breast cancer in women using HRT is increased (RR 1.35), the mortality risk from all three diseases is decreased. Cardiovascular disease is much more prevalent than breast cancer and reducing the incidence and mortality for a more prevalent disease provides greater population benefit than influencing a less common condition, and is therefore viewed as beneficial from a public health perspective. The range for the reduction in overall mortality has been reported to be between 21% and 37%. However, the greatest gain in life expectancy (of up to 41 months) is for women with greatest risk for cardiovascular disease and lowest risk for breast cancer. The only women not expected to live longer following the administration of HRT are those at low risk for cardiovascular disease and high risk for breast cancer.

**Sources:**

Col NF, Eckman MH, Karas RH, et al. Patient-specific decisions about hormone replacement therapy in postmenopausal women. *JAMA* 1997;277:1140-1147.

Grodstein F, Stampfer MJ, Colditz JA, et al. Post-menopausal hormone therapy and mortality. *N Engl J Med* 1997;336:1769-1775.

Cauley JA, Seeley DG, Browner WS et al. Estrogen replacement therapy and mortality among older women. A study of osteoporotic fractures. *Arch Intern Med* 1997;157:2181-2187

Chlebowski RT, Hendrix SL, Langer RD, et al. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: the Women's Health Initiative Randomized Trial. *JAMA* 2003;289:3243-3253.

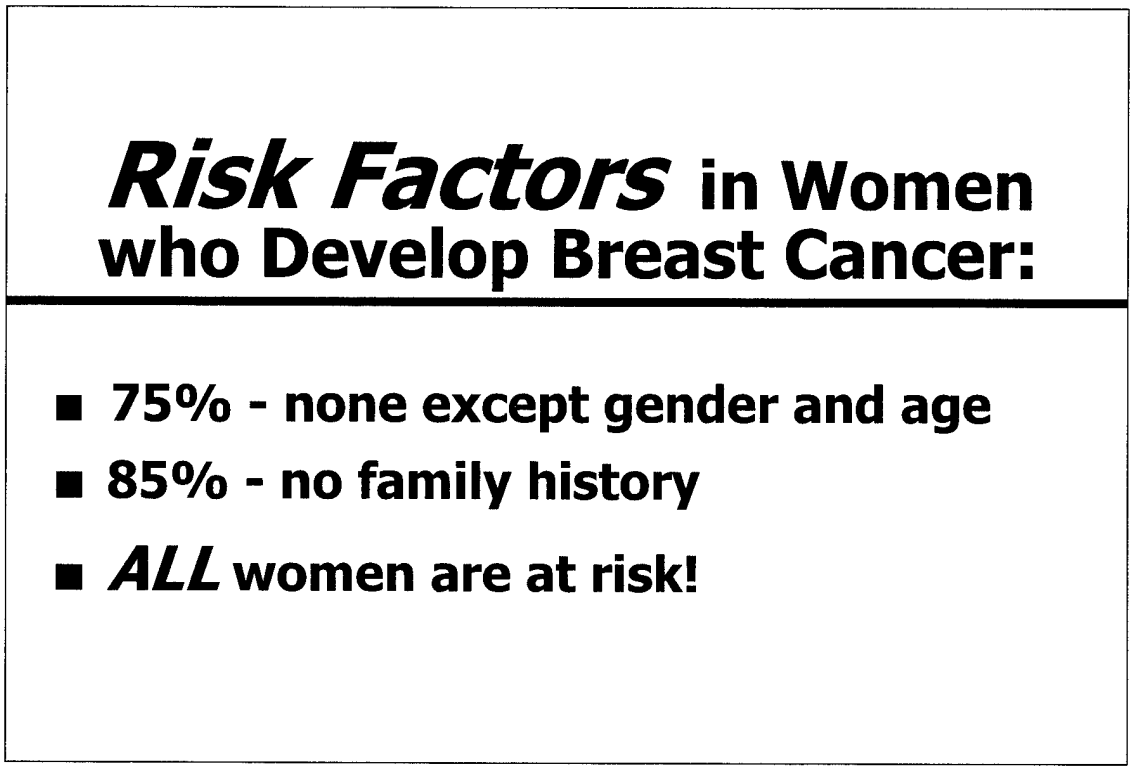
# *Alcohol Intake*
## & Breast Cancer Risk

- **Over 50 studies**
- **Most show an increased risk of 30-40% for ETOH consumption of 1-2 drinks/day**
- **Alcohol may increase the level of circulating estrogen in the bloodstream**
- **Benefit of alcohol on mortality from cardiovascular disease must be considered**

SLIDE 44

Over 50 studies examining the relationship between breast cancer risk and alcohol intake have been done. Most have shown a 30-40% increase in risk when women ingest 1-2 drinks per day. Alcohol has been reported to alter metabolism and increase the level of circulating estrogen. When counseling women about alcohol intake and breast cancer risk, the beneficial effect of alcohol on cardiovascular risks must be weighed.

**Source:** Smith-Warner SA, Spiegelman D, Yaun S-S, et al. Alcohol and breast cancer in women: A pooled analysis of cohort studies. *JAMA* 1998;279:535-540.




SLIDE 45

It should be re-emphasized that 75% of women diagnosed with breast cancer have no risk factors other than age and gender, and that 85% of women diagnosed have no family history of the disease. In summary, then, all women are at risk for breast cancer, all women should be screened, and all primary care physicians should be confident of their ability to conduct in-office risk counseling. Next we will practice risk counseling using the Gail Model Risk Assessment Tool.

**Sources:** Seidman H, Stellman SD, Mushinski MH. A different perspective on breast cancer risk factors: Some implications of the nonattributable risk. *CA Cancer J Clin* 1982;32(5):301-313. Thompson WD. Genetic epidemiology of breast cancer. *Cancer* 1994;74:279-287.

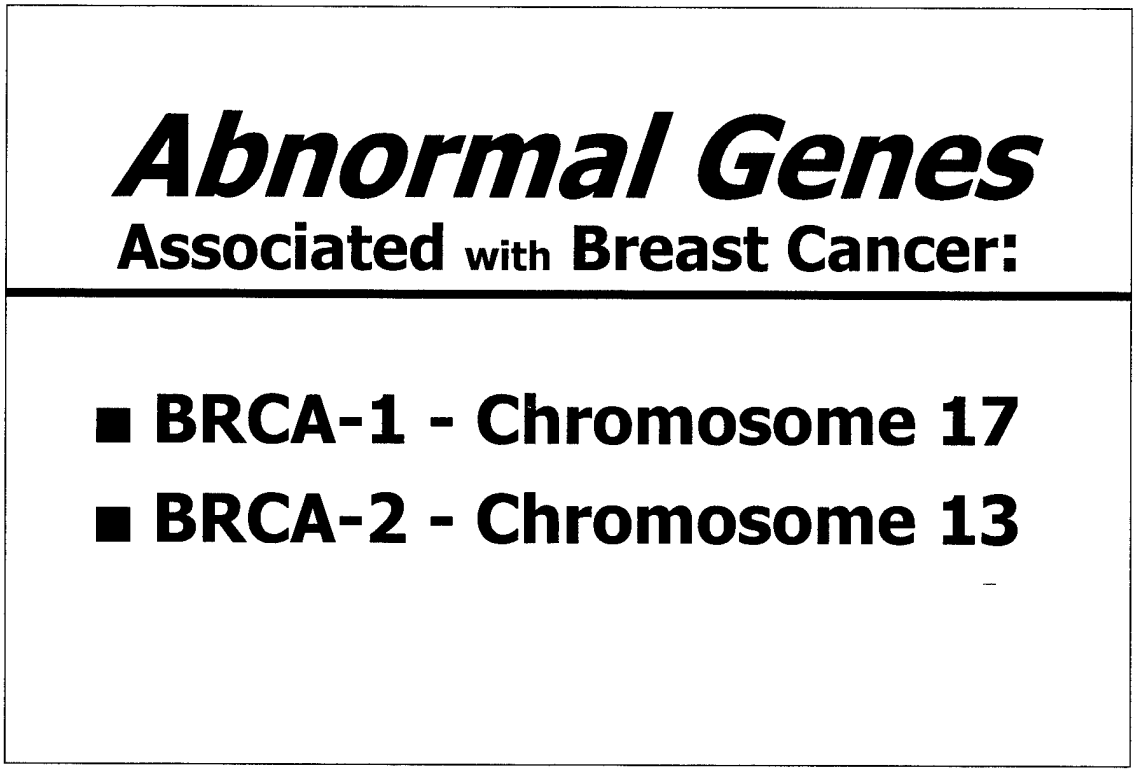
## Family History & Genetic Predisposition to Breast Cancer

| Family History | Distribution of Breast Cancer | Absolute Lifetime Risk |
|---|---|---|
| None | 80%-85% | 11%-12% |
| One-two postmenopausal relatives | 10% | 15%-20% |
| Known genetic mutation | 5%-10% | 60%-90% |

SLIDE 46

The Gail Model Risk Assessment Tool does not consider those women who may have inherited a genetic mutation predisposing them to breast cancer. Inherited mutations account for only about 5% to 10% of total breast cancer cases, but it is important to understand the issues pertinent to this topic. If a woman has inherited a genetic mutation predisposing her to breast cancer, her estimated lifetime risk is between 60% and 90%. Compare this with a woman with one or two postmenopausal relatives affected with breast cancer, whose lifetime risk is 15% to 20%. Patients who may have inherited a mutation that might predispose them to breast cancer should receive appropriate education, risk assessment, and counseling.

**Source:** Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M, and Hellman S (eds). *Diseases of the Breast.* New York, NY: Lippincott - Raven, 1996, pp. 335-341.

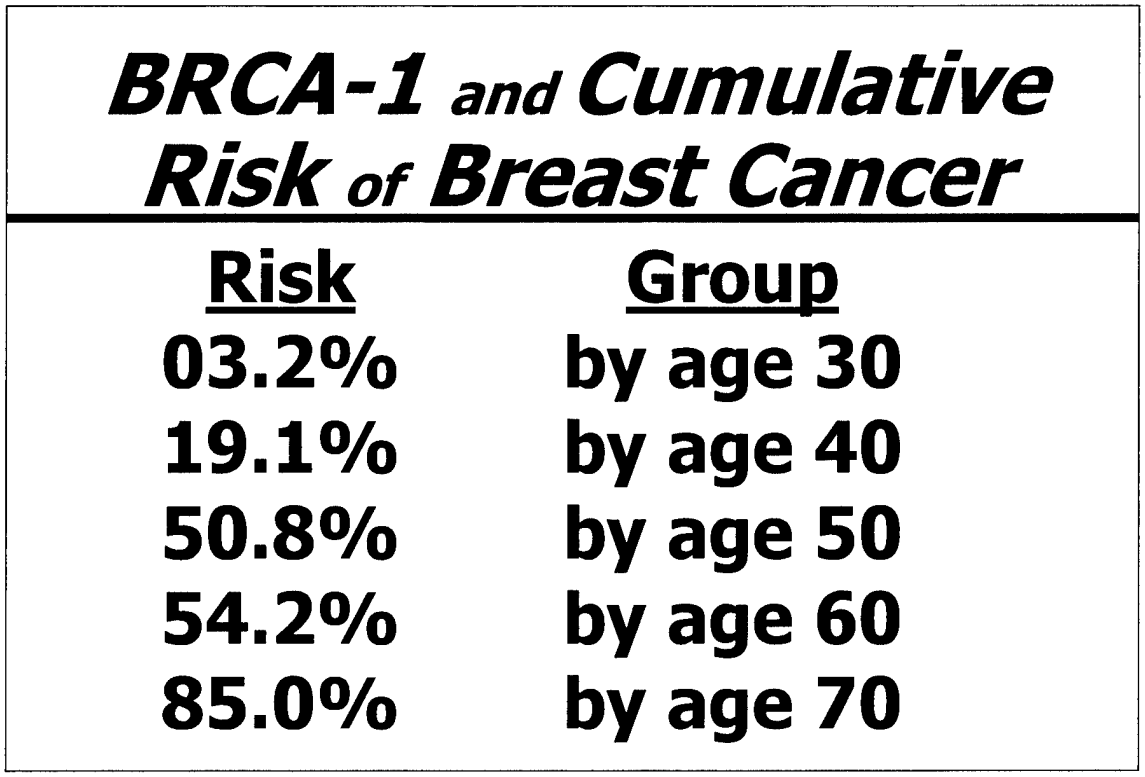



SLIDE 47

All women and men have BRCA-1 and BRCA-2 genes. A mutation of one of these genes is associated with an increased risk of breast cancer. These mutations are inherited in an autosomal dominant pattern and therefore can be passed through the maternal or paternal lineage.

If a parent is affected, there is a 50% probability that the mutation will be passed to the offspring. Men who inherit the mutation may be at a higher risk for cancer, but not breast cancer. However, if a man passes the mutation to a daughter, she will have a lifetime risk for breast cancer of between 60% and 90%, just as if she had inherited the mutation from her mother. In addition, both BRCA1 and BRCA2 mutations are associated with an absolute lifetime risk for ovarian cancer of between 15% and 60% and an increased risk of colon cancer to a level of about 6%.

**Source:** Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M, and Hellman S (eds). *Diseases of the Breast.* New York, NY: Lippincott - Raven, 1996, pp. 335-341.

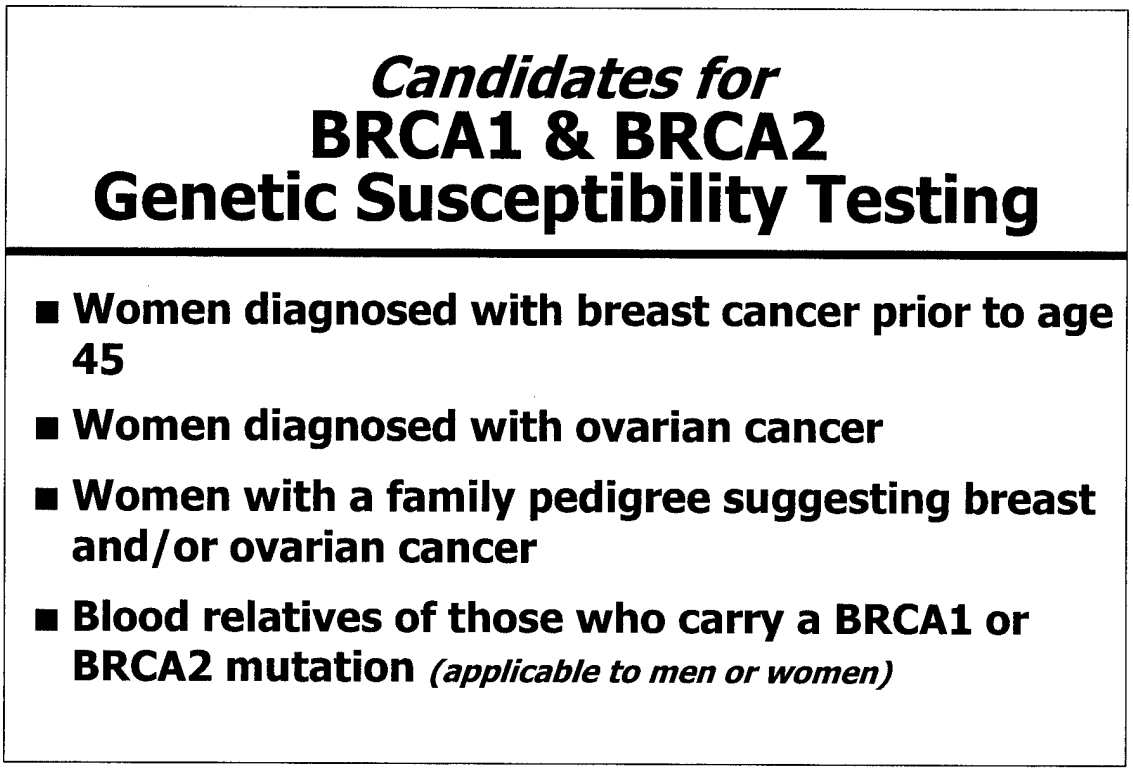



SLIDE 48

Similar to the increase in breast cancer risk with age in women without genetic mutations, we see among women with the BRCA-1 mutation an increased risk with age, but it is exaggerated. This slide demonstrates the risk of breast cancer in women with the BRCA-1 mutation by a given age.

Women with breast cancer and no mutation have a 1% per year risk of developing breast cancer in the contralateral breast. Compare this to the woman with the mutation, who has a 64% risk of developing contralateral breast cancer by age 70.

**Source:** Burke W, Daly M, Garber J, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II BRCA1 and BRCA2. Cancer Genetics Consortium. *JAMA* 1997;277;997-1003.



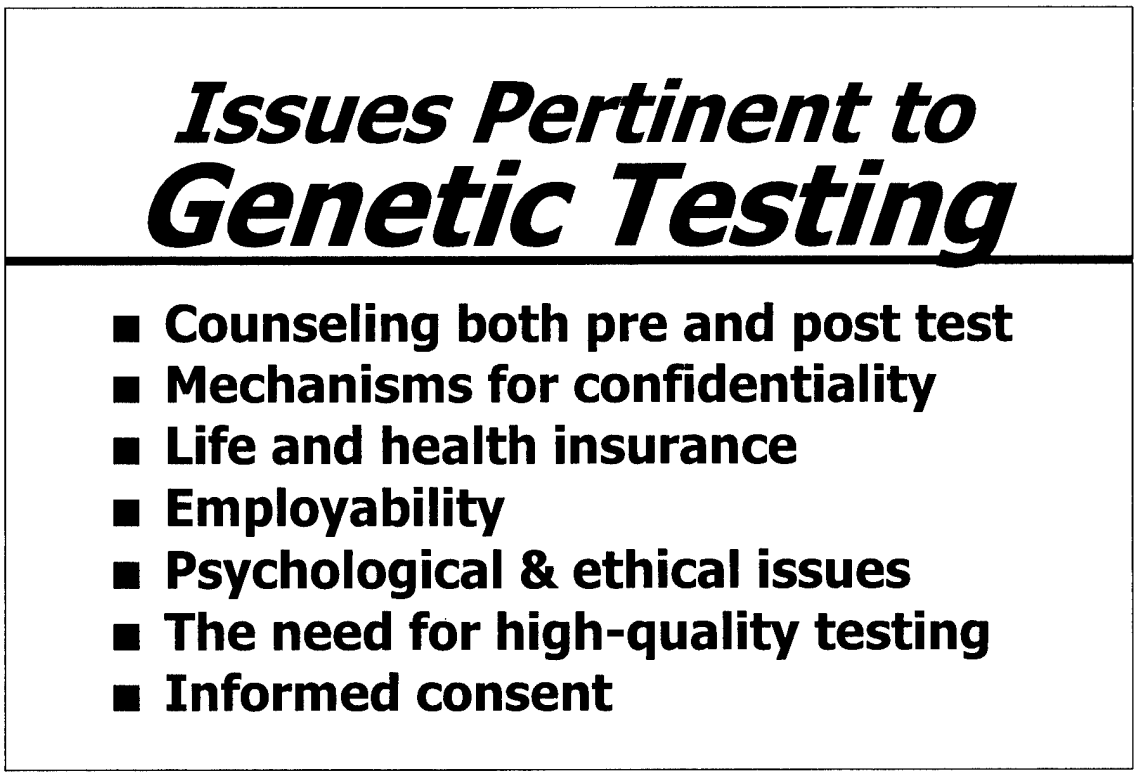

SLIDE 49

Blood tests are available that can identify genetic mutations in BRCA 1 or 2. Many women request these tests without full knowledge of their implications. Potential candidates for genetic susceptibility testing include:

- Women diagnosed with breast cancer prior to age 45
- Women diagnosed with ovarian cancer
- Women with a family pedigree suggesting familial breast or ovarian cancer
- Blood relatives of those who carry a BRCA1 or BRCA2 mutation

  (applicable to men or women).

**Source:** Biesecker B, Boehnke M, Calzone K, et al. Genetic counseling for families with inherited susceptibility to breast and ovarian cancer *JAMA* 1993:269:1970-1974. (Published erratum appears in *JAMA* 1993;270;839.)



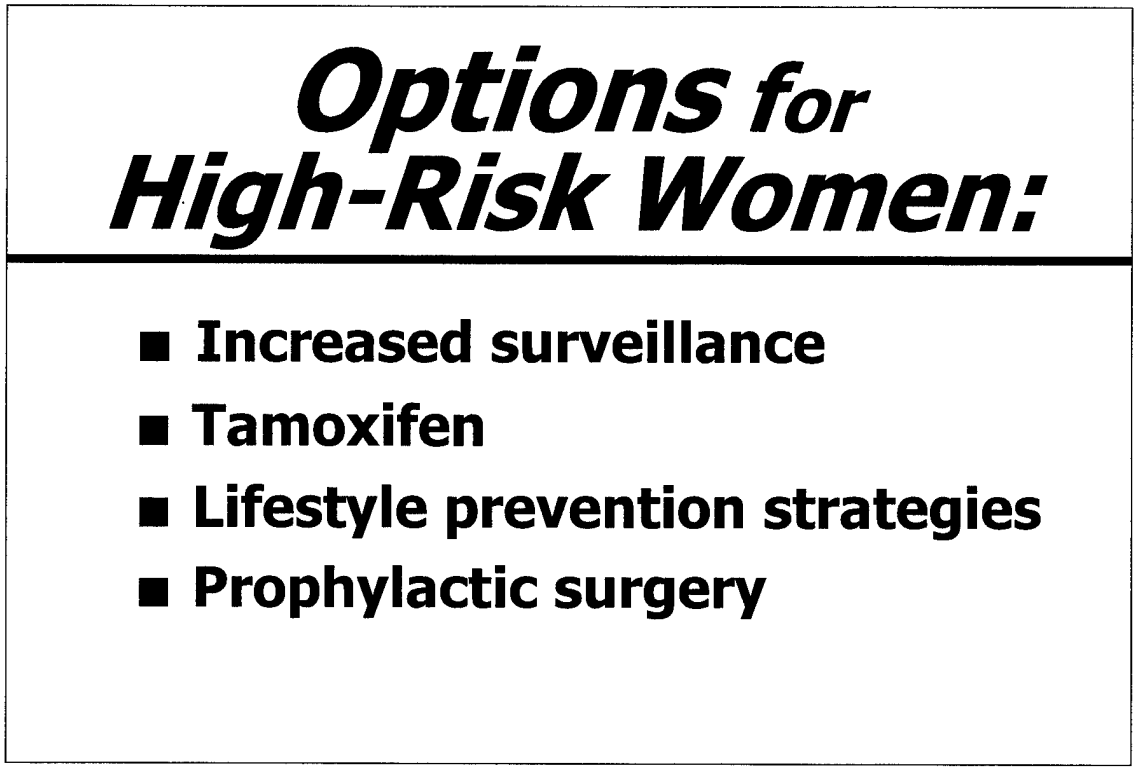

SLIDE 50

Factors that need to be considered before advising a woman to undergo genetic testing include the following:

- The woman will need pre and post test counseling
- Confidentiality must be maintained
- Potential exists for discrimination with life insurance, health insurance, and employability
- Potential exits for the development of profound psychological, emotional, and ethical issues for the patient and her family.
- High-quality testing is necessary
- Informed consent is mandatory and those unable to give consent are ineligible for testing.

Genetic testing is an extremely personal issue and testing should never be recommended, but instead the issue presented as one of informed choice.

**Source:** Ostrer H, Allen W, Crandall LA, et al. Insurance and genetic testing: Where are we now? *Am J Hum Genetics* 1993;52:565-577.



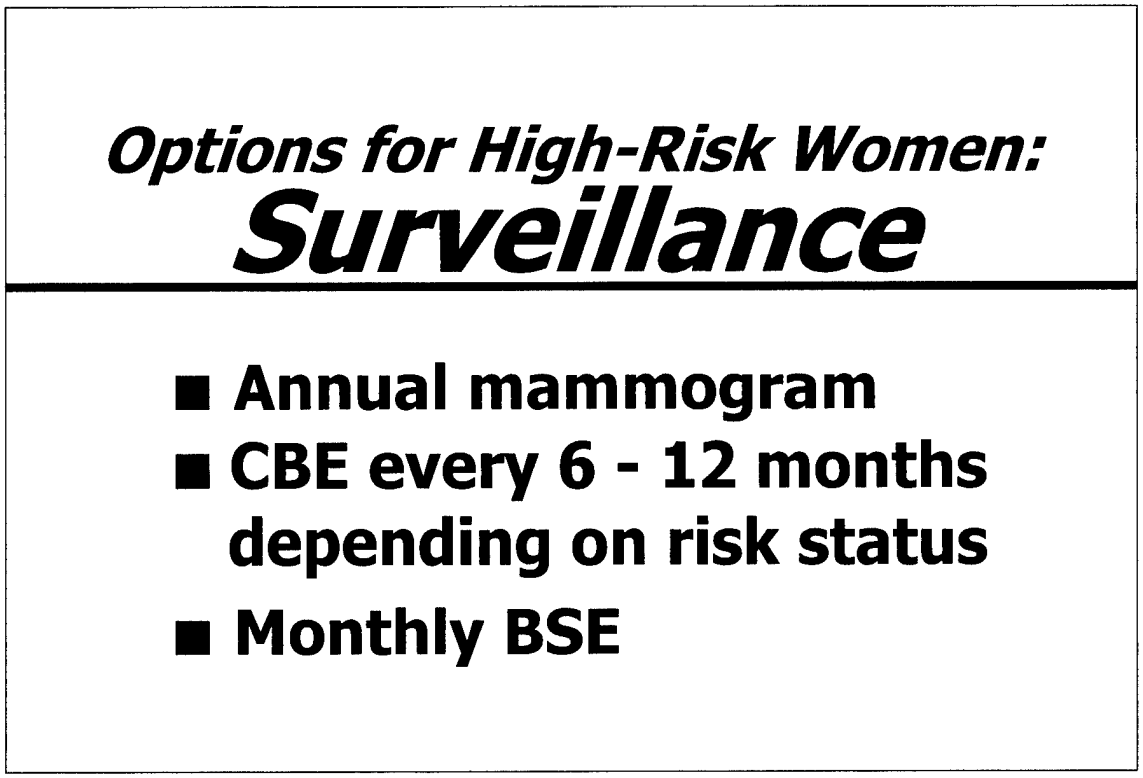

SLIDE 51

Whether she chooses to be tested, and whether she tests positively or not, there are several possible options for a woman at high risk for breast cancer. These include increased surveillance, the use of tamoxifen, preventive lifestyle strategies, and prophylactic surgery.

**Sources:**

Burke W, Daly M, Garber J, et al. Recommendations for follow-up care of individuals with an inherited predisposition to cancer. II BRCA1 and BRCA2. Cancer Genetics Consortium. *JAMA* 1997;277;997-1003.

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.



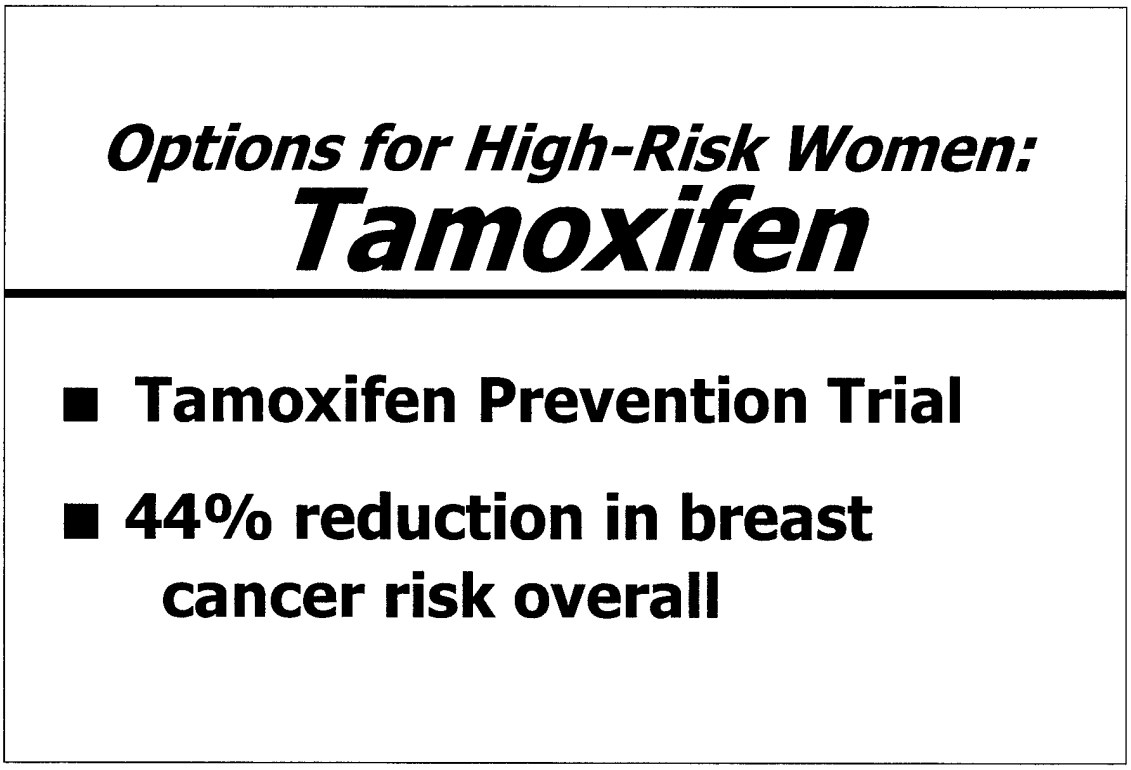

SLIDE 52

For patients at high risk, recommendations for surveillance include:

- Annual mammography starting at the age at which high risk is identified, but not before age 25
- Clinical breast examination every 6 - 12 months, depending on risk status
- Breast self examination monthly.

We will discuss these recommendations in more detail later.

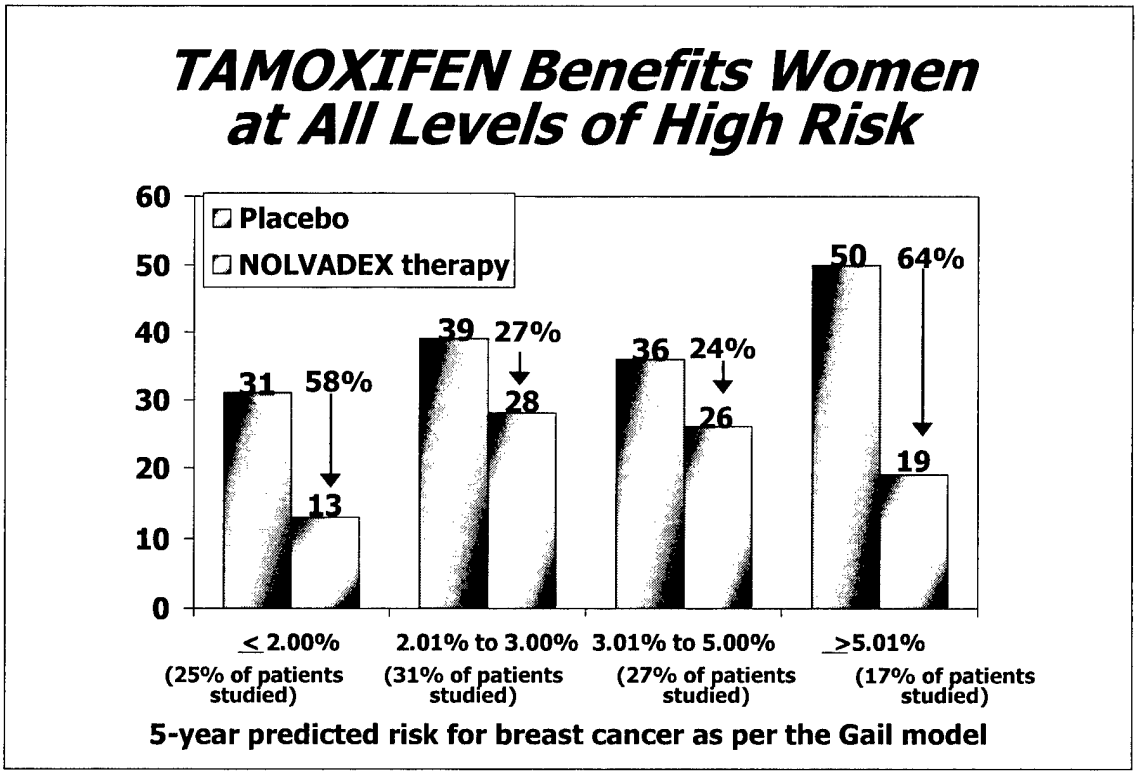
**Source:** Garber JE, Smith BL. Management of the high risk and the concerned patient. In: Harris JR, Lippman ME, Morrow M (Eds). Lippincott - Raven, 1996, pp 335-341.




SLIDE 53

Another option that should be considered for high-risk women is Tamoxifen use. The P-1 trial of the National Surgical Adjuvant Breast Project (NSABP), published in 1998, demonstrated a statistically significant 44% overall reduction in breast cancer risk in women who used 20 mg per day of Tamoxifen for 5 years. Zeneca pharmaceuticals, the manufactures of Tamoxifen (Nolvadex) has spent a large amount of time and money to promote public education regarding this issue, and the messages always end with advice to "ask your doctor" . Patients will expect you to know the benefits, risks, side effects, and contraindications to the prophylactic use of Tamoxifen.

**Source:** Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.




SLIDE 54

Remember that to be eligible for the Tamoxifen Prevention Trial, the 5-year predicted absolute risk for breast cancer had to be at least 1.67%. The patients are being advised that a 5-year predicted absolute risk of 1.7% is the risk figure at which they should consider Tamoxifen use. The P-1 study demonstrated risk reductions for all levels of high risk, ranging from 24 to 64%. Note on the far left section of the graph that women with a 5-year absolute-risk of 2% or less had a 58% reduction in risk. These figures refer to incidence; there have been no mortality reduction benefits to date, but the time on trial has not been long enough to assess this endpoint with any degree of accuracy.

**Sources:**

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

NOLVADEX prescribing information, AstraZeneca Pharmaceuticals, Wilmington, DE.

# Health Effects in NSABP P-01 Trial

**#Cases /1000 Women Annually**

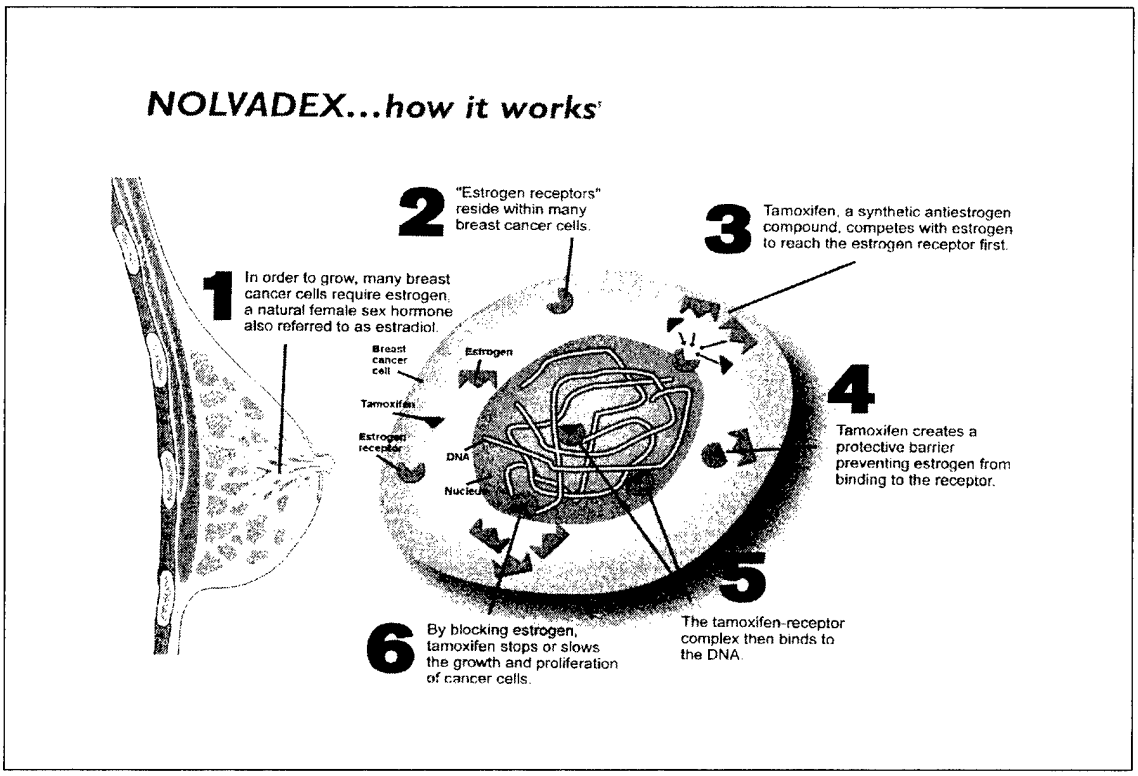
| | Tamoxifen | Placebo |
|---|---|---|
| **Breast Cancer** | **3.58** | **6.49*** |
| **Hip fractures** | **0.38** | **0.84** |
| **Wrist fractures** | **2.91** | **3.11** |
| **Ischemic Heart Disease** | **2.57** | **2.47** |

**** = Statistically significant***

SLIDE 55

In the trial, health effects of Tamoxifen were studied for diseases other then breast cancer. It was initially hoped that Tamoxifen might reduce the risk of cardiovascular disease and osteoporosis. However, there was no effect of Tamoxifen on risk of ischemic heart disease, and although the risk of fracture was lessened in the Tamoxifen group, this result was not statistically significant.

**Source:** Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.




SLIDE 56

This slide illustrates one mechanism by which Tamoxifen is thought to work. Tamoxifen, which is an anti-estrogen, competes with estrogen for binding to the estrogen receptor. When the estrogen receptor is bound by Tamoxifen instead of estrogen, this complex inhibits the proliferation of cancer cells which would otherwise occur in the presence of estrogen.

**Source:** Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

# *Tamoxifen Counseling:*

**Contraindications based on Lifestyle**

- **Pregnancy, lactation**
- **Hormonal contraception**
- **Hormone replacement therapy**

**Contraindications based on Medical History**

- **Current anticoagulant therapy**
- **History of DVT, PE, Stroke**

SLIDE 57

The recommended treatment for breast cancer prevention is 20 mg of Tamoxifen every day for 5 years. This should be an uninterrupted course. The teratogenic effects to Tamoxifen have not been studied and use during pregnancy and lactation is contraindicated. Since hormone-containing birth control methods have a mechanism of action which involves the estrogen receptor, barrier methods of contraception should be used for birth control. For similar reasons, HRT use is discouraged while a woman is taking Tamoxifen. HRT use after a 5-year course of Tamoxifen is acceptable. Contraindications to Tamoxifen therapy based on medical history include current use anticoagulant therapy or a history of deep-vein thrombosis, pulmonary embolism or stroke.

**Sources:**

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, 1999, Wilmington, DE.

# Tamoxifen Counseling: Side Effects

**#Cases / 1000 Women Annually**

| | Tamoxifen | Placebo |
|---|---|---|
| **Endometrial CA** | **2.3** | **0.9** |
| **Venous thromboembolism** | **1.3** | **0.8** |
| **Pulmonary embolism** | **0.7** | **0.2*** |
| **Stroke** | **1.5** | **0.9** |
| **Cataracts** | **24.8** | **21.7*** |

**Frequency in Participants**

| | | |
|---|---|---|
| **Hot flashes** | **80%** | **68%** |
| **Vaginal discharge** | **55%** | **35%** |

**** = Statistically significant***

SLIDE 58

The side effects of Tamoxifen are those listed. Tamoxifen has an estrogenic effect on the uterus and in the P-1 study, there was 2.5 times the incidence of endometrial carcinoma in the Tamoxifen group as compared with the placebo group overall. The increased incidence was not observed in premenopausal women and was 4.0 for the postmenopausal group. All women with endometrial carcinoma randomized to the Tamoxifen arm were diagnosed with Stage I disease. There is a significantly increased risk of pulmonary embolism and cataracts in women on Tamoxifen. Risk was increased for deep-vein thrombosis and stroke, although those were not statistically significant. Less serious but much more frequent side effects of Tamoxifen include hot flashes and vaginal dischange, both of which were elevated in the Tamoxifen group.

**Sources:**

Fisher B, Constantino JP, Wickerham DL, et al. Tamoxifen for prevention of breast cancer: Report of the National Surgical Adjuvant Breast and Bowel Project P-1 study. *J Natl Cancer Inst* 1998;90:1371-1388.

Nolvadex Patient Counseling Card. AstraZeneca Pharmaceuticals, 1999, Wilmington, DE.

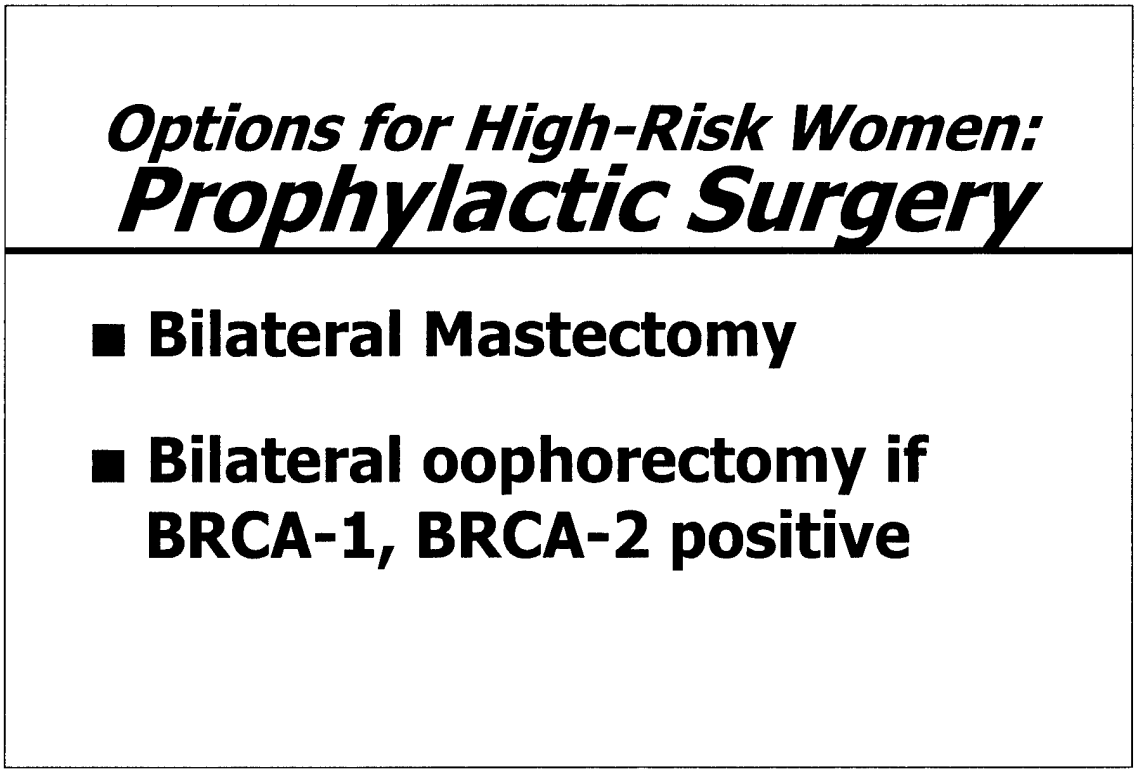
## *Options for High-Risk Women: Lifestyle Prevention Strategies/Considerations*

- **Reproductive Choice:**
  - **Use of estrogen-containing contraceptives**
  - **Age at first birth**
  - **Lactation**
- **Exercise, maintenance of ideal body weight**
- **Diet**
  - **High fiber?**
  - **Phytoestrogens?**
  - **Dietary fat - role doubtful**
  - **Alcohol**
- **Menopause:**
  - **HRT use**

SLIDE 59

Many lifestyle issues are pertinent to breast cancer risk, some of which compete with other issues in women's health and some of which do not. We have reviewed the concept of endogenous and exogenous estrogen exposure in previous slides. There is some evidence that exercise can decrease the risk of premenopausal breast cancer and that maintenance of ideal body weight can decrease the risk of post-menopausal breast cancer. Diet is currently being investigated. Low fat diet has long been studied with little evidence for benefit. High-fiber diets may be beneficial, and there is early evidence that dietary phytochemicals, present in soy products and some fruits and vegetables, may be helpful. Avoidance of alcohol is thought to decrease risk, but this needs more investigation, especially as it pertains to overall mortality.

**Source:** Brinton, LA. Ways that women may possibly reduce their risk of breast cancer. *Breast Diseases: A Year Book Quarterly* 1995;6:152-154.




SLIDE 60

The option of prophylactic surgery is complicated. If a woman tests positively for a genetic mutation, options will need to include a discussion of consideration for bilateral oophorectomy in addition to bilateral mastectomies. Women should be made aware that while prophylactic surgery markedly decreases risk, it does not eliminate it with 100% certainty. For high risk women based on family history, but who have not had genetic testing, 1 case of breast cancer is prevented for every 6 undergoing bilateral prophylactic mastectomy, and 1 death prevented for every 25 undergoing the procedure. Prophylactic surgery is a highly personal decision and should include counseling in a specialty setting. Making a recommendation for prophylactic surgery is strongly discouraged; instead, high-risk women should be encouraged to become as educated as possible about their options.

**Sources:**

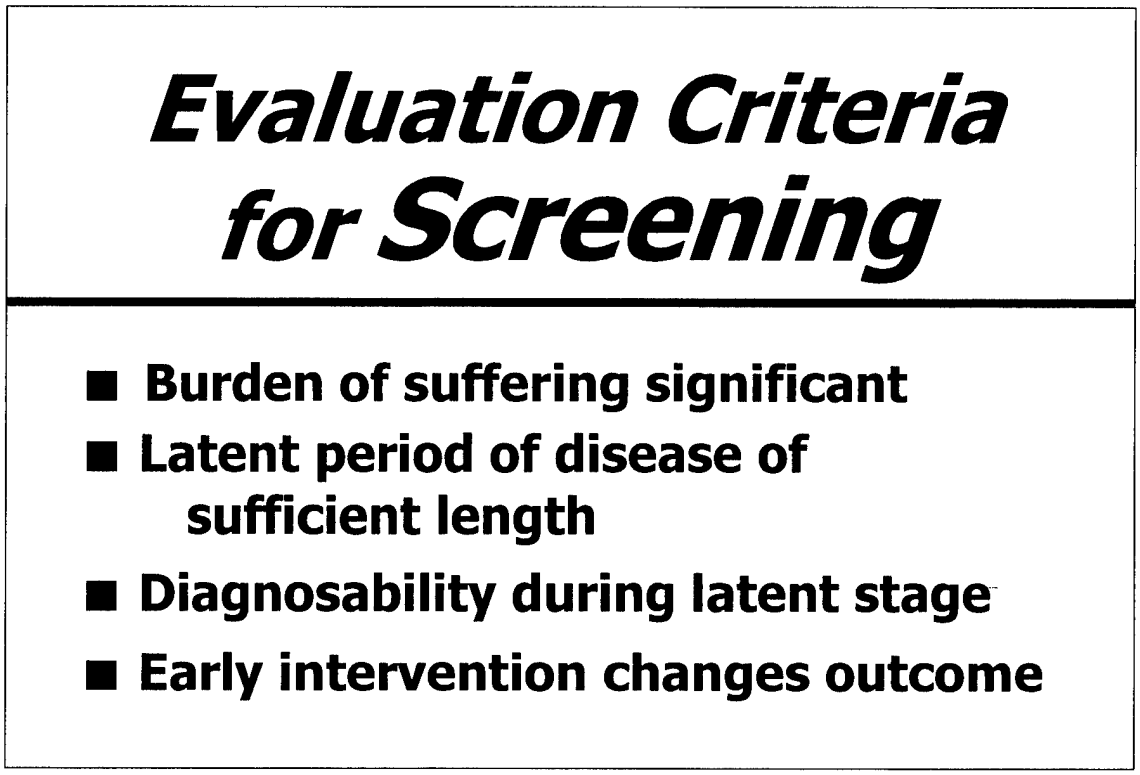
Schrag D, Kuntz KM, Garber JE et al. Decision analysis, effects of prophylactic mastectomy and oophorectomy on life expectancy among women with BRCA-1 or BRCA-2 mutations. *NEJM* 1997; 336:1465-1471.

Hartmann LC, Schaid DJ, Woods JE et al. Efficacy of bilateral prophylactic mastectomy in women with a family history of breast cancer. *NEJM* 1999;340:77-84

# Breast Cancer Screening and Evidence-Based Medicine

SLIDE 61

Because we have clues but no definitive answers to the primary prevention of breast cancer, we currently must depend on secondary prevention--that is, screening--to achieve maximum cancer control. But there are risks as well as benefits to any screening effort. Who should be screened? How often? Should screening be curtailed at some point? This section of the curriculum will address these issues.




SLIDE 62

Any screening test is subject to well-established evaluation criteria. These include:

- The disease burden is significant
- The natural history of the disease includes a latent period of sufficient length
- The disease can be diagnosed during the latent period using the screening test
- The outcome of the disease can be changed through application of the screening test

We will discuss each of these as they relate to screening with mammography.

**Source:** Cole P, Morrison AS. Basic issues in cancer screening. In: Miller AB (ed). *Screening in Cancer*. Vol 40. Geneva: UICC, 1978:7.

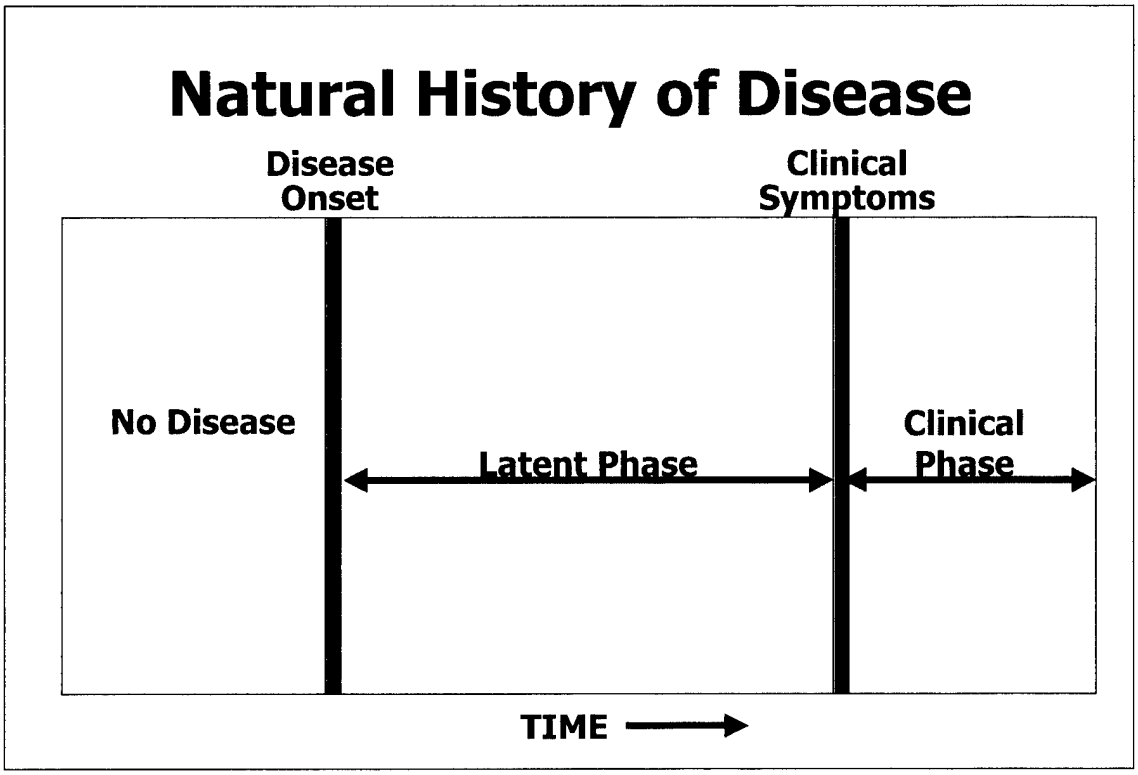
# *Breast Cancer:*
# Burden of Disease

| AGE GROUP | PERCENTAGE | # / 1000 |
|---|---|---|
| <40 | 6.5% | 0.03 |
| 40 - 49 | 16.0% | 1.60 |
| 50 - 59 | 17.0% | 2.50 |
| 60 - 69 | 24.0% | 3.80 |
| 70 - 79 | 23.0% | 4.30 |
| 80 - 89 | 13.0% | 4.10 |

SLIDE 63

There is no debate that breast cancer is a significant public health problem. This slide demonstrates the frequency in percentage of breast cancer cases diagnosed by age group. The burden of disease begins about age 25, and escalates after that. Although breast cancer incidence increases with age, the percentage of women diagnosed by age reflects the uneven distribution of age groups in the population. Breast cancer is the most common cause of mortality for any reason for the 35-54 age group.

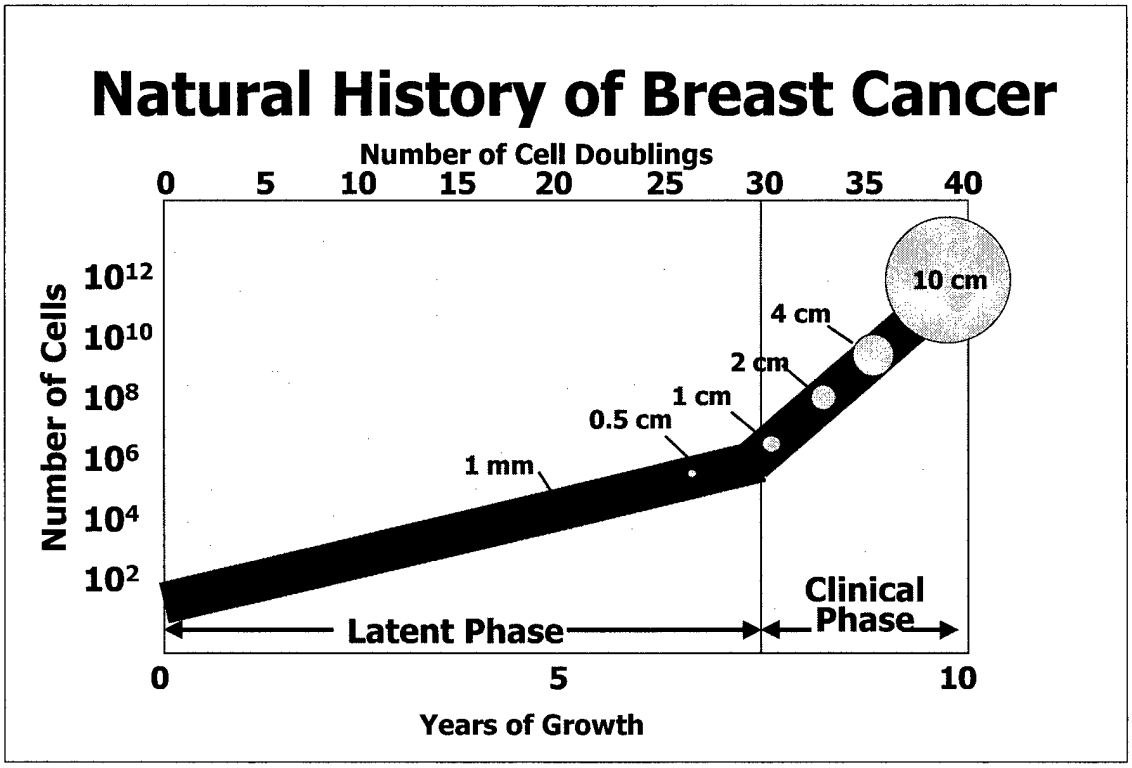
**Source:** Reis LAG, Miller BA, Hankey BF et al. (eds): SEER Cancer Statistics Review, 1973-1991: Tables and Graphs. Bethesda, MD: National Cancer Institute. NIH Pub. No. 94-2789, 1994:116-135.




SLIDE 64

Before addressing the next criteria for screening for breast cancer, we must briefly discuss the natural history for any disease. This slide plots out phases in a disease process. The latent phase of a disease refers to the period of time from the onset of exposure to the clinical manifestation of the disease. In infectious diseases, this is typically quite short, a matter of hours or days. For cancer, the latent period is usually months or years. The clinical phase of disease represents the symptomatic phase, which also encompasses months or years for breast cancer.

**Source:** Last JM (ed). *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.




SLIDE 65

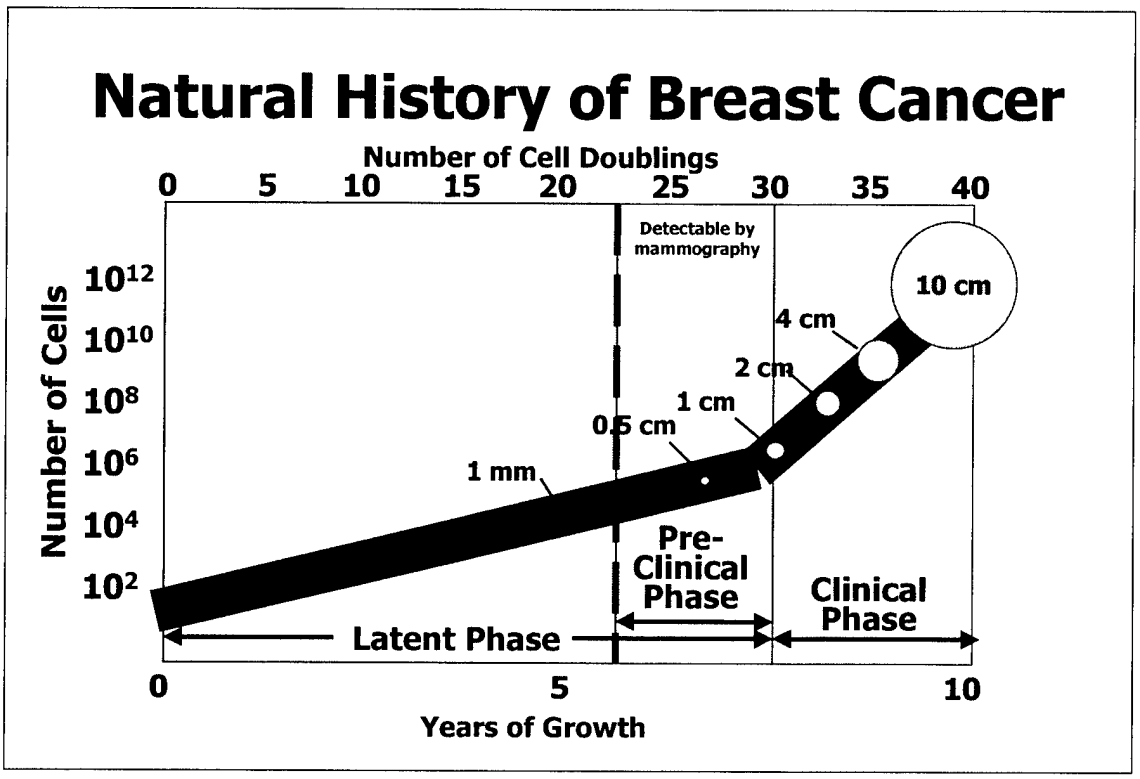
This slide demonstrates the natural history of breast cancer. In general, the doubling time for breast cancer averages about 100 days. This means that it takes 100 days for one cell to become two, two to become four, and so on. By the time that a tumor is one centimeter in size, it contains over 1 billion cancer cells and may be palpable. It averages 8 years between the onset of disease and the time that cancer growth reaches one centimeter. This period represents the latent phase of tumor growth. Because of the length of the latent phase for breast cancer, application of a screening test is theoretically possible.

**Sources:**

Harris JR, Hellman S. Natural history of breast cancer. In: Harris JR, Hellman S, Henderson IC, et al. (Eds.) *Breast Diseases*. 2nd ed. Philadelphia, PA: JB Lippincott Company; 1991:165-181.

Collins VP, Loeffler RK, Tivey H. Observations on growth rates of human tumors. *Am J Roentgenol.* 1956;76:988-1000.

Fisher B. The evolution of paradigms for the management of breast cancer: A personal perspective. *Cancer Res.* 1992;52:2371-2383.




SLIDE 66

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 this criteria. 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. We will discuss this further in future slides.

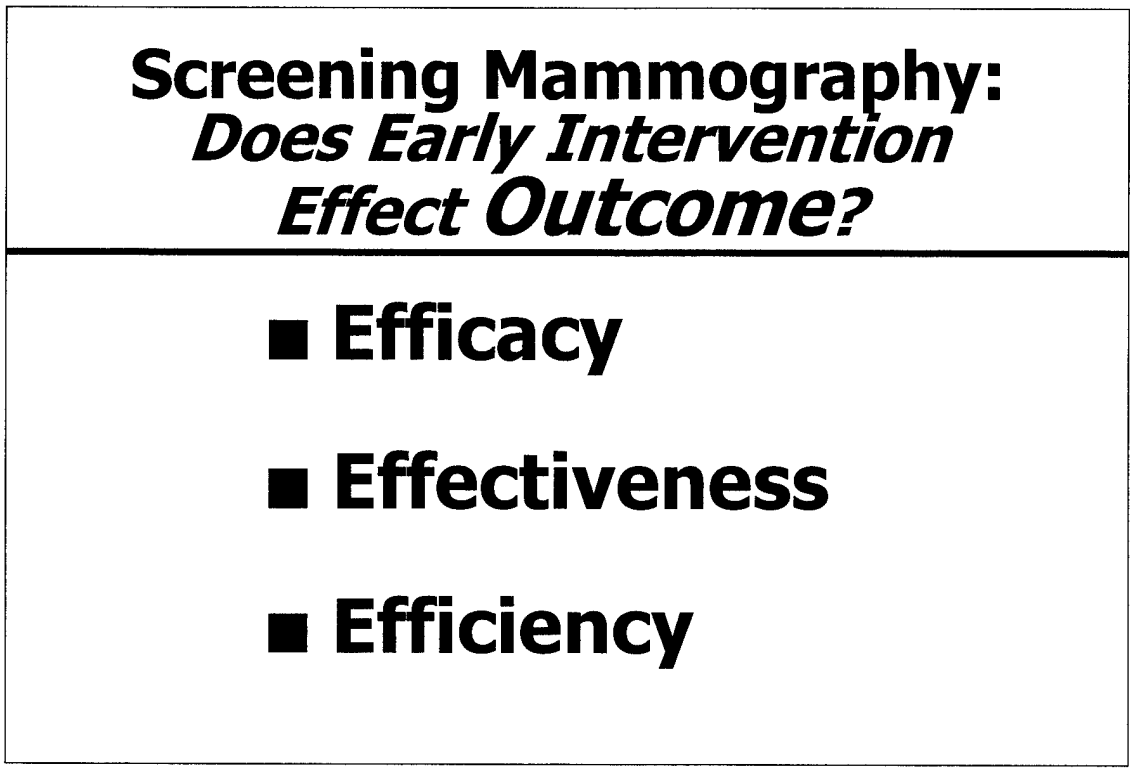
The last and most important criteria in the evaluation of a screening test evaluates if outcome is effected.

**Sources:**

Harris JR, Hellman S. Natural history of breast cancer. In: Harris JR, Hellman S, Henderson IC, et al. (Eds.) *Breast Diseases.* 2nd ed. Philadelphia, PA: JB Lippincott Company; 1991:165-181.

Collins VP, Loeffler RK, Tivey H. Observations on growth rates of human tumors. *Am J Roentgenol.* 1956;76:988-1000.

Fisher B. The evolution of paradigms for the management of breast cancer: A personal perspective. *Cancer Res.* 1992;52:2371-2383.




SLIDE 67

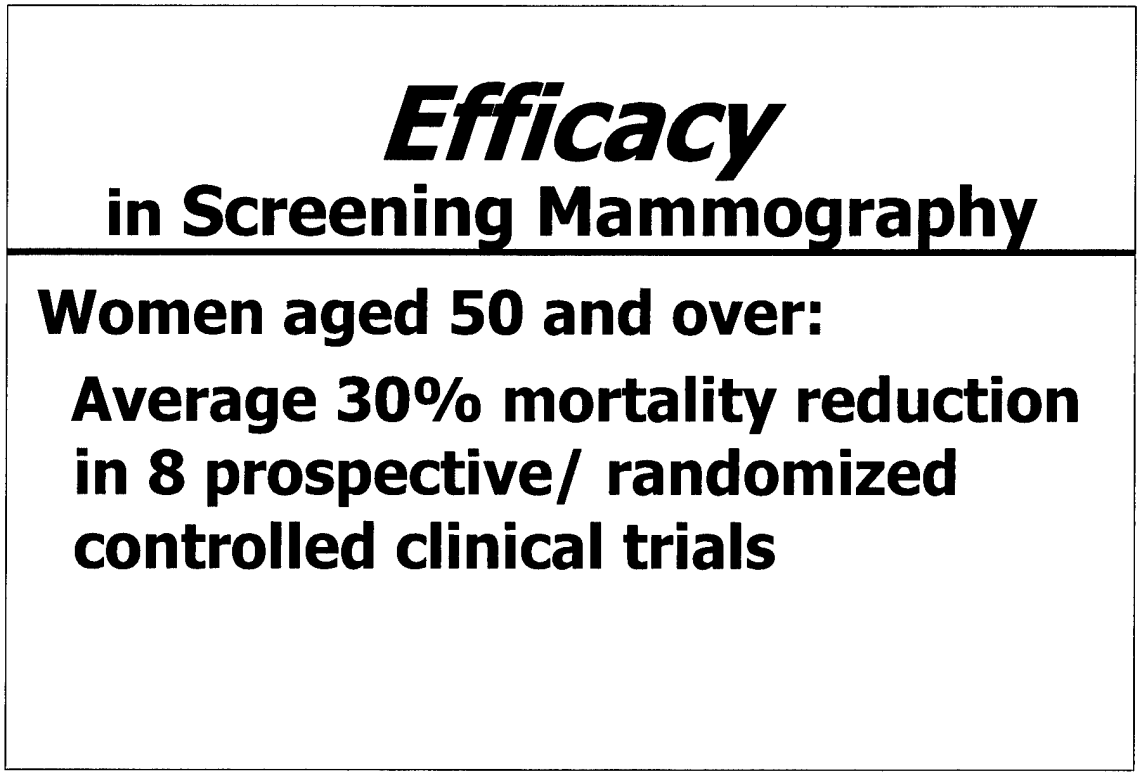
There are three pertinent terms to understand in the evaluation of the outcome of a screening intervention.

First is efficacy, meaning "can it work"? This question is answered through randomized clinical trials.

The second is effectiveness, meaning "does it work"? This refers to the applicability of the intervention in the general population and includes issues of feasibility, availability, compliance, etc. It is answered through observational studies.

The third is efficiency, or "is it worth doing"? This considers the benefit risk ratio, costs to individuals, and costs to society.

**Source:** Last JM. *A Dictionary of Epidemiology*. New York, NY: Oxford University Press, 1995.




SLIDE 68

The gold standard for evaluating screening efficacy is mortality reduction within the context of a prospective controlled, randomized trial. Death is an easily measured outcome that is not subject to the biases inherent in the measurement of other endpoints. Mammography has been studied in asymptomatic women in at least eight randomized, controlled prospective clinical trials. An average 30% mortality reduction has been demonstrated in each of these trials for women 50-74 years old. Translating this to the entire U.S. population theoretically could result in a reduction in breast cancer deaths from 46,000 per year to approximately 32,000 per year. This assumes that none of the 46,000 were screened prior to their diagnosis.

**Source:** Shapiro S. Screening: Assessment of current studies. *Cancer* 1994;74:231-238.

# *Efficacy*
## in Screening Mammography

**Women aged 40-49:**

**Meta-Analysis 1997:**

**18% mortality reduction**

**RCT:**

**Malmo: 36% mortality reduction**
**Gothenberg: 44% mortality reduction**

SLIDE 69

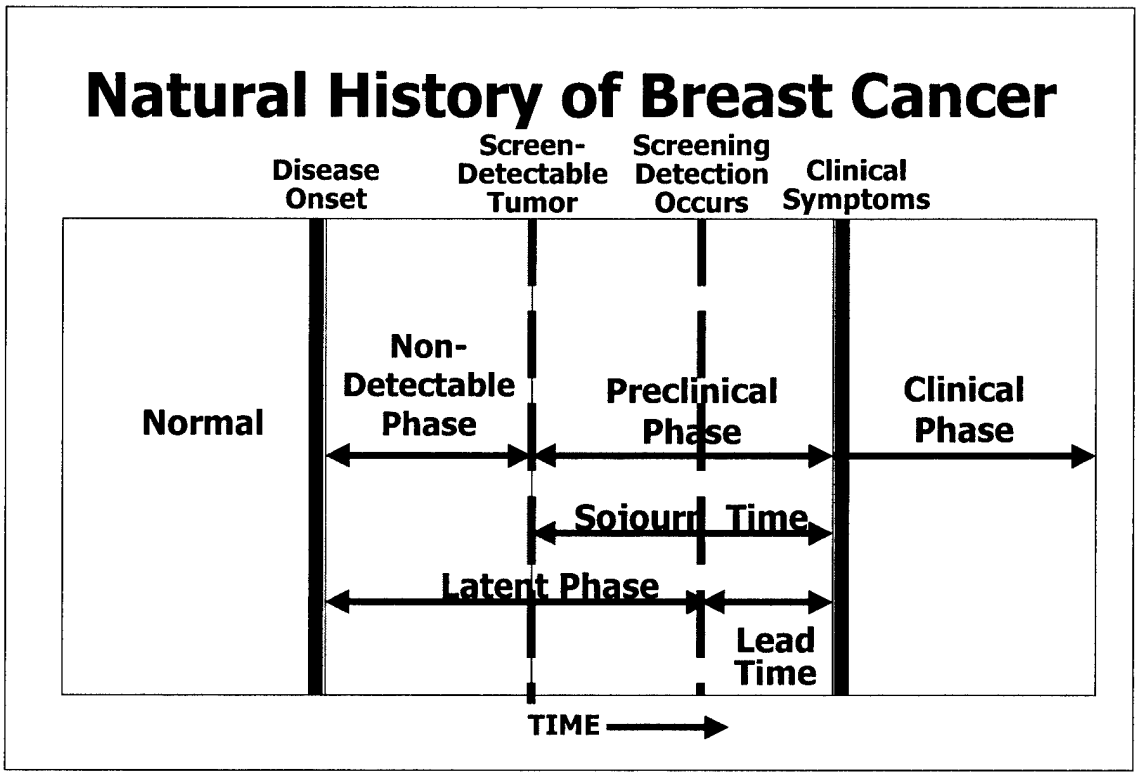
The efficacy of screening mammography for women in their forties has generated much debate. In 1997, a meta-analysis of eight controlled prospective clinical trials demonstrated a statistically significant mortality reduction of 18% in this groups of women. The results of two individual Swedish randomized trials also were published that year, demonstrating a 36% and 44% mortality reduction, respectively.

**Sources:**

Hendrick RE, Smith RA, Rutledge JH, et al. Benefit of screening mammography in women aged 40-49: A new meta-analysis of randomized controlled trials. *J Natl Cancer Inst Monogr* 1997;22:87-92.

Bjurstam N, Bjorneld L, Duffy SW, et al. The Gothenburg breast screening trial: First results on mortality, incidence, and mode of detection for women ages 39-49 years at randomization. *Cancer* 1997;80:2091-2099.

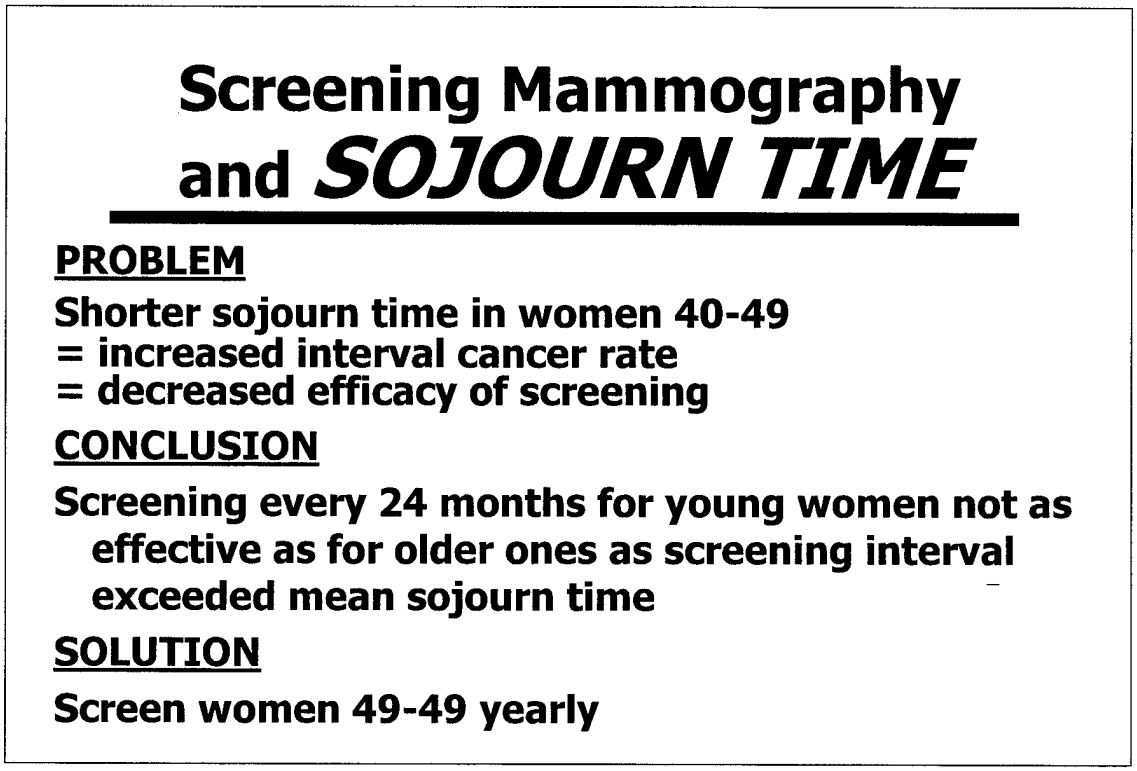
Andersson I, Janzon L. Reduced breast cancer mortality in women under age 50: Updated results from the Malmo Mammographic Screening Program. *J Natl Cancer Inst Monogr* 1997;22:63-67.




SLIDE 70

This finding of efficacy in women 40-49 was dependant on follow-up times of about 8 years as opposed to 5 years for women 50 and over. To explain this, an understanding of the meaning of sojourn time and lead time is necessary. Remember that the latent phase of a tumor consists of a non-detectable phase and a preclinical phase, during which the disease is potentially detectable. The application of screening shifts the definition of the latent phase, so that it ends at the point at which the disease becomes potentially detectable through screening, even though it remains asymptomatic. The time during which the disease is potentially detectable in an asymptomatic individual is called the sojourn time and corresponds to the preclinical phase of disease. Lead time represents the length of time from disease detection using screening to the time that symptoms would have occurred had screening not occurred.

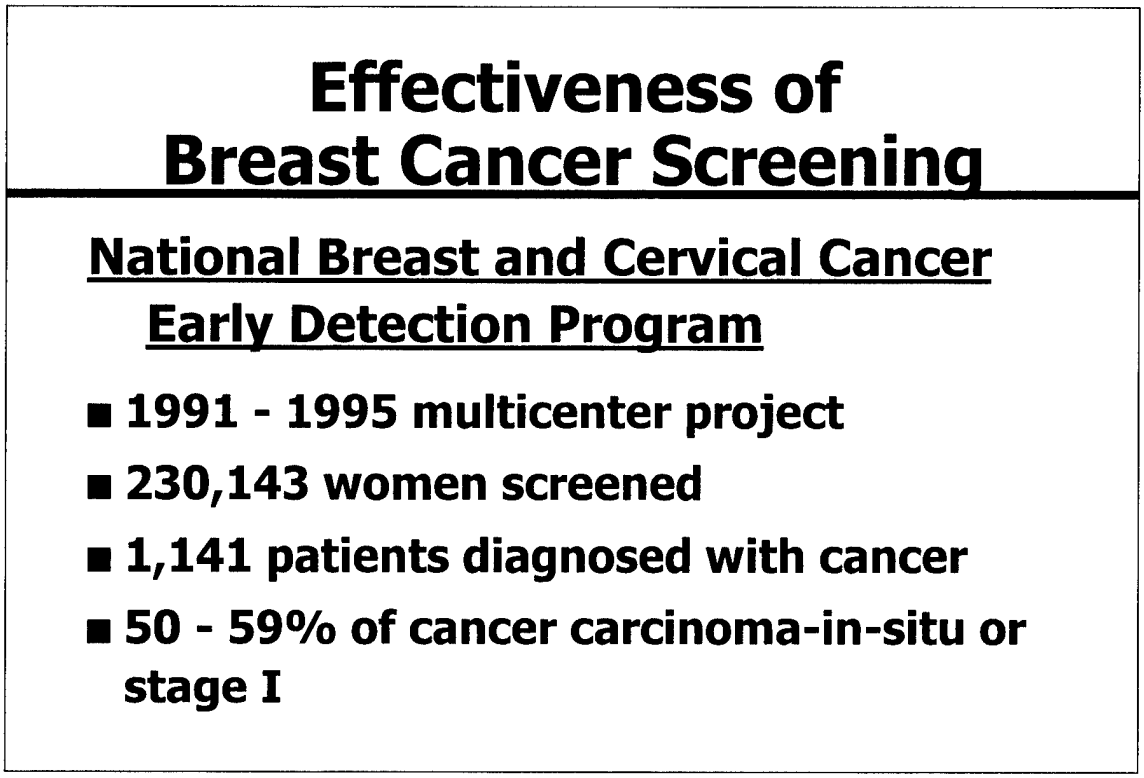
**Source**: Feig SA. Estimation of currently attainable benefit form mammographic screening of women aged 40-49 years. *Cancer* 1995;75:2412-2419.




SLIDE 71

Women 40-49 have been shown to have a greater frequency of aggressive tumors with shorter sojourn times or shorter preclinical phases than in women 50 and over. This leads to an increased interval cancer rate, meaning an increased frequency of symptomatic tumors appearing between screens. This results in decreased efficacy of screening. The solution to this important problem is to decrease the screening interval to exceed the mean sojourn time. Application of this principle leads to the recommendation for annual mammography screening in this age group.

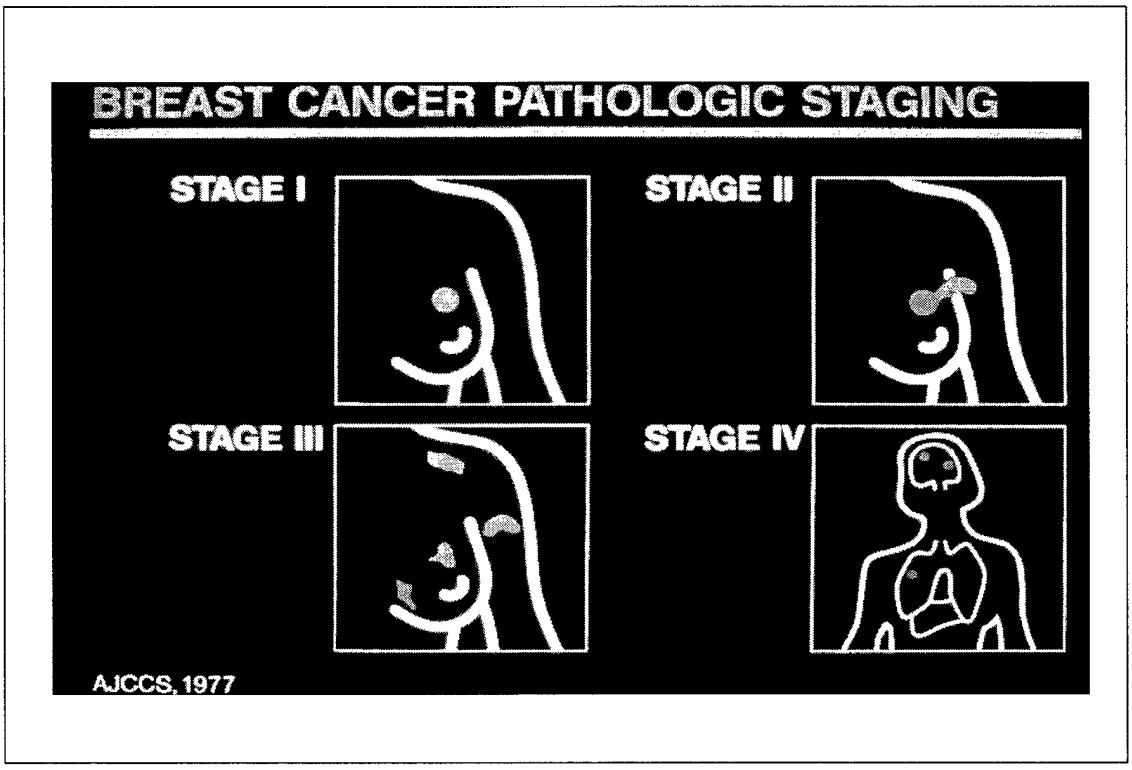
**Source:** Feig SA. Estimation of currently attainable benefit form mammographic screening of women aged 40-49 years. *Cancer* 1995;75:2412-2419.




SLIDE 72

Now that we have concluded that screening mammography can work in the clinical trial setting, we need to evaluate whether it does work in the community setting. The most recent study to demonstrate screening mammography effectiveness is the National Breast and Cervical Cancer Early Detection Program, a congressionally mandated program for low-income women conducted by the Centers for Disease Control. In this project, all goals of the Quality Determinants of Mammography guidelines panel were met, and 50-59% of the cancers diagnosed were stage 0 or I. Although successful at detecting incident cancers in early stages, optimal effectiveness has been compromised by low compliance with rescreening.

**Source:** May DS, Lee NC, Nadel MR et al. The National Breast and Cervical Cancer Early Detection Program: Report on the first 4 years of mammography provided to medically underserved women. *AJR* 1998;170:97-104.




SLIDE 73

This is a good time to discuss breast cancer staging. Stage 0 refers to carcinoma-in-situ.

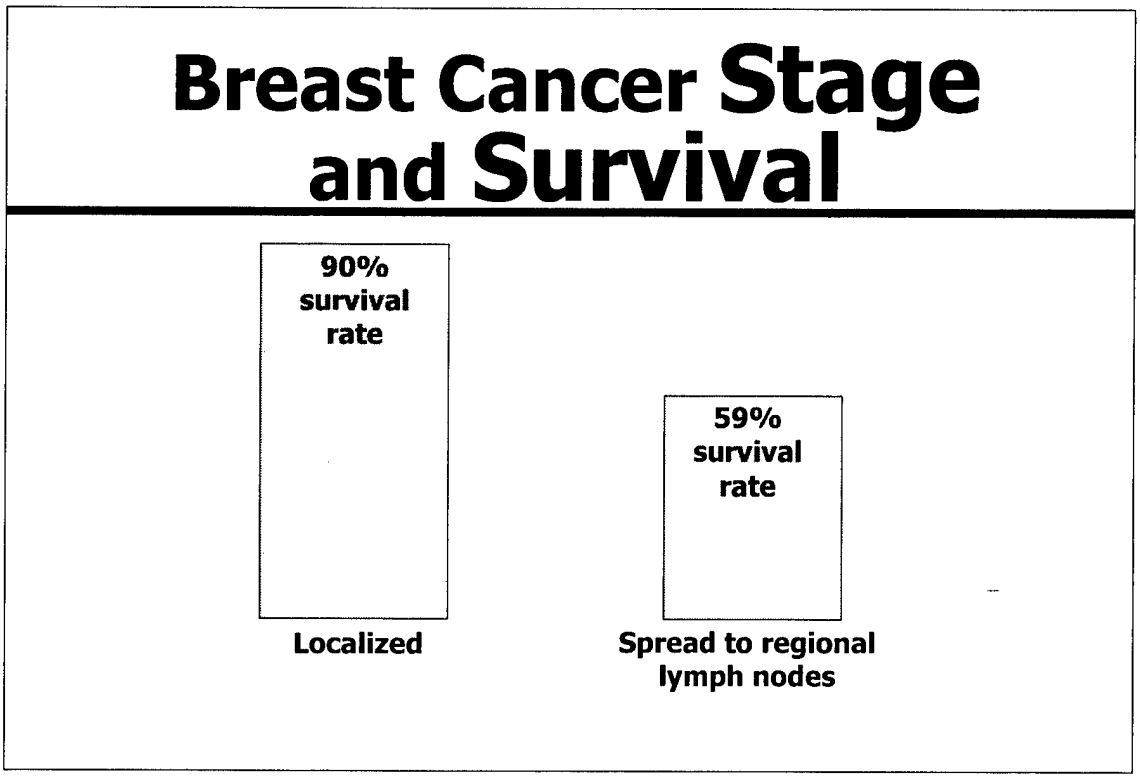
Stage I refers to the presence of a tumor measuring 2 cm or less with no lymph node metastasis. Both criteria must be met for the diagnosis of stage I disease.

If the tumor is larger than 2 cm, or a patient has positive lymph nodes, she is classified as stage II or above.

Stage III disease implies locally advanced breast cancer, usually involving the skin or chest wall.

Stage IV refers to the presence of metastatic disease. The most common distant sites of metastases include the lung, liver, bones, and brain.

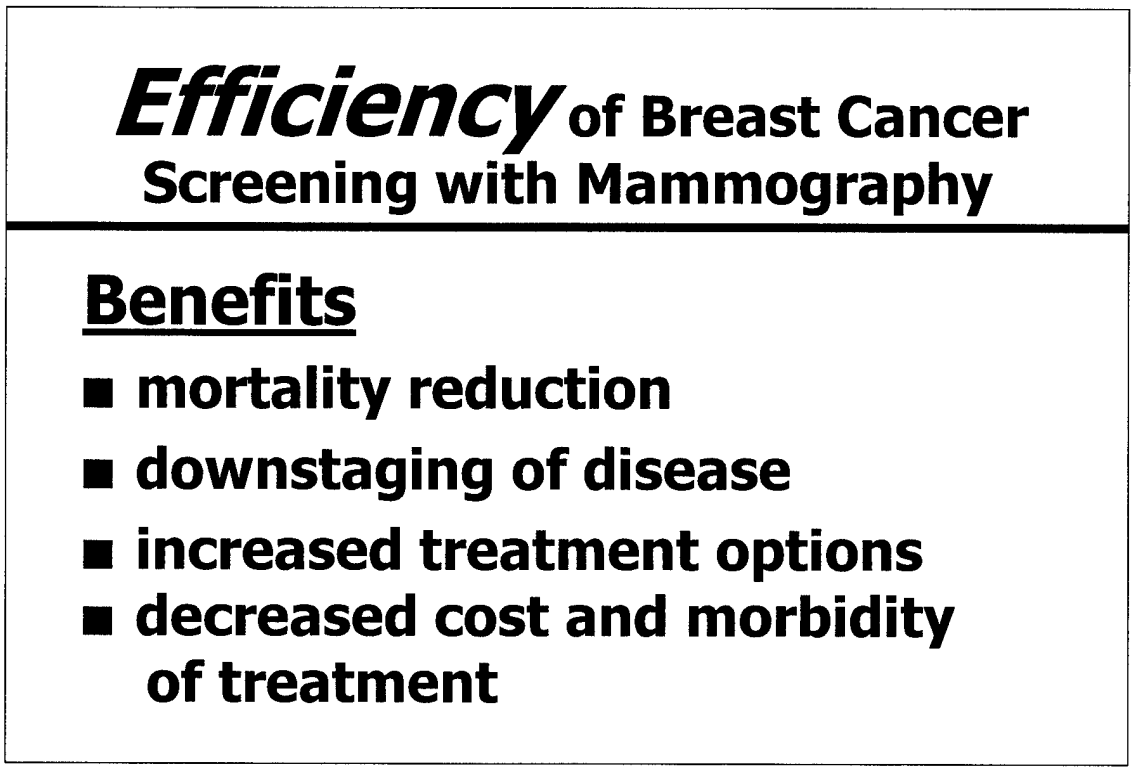
**Source:** American Joint Committee on Cancer: *Manual for Staging of Cancer.* 4th ed. Philadelphia, PA: J.B. Lippincott, 1992, pp. 149-154.




SLIDE 74

Survival rates are most commonly quoted as 5-year survival by stage. The 5-year survival of stage I disease is over 90%, and for stage 0, approaches 100%. On the other hand, if there is spread to the regional lymph nodes, 5-year survival can be below 60%. Mammography is capable of diagnosing cancer in earlier stages than are possible with CBE alone. This leads to earlier stage at diagnosis and improved survival.

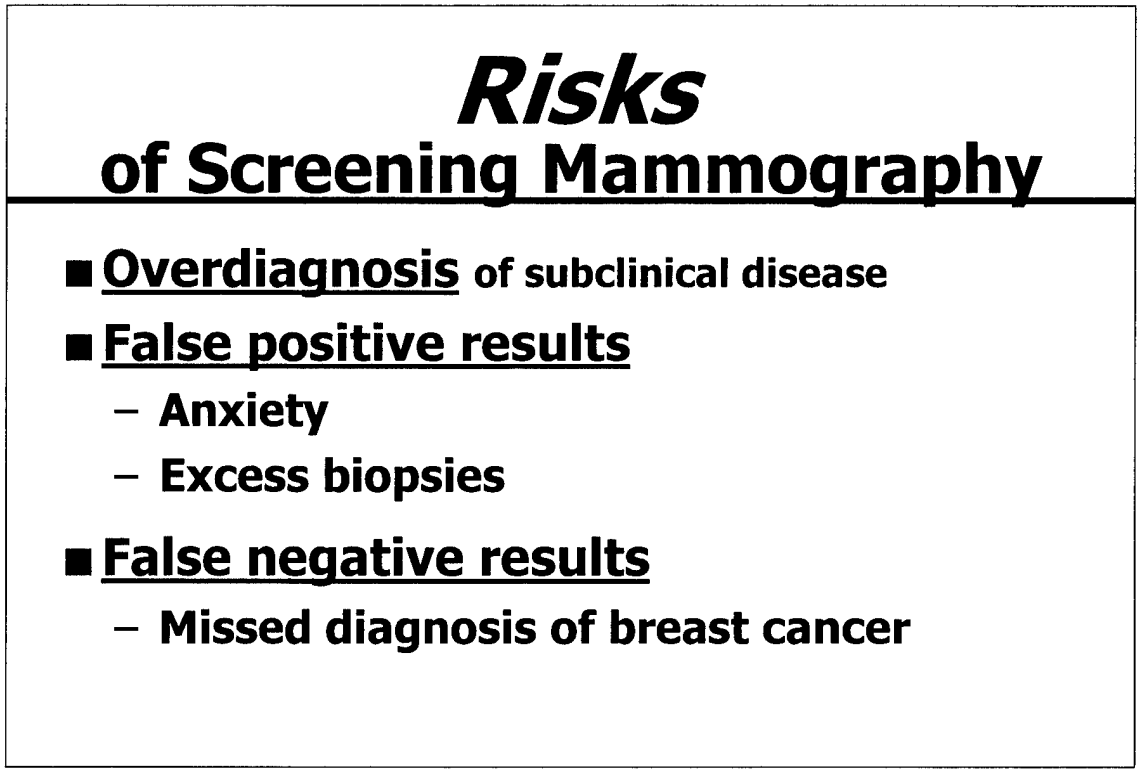
**Source:** National Cancer Institute, Division of Cancer Prevention and Control. 1987 Annual Cancer Statistics Review, Including Cancer Trends 1950-1985. NIH Publication No. 88-2789. Bethesda, MD: National Institutes of Health, 1988.




SLIDE 75

One of the most important criterion for the evaluation of screening worth is efficiency, "is it worth doing?" We have discussed screening benefits related to mortality reduction, and down-staging of disease. Smaller tumors at diagnosis also imply more treatment options and decreased cost and morbidity of treatment.

**Source:** Hurley SF, Kaldor JM. The benefits and risk of mammographic screening for breast cancer. *Epidemiol Rev* 1992; 14:101-130.



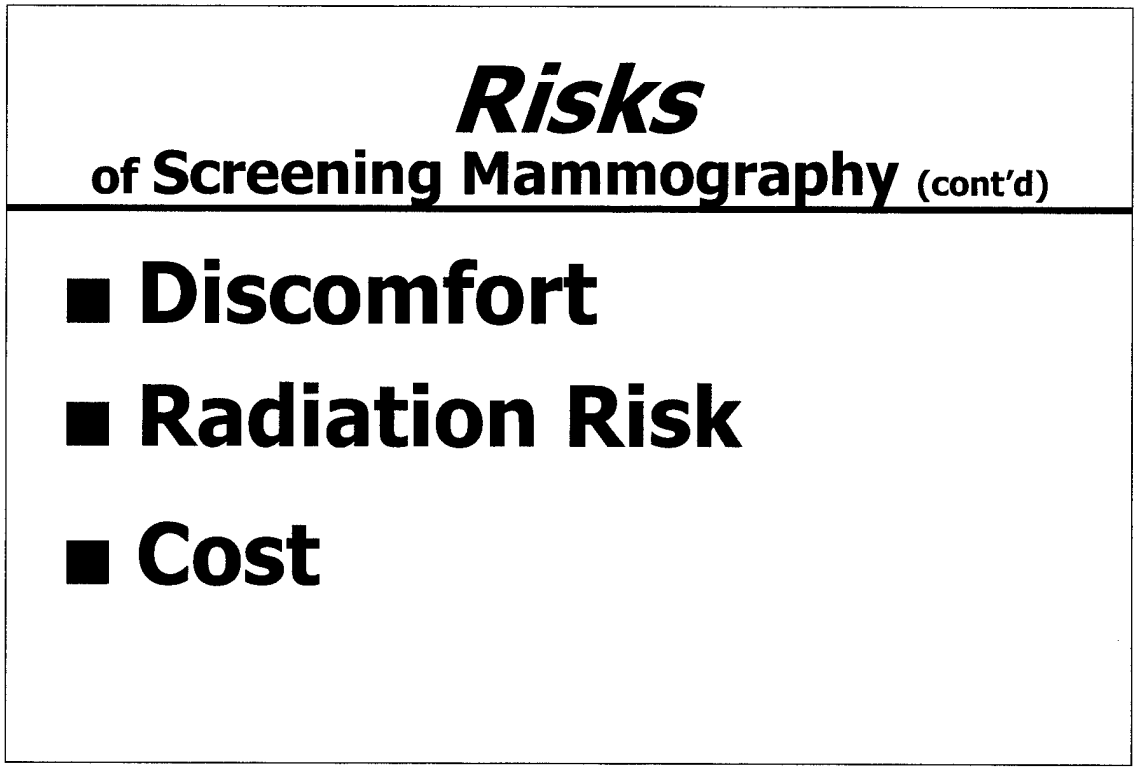

SLIDE 76

The risks of screening mammography include the risks of any screening procedure. Overdiagnosis of subclinical disease precipitates treatment that may not benefit the patient. False positive results precipitate anxiety and an excess number of interventions and false negative results can delay the diagnosis of breast cancer. We will focus on this latter problem in the next module.

**Sources:**

Hurley SF, Kaldor JM. The benefits and risk of mammographic screening for breast cancer. *Epidemiol Rev* 1992; 14:101-130.

National Institutes of Health Consensus Development Panel. National Institutes of Health Consensus Development Conference Statement: Breast Cancer Screening for Women Ages 40-49, January 21-23, 1997. *J Natl Cancer Inst* 1997;89:1015-1026.




SLIDE 77

Other risks include discomfort, radiation risk and cost. Discomfort is a reality for many women and should be acknowledged and validated. Anecdotally, over-the-counter pain medicine taken 1 hour before the procedure has been helpful. The procedure should be scheduled in ovulating women during the follicular phase of the menstrual cycle in order to reduce discomfort and avoid suboptimal breast compression that can occur during the luteal phase.

## Risks of Screening Mammography:
## *Radiation Risk*

**Number cases per 1 million women screened with mammography at age 45:**

| | Theoretical # |
|---|---|
| **Excess deaths** | **5** |
| **Number of deaths averted** | **225** |

*** Estimates based on mammogram radiation dose of 0.25 rads/2 view film/breast**

**Hypothetical risk from extrapolated data**

SLIDE 78

Concern about excess breast cancer incidence from radiation exposure comes from studies showing increased risk from multiple chest flouroscopies during treatment for tuberculosis in the 1920s and 1930s, and from studies of atomic bomb survivors in Japan. The doses delivered in these studies ranged from 100 to 1000 rads and the risk was greatest in adolescents and women in their early 20s in these studies. The average mammogram in the late 1990s delivers 0.25 rads per 2 view film per breast. Mammography may cause five excess deaths from breast cancer per 1 million women screened at age 45. However, 225 deaths theoretically are averted through screening. The benefits clearly outweigh the theoretical risks. For asymptomatic women less than age 40, routine mammography is not recommended unless risk status is extremely high. Symptomatic women will be discussed in a later section. Mammography is usually not done in women less than 30 years of age unless at extremely high risk, because the risk:benefit ratio is not favorable.

**Source:** Feig SA, Dodd GD, Hendrick RE. Mammography risks and benefits. In: Poznanski AK (Ed). *Radiation Protection Twenty-Eight Annual Meeting of the National Council on Radiation Protection and Measurements*. Bethesda MD: National Council on Radiation Protection and Measurements, 1993, pp 240-253.

## Risks of Screening Mammography: *Cost*

- **Cost/yr life saved assuming 30% mortality reduction: $6,000 - $13,000**
- **Median costs per year of life saved in appropriate age groups:**

| Screening/Intervention | $$ |
|---|---|
| Cholesterol | 6,000 |
| Annual mammography | 8,900 |
| Cervical cancer | 12,000 |
| Seatbelts/Airbags | 32,000 |
| Hormone replacement therapy | 42,000 |

SLIDE 79

The cost of screening is usually measured as cost per year of live saved. This list demonstrates that annual mammography compares favorably with other interventions accepted in public health.

**Source:** Feig, SA. Mammographic screening of women aged 40-49 years. Benefit, risk, and cost considerations. *Cancer* 1995 Nov 15;76(10 Suppl):2097-2106.

## Mammography Screening Guidelines
### *Normal Risk Women*

| Age | AAFP | ACS, ACR | NCI | USPSTF |
|---|---|---|---|---|
| 40 - 49 | Counsel | Annual | 1-2 Yrs | NR* |
| 50 - 69 | 1-2 Yrs | Annual | 1-2 Yrs | 1-2 Yrs |
| 70 & over | NR* | Annual | 1-2 Yrs | NR* |

*NR = No Recommendation

AAFP = American Academy of Family Physicians
ACS = American Cancer Society
ACR = American College of Radiology
NCI = National Cancer Institute
USPSTF = United States Preventive Services Task Force

SLIDE 80

Recommendations for screening mammography in normal-risk women vary by organization. A summary of recommendations of leading organizations is listed here. Every major organization recommends screening in women 50-69 at intervals of 1-2 years. Recommendations are inconsistent for women aged 40-49 and 70 and over. Patients of all ages should be made aware of the benefits and risks of medical procedures but especially those related to screening.

**Sources:**

American Academy of Family Physicians: Summary of Recommendations for Periodic Health Examination. Http://www.aafp.org/exam/app-d2.html

American Cancer Society: Statement on Mammography Guidelines. Http://www.pslgroup.com/dg/196ba.htm.

National Cancer Institute: PDQ®: Screening for Breast Cancer. Http://cancernet.nci.nih.gov/clinpdq/screening_for_breast_cancer_physician.html.

U.S. Preventive Services Task Force. Http://www.ahcpr.gov/clinic/

Feig SA, D'Orsi CJ, Hendrick RE, et al. American College of Radiology Guidelines for Breast Cancer Screening. *AJR Am J Roentgenol.* 1998;171:29-33.

# Most Common *Barrier* Cited by Women for not having a Screening Mammogram:

## *"My doctor didn't tell me that I needed one."*

SLIDE 81

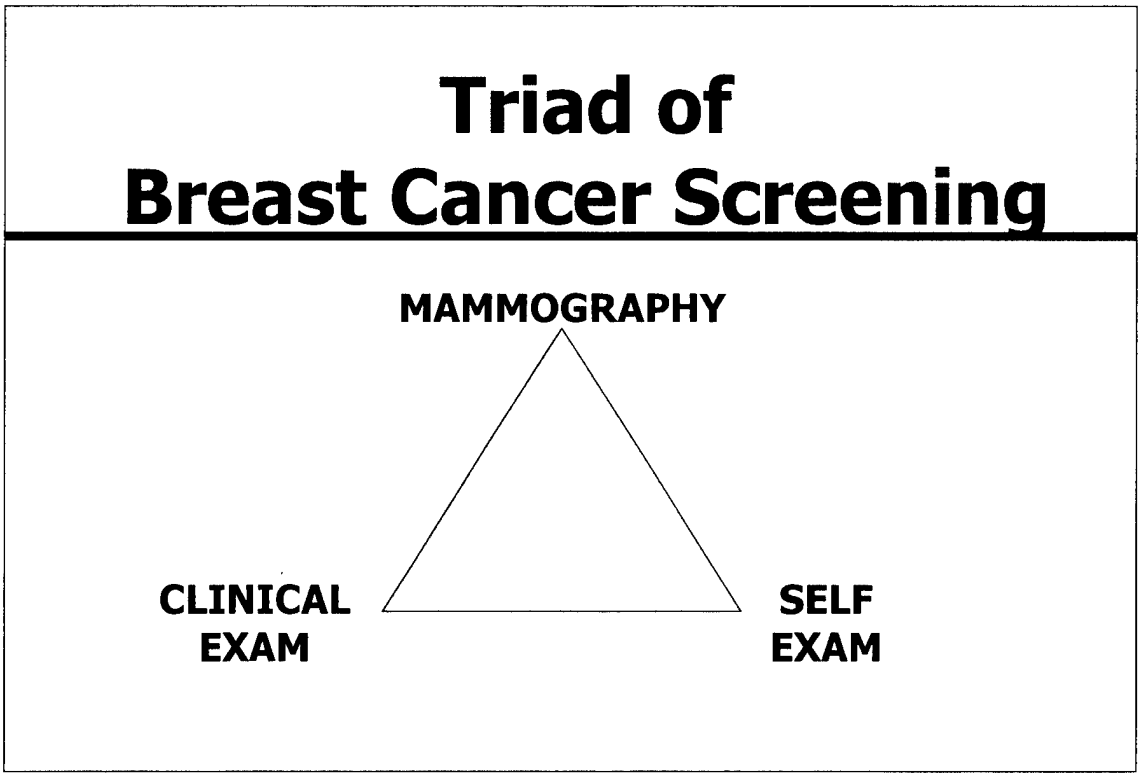
In multiple studies, the most common reason that women cite for not having a mammogram is that their doctor did not tell them that they needed one. Other reasons for underutilization of mammograms include: cost and/or lack of health insurance, and the misconception that without symptoms there is no need for mammography. Many studies have documented that older women are less likely to utilize mammography than younger women, and that physicians are less likely to recommend it. Although no randomized trials have been conducted in women older than 74, the exam is easier to interpret in elderly women whose breasts contain mostly adipose tissue because of the natural process of involution. As long as a woman would benefit from detection of breast cancer at an early stage, screening should continue. A recent case-control study of mammography in women over 65 years of age suggests a 45% reduction in mortality.

**Sources:**

Ackerman SP, et al. Cancer screening behaviors among U.S. women: Breast cancer 1987-1989, and cervical cancer, 1988-1989. *MMWR* 1992;41(55-2):17-34.

Dolan NC, Lee AM, McDermott MM. Age-related differences in breast carcinoma knowledge, beliefs, and perceived risk among women visiting an academic general medicine practice. *Cancer* 1997;1:413-420.

VanDijck JA, Verbeck AL, Beex LV, et al. Mammographic screening after the age of 65 years: Evidence for a reduction in breast cancer mortality. *Int J Cancer* 1996;66:727-731.




SLIDE 82

Breast cancer screening involves not only mammography but also clinical examination and breast self-examination. Clinical breast exam (CBE) has not been formally evaluated regarding its ability to reduce mortality from breast cancer, but the prevalence of breast disease and the complimentary role that it plays in the diagnosis of breast cancer make it an important part of the screening exam in asymptomatic patients.

# Breast Self-Exam (BSE)

## *Randomized Studies*

***1996 - St. Petersburg WHO Study: No effect, poor compliance***

***1997 - Shanghai: No effect***

## Response to promote BSE:

- **Reinforces provider-patient partnership**
- **Reinforces patient's role in her own health**
- **Encourages consultation with provider**

SLIDE 83

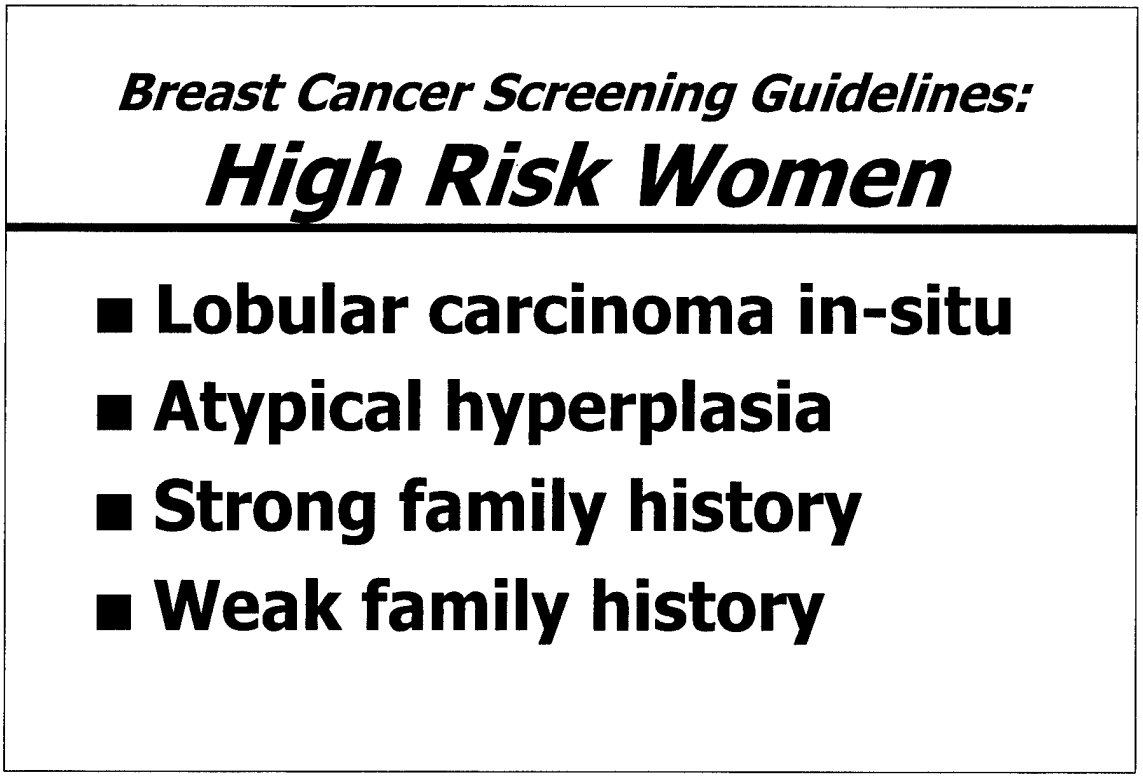
Two randomized controlled trials recently examined the effectiveness of BSE at decreasing mortality from breast cancer. Neither had screening mammography available to its participants. A study in St. Petersburg, Russia begun in 1985 is inconclusive because only 18% of patients performed BSE at year 4. In Shanghai, 5-year data analysis shows no mortality reduction between the control and intervention arms.

Teaching our patients breast self-examination reinforces the partnership between the patient and the physician and the patient's role in breast cancer screening. Encouraging patients to perform BSE should be used to empower our patients. It should never be used as a tool to make patients feel guilty for undetected lumps. The purpose is to help women understand what their normal healthy breast feels like so that if anything changes, the patient will see a physician to find out if the change is of clinical significance.

**Sources:**

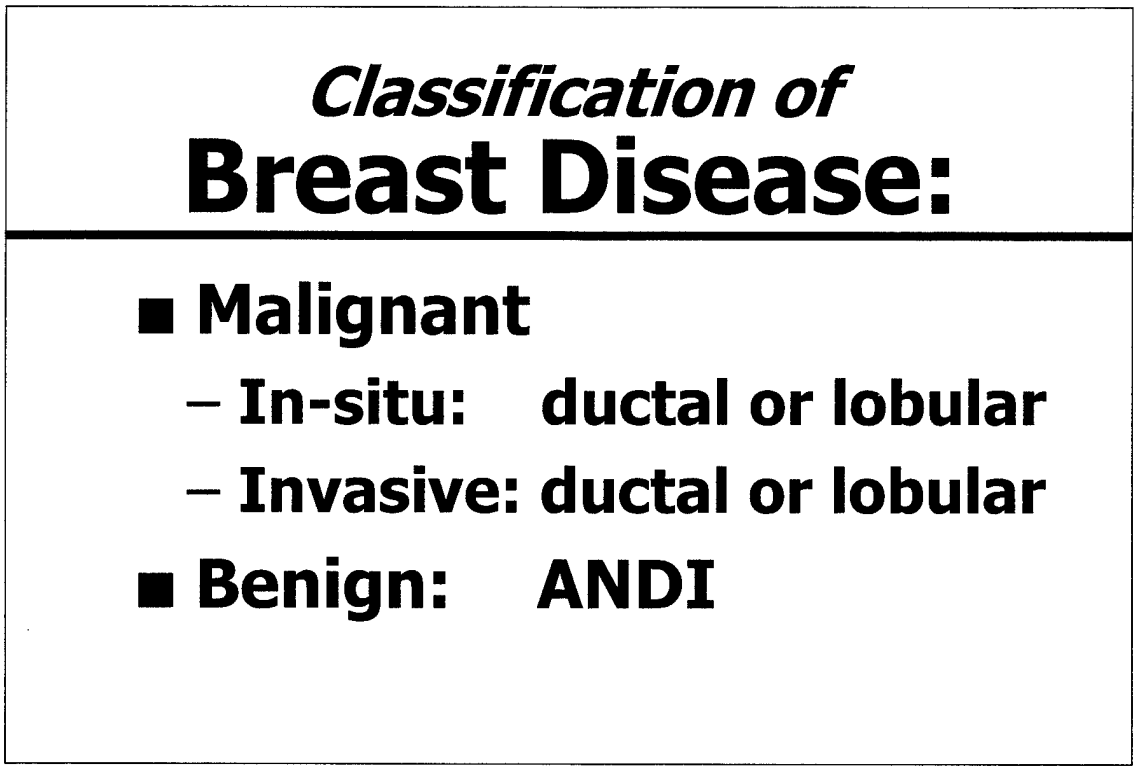
Thomas DB, Gao DL, Self SG et al. Randomized trial of breast self-examination in Shanghai: Methodology and preliminary results. *J Natl Cancer Inst,* 1997;89:355-365.

Semiglazov VF, Moiseenko VM, Protsenko SA et al. Preliminary results of the Russia (St. Petersburg) WHO program for the evaluation of the effectiveness of breast self-examination. *Vopr Onkol* 1996;42:49-55.




SLIDE 84

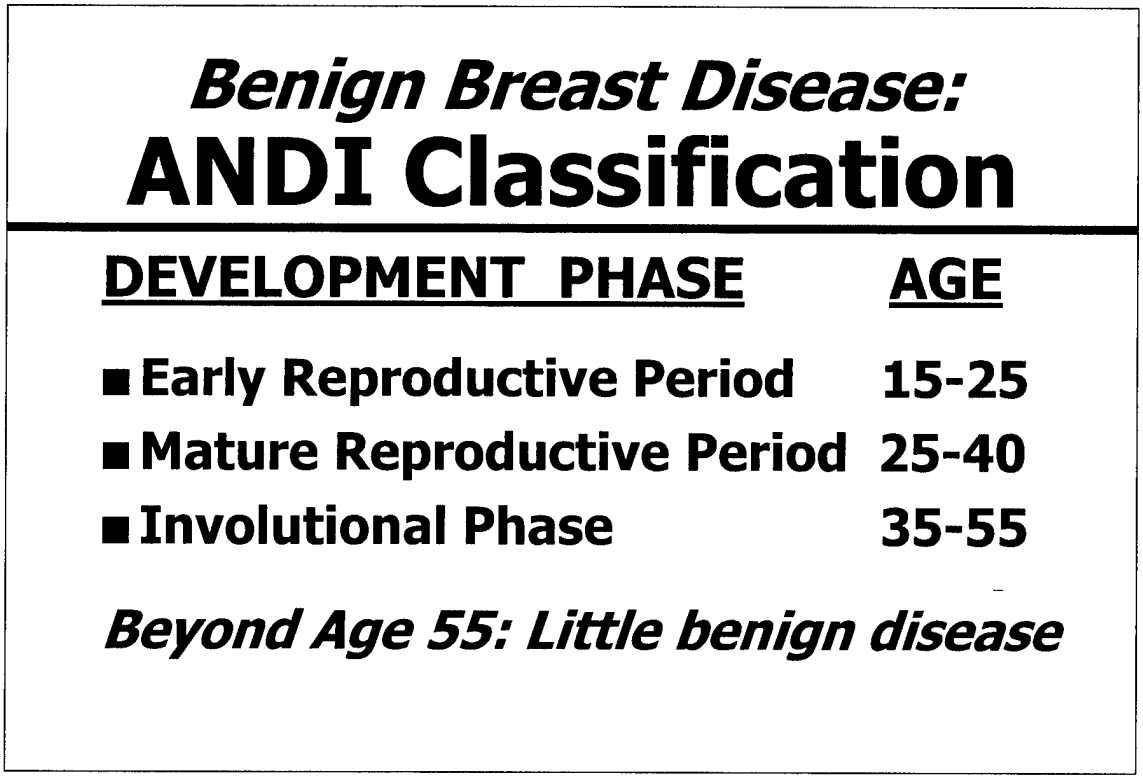
Screening guidelines for high-risk women are not established, but expert opinion has generated a set of suggestions that can be followed. This can be found in appendix 1 of the manual.




SLIDE 85

A basic classification divides breast disease into benign or malignant. Malignant disease classifications are logical: cancer can arise from lobules or ducts, presenting as invasive or in-situ disease. In contrast, confusion about the classification of benign disease is pervasive. Several terms are used to refer to the same condition, most being neither descriptive nor useful in directing the clinician to an effective management scheme. Normal physiologic processes in the breast are often described as "diseases", which adds to the confusion and can be very frightening to patients. Hughes recently introduced the ANDI classification for benign disease - Aberrations of Normal Development and Involution.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.




SLIDE 86

The ANDI classification is logical, practical, and based on normal breast development. It considers age, classifying breast problems into 1 of 3 reproductive periods: early (ages 15-25), mature (ages 25-40) and involution (ages 35-55). Note that the classification ends at age 55; it is uncommon for a postmenopausal woman to have benign breast disease. This will be discussed in more detail later. A table of the common benign breast conditions can be found on page 2 of the appendix. It will be helpful to keep this classification in mind throughout the remainder of this presentation.

**Source:** Aberrations of normal development and involution (ANDI): A concept of benign breast disorders based on pathogenesis. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London, 1989, Bailliere Tindall, 15-25.

SLIDE 87

Breast disorders can be classified into one of five signs or symptoms. These include:

- Breast pain
- Non-palpable mammographic abnormalities
- Breast mass or asymmetrical thickening
- Nipple discharge
- Skin or nipple changes

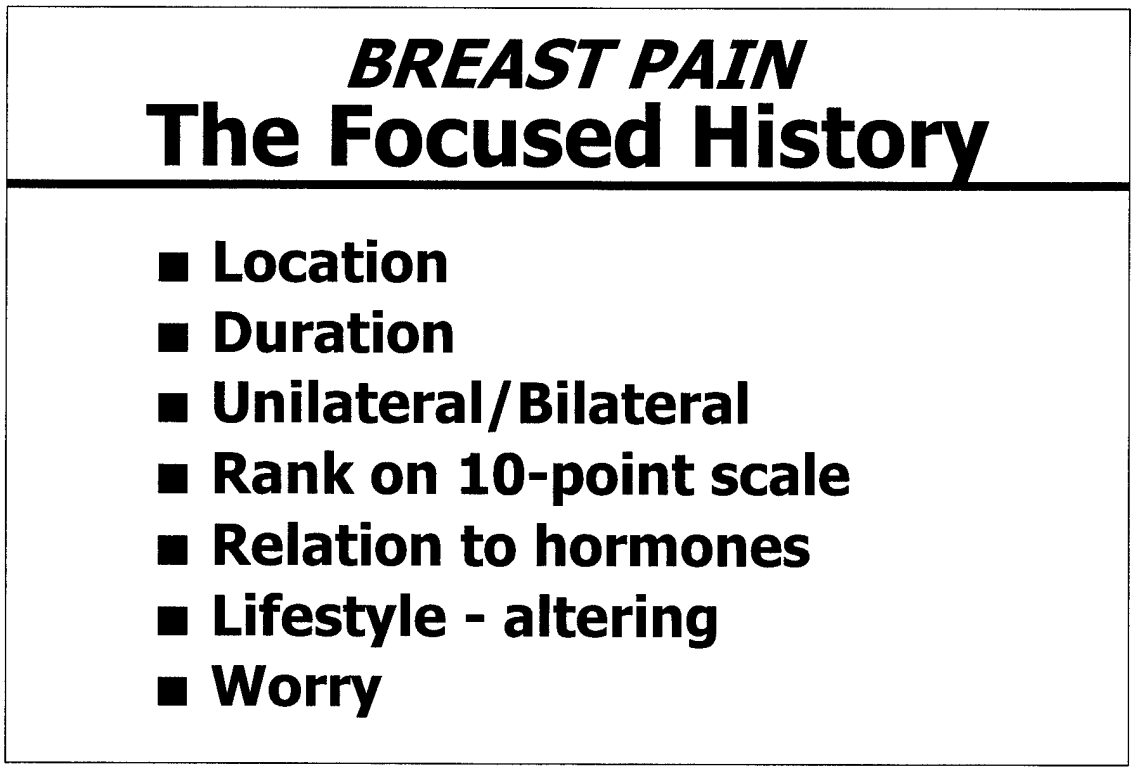
We will discuss each in detail in the following sections.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

SLIDE 88

Breast pain is the most common breast complaint, and in one large survey, 66% of women reported it. It is a symptom that can cause worry and anxiety about breast cancer. Unfortunately, the etiology is often unclear. The symptom is hormonally related in that it occurs most commonly 1 week prior to menses, and in some women taking hormone replacement therapy. Breast pain is self-limited in up to 85% of patients.

**Source:** Maddox PR, Mansel RE. Management of breast pain and nodularity. *World J Surg* 1989;13:699-705.




SLIDE 89

The complaint of breast pain should be taken seriously. Ask about location, duration, and whether it is unilateral or bilateral. To assess the degree of discomfort, ask the patient to rank the pain on a 10-point scale. Establish if it is cyclic by asking if the pain changes with her menstrual cycle, and when appropriate, if it is related to hormone replacement therapy. Evaluate the degree to which it worries the patient, and whether it alters lifestyle by inquiring about interference with exercise, hugs, sexual activity, and sleep. Pay attention to areas of focal pain; many women with masses have their attention drawn to the area because of pain. If the pain is diffuse, reassure the patient. If it is lifestyle altering, it may be necessary to intervene. This will be discussed in more detail in a later slide.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

# Breast Pain and Breast Cancer:

## Cardiff Mastalgia Clinic: 1982

**15% cancer patients presented with breast pain**

**7% cancer patients presented with mastalgia alone**

- **Unilateral**
- **Localized**
- **Constant**
- **Persistent**

SLIDE 90

The Cardiff Clinic reported on 240 cancer patients with operable breast cancer studied prior to the era of screening mammography. Fifteen percent had breast pain in addition to other symptoms. Seven percent had breast pain as their only presentation. In most of these, a mass was found on initial or subsequent CBE.

There is a low yield from diagnostic mammography when the sole symptom is breast pain, but screening mammography should be done according to the guidelines. Of women presenting with breast pain who have a normal CBE and radiologic studies, cancer will be found in about 0.5% on follow-up. This necessitates 3-6 month follow up exams in all women with persistent mastalgia.

**Sources:**

Preece PE, Baum M, Mansel RE, et al. The importance of mastalgia in operable breast cancer. *Br Med J* 1982:284;1299-1300.

Klimberg VS. Etiology and management of breast pain. In: Bland KI and Copeland EM (eds). *The Breast: Comprehensive Management of Benign and Malignant Disease*. Philadelphia, PA: W.B. Saunders Company, 1998, pp. 247-260.

# *Management of*
# BREAST PAIN

- **Reassurance**
  - **no sign of breast cancer**
  - **common symptom**
  - **self-limited**
- **Eliminate caffeine**
  - **may affect pain, but not nodularity or cancer**
- **Supportive brassiere**
- **Lower estrogen dose or substitute different estrogen**
- **Evening primrose oil - 3 gram/day**
- **Danazol - 200 mg/day - days 14-28**

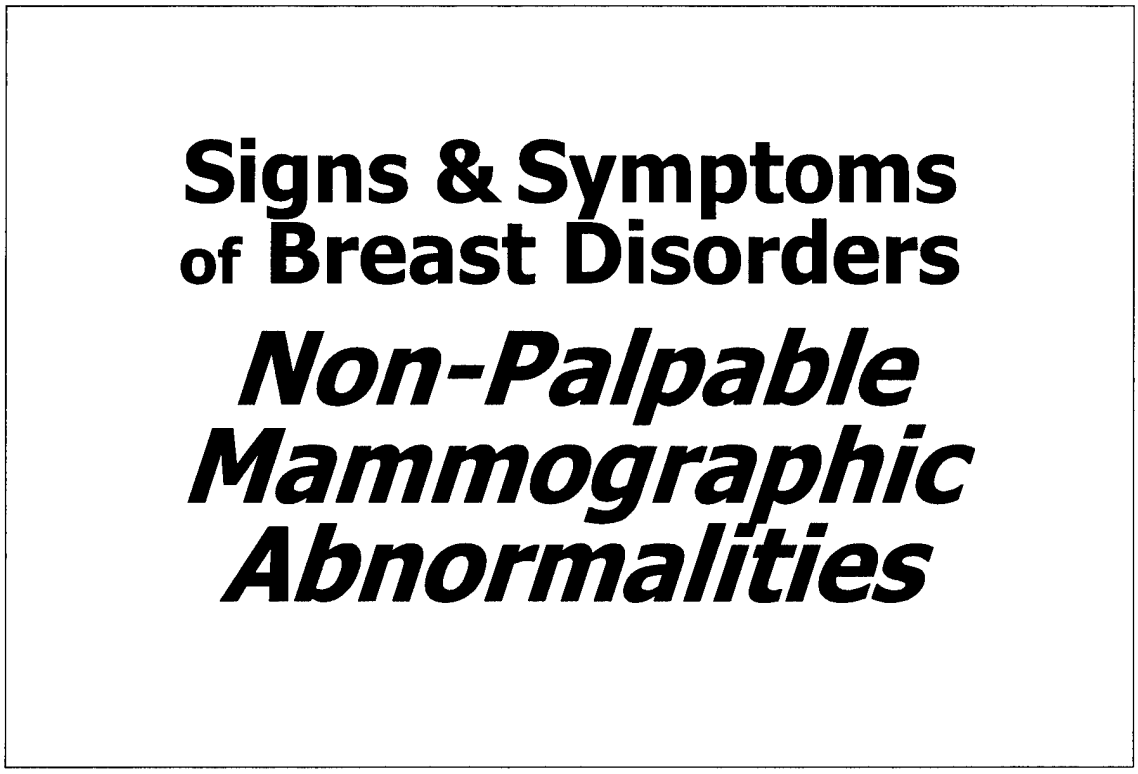
SLIDE 91

Once breast cancer has been ruled out, the most useful and successful next step is reassurance. Communicating that no serious problem can be detected, that mastalgia is very common, and that it is usually self-limited will alleviate concern in most cases. In the remainder, some women find that avoiding methylxanthine intake may be helpful. Controlled studies of methylxantine avoidance for relief of mastalgia are conflicting; avoidance does not alleviate nodularity nor reduce breast cancer incidence. Occasionally, substituting a more supportive brassiere, lowering the dose of estrogen, or substituting a different form of estrogen can be helpful. In women unrelieved by these measures, drug intervention can be useful. Cyclic pain is more responsive than non-cyclic pain. No benefits from vitamin B or E supplements have been demonstrated, but three drugs have proven useful: Evening primrose oil, danazol, and bromocriptine. The latter two have side effects which have historically limited their use for extended periods. However, a recent randomized controlled trial of 200 mg of danazol on days 14-28 of the menstrual cycle for three cycles demonstrated clinical efficacy during all 3 months of drug administration with a drop-out rate of only 3%. An algorithm of breast pain management can be found in Appendix 3.

**Sources:**

Klimberg VS. Etiology and management of breast pain. In: Bland KI and Copeland EM (eds). *The Breast: Comprehensive Management of Benign and Malignant Disease*. Philadelphia, PA: W.B. Saunders Company, 1998, pp. 247-260.

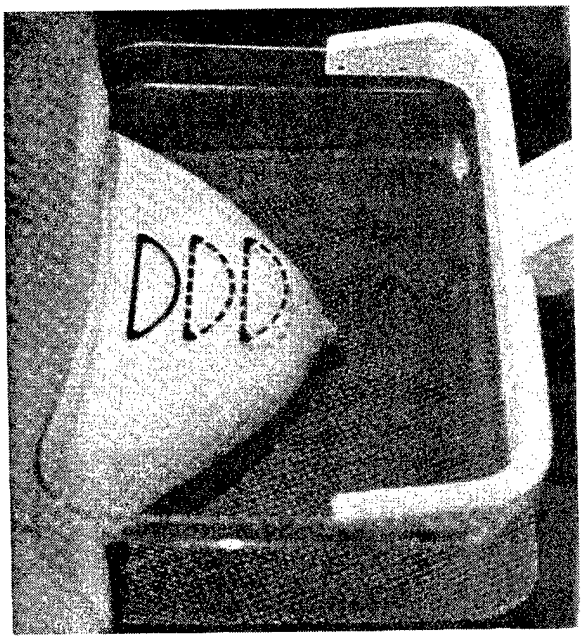
O'Brien PMS, Abukhalil IEH. Randomized controlled trial of the management of premenstrual syndrome and premenstrual mastalgia using luteal phase-only danazol. *Am J Obstet Gynecol* 1999;180:18-23.




SLIDE 92

Most screening mammograms will be interpreted as normal, but 5-10% will demonstrate a finding which requires further work up. Let's begin with a review of the techniques of mammography and what your patient experiences in the radiology department.

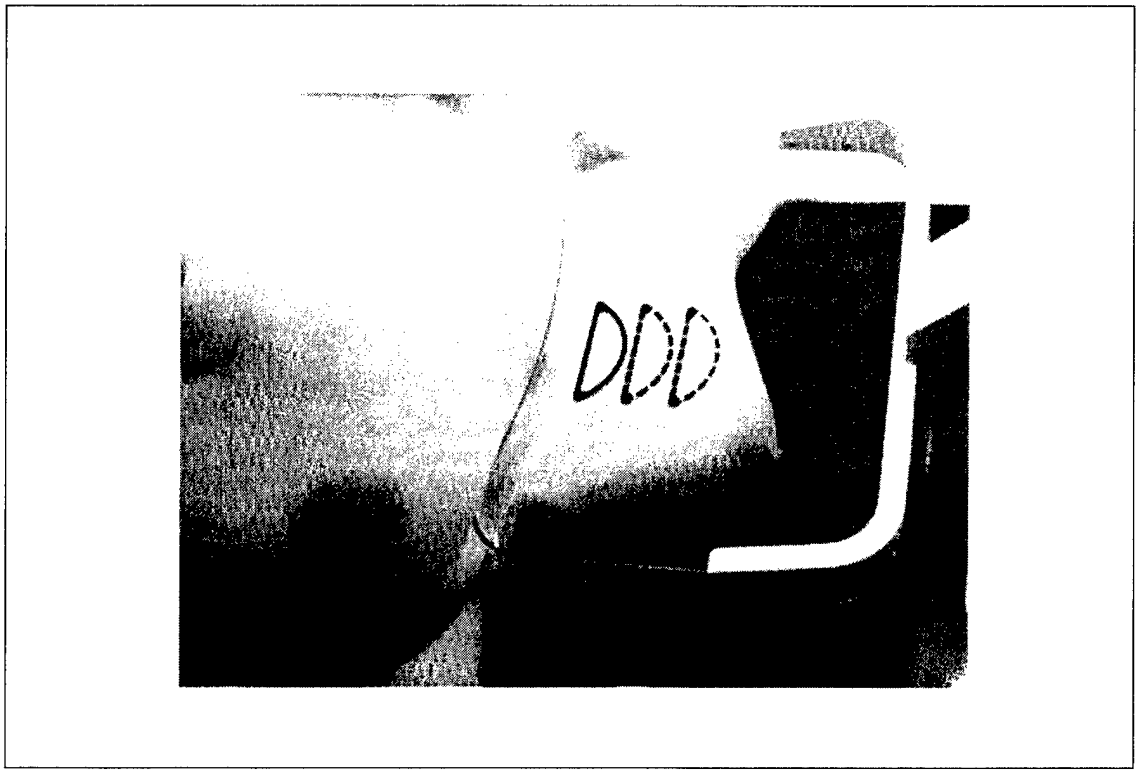
**Source:** Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994, Agency for Health Care Policy and Research, US Department of Health and Human Services.



SLIDE 93

The two standard views of a screening mammogram are the crandio-caudal (CC) and mediolateral oblique (MLO) views and these are usually performed in the standing position with the cassette parrallel to the floor. This is an example of a CC, or head-to-toe view, with optimal breast compression. The CC view best demonstrates the subareolar, central, and medial portions of breast tissue.

**Source:** Svane G, Potchen EJ, Sierra A, and Azavedo E (eds). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women.* St. Louis: Mosby Publishers, 1993.

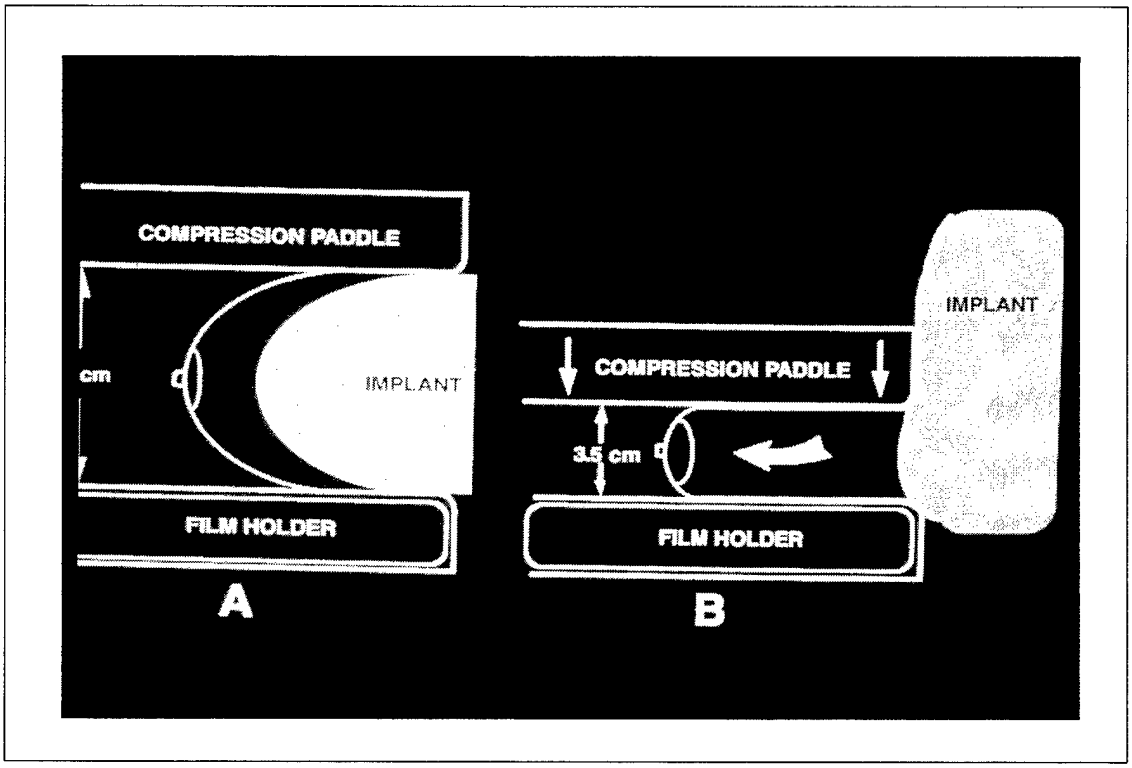



SLIDE 94

The MLO view images more of the breast than the CC view. In the MLO view the cassette is angled between 30 and 60 degrees. Adequate positioning includes visualization of the pectoralis major muscle to at least the nipple line, an open inframammary fold, and inclusion of the axillary tail of the breast.

Many patients complain about breast compression. Helping patients understand the purpose of the temporary discomfort of the test can increase compliance as well as patient satisfaction. The more the breast is compressed, the less radiation is required and the better the image produced. In addition, patients should be told that multiple films may be required to produce images that meet quality standards and that extra views do not necessarily imply that an abnormality has been found.

**Source:** Svane G, Potchen EJ, Sierra A, and Azavedo E (eds). *Screening Mammography: Breast Cancer Diagnosis in Asymptomatic Women.* St. Louis: Mosby Publishers, 1993.



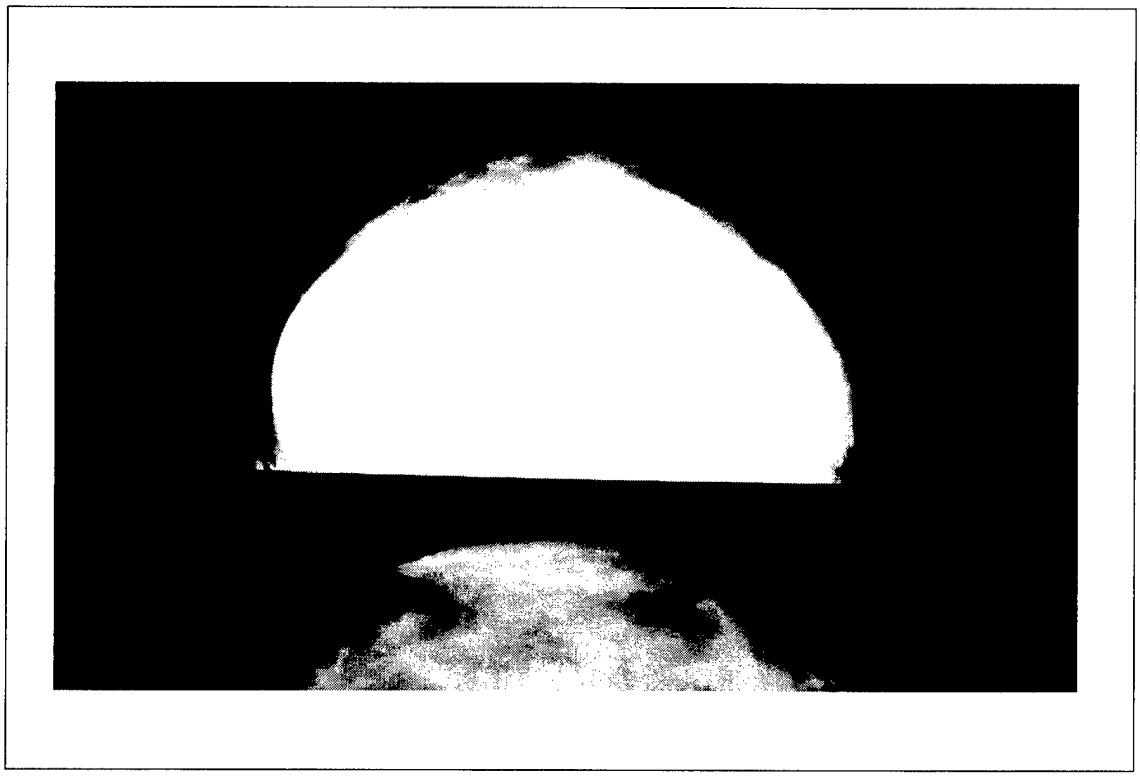

SLIDE 95

Special consideration should be given to patients with breast implants, and technologists need proper training to perform a mammogram in these patients. This drawing illustrates the technique for positioning the breast in a woman with augmented breasts. Note that the implant is displaced behind the compression plates in illustration B on the right. This is called an Eklund view.

**Sources:**

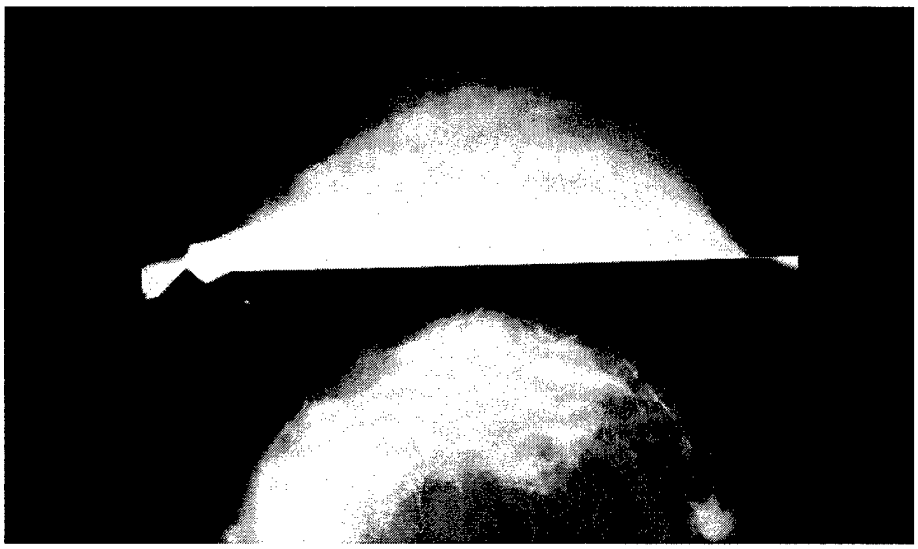
Slide - lecture series, *Breast Imaging : A Guide for Clinicians.* Sandowsky NL, Feig SA, McLelland R. American College of Radiology, Reston, VA.

Eklund GW. Improved imaging of the Augmented Breast. *AJR* 1988;151:469-473.



SLIDE 96

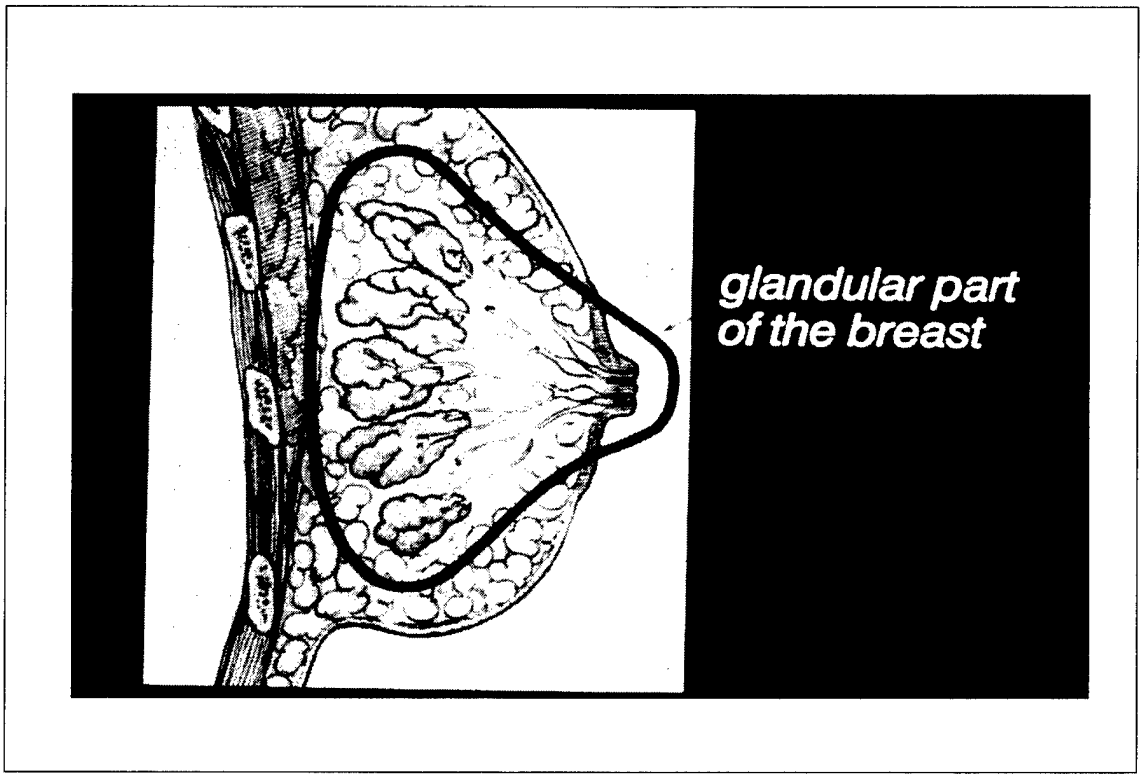
The mammogram at the top of this slide shows the image produced when an implant is compressed in the typical manner. The implant is seen as an iso-dense area that comprises most of the film. A rim of breast tissue can be seen around the implant. By pushing the implant out of the way, a much better breast image is obtained, as shown in the lower portion of the slide, representing results produced with an Eklund view.



SLIDE 97

Mammogram interpretation is dependent on proper image quality. These images are of the same breast. The top image shows a breast that is not properly compressed. It could have mistakenly been read as a dense, glandular breast with no abnormality visualized. The image on the bottom shows the same breast with proper compression. It visualizes a small infiltrating cancer which would have been missed by the image on the top of the screen. An example such as this one can help patients understand the importance of adequate breast compression.

**Source:** *Mammography Quality Control Manual.* Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology (ACR), 1990.




SLIDE 98

A mammogram images glandular tissue and fat differently and its interpretation depends on the contrast between the two. The anatomical features of the breast are life-cycle dependent and can influence the appearance of the mammogram. The parenchymal cells and ducts make up the glandular part of the breast, and will have a white appearance on the mammogram, whereas fat will appear dark or lucent. A radiologist's statement that the breasts are very glandular or dense indicates that there is little fatty tissue present in the breast; the mammogram will therefore be more difficult to interpret.

**Source:** Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994, Agency for Health Care Policy and Research, US Department of Health and Human Services.

SLIDE 99

When interpreting the mammogram, the radiologist will look for asymmetry in the appearance of white areas, indicating differences in the density of the tissues. The arrow here shows a density in the breast that is not matched on the opposite side, representing an infiltrating ductal carcinoma. It is possible to visualize it because it is located in a relatively fatty area of the breast. However, if this infiltrating ductal carcinoma were in the subareolar location of this breast, it would be impossible to visualize and detection of this cancer would be solely dependent on clinical breast examination.

## Categories of Mammographic Readings
## *BI-RADS™ System*

**Category 1 - Normal mammogram**

**Category 2 - Benign-appearing abnormality**

**Category 3 - Probably benign/possibly malignant, indeterminate**

**Category 4 - Suspicious for malignancy**

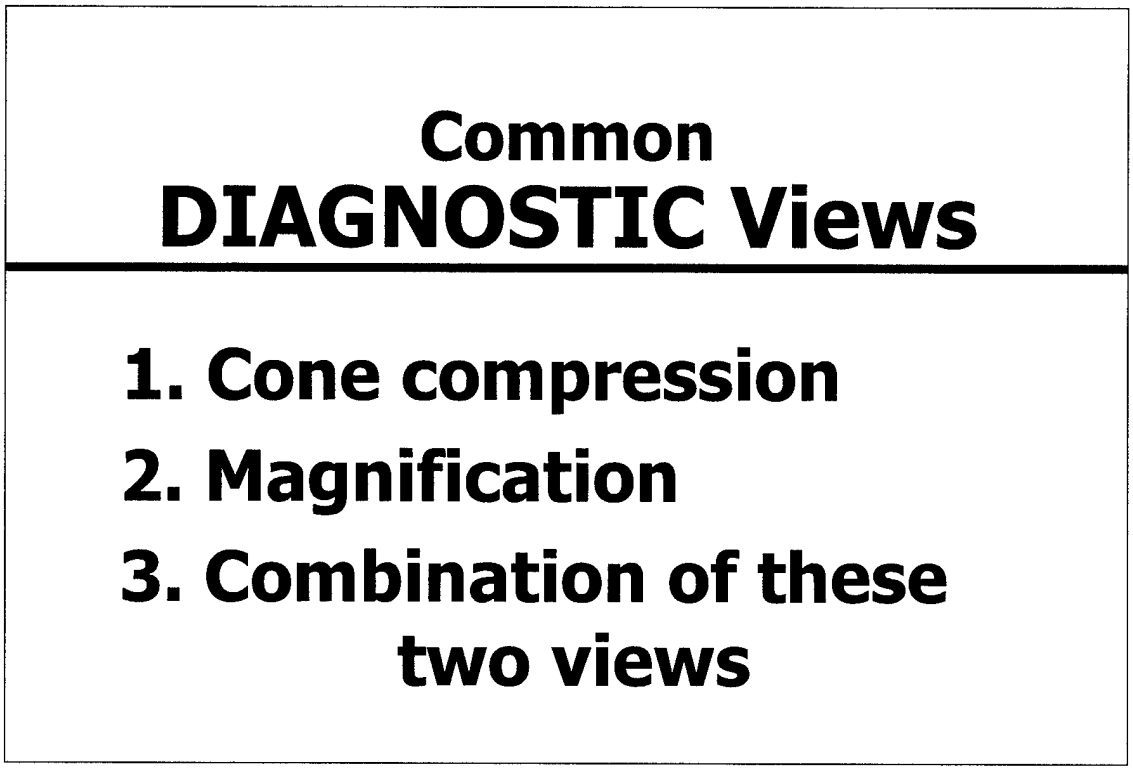
**Category 5 - Malignant until proven otherwise**

**Assessment Incomplete**

SLIDE 100

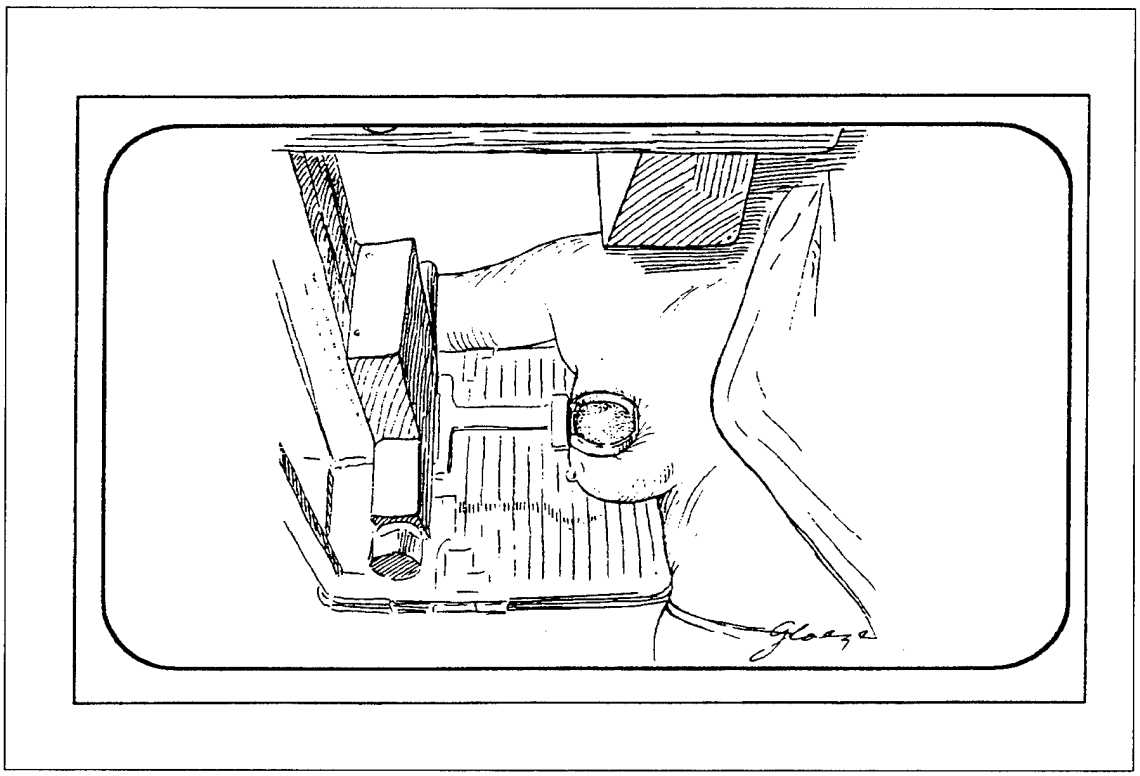
Variability in interpretation of mammograms is a recognized problem. To address it, the American College of Radiology has developed the BI-RADS™ system of mammogram interpretation, which uses a standardized reporting format as follows: **Category 1--**Negative, **Category 2**--Benign Finding, **Category 3**--Probably Benign Finding (indeterminate), **Category 4**--Suspicious Finding, and **Category 5**--Finding Highly Suggestive of Malignancy. Another category is termed assessment incomplete and additional diagnostic mammographic views or ultrasound are needed before a report is released by the radiologist.

**Source:** American College of Radiology (ACR). *Breast Imaging Reporting and Data System (BI-RADS™), Second Edition.* Reston, VA: American College of Radiology, 1995.




SLIDE 101

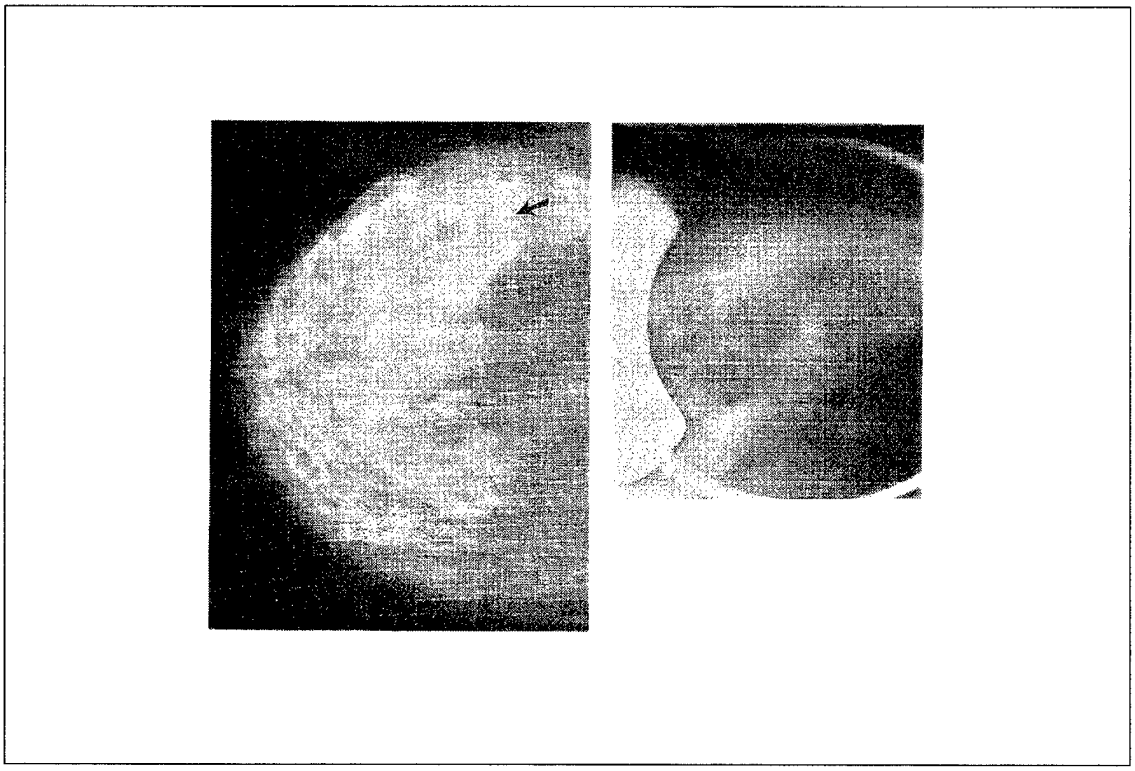
The most common diagnostic mammography views are (1) cone-compression (also called spot-compression), (2) magnification views, and (3) a combination of these two views.



SLIDE 102

A cone compression view is performed using a device to selectively compress that portion of the breast in which the mammographic abnormality is imaged. This technique is used to evaluate densities; if a density persists after compression, its characteristics will be further defined, and if not, it will disappear. The disappearance of densities with cone compression can be explained by the overlapping of breast tissue that will naturally occur in some patients when a three-dimensional structure is imaged onto an X-ray film.

**Source:** American College of Radiology (ACR). *Mammography Quality Control Manual.* Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology, 1990.



SLIDE 103

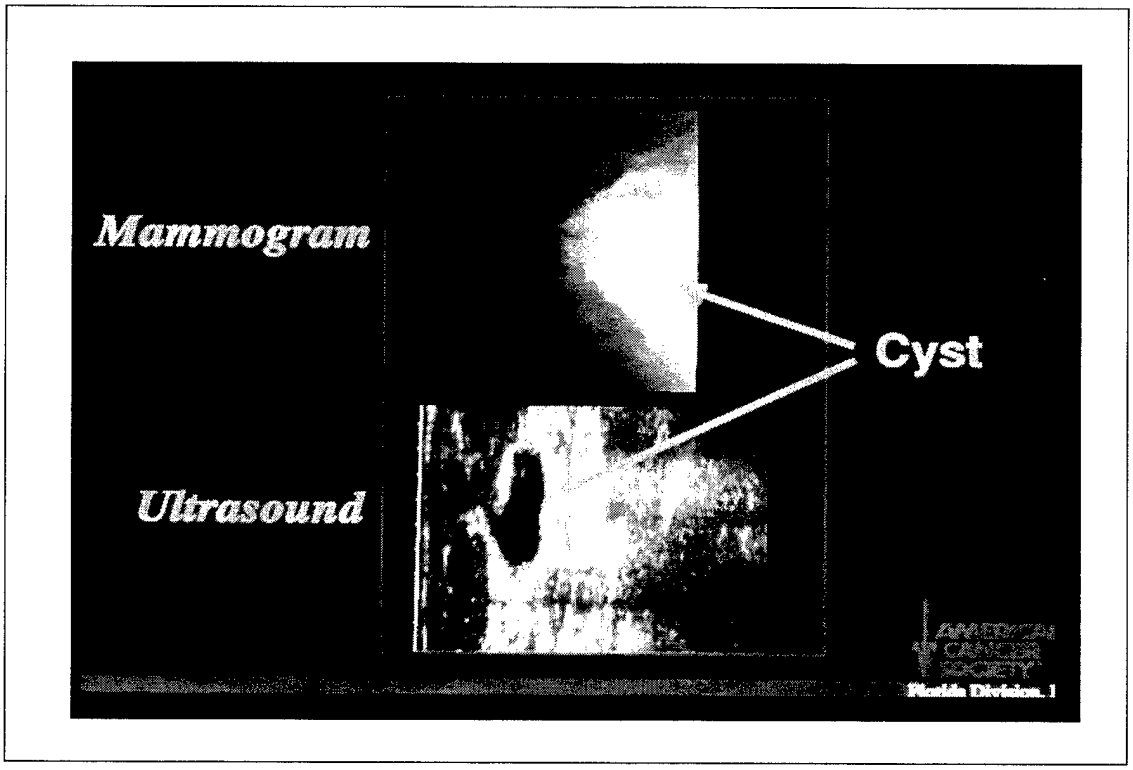
The mammogram on the left imaged a density in the breast, indicated by the black arrow. The film shown on the right illustrates the value of cone-compression, which demonstrated that the questionable abnormality simply represented a superimposition of normal tissue.

**Source:** *Mammography Quality Control Manual.* Committee on Quality Assurance in Mammography. Reston, VA: American College of Radiology, 1990.

SLIDE 104

The diagnostic film shown on the right uses both magnification and spot-compression to more clearly demonstrate the abnormalities in the screening film on the left. The magnification component uses a special device which magnifies the calcifications, and demonstrates them to have a pleiomorphic character. The cone compression component demonstrates an irregular density which is even more suspicious than on the original film. This patient has a mammogram highly suspicious for cancer.

**Source:** Mitchell R, Mitchell M, Nunnerty HB. Evaluation of magnification and paddle compression techniques in the assessment of mammographic screening detected abnormalities. *Clin Radiol* 1991;44:158-160.




SLIDE 105

Non-palpable mammographic smooth-walled densities can represent cysts or solid masses, and ultrasongraphy is used to distinguish the two. The top of this slide shows a smooth-walled density on a mammogram. This mass was not palpable on CBE. The corresponding ultrasound documents that the density is a cyst. This is apparent because of the dark interior which indicates fluid by ultrasound examination. To qualify as a simple cyst, a nodule must be void of internal echoes, or anechoic, have well-defined margins, and possess posterior acoustic enhancement. It is a dangerous practice to assume that a smooth-walled mammographic density is a cyst without proving it, as the differential diagnosis in the case of a solid mass includes carcinoma. If the mammographic abnormality is proven to be a simple cyst by ultrasound, no further intervention is needed, referral is unnecessary, and the woman can be reassured and placed into routine screening.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

# Occult Mammographic Abnormalities

**5-10% of screening mammograms need "call back" for diagnostic views**

**50-60% of diagnostic studies will resolve the initial problem**

**Current follow-up of radiologist recommendations is suboptimal**

SLIDE 106

Most radiologists will indicate a need for further work-up when a mammogram is abnormal. Many unnecessary referrals to breasts specialists can be avoided by following the recommendations of the radiologist and ordering the suggested diagnostic tests. Approximately 50-60% of initially abnormal screening mammograms will be placed into routine screening based on results of diagnostic views and ultrasound results. This approach is cost-effective and limits the fear and anxiety that is precipitated when patients are referred to a specialist.

On the opposite end of the follow-up spectrum, it has been repeatedly documented that there is inadequate follow-up of abnormal mammograms. Usually this is because women are not aware that the results are abnormal. In-office tracking systems are critical to good quality care and sound risk management.

**Sources:**

Bassett LW, Hendrick RE, Bassford TL et al. Quality Determinants of Mammography. Clinical Practice Guidelines No. 13. AHCPR Publication No. 95-0632. Rockville, MD. 1994, Agency for Health Care Policy and Research, US Department of Health and Human Services.

Mitchell R, Mitchell M, Nunnerty HB. Evaluation of magnification and paddle compression techniques in the assessment of mammographic screening detected abnormalities. *Clin Radiol* 1991;44:158-160.

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

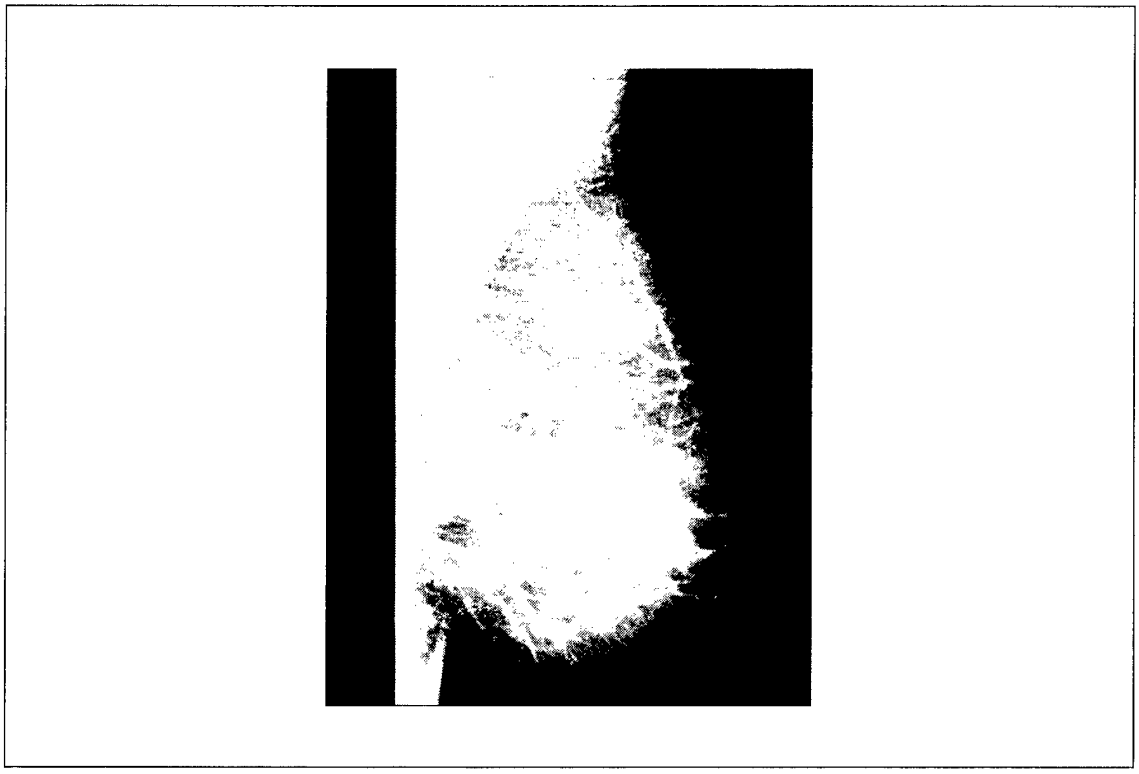
Signs and Symptoms of

# Breast Disorders

# NON-PALPABLE MAMMOGRAPHIC ABNORMALITIES: WORK-UP

SLIDE 107

The approach to a non-palpable mammographic abnormality depends in large part on the appearance of the abnormality and to the BI-RADS™ category into which it is placed.



SLIDE 108

This is an example of an intramammary lymph node. Intramammary lymph nodes are easy to identify mammographically, because they have a lucent center. They need no further work up. This is an example of a category 2, benign mammogram. The patient should be reassured, and continued on a routine screening schedule.

**Source:** Tabar L, Dean P. *Teaching Atlas of Mammography, 2nd Edition.* New York, NY: Thieme Medical Publishers, Inc., 1985.

## Occult Mammographic Abnormalities

# *INITIAL WORK UP*

## 1. Diagnostic mammogram

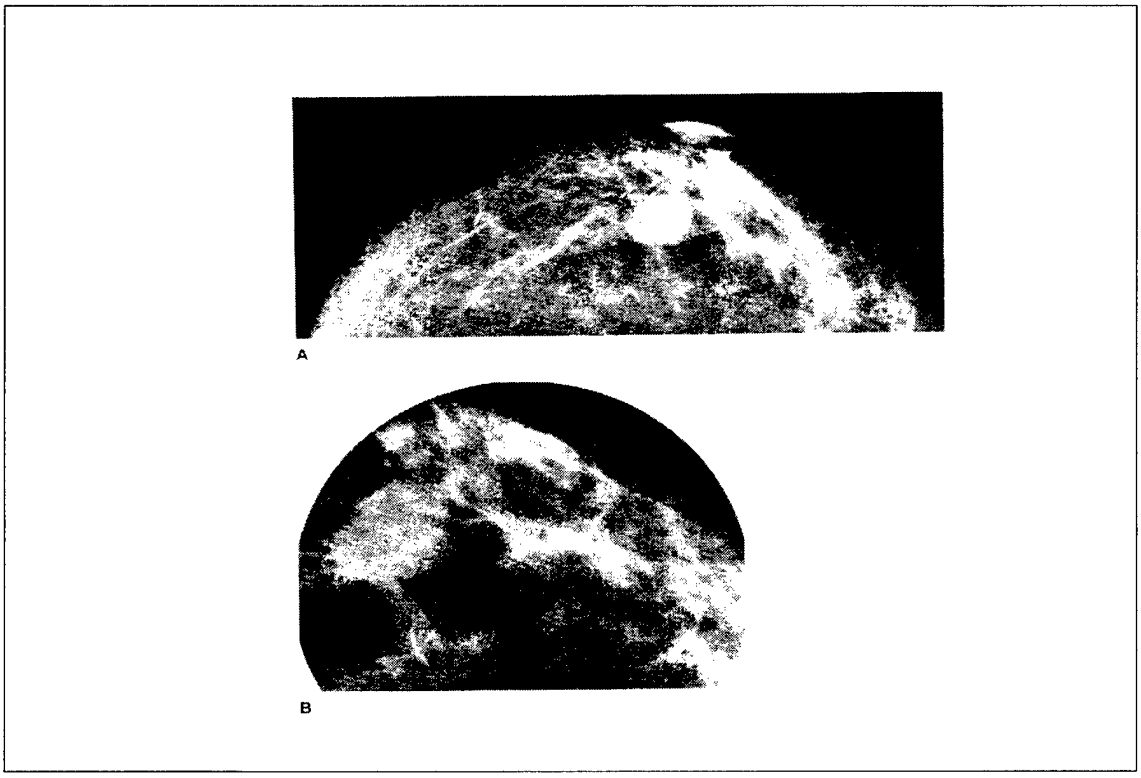
- **Cone or spot compression**
- **Magnification**

## 2. Ultrasound

SLIDE 109

When a mammogram is read as abnormal, a recommendation will usually be made for additional diagnostic views. At some facilities, these will be done at the same time as the screening views. At others, the patient will be called back. This call back is sometimes done by the radiology department, but usually the primary care physician is responsible for communicating the results of the mammogram and the need for further work up to the patient. As discussed previously, cone or spot compression is usually requested in order to delineate the edges of a density with more accuracy, magnification views are ordered to assess microcalcifications and small densities, and ultrasounds are ordered to differentiate cysts from solid masses.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.




SLIDE 110

This is another example of the application of diagnostic studies. The top film illustrates a smooth-walled mass on mammography. An ultrasound demonstrated the density to be solid. Although it appears smooth-walled on routine films, spot magnification delineates a poorly defined border. This finding warrants further work-up.

**Source:** Tabar L, Dean P. *Teaching Atlas of Mammography, 2nd Edition.* New York, NY: Thieme Medical Publishers, Inc., 1985.

## Occult Mammographic Abnormalities

# Category 3 Mammogram - *OPTIONS*

- **Interval mammography**
- **Image-guided biopsy**
- **Surgical removal**

SLIDE 111

Category 3 mammograms include indeterminate findings which could represent malignancy but are most often benign. Depending on the preferences of the patient, her risk factors and her hormonal status, options for a woman with a category 3 mammogram include 6-month follow-up of the lesion for 1 year with yearly follow-up for two more, image-guided biopsy, or surgical removal. The interventional techniques will be discussed at the end of this section. The patient chose surgical removal of the lesion demonstrated in the last slide and it proved to be a fibroadenoma.

**Sources:**

McCombs MM, Bassett LW, DeBruhl N, et al. Imaging-guided needle biopsy of the breast. In: Bassett LW, Jackson V, Gahan R, et al (Eds.), *Diagnosis of Diseases of the Breast.* Philadelphia, PA: W.B.Saunders, 1997.

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

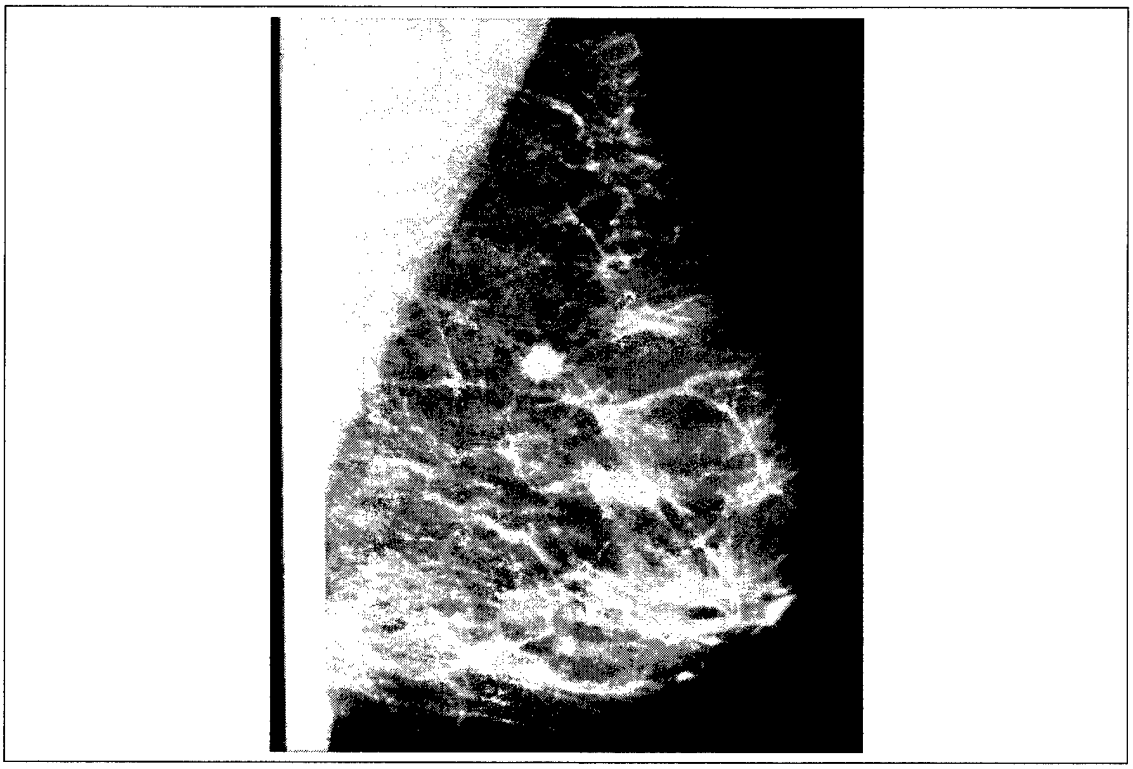
SLIDE 112

The arrow on the left side of this slide demonstrates the presence of microcalcifications which appear suspicious for malignancy. Magnification views demonstrate the pleiomorphic nature of these calcifications, raising the index of suspicion. Rather than being suspicious, most mammographic calcifications are associated with benign processes (80% of the time), and it is helpful for patients to understand this. Terms used to describe benign-appearing calcifications include "scattered, punctate, milk-of-calcium, or lobular," among others. Malignant descriptors include terms such as "clustered, pleiomorphic, granular, or casting," among others. This mammogram is classified at least as a category 4. To be most cost-effective, the abnormality should be removed surgically rather than undergo radiologic intervention, as the chances of malignancy are extremely high and one procedure will potentially be both diagnostic and therapeutic.

**Sources:**

Tabar L, Dean P. *Teaching Atlas of Mammography, 2nd Edition.* New York, NY: Thieme Medical Publishers, Inc., 1985.

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 113

The density in the upper portion of this film is an example of a mass with irregular borders and, in this case they are spiculated. This is highly suggestive of carcinoma, and a surgical excision will be necessary.

**Source:** Tabar L, Dean P. *Teaching Atlas of Mammography, 2nd Edition.* New York, NY: Thieme Medical Publishers, Inc., 1985.

## Occult Mammographic Abnormalities--Work-up

## *Interventional Procedures*

- **Image-guided biopsy**
  - **Ultrasound**
  - **Stereotaxic**
- **Surgical excision**
  - **Needle localization/biopsy**

SLIDE 114

Mammograms read as category 3 (probably benign or indeterminate) can be managed by the primary care clinician or by referral, depending on the preferences and anxiety level of the woman and the confidence of the clinician in her/his own skills as well as those of the interpreting radiologist.

As indicated earlier, if a mammogram is read as indeterminate (category 3) a patient has three options: interval mammography with intervention if there are changes, image-guided biopsy, or surgical excision. This section briefly explains the techniques used in interventional procedures from the patient's perspective. There are three types of interventional procedures: Image-guided biopsy under either ultrasound, or stereotaxic guidance, or surgical excision using needle localization/biopsy.

**Sources:**

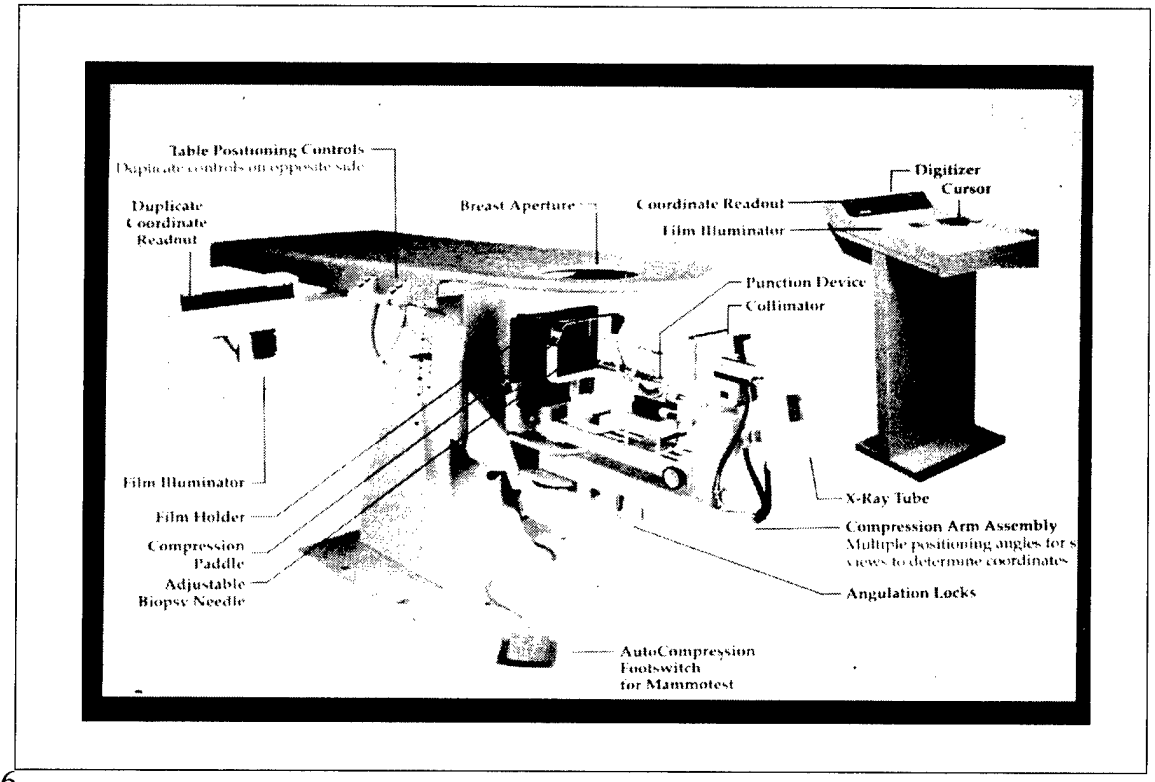
McCombs MM, Bassett LW, DeBruhl N, et al. Imaging-guided needle biopsy of the breast. In: Bassett LW, Jackson V, Gahan R, et al (Eds.), *Diagnosis of Diseases of the Breast.* Philadelphia, PA: W.B.Saunders, 1997.

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

SLIDE 115

When an interventional procedure is done under ultrasound guidance, the patient is placed in the supine position. The procedure is relatively comfortable, although the equipment for it is visible to the patient, which can be troubling for some.

**Source:** Acoustic Imaging Technologies Corporation Brochure, Phoenix AZ, 1996.




SLIDE 116

When an interventional procedure is done under stereotaxic guidance, the patient lies prone for the procedure, with her head turned to the side. This position may be difficult to sustain for frail women or those with shoulder or neck arthritis, as the procedure takes approximately 45 minutes. Women over 300 pounds are not candidates because the table for the procedure will not accommodate the weight of the patient. All of the equipment is located under the table, out of the patient's view. The procedure requires breast compression which can make it uncomfortable for some patients. An alternative stereotaxic device attaches to a standard mammogram machine and the patient sits during the procedure, but its use is not common.

**Source:** Kopans DB (Ed.) *Breast Imaging*. Philadelphia, PA: Lippincott-Ravin, 1997.

## Occult Mammographic Abnormalities--Work-up

## *Interventional Procedures*

# IMAGE-GUIDED BIOPSY

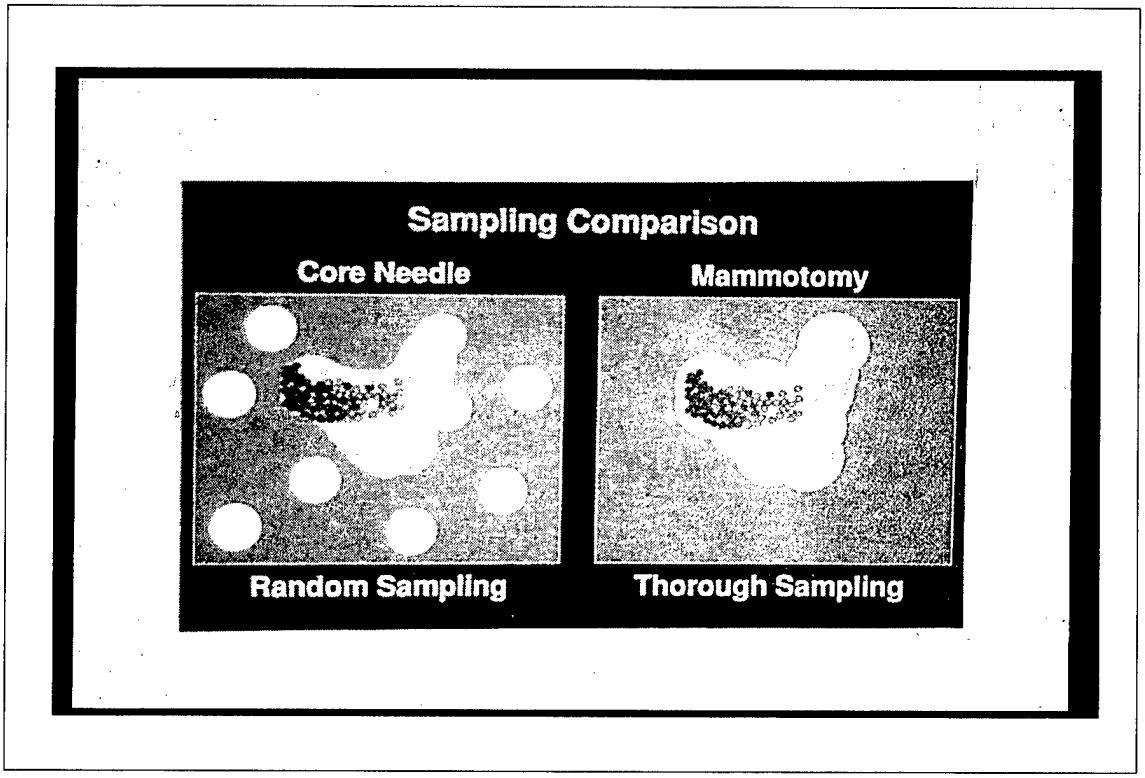
- **Fine needle aspiration**
- **Core biopsy**
- **Mammotome**

SLIDE 117

There are three biopsy methods that can be performed under image guidance, whether using ultrasound or stereotaxic techniques. The radiologist will select the most appropriate for each patient and lesion. Fine-needle aspiration uses a 21-23 guage needle and samples tissue cytologically. Core biopsy and mammotome procedures sample tissue histologically.

Image-guided biopsies provide a more definitive answer than interval mammography while avoiding surgical intervention.

**Source:** Kopans DB (Ed.) *Breast Imaging*. Philadelphia, PA: Lippincott-Ravin, 1997.




SLIDE 118

Core needle biopsies are done with 14 to 18-gauge devices that take a random sampling of tissue. A mammotomy removes all of the radiologic abnormality through a series of sequential core biopsies aided with a suction device. Another technique called ABBI uses a 1-2 cm large coring device to remove an abnormality. This can only be done under stereotaxic guidance. Neither the ABBI or mammotome techniques are widely available in 1999, but they are becoming more common. Many protocols for image-guided biopsies require interval follow-up to ensure mammographic stability of the lesion. The false-negative rate is yet to be firmly established, but early indications are that it is quite low.

Sometimes a woman desires a definitive answer regarding an indeterminate mammographic lesion, and in this case, needle localization/biopsy will be recommended.

**Sources:**

Parker SE, Jobe WE (Eds.). *Percutaneous Breast Biopsy*. New York, NY: Raven Press, 1993.
Oncology News, *"Mammotomy Technique May Reduce Biopsy Sampling Errors,"* 1997, 6:3, 7.
Meyer JE: Value of large-core biopsy of occult breast lesions. *AJR* 1992;158:991-992

## Occult Mammographic Abnormalities

# *NEEDLE LOCALIZATION*

- **Mammographic Guidance**
- **Ultrasound Guidance**
- **Stereotaxic Guidance**

SLIDE 119

When surgical excision of an occult mammographic abnormality is preferred for category 3 mammograms or recommended for category 4 or 5 mammograms, the radiologist will perform a needle localization prior to the procedure. This can be done using any of the three imaging techniques already discussed.

Although routine mammographic guidance is usually preferred, it is important to know that the procedure depends on the skill of a radiologist to estimate the location of an occult abnormality using two mammographic images, the craniocaudal and straight medial-lateral view. Note that the latter view is different from the mediolateral-oblique view done during screening mammography. If the lesion is not visible on both views, mammographic needle localization is difficult and usually impossible.

Cancellation of a surgical procedure due to inability to localize the abnormality in both views can be extremely distressing to patients and their families. The most comforting discussion that a patient can have under these circumstances is an explanation of why the event occurred, the current impression of the mammographic abnormality, and a plan of action for further work up.

**Source:** Hermann G, Schwartz I, Tartter PI (Eds.). Nonpalpable breast cancer: Diagnosis and management. New York, NY: Igaku-Shoin, 1992

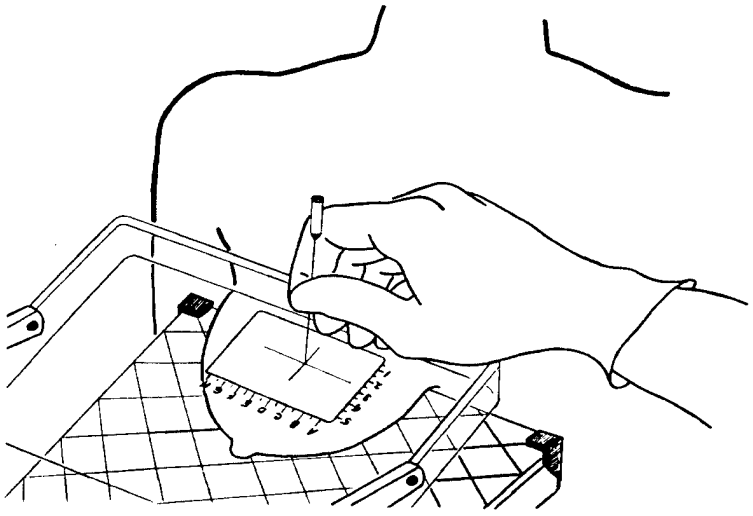


**Figure 4.4.** Needle localization.

SLIDE 120

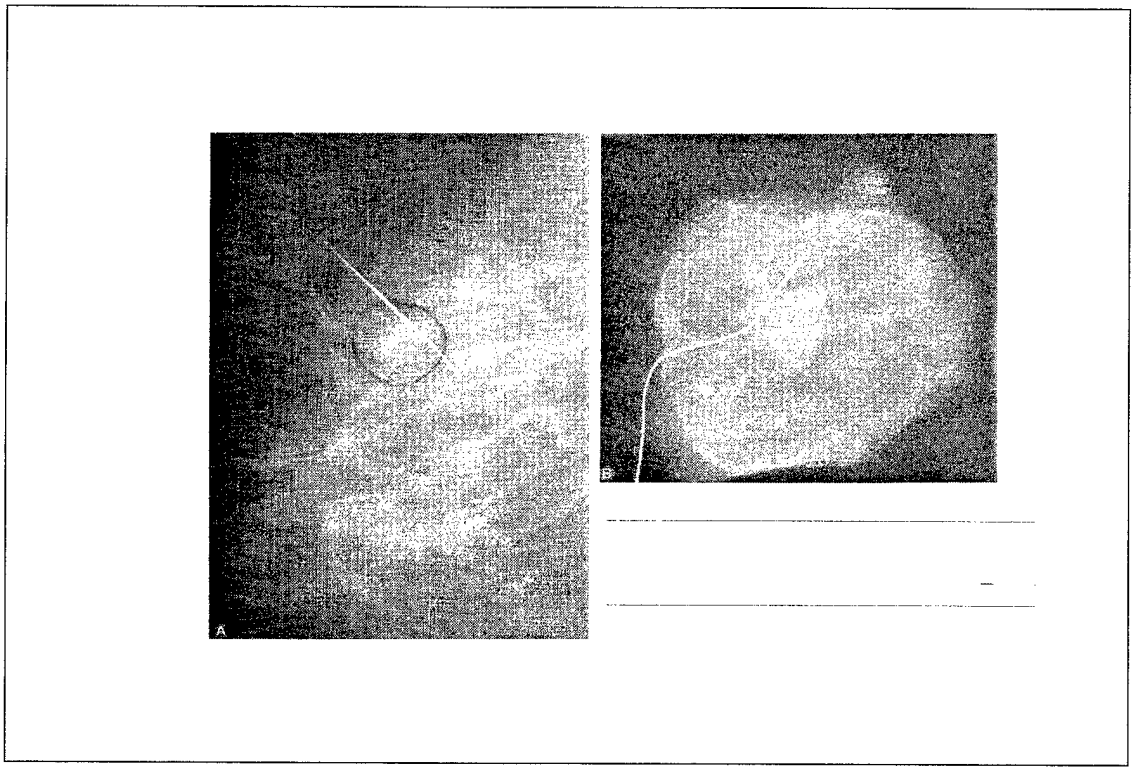
It is important for the referring provider to know that a patient is required to be in the sitting position during the needle localization procedure using standard mammography. Administration of sedatives prior to the procedure is contraindicated because of hypotension and loss of consciousness when upright. Despite this, most women tolerate the procedure well.

Alternative methods of localization include use of stereotaxic mammography, ultrasonography, or CT scan, all of which are usually capable of imaging an abnormality in a single view. It is important to know, however, that ultrasound is not capable of imaging calcifications and some other mammographic abnormalities, and lesions cannot be imaged using CT scan or stereotaxic techniques with 100% assurance. In these rare cases, interval mammography will be recommended.

**Sources:**

Hermann G, Schwartz I, Tartter PI (Eds.). Nonpalpable breast cancer: Diagnosis and management. New York, NY: Igaku-Shoin, 1992

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



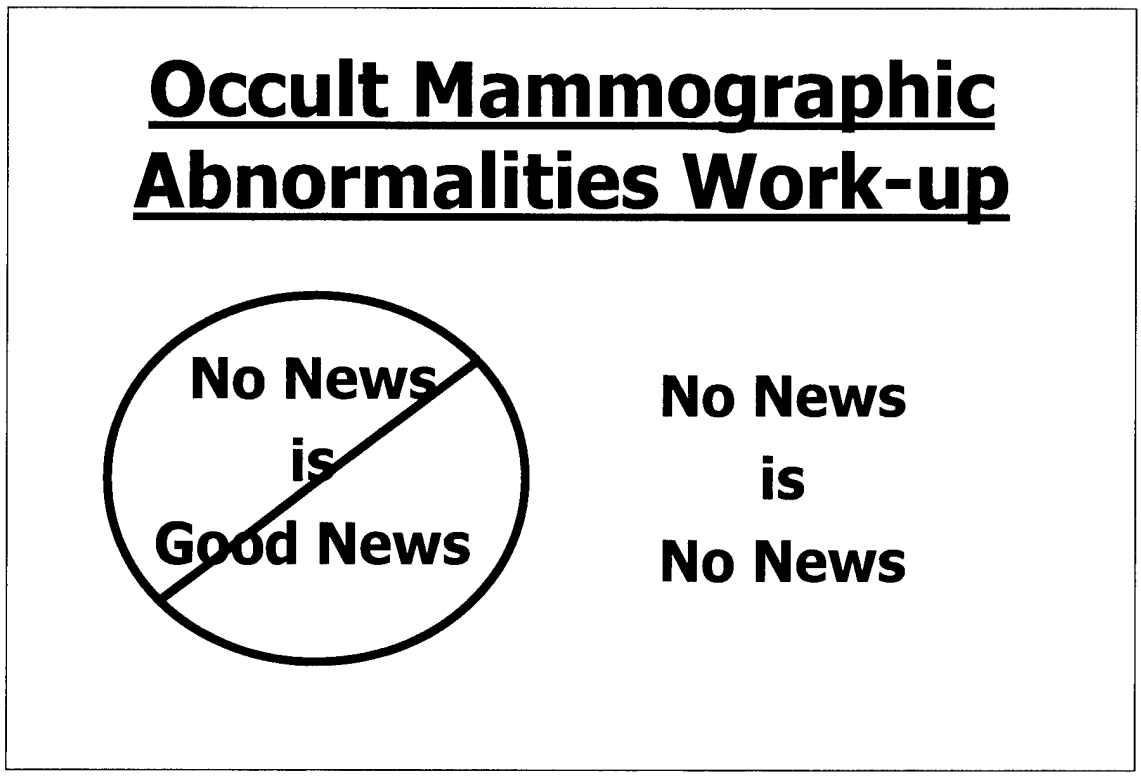
SLIDE 121

If needle localization can be accomplished, a needle will be directed towards the estimated location of the abnormality, an image obtained, and the needle redirected until it is as close to the abnormality as possible. A wire will then replace the needle and the surgeon will remove the abnormality using the wire as a guide. It is critical that the surgeon document successful removal of the abnormality by obtaining an intraoperative mammogram of the specimen (specimen mammogram), as shown on the right in the above slide. If unsuccessful, a second specimen is usually obtained and if that is unsuccessful, the needle localization/biopsy is repeated when the patient can tolerate it, usually in 2-3 weeks.

**Sources:**

Hermann G, Schwartz I, Tartter PI (Eds.). Nonpalpable breast cancer: Diagnosis and management. New York, NY: Igaku-Shoin, 1992

Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.). *Textbook of Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.




SLIDE 122

To conclude this section on work-up of occult mammographic abnormalities, a discussion of communication and follow-up is important. Many studies have documented that tracking and follow-up of abnormal screening mammograms is not optimal. It is the responsibility of the clinician ordering the mammogram to be sure that the results are obtained and that follow-up of abnormalities is done in a timely fashion. It is very helpful to have the patient involved in the follow-up loop. A "no-news-is-good-news" policy for reporting results is not an optimal policy and a tracking system with clear communication of results to all patients should be considered as a sound alternative from both risk management and patient care perspectives. Do not depend on the receipt of reports as your only method of tracking. It is possible for reports to be delayed, filed inappropriately, or never received at all. An algorithm summarizing the work up of a non-palpable mammographic abnormality can be found in Appendix 4.

**Sources:**

Bassett LW, Henrick RE, Bassford TL, et al. *High-Quality Mammography: Information for Referring Providers.* Quick Reference Guide for Clinicians No. 13. Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services, 1994. AHCPR Publication No. 95-0633

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998: Vol. 3. No. 5, http://www.Medscape.com. (Appendix 10).

# Signs and Symptoms of Breast Disorders:

# Breast Mass

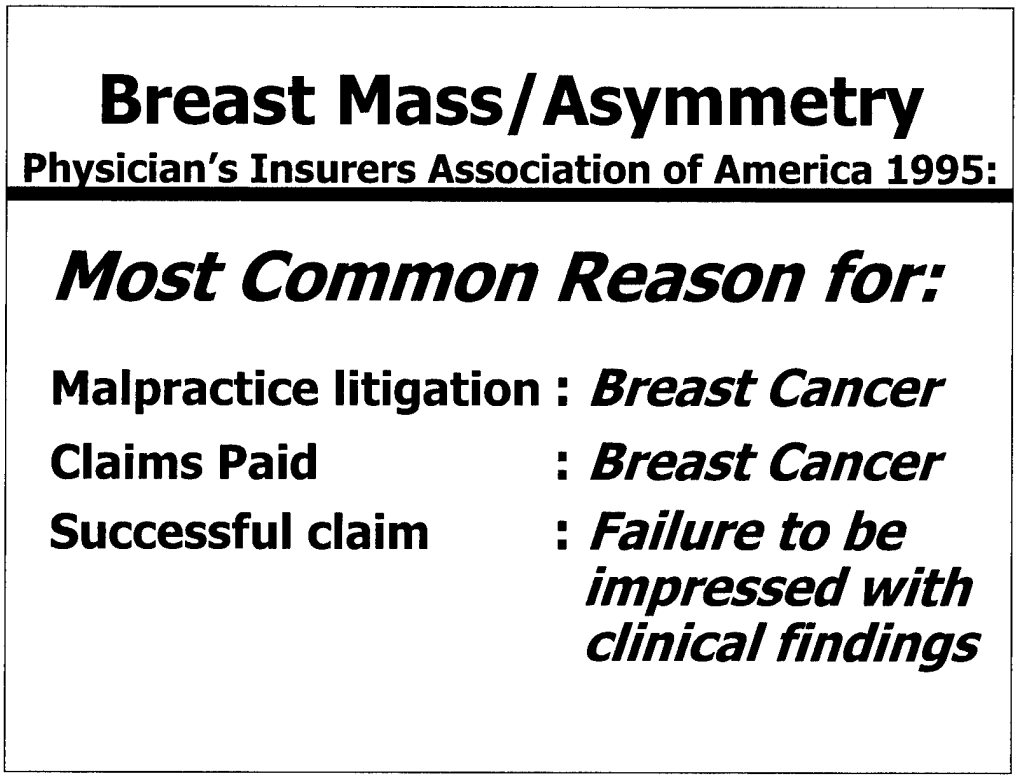
# or

# Asymmetrical Thickening

SLIDE 123

Breast cancer presents as a palpable mass in the majority of cases, despite the widespread use of screening mammography. The prevalence of benign breast masses compared to those of malignant origin is at least 4:1. Distinguishing between benign disease and malignancy can be challenging, and demands balance between the goals of high quality, cost-effective care that maximizes the timely diagnosis of malignancy, while avoiding unnecessary surgical biopsy.

**Source:** Rimer B. *Breast Cancer Screening*. Philadelphia, PA: Lippincott-Raven, 1996.




SLIDE 124

In a 1995 study by the Physician's Insurers Association of America, the most common reason for malpractice litigation was breast cancer. Breast cancer claims also accounted for the highest amount of claim dollars paid. The most common error made by physicians in these cases was to discount either the patient's or their own findings of a palpable abnormality on CBE.

**Source:** Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of American, 1995.

# Breast Mass/Asymmetry

**Median Tumor Size**

| | |
|---|---|
| **Routine CBE** | **- 28mm** |
| **Experienced examiners** | **- 16mm** |
| **Screening mammography*** | **- 13mm** |
| **Physical palpation threshold** | **- 6mm** |

***Goal of screening mammography - >50%* Stage 0 or I**

SLIDE 125

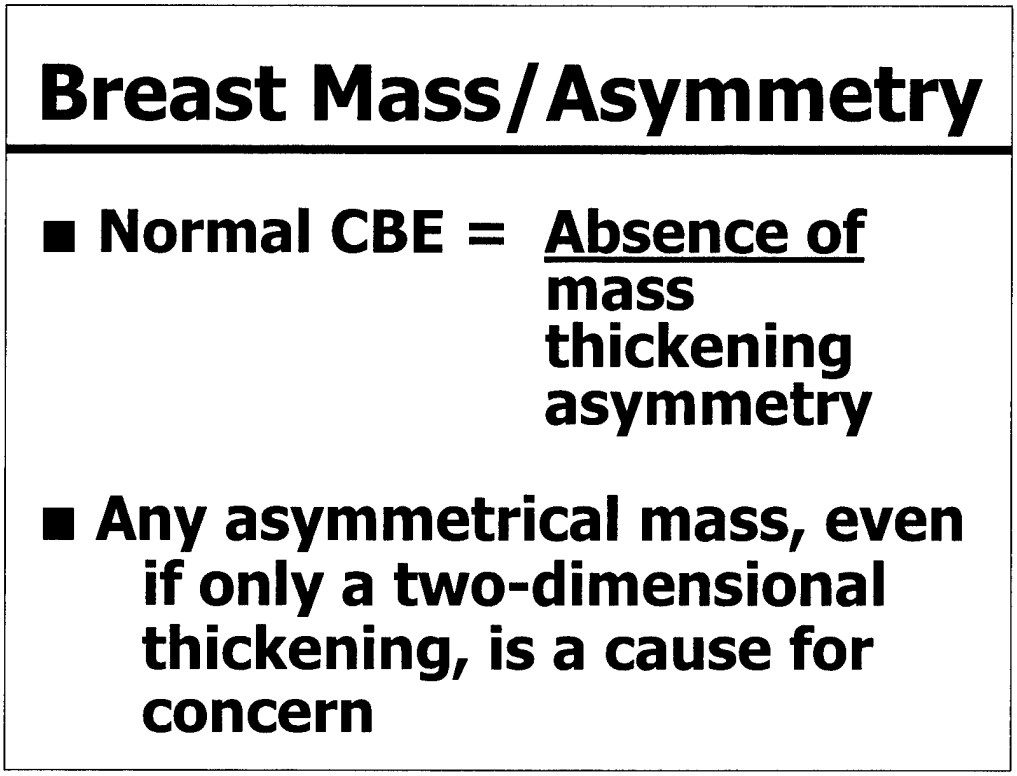
In the 1940s, when BSE was first advocated, the majority of breast cancer presented in locally advanced stages. The breast exam was not considered part of the routine physical exam, and the tumor size at diagnosis was usually greater than 5 cm.

As mammography screening trials began in the 1970s, we began to ask ourselves whether we could palpate what the x-ray demonstrated. This feedback allowed our skills to improve. Currently, the mean size of palpable breast cancer is 28 mm, and of mammographically detected cancer, 13 mm. The threshold for detection of palpable tumors is much lower, however, estimated to be about 6 mm, and about 3 mm for some mammographic tumors. Most breast cancers examined by those with experience are palpable by about 16 mm in size. The goal of the session this afternoon will be to teach the skills of palpation of tumors 1 cm or less in size. This section of the workshop will focus on work up of detected palpable abnormalities.

**Sources:**

Reintgen D, Berman C, Cox C, et al. The anatomy of missed breast cancers. *Surg Oncol* 1993;2:65-75.

Bassett LW, Liu T-H, Giuliano AE, et al. The prevalence of carcinoma in palpable vs impalpable mammographically detected lesions. *AJR Am J Roentgenol* 1991;157:21-24.

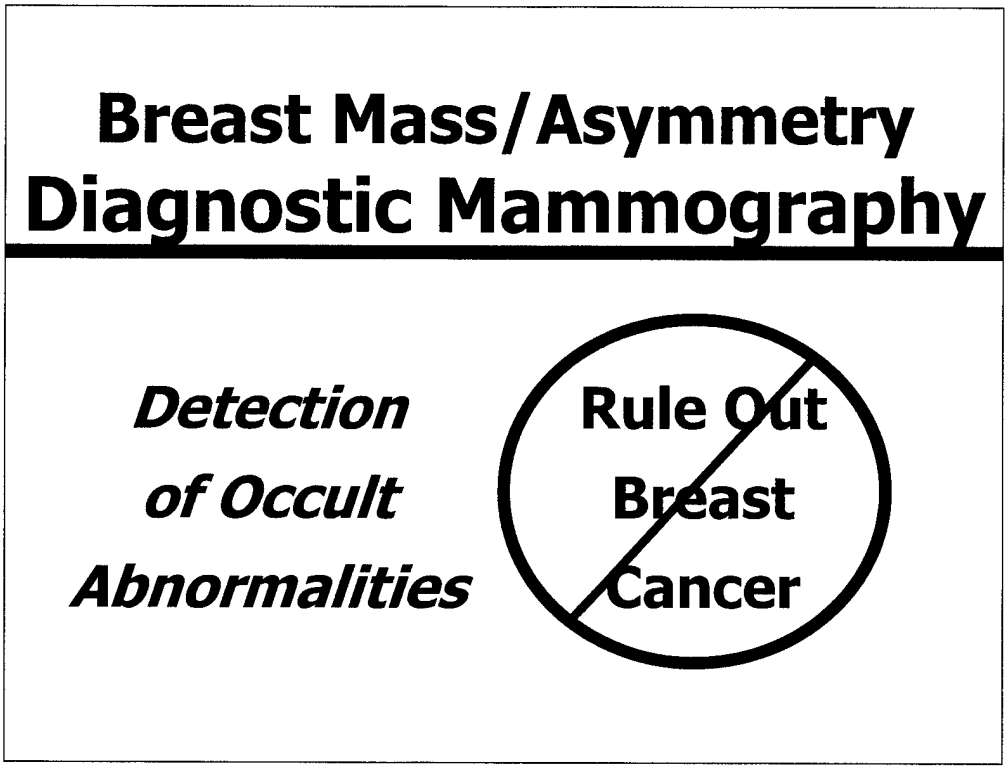



SLIDE 126

The detection and diagnosis of breast masses is far more challenging than in the past, and can be subtle. The definition of a normal clinical breast exam is one of exclusion - the absence of an abnormality.

Although it is correct that breast cancer usually presents as a three-dimensional firm, non-tender mass, exceptions to this statement make reliance on it to distinguish cancer from benign disease very hazardous. Any asymmetrical mass, even if only a two-dimensional thickening, demands further attention.

**Source:** Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.

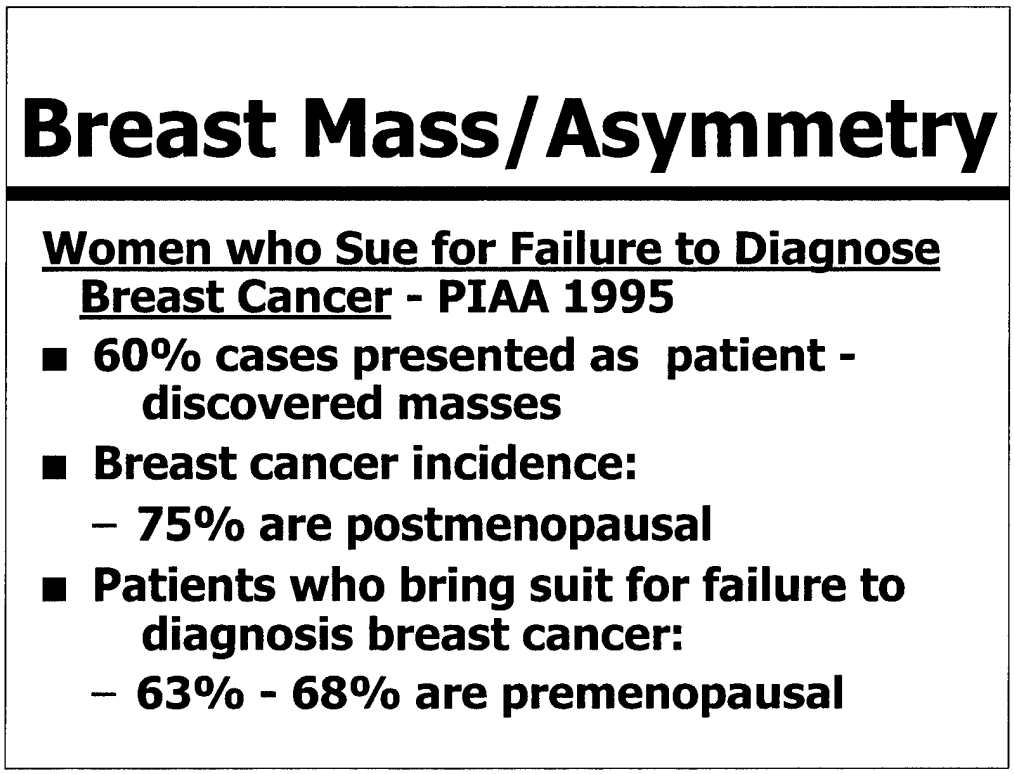



SLIDE 127

Up until this point, we have discussed mammography in asymptomatic women. Its application in symptomatic disease is much different and this understanding is critical in making a timely diagnosis of breast cancer.

Mammography in a women with a breast mass is primarily done to rule out clinically occult lesions in the non-involved breast tissue. **Diagnostic mammography is <u>not used</u> to rule out breast cancer in the palpable abnormality, and this point cannot be overemphasized.**

**Source:** Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.




SLIDE 128

In the 1995 PIAA study, 60% of the women with breast cancer presented with a self-discovered mass. Although most women who present with breast masses who have breast cancer are post-menopausal, the majority who sue for failure to diagnose breast cancer are premenopausal.

**Sources:**

Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74-271-278.

Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of American, 1995.

## Breast Mass/Asymmetry

# False Negative Mammography

**Breast Cancer Detection & Demonstration Project**

| AGE | Rate of False-Negative Mammography |
|---|---|
| 40 | 36% |
| 70 | 9% |

**Physician Insurance Association of America 1995**

| Mammogram Results | Frequency |
|---|---|
| Normal | 49% |
| Equivocal | 19% |
| Abnormal | 32% |

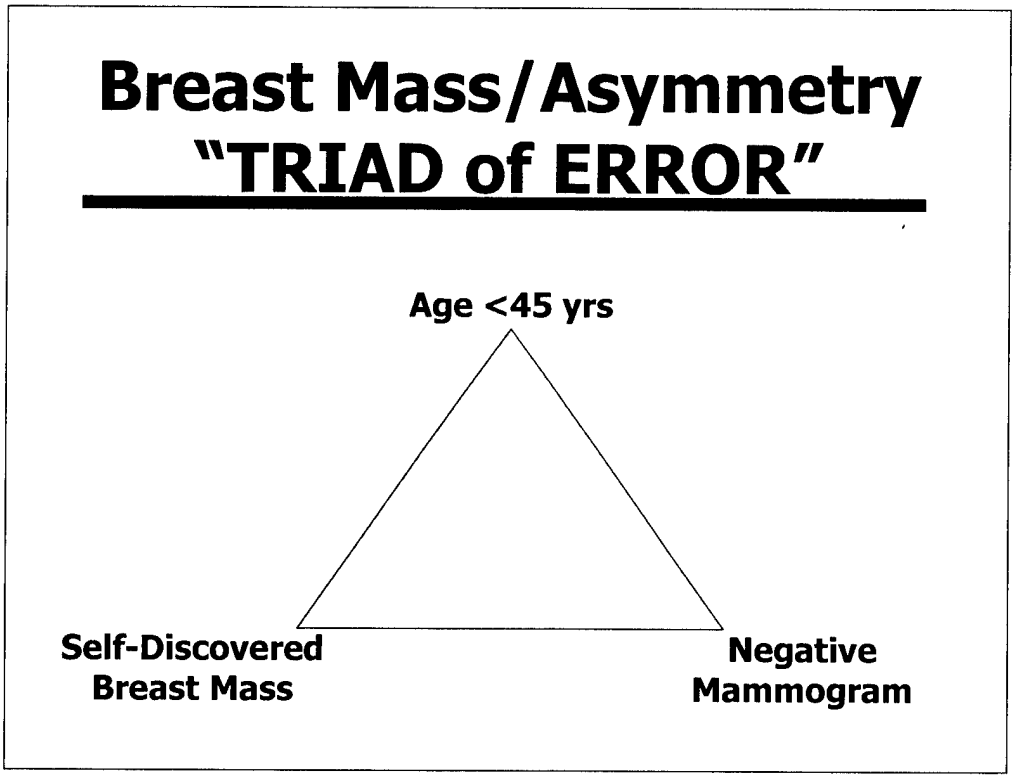
SLIDE 129

Although mammograms can be read as normal in women with breast masses because of technical or reading errors, obscuring of the lesion by dense normal tissue is the most common reason for a false-negative mammogram. Dense tissue is more common in young women but can occur in any age group. In the Breast Cancer Detection and Demonstration Project in the late 1970s and 1980s, 36% of women aged 40 with breast cancer had a normal mammogram, compared with 9% of women 70 years of age. In a population of women who successfully sued for failure to diagnose breast cancer, almost 70% had a normal or equivocal mammogram.

**Sources:**

Kern KA. The delayed diagnosis of symptomatic breast cancer. In: Bland KA, Copeland EM (Eds.). *The Breast: Comprehensive Management of Benign and Malignant Disease.* 2nd Edition. Philadelphia, PA: WB Saunders Company, 1998, pp. 1588-1631.

Physician Insurers Association of America. *Breast Cancer Study.* Lawrenceville, NJ: Physician Insurers Association of American, 1995.




SLIDE 130

Kern has proposed a "triad of error" for the misdiagnosis of breast cancer. Although each is by no means necessary for diagnostic delay, together they account for 75% of cases filed for failure to diagnose breast cancer. This section of the curriculum is meant to outline the principles used to achieve a timely diagnosis of breast cancer while simultaneously avoiding needless work-up and/or referral.

**Source:** Kern KA. The delayed diagnosis of symptomatic breast cancer. In: Bland KA, Copeland EM (Eds.). *The Breast: Comprehensive Management of Benign and Malignant Disease*. 2nd Edition. Philadelphia, PA: WB Saunders Company, 1998, pp. 1588-1631.

# Types of Breast Masses

**I. Benign - Aberrations of Normal Development and Involution (ANDI)**

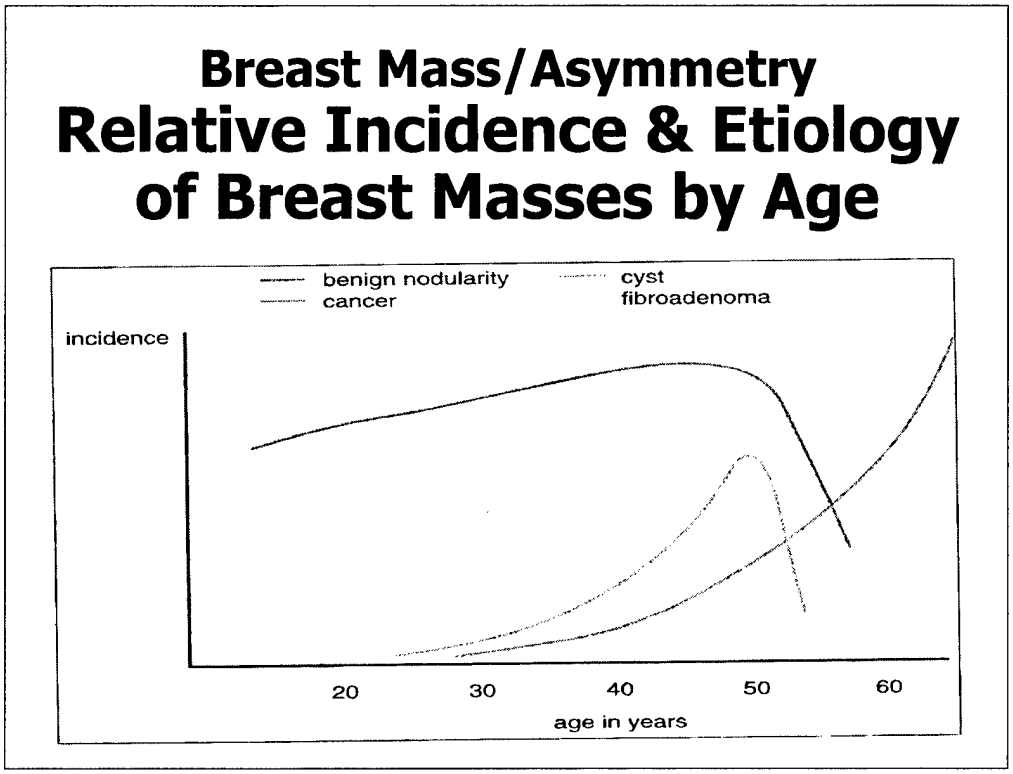
- **Cyst**
- **Fibroadenoma**
- **Fibrocystic mass**

**II. Malignant**

SLIDE 131

Before discussing the management of breast masses, it will be helpful to review the classification. Whether a thickening or a dominant mass, there are four basic types of palpable abnormalities that occur in a woman's breast. These include: 1) a cyst, 2) a fibroadenoma, 3) a fibrocystic mass, and 4) cancer.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 132

This slide demonstrates the relative incidence by age of the four common etiologies of breast masses. Note that:

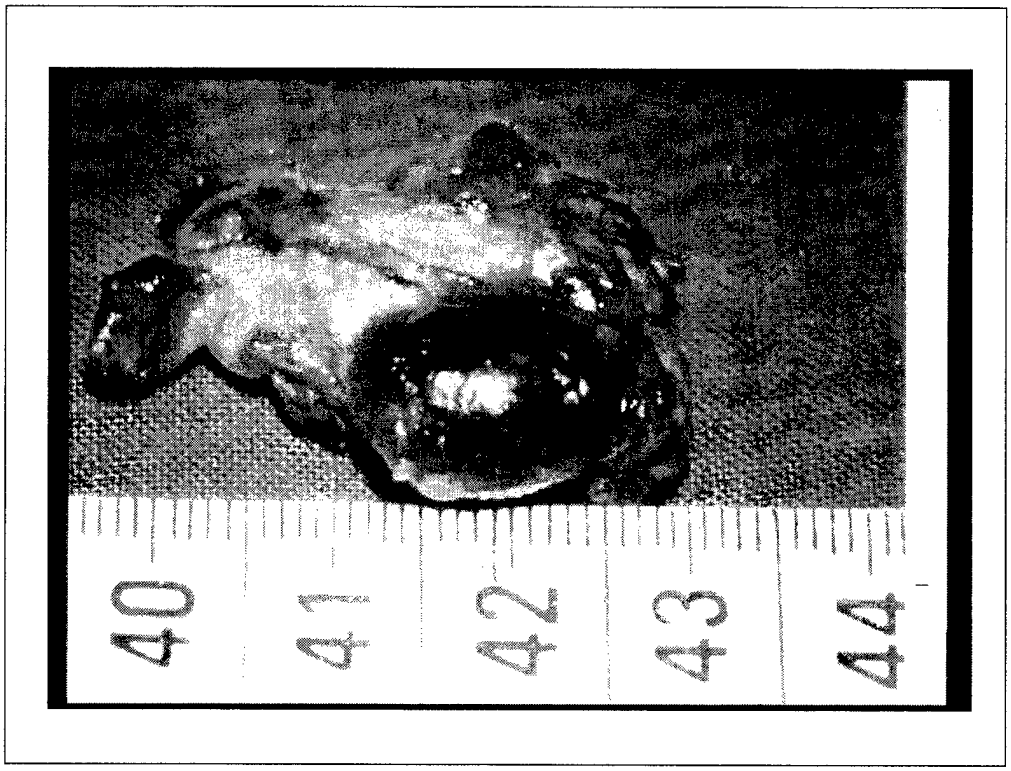
1) Fibroadenomas are common in adolescents and women in their 20s and 30s.

2) Cysts are most common in women in their 40s.

3) Benign breast nodularity is common at all premenopausal ages and uncommon after age 55.

4) In women above age 55, the most common etiology of a breast mass is cancer.

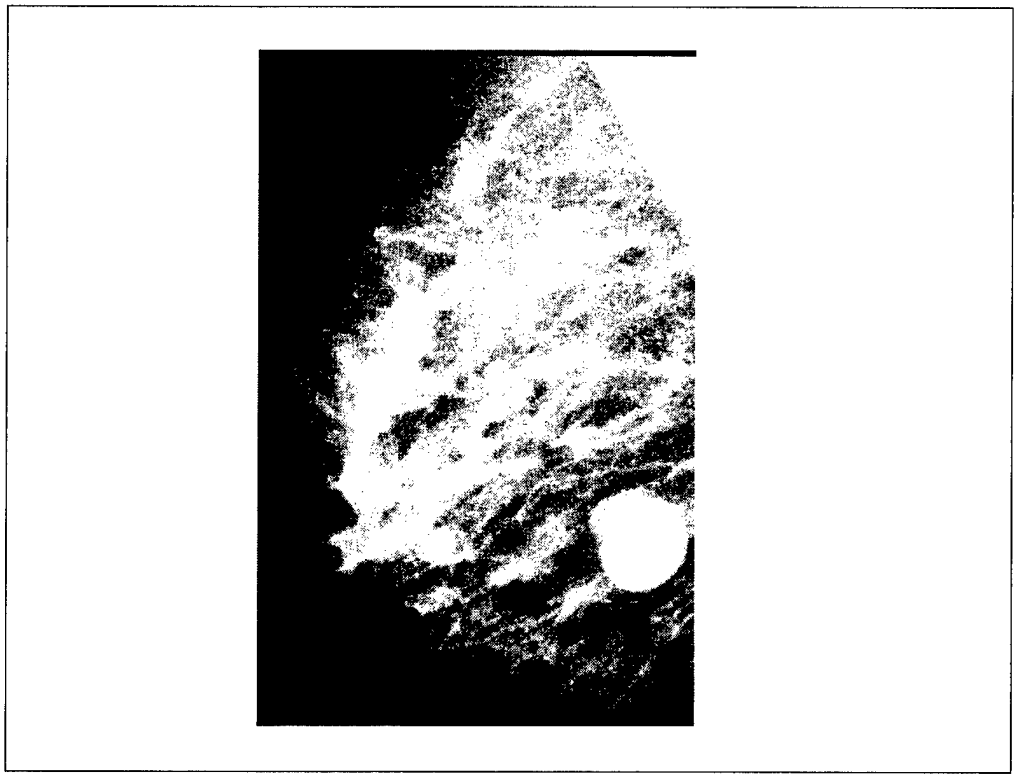
**Source:** Breast Lumps. In: Mansel RE, Rundred NJ (Eds.), *Color Atlas of Breast Diseases.* London: Times Mirror International Publishers Limited, 1995.




SLIDE 133

This is a cyst present on the underside of removed breast tissue. A breast cyst is similar to a cyst elsewhere in the body; it represents a fluid-filled structure which is benign. A breast cysts is a process of lobular involution and as such, is found mostly in perimenopausal women. It is uncommon to find cysts present in women before the age of 35. A cyst can exist in postmenopausal women, but is uncommon unless the woman is taking hormone replacement therapy. Keep in mind the gross appearance of a cyst. Because the sac is under tension, it cannot be distinguished from a solid mass by physical examination. Breast cysts are not usually removed in the operating room, but instead, are drained therapeutically in the office.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

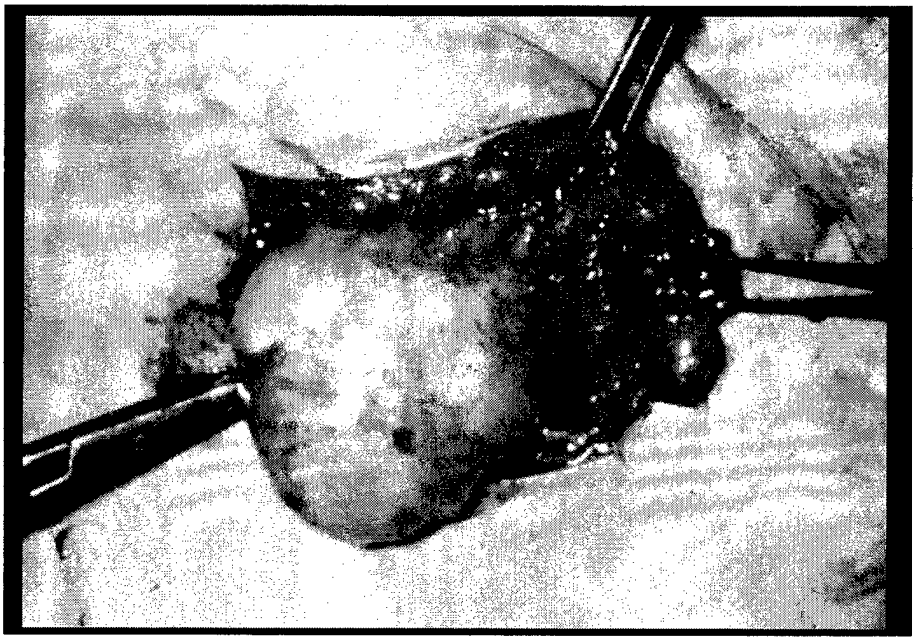


SLIDE 134

This mammogram demonstrates a round, smooth-walled density which could represent a fluid-filled or solid structure. The differentiation can be made by neither CBE nor mammography.

**Sources:**

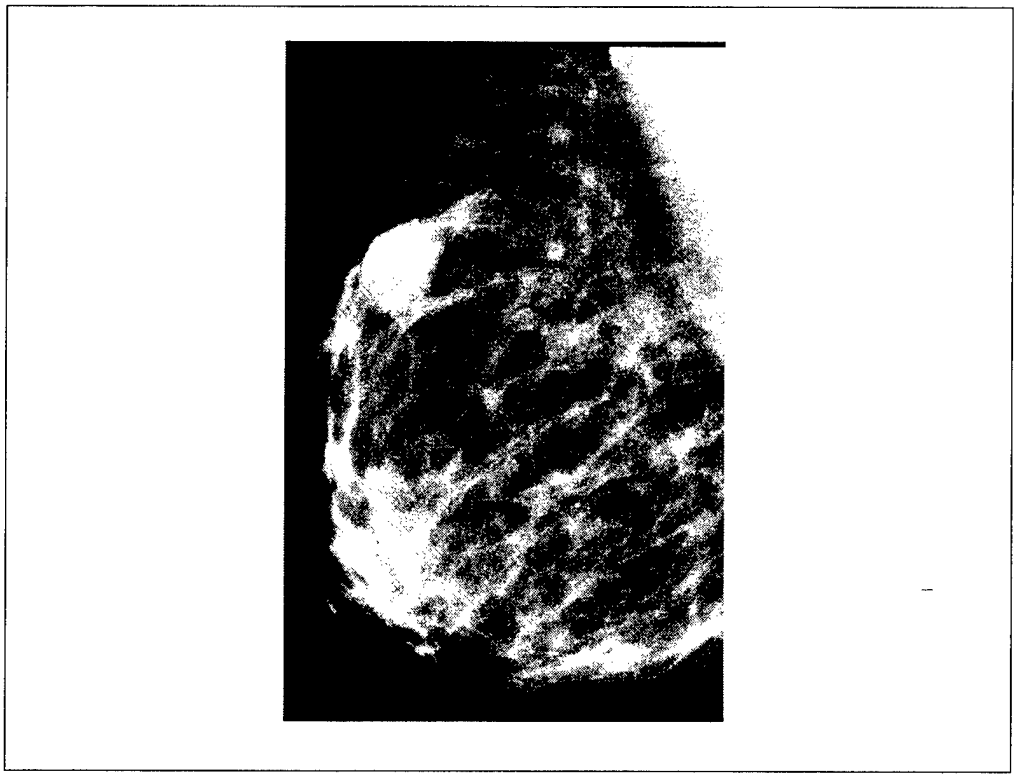
Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 135

This slide represents a fibroadenoma being removed in the operating room. A fibroadenoma is a benign solid mass that occurs most frequently in young women, beginning with adolescence. These masses are usually quite mobile on physical examination and represent a benign process of encapsulated connective tissue proliferation that incorporates epithelial elements within it. The mass has a smooth or lobulated characteristic on palpation.

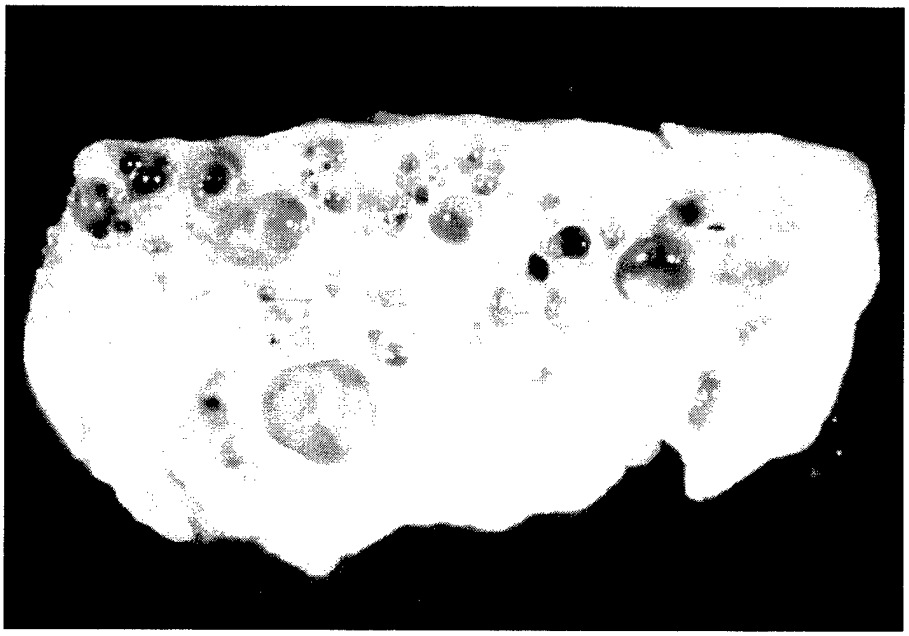
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 136

This slide represents a mammographic finding of a fibroadenoma. Notice that it appears exactly like the cyst in the previous mammogram. The radiologist will also read this report as a smooth-walled density consistent with a cyst or a fibroadenoma.

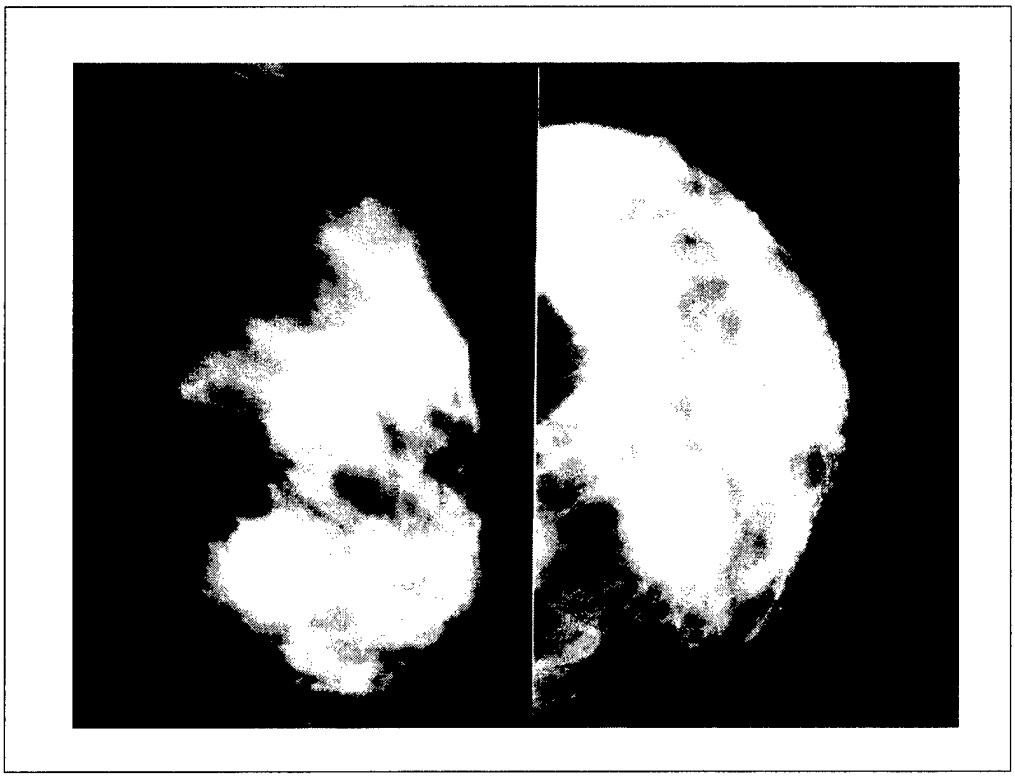
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 137

This is an example of fibrocystic change in the breast. Note the presence of several microcysts within the breast structure. The white portions on the slide represent the parenchymal and fibro-connective tissue. Women are often very fearful about the diagnosis of any type of fibrocystic change. Physicians often use this diagnosis to denote nodularity, but it must be made clear to the patient that this is an all - encompassing term which need not be feared. When it is made clinically rather than pathologically, reference is literally being made to nodularity which does not appear to be cancer clinically. It is often helpful to explain this to patients using this phrase. Fibrocystic change is very common in premenopausal women and in some postmenopausal women on hormone replacement therapy, owing to the influence of ovarian hormones on the physiology of breast tissue. Unfortunately, it is not possible to definitively distinguish a fibrocystic mass from a malignant one by physical examination or by radiologic studies. It is especially dangerous to attribute a changing breast examination to fibrocystic change in postmenopausal women, who should not be undergoing dynamic breast changes because ovarian function has ceased.

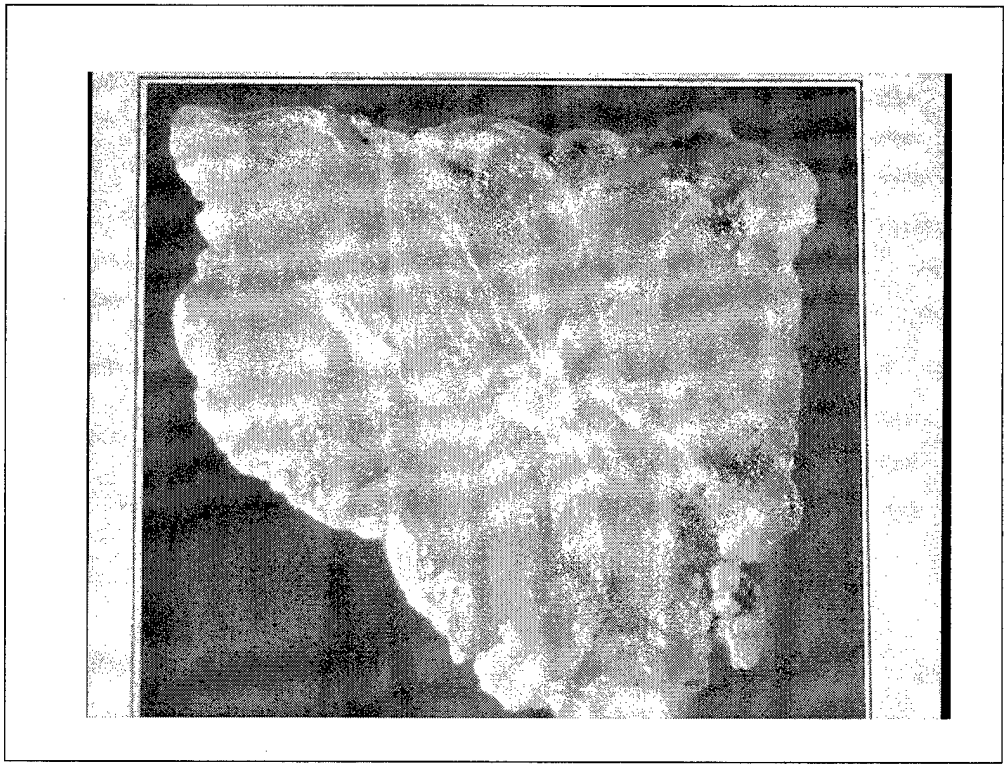
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 138

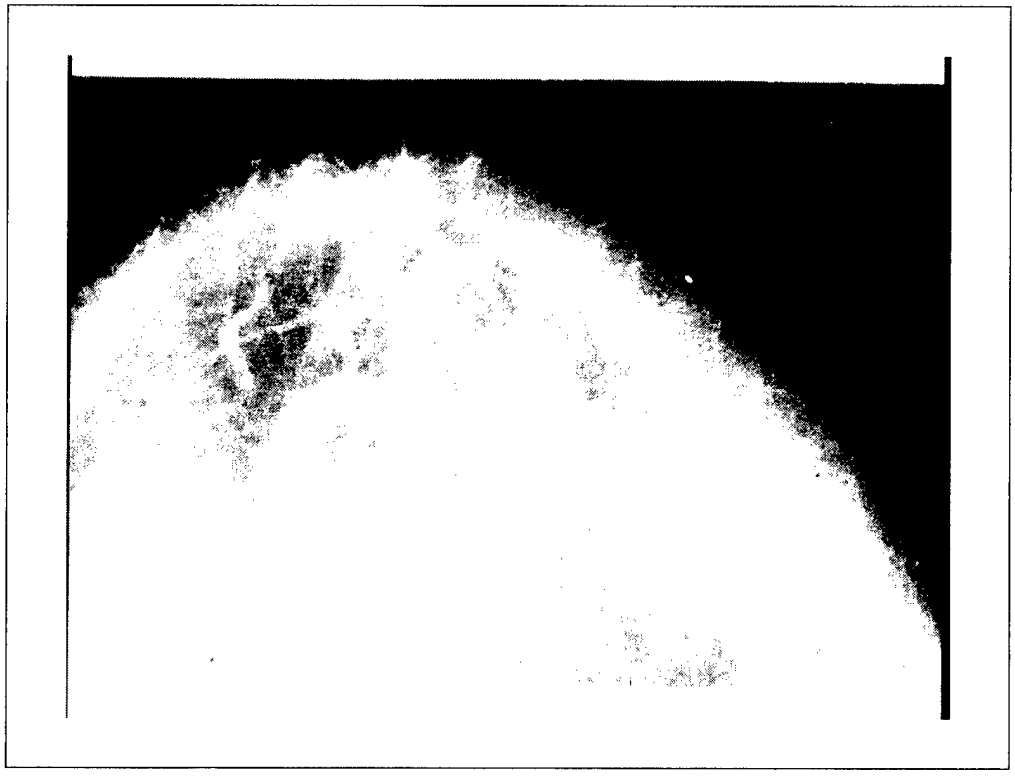
This is a mammogram demonstrating dense tissue with multiple cysts. It is very difficult to distinguish normal from abnormal findings in this mammogram.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



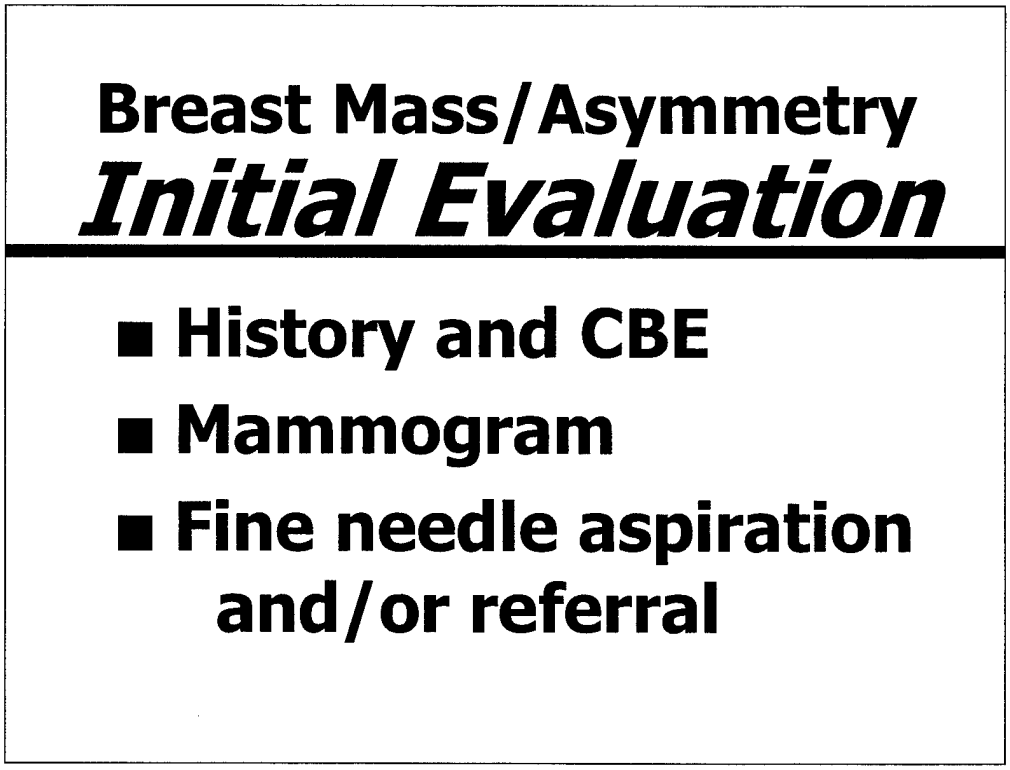
SLIDE 139

The white central area represents a spiculated mass and is malignant. It is surrounded by adipose tissue, a common finding in post-menopausal women. Any breast mass in a post-menopausal woman should be assumed to represent cancer until proven otherwise. Hormone replacement therapy may influence this caveat, as cysts are slightly more common in this setting.



SLIDE 140

This is how that mass would appear mammographically. Note the spiculated density in the mammogram, and the lucent appearance of the surrounding adipose tissue.




SLIDE 141

The complete evaluation of a breast mass involves three steps. They include:

1) A history and clinical breast exam

2) A mammogram before or after aspiration

3) A fine needle aspiration and/or referral

# Breast Mass/Asymmetry

## *HISTORY*

### *Step 1:* Read presenting complaint

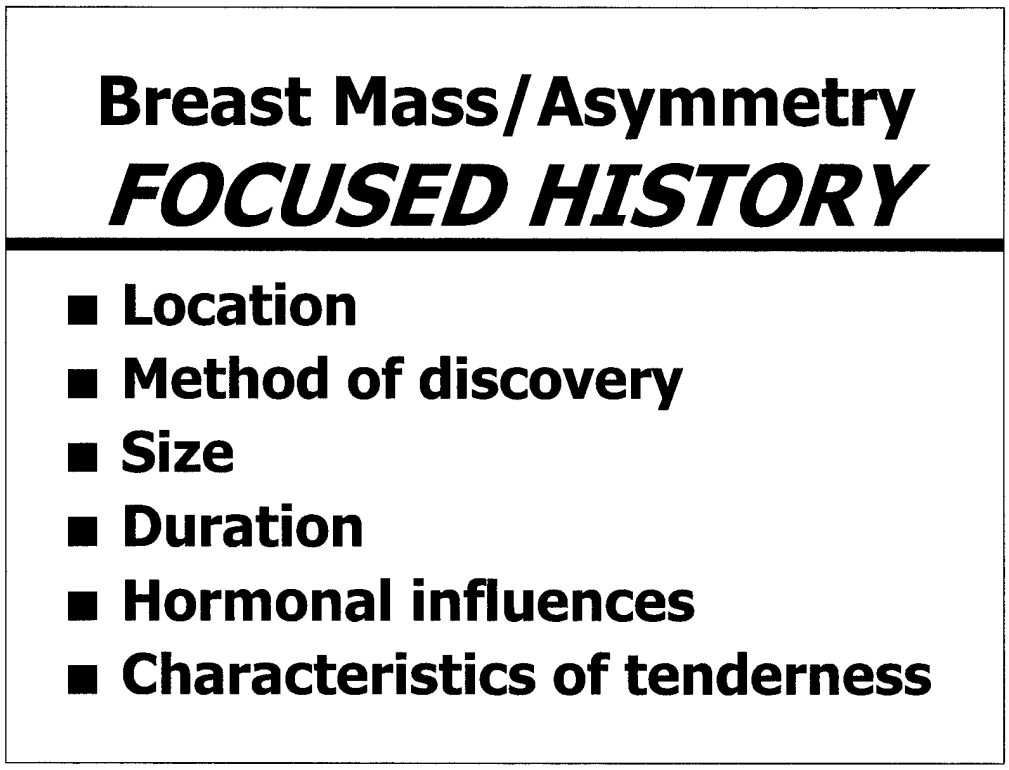
### *Step 2:* Employ a systematic method of inquiry

SLIDE 142

Many physicians rely on office assistants to room patients and solicit the reason for the visit. In the midst of busy days with many interruptions, the note written by the assistant will sometimes be inadvertently overlooked by the clinician. This is a dangerous habit from a risk management standpoint. Many women find it easier to tell an assistant, rather than a clinician, about a problem that causes them fear. If the clinician does not address the problem, the woman can easily assume that the clinician does not perceive the problem as significant and will do nothing to address it further until it is impossible to deny its significance.

Every clinician should have a systematic method to address a breast mass as a presenting complaint.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 143

The essential components of the inquiry include: **(1) Location:** Ask the woman to point to her area of concern with one finger. Document this area on the physical examination record pictorially, with an "X". **(2) Method of discovery:** Establish how familiar the woman is with her own breast examination. How often does the woman perform breast self-examination (BSE)? Did she discover the lump during BSE or by accident? Was it found in the supine position, standing in the shower, or by a different method? The evaluation may be very different if a patient is not sure that a mass is present and rarely does BSE, as opposed to a patient doing regular BSE who feels a difference on her exam compared to baseline. **(3) Size:** How big is the lump currently? Liken the size to familiar items, such as a pea, a grape, a walnut. **(4) Duration:** When was the lump first found? Has it changed since first date of discovery? **(5) Hormonal influences:** What is the woman's ovulatory status? Is she premenopausal? If so, does the mass change depending on the phase of her ovulatory cycle? Is she on hormone replacement therapy? **(6) Tenderness:** Is the mass tender? Does the tenderness change with the ovulatory cycle if she is premenopausal?

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

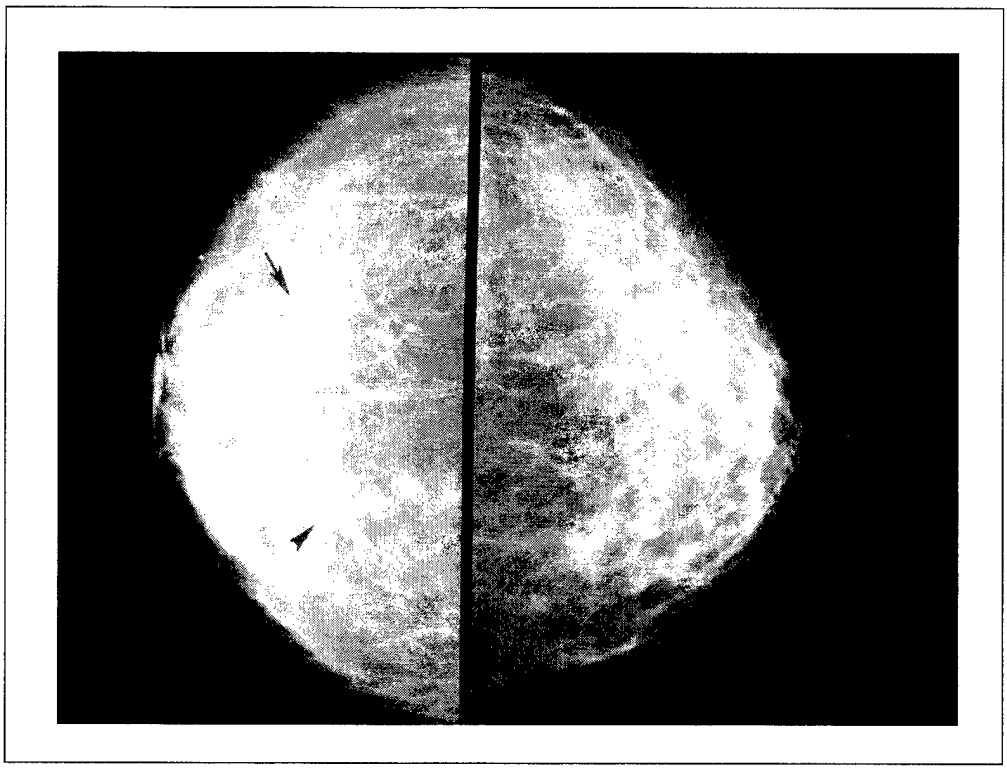
## Breast Mass/Asymmetry

# *Clinical Breast Exam*

SLIDE 144

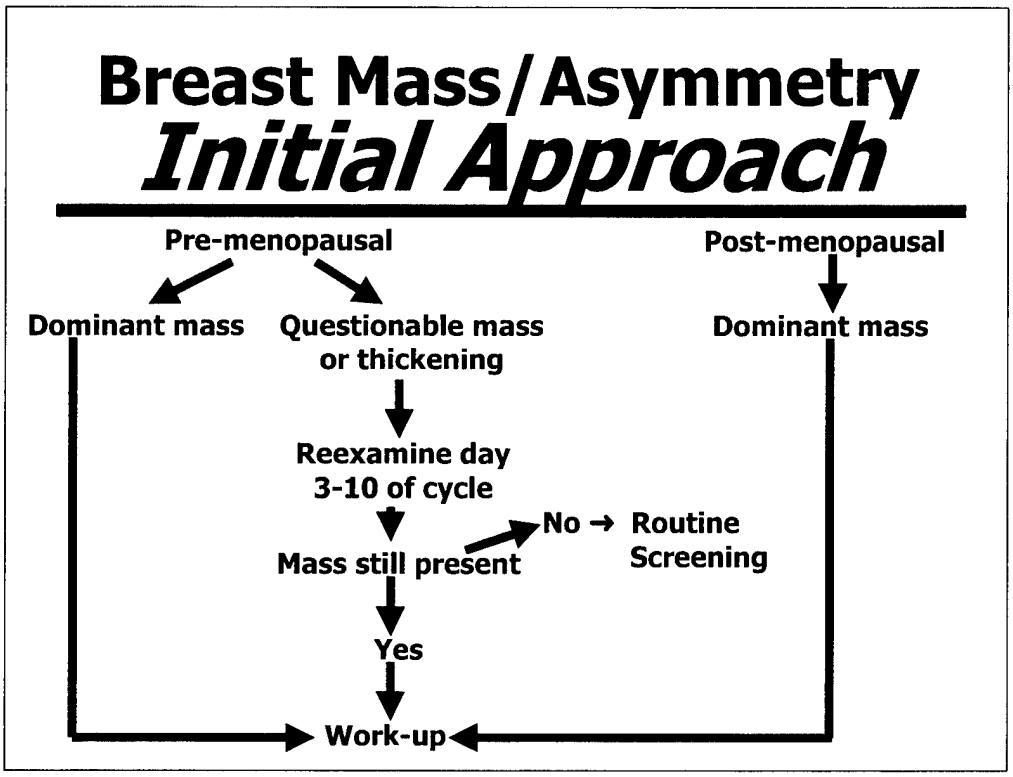
Our focus this afternoon will be skill teaching, practice, and evaluation of the clinical breast exam. Many physicians have acknowledged the inadequacy of their medical school experience in learning this skill and request refresher courses. The clinical breast exam will take time to perform correctly, but is one of the most important components of physical exam in the ambulatory patient.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 145

This diagnostic mammogram was performed in a woman who presented with a breast mass. In the upper portion of the slide, the palpable mass which proved to be a fibroadenoma is imaged. Also imaged is a non-palpable abnormality which proved to be a small infiltrating ductal carcinoma. This would have been missed had the mammogram not been ordered.




SLIDE 146

When a mass or asymmetry is confirmed on CBE, the initial clinical approach is dependent on the ovulatory status of the patient. Subtle abnormalities in premenopausal women are best approached by a repeat exam at the best phase of the menstrual cycle. Many masses resolve under these circumstances. If the mass persists, or if it is dominent, found in the best phase of the cycle, or present in a post-menopausal woman, immediate work-up should be pursued.

**Source:** Osuch JR. Abnormalities on physical examination. In Harris JR, Lippman ME, Morrow M, et al., (Eds.), *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.

# Breast Mass/Asymmetry

## CBE/Mammography

**It is impossible to distinguish a cyst from a solid mass by CBE or mammography**

## Fine Needle Aspiration (FNA)

**Purpose: To distinguish a cyst from a solid mass**

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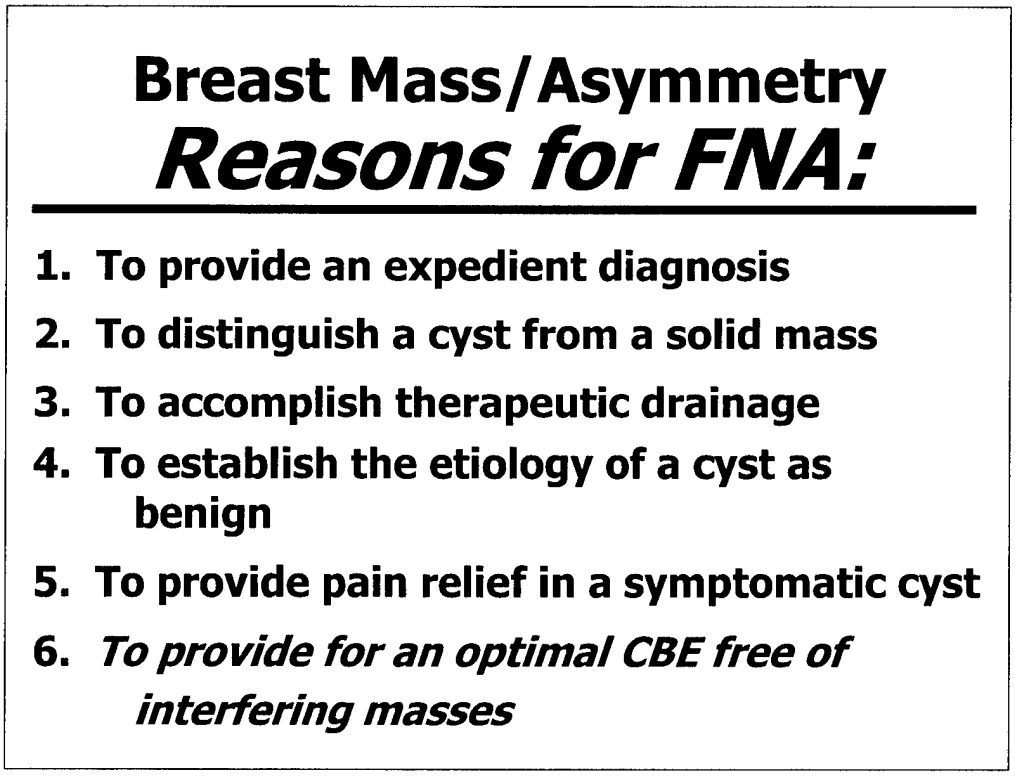
The clinician's single most important duty in a patient who presents with a breast mass is to establish the etiology of the mass as cystic or solid. This is impossible by either CBE or mammography. FNA refers to the insertion of a small needle into a mass with subsequent aspiration of its contents. FNA is possible using ultrasound guidance, but this is not necessary in the case of palpable masses. If a mass is solely cystic, it will disappear following a complete aspiration.

Ultrasound alone can also distinguish between cysts and solid masses, and as we have discussed , is the only method available for distinguishing the two in non-palpable abnormalities. For a palpable mass the most expedient and cost-effective method is needle aspiration.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

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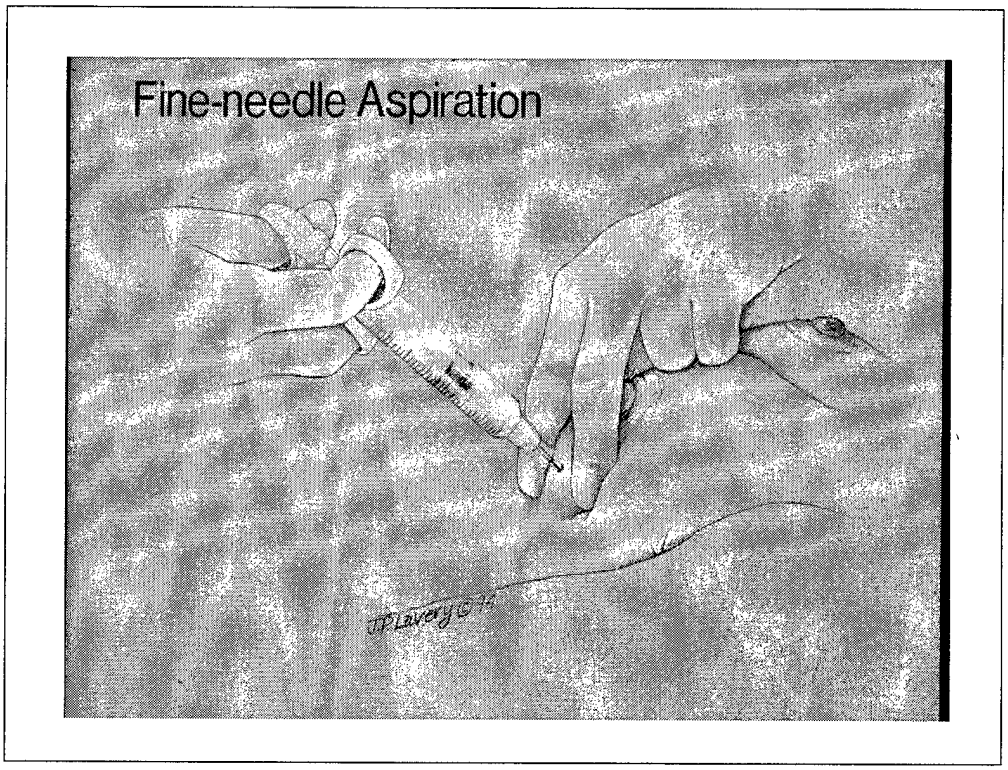
Needle aspiration of a breast mass: (1) provides for an expedient diagnosis; (2) distinguishes a cyst from a solid mass; (3) accomplishes therapeutic drainage; (4) establishes the etiology of a cyst as benign; (5) provides relief of pain in the symptomatic cyst, because cysts that are under tension are often tender, and *most importantly*; (6) provides for an optimal clinical breast examination free of interfering masses.

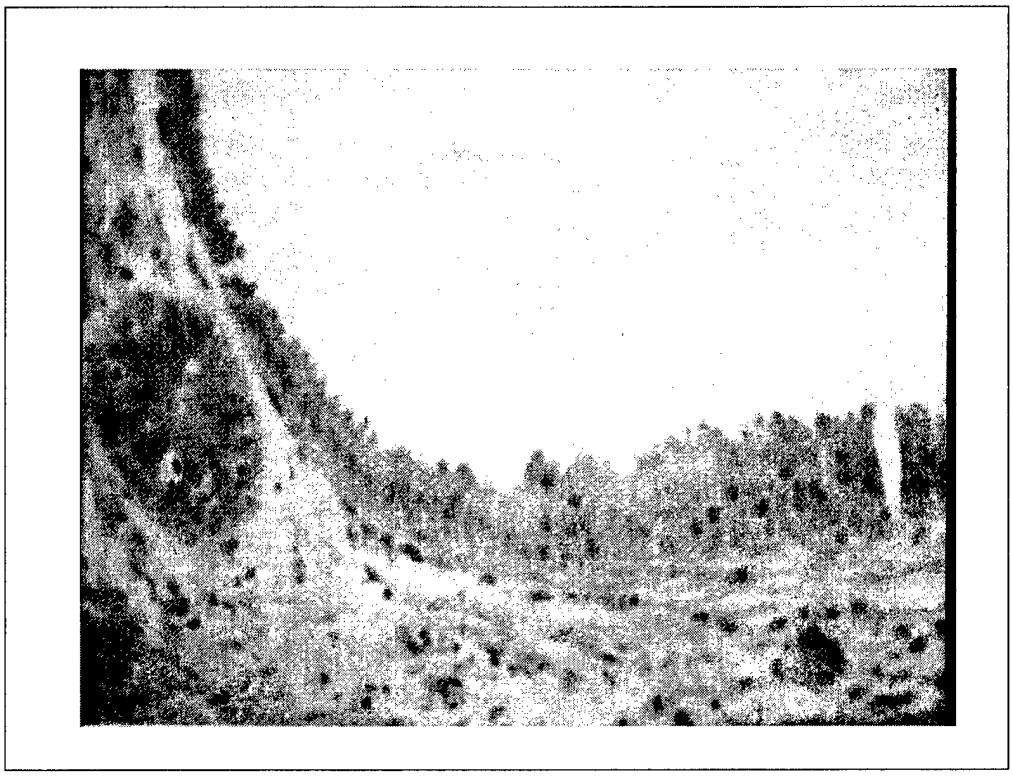
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 149

A cyst aspiration is a very simple procedure that can be done in the office setting. It involves the placement of a 21-23-gauge needle attached to a 5 cc - 10 cc syringe into the mass, with vacuum aspiration applied manually during the procedure. If the mass is cystic, fluid will fill in the barrel of the syringe and the mass will disappear. It is very important to palpate for total mass disappearance and to ensure that there is complete symmetry between one breast and the other at the end of the procedure.

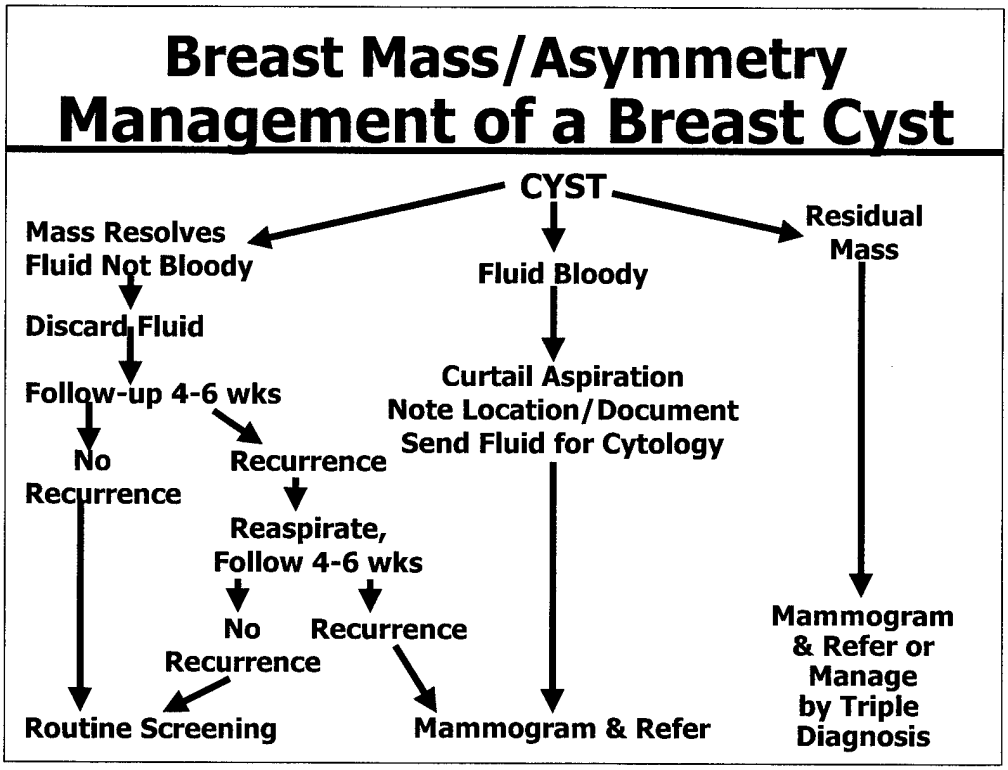
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).



SLIDE 150

This slide demonstrates the apocrine cell lining of one wall of a cyst. It is important to compress the cyst during aspiration to assure that the walls of the cyst are in contact with one another at the end of the aspiration and that the cyst has been emptied of fluid. This maneuver increases the chances that the cyst will not recur.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

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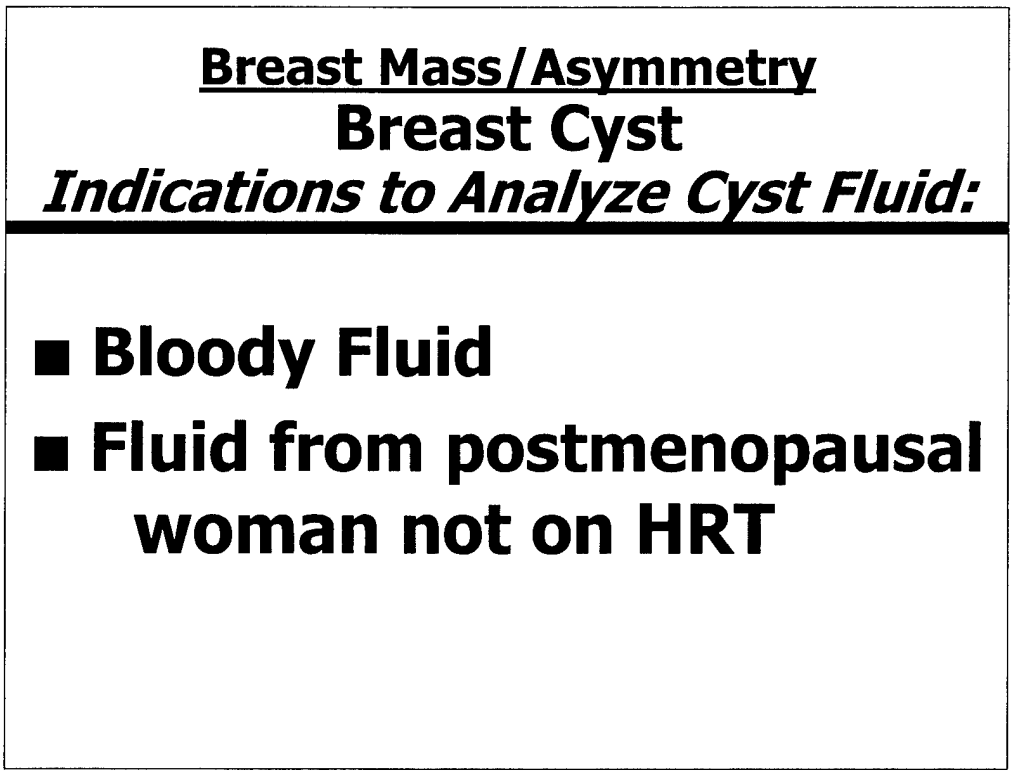
If the mass disappears following needle aspiration, the fluid can be discarded. The patient is then asked to come back to the clinic 4 to 6 weeks later. If there has been no recurrence of the mass, the patient is put on routine follow-up schedule. If the cyst recurs in the same location, it can be re-aspirated, but if it recurs after a second 4 to 6 week follow-up, this is an indication for referral to rule out intracystic carcinoma. Some may choose to refer after the first cyst recurrence. If the initial fluid that was aspirated is grossly bloody, the fluid is sent for cytology and the patient referred to rule out intracystic carcinoma. It is important to know that if bloody fluid is encountered, the aspiration should be stopped so that the consulting physician knows the exact location of the bloody cyst. It is possible for a residual mass to be present on post-aspiration examination or follow-up. Under these circumstances, the mass should be managed as any solid mass.

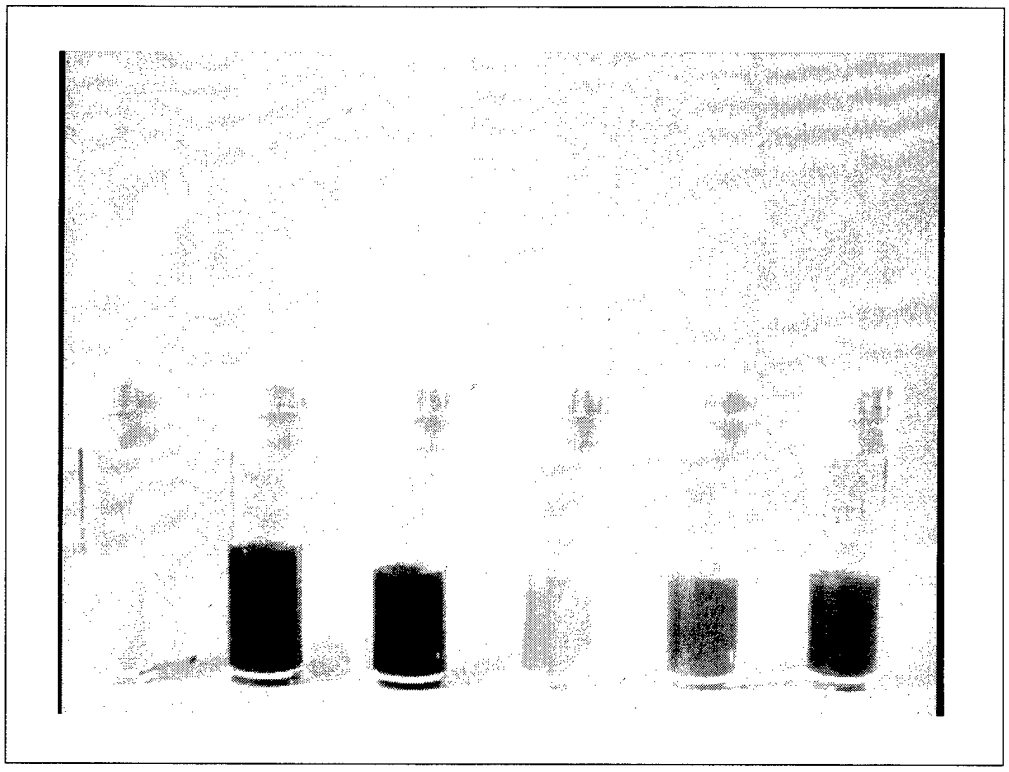
**Source:** Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.




SLIDE 152

If the fluid is grossly bloody, it should be analyzed. If a cyst is aspirated in a postmenopausal woman and she is not on hormone replacement therapy, the fluid is also commonly analyzed. No matter what the cytology demonstrates; however, further evaluation will be necessary, usually through referral. In all other patients the fluid can be discarded.

**Source:** Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.



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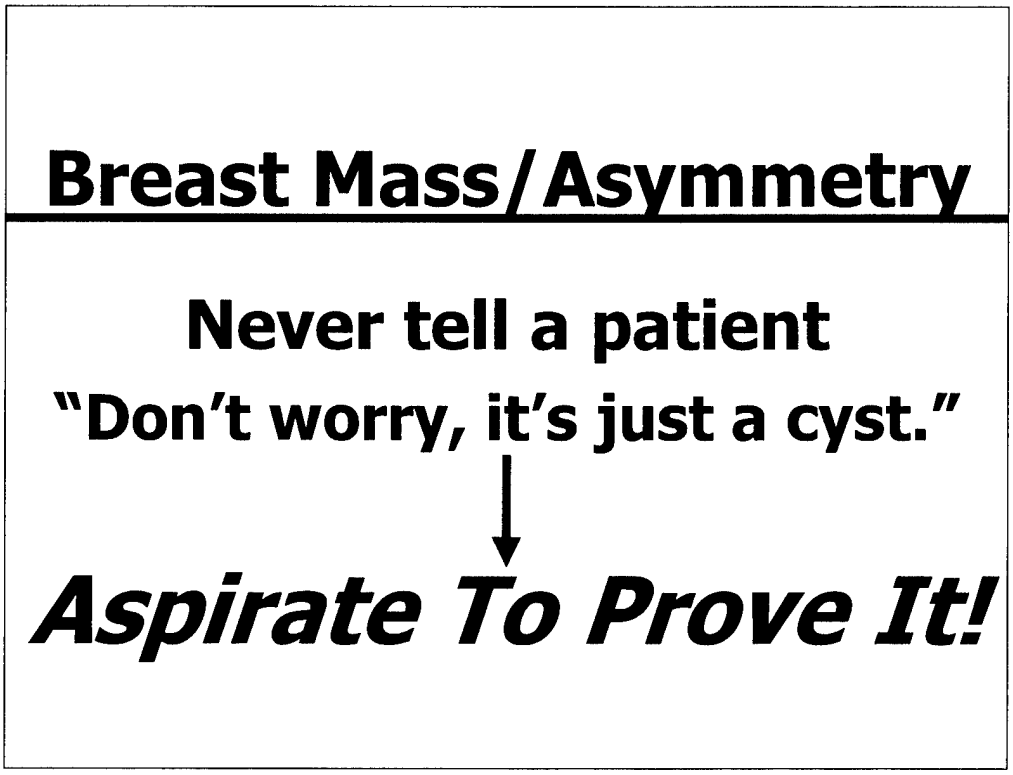
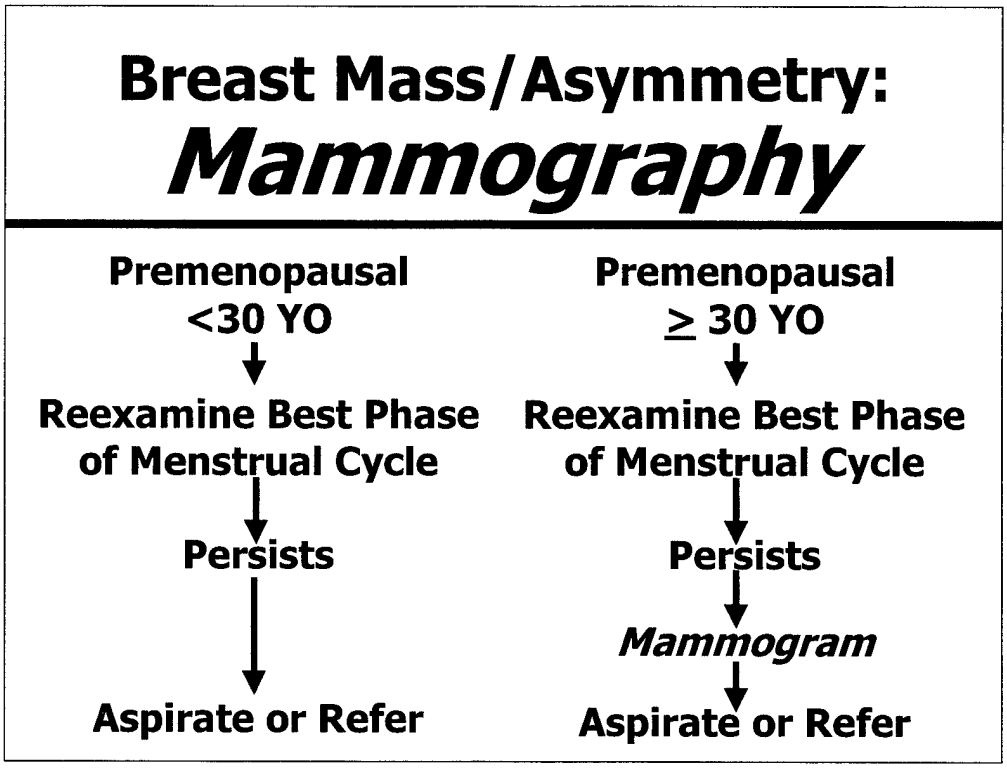
The color of the fluid removed from a cyst covers a wide spectrum. On the far left is fluid typical of a galactocele in a lactating woman. The other vials contain fluid from a variety of cysts. In general, the darkness of the cyst fluid corresponds to the age of the cyst. Cysts of recent onset are a serous-colored, while older ones are darker. The changes in pigments occur when the epithelial lining of a cyst degenerates, and the cells fall into the cystic fluid.

**Source:** Breast anatomy and physiology. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast - Concepts and Clinical Management.* London: Bailliere Tindal, 1989, pp.93-101.




SLIDE 154

Remember that the only way to document that a palpable abnormality is a cyst is by needle aspiration or ultrasound, with the former preferred. Many anxious weeks experienced by women could be eliminated if primary care physicians became comfortable with this simple in-office procedure.

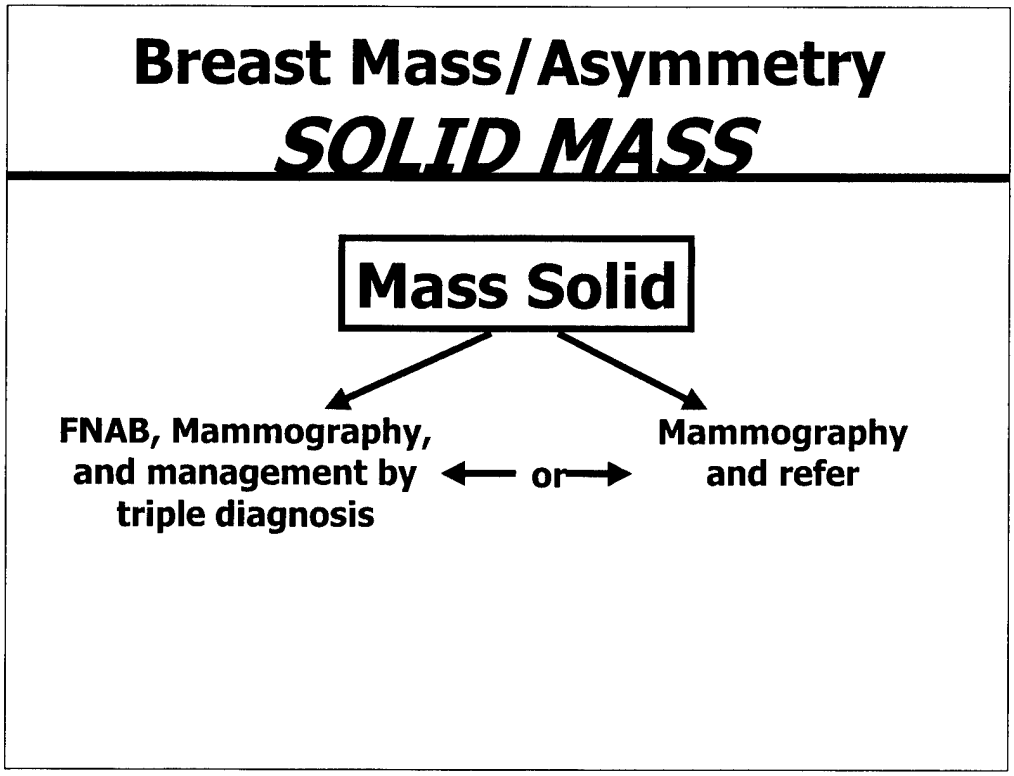



SLIDE 155

Whether mammography is done for a mass or other breast symptoms, certain guidelines apply to its appropriate application. On the left is an algorithm for women <30 years of age. Note that this algorithm does not include a mammogram. Instead, a woman would be asked to return at the best phase of her menstrual cycle for an examination, and if the mass persists at that time, one of two courses is possible. The primary provider can aspirate the mass, or the patient can be sent to a surgeon who will perform this procedure.

The course is the same for women ≥ 30 years of age who are premenopausal, except that they are asked to get a mammogram. The reason for the differentiation is that mammograms are unlikely to be helpful in women less than 30 years of age, as discussed previously.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 156

Aspiration will often establish a mass to be solid rather than cystic. Three characteristics suggest the presence of a solid mass: (1) the lack of fluid in the syringe barrel, (2) the solid nature of the aspirate, and (3) persistence of the mass following aspiration. The next portion of the curriculum will address the management of a solid mass or asymmetry.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

## Breast Mass/Asymmetry:
## *Masses: Diagnostic Approach*

- **Open biopsy**
- **Core biopsy**
- **Fine needle aspiration biopsy (FNAB) and management by triple diagnosis**

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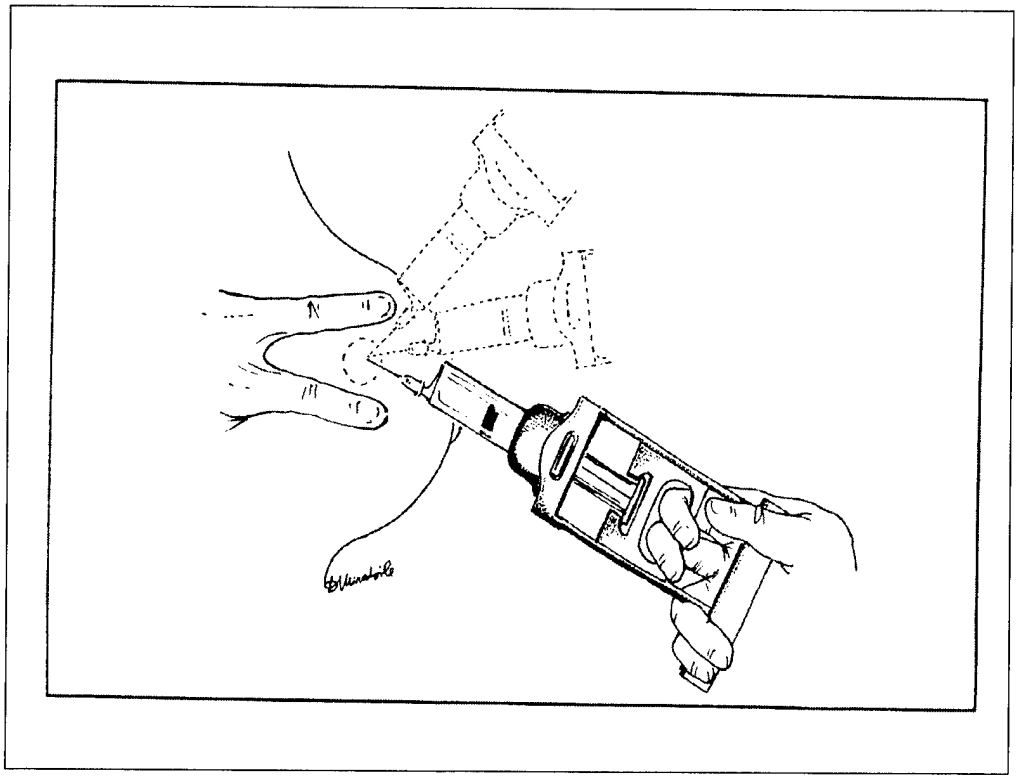
Options for work-up of solid masses include open biopsy, core biopsy, or fine needle aspiration biopsy. Note that each of the approaches includes the word **BIOPSY**. FNAB refers to the aspiration of a solid mass in order to obtain cytopathologic representation of its contents. The distinction between simple FNA and FNAB is extremely important. Whereas FNA is an either/or phenomenon (either a mass is cystic or solid), FNAB requires knowledge of the technical aspects of the procedure, an aspirator experienced in obtaining an optimal sampling of cells, a skilled cytopathologist for cellular interpretation, and interpretive knowledge of the many pitfalls inherent in the technique.

**Source:** Osuch JR. Abnormalities on physical examination. In: Harris JR, Lippman ME, Morrow M, et al (Eds.). *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996, pp. 110-114.



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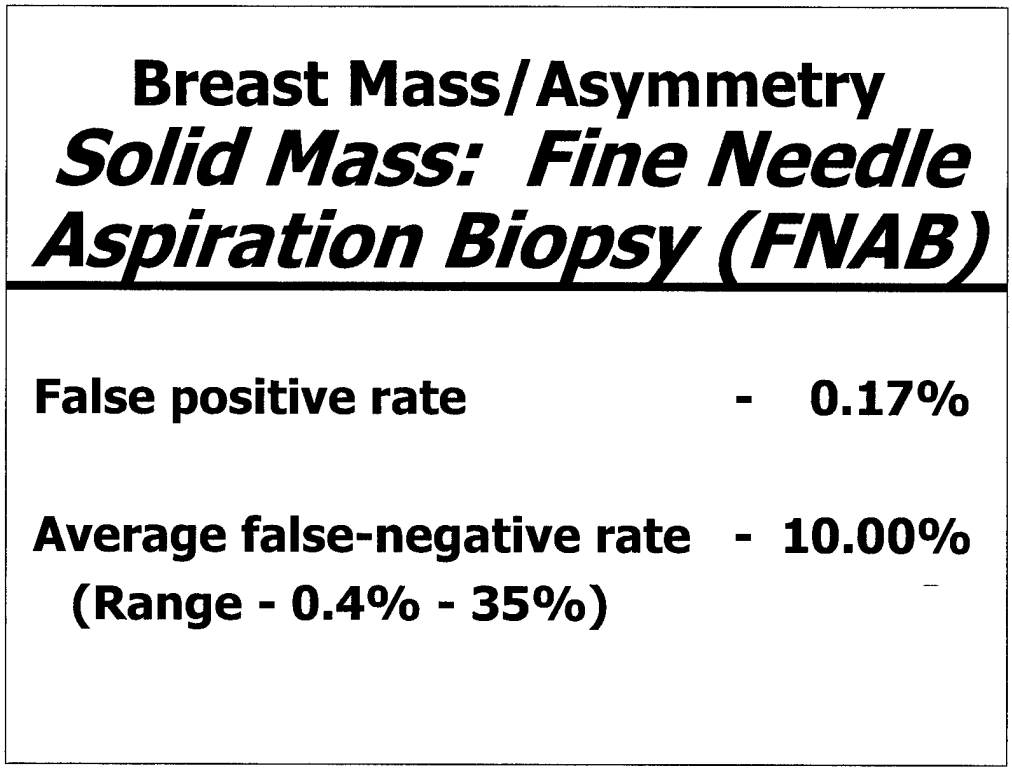
When fine needle aspiration biopsy is done, the same instrumentation is used as for cyst aspiration. However, instead of fluid being aspirated into the barrel of the syringe, the sample is contained within the needle. The needle is passed into the lesion several times in order to sample it to obtain an adequate number of cells. This procedure is commonly done only by personnel who are well trained in the technique and who have cytopathologists comfortable with slide interpretation.

**Source:** Catania S, Ciatto S. Breast cytology: Instruments and techniques. In: Catania S, Ciatto S (Eds.), *Breast Cytology in Clinical Practice*. London: Martin Dunitz Ltd., 1992.




SLIDE 159

The false-positive rate for fine needle aspiration biopsy is low, averaging 0.17%. The false-negative rate, however, averages about 10%, and has a range between 0.4% and 35%.

**Source:** Layfield LJ, Glasgow BJ, Cramer H. Fine needle aspiration in the management of breast masses. *Pathol Annu* 1989; 24:23-62.

# Breast Mass/Asymmetry
# *Solid Mass: FNAB*

## Reasons for False-Negative Results:

**Inadequate sampling**

**Lack of target tissue sampling**

**Tumors with extensive fibrosis/necrosis**

**Well-differentiated tumors**

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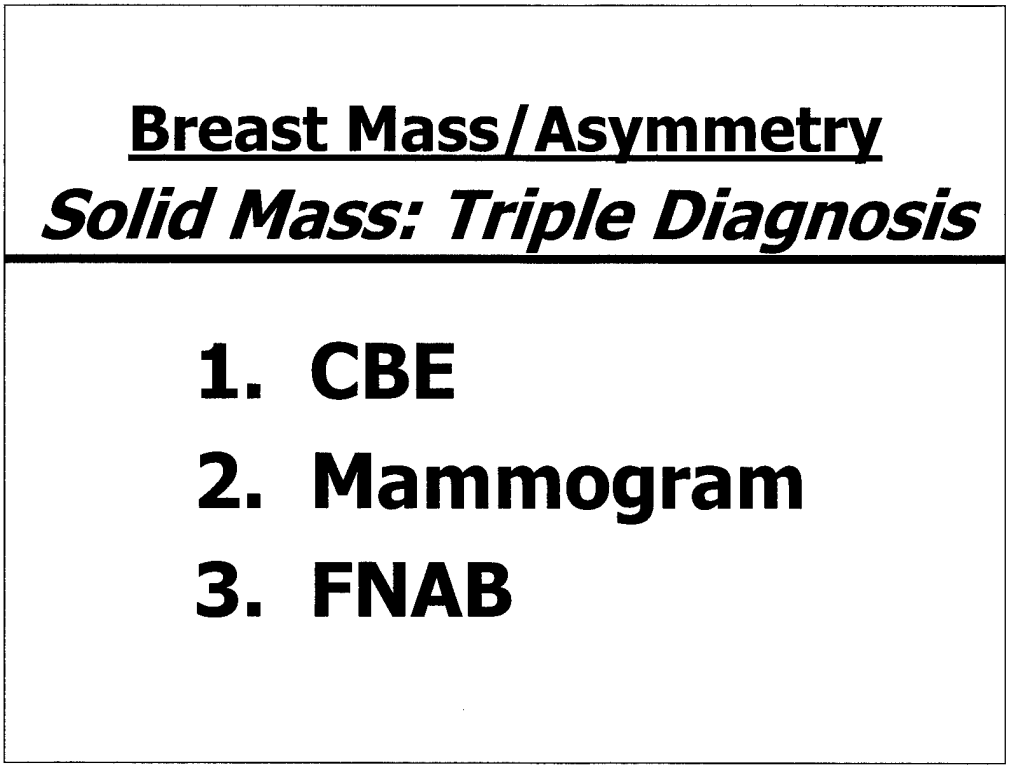
Inadequate sampling represents the most common reason for a false-negative result and is usually a result of inadequate experience on the part of the aspirator. If the clinician plans to use FNAB in the diagnostic evaluation of a breast mass, the method of reporting inadequate cellularity must be explored with the cytopathologist. If inadequate cellularity is reported, a repeat FNAB or open biopsy should be done.

Other reasons for false negative results have been cited, including lack of target tissue sampling, technical problems with slide preparation or reading, tumors with extensive fibrosis or necrosis, and well-differentiated tumors. Because of the latter problem, *any FNAB interpreted as atypical will require an open biopsy for diagnosis*. However, full awareness of all of these diagnostic pitfalls will still not achieve 100% accuracy with this technique.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 161

In order to increase diagnostic accuracy, the principles of "triple diagnosis" have been used. "Triple diagnosis" refers to the application of three steps to evaluate a breast mass: (1) clinical assessment by palpation, (2) results of mammography, and (3) results of FNAB. A principle of this evaluation method is that if any one of the variables is "suspicious", then open biopsy is warranted.

The false-negative rate of CBE, mammography, and FNAB will need to be kept in mind when applying this method. In circumstances in which the radiologic study does not actually demonstrate the lesion, it is not known if it is safe to use the technique of triple diagnosis and it is safer to simply biopsy persistent masses.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

## Breast Mass/Asymmetry

## *Solid Mass: Triple Diagnosis*

- **If all three components are benign, there is a 99% chance that the lesion is benign**

- **Suggested follow up**
  - **Every 3 months until resolution of mass or for at least 1 year.**

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When all three components of triple diagnosis are interpreted as benign, there is about a 99% chance the lesion is benign. A patient should given this fact in order to decide between biopsy and follow up. If she chooses the latter, it is suggested that the first visit occur 3 months later. Subsequent visits should be 3 months after that until the lesion has resolved or has remained stable for at least 1 year. Using this technique, a 1% risk of missing cancer on the initial evaluation must be accepted.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

## Breast Mass/Asymmetry

# Interpretation of Mammography and Aspiration

**Ensure that aspirated mass is in same location as any imaged mammographic density consistent with an abnormality.**

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There is an important caveat in interpretation of mammography and aspiration of a palpable mass, whether done as FNA or FNAB. It is very important to ensure that an aspirated mass is in the same location as any imaged mammographic density. If concern exists that a palpable lesion does not correlate with the film, then additional consultation with the radiologist, or examination of the films is suggested. If one does not make this correlation , it is possible to aspirate a mass and still have a mammographic abnormality left behind which has not been evaluated.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

## Breast Mass/Asymmetry

# Timing of Mammography and Aspiration

**If aspiration is done prior to mammography, avoid radiographic imaging for 2-3 weeks to avoid false-positive results.**

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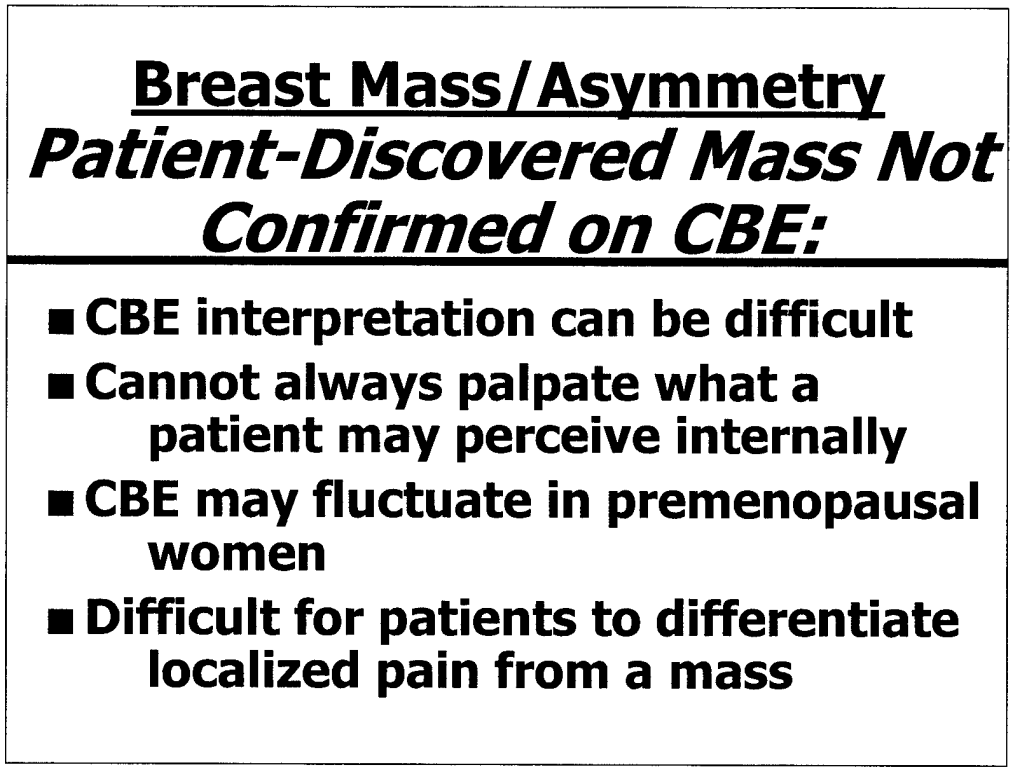
If an aspiration is done prior to mammography, then the radiologic imaging should be avoided for 2-3 weeks. This is because hematomas can form when aspiration is done, and can cause false positive mammographic results visible as a spiculated density.

Algorithms summarizing the initial approach to a breast mass, management of a breast cyst, and management of a solid mass by triple diagnosis can be found in Appendices 5a, 5b, and 5c.

**Source:** Sickles EA, Klein DL, Goodson WH, Hunt TK. Mammography after needle aspiration of palpable breast masses. *Am J Surg* 1983;145:395-397.



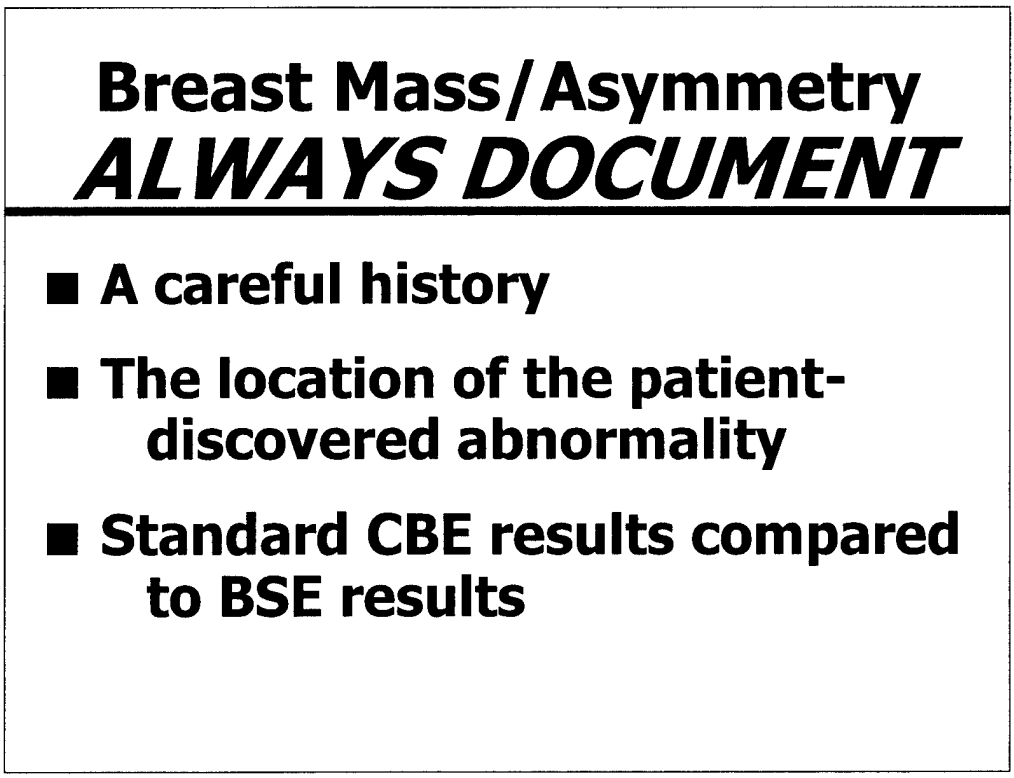

SLIDE 165

CBE interpretation can be difficult, and it is not always possible to palpate what the patient may perceive as "something different". An ovulating woman's examination can change, depending on ovarian hormone fluctuations. In addition, patients often have their attention drawn to a particular area because of breast pain. It can be difficult for a patient to distinguish pain from a breast mass on self-examination. The acknowledgement that "Failure to be impressed with clinical findings" was the single most common clinician error found in the Physicians Association of America (PIAA) study makes it important to have a systematic approach to this problem.

**Sources:**

Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).

Physician Insurers Association of America. *Breast Cancer Study*. Lawrenceville, NJ: Physician Insurers Association of America, 1995.

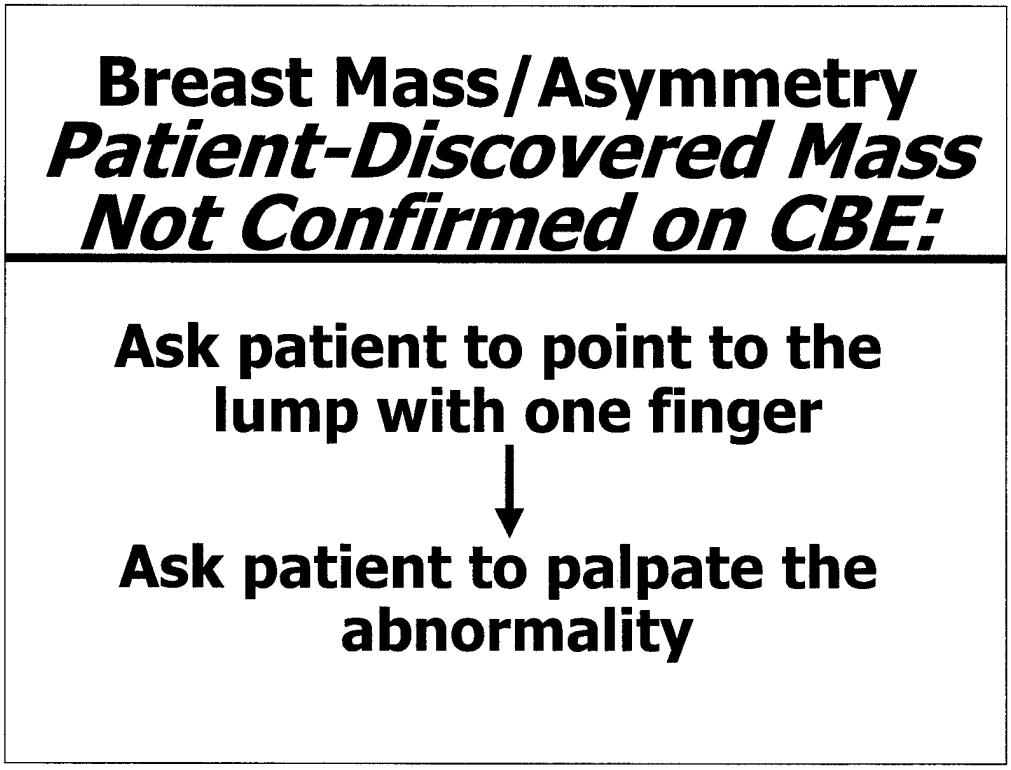



SLIDE 166

After the patient identifies her specific areas of concern, it is extremely important that the following components be documented:

- A careful history
- The location of the patient-discovered abnormality
- The CBE results using both standard technique examination and in the position in which the patient found the mass.

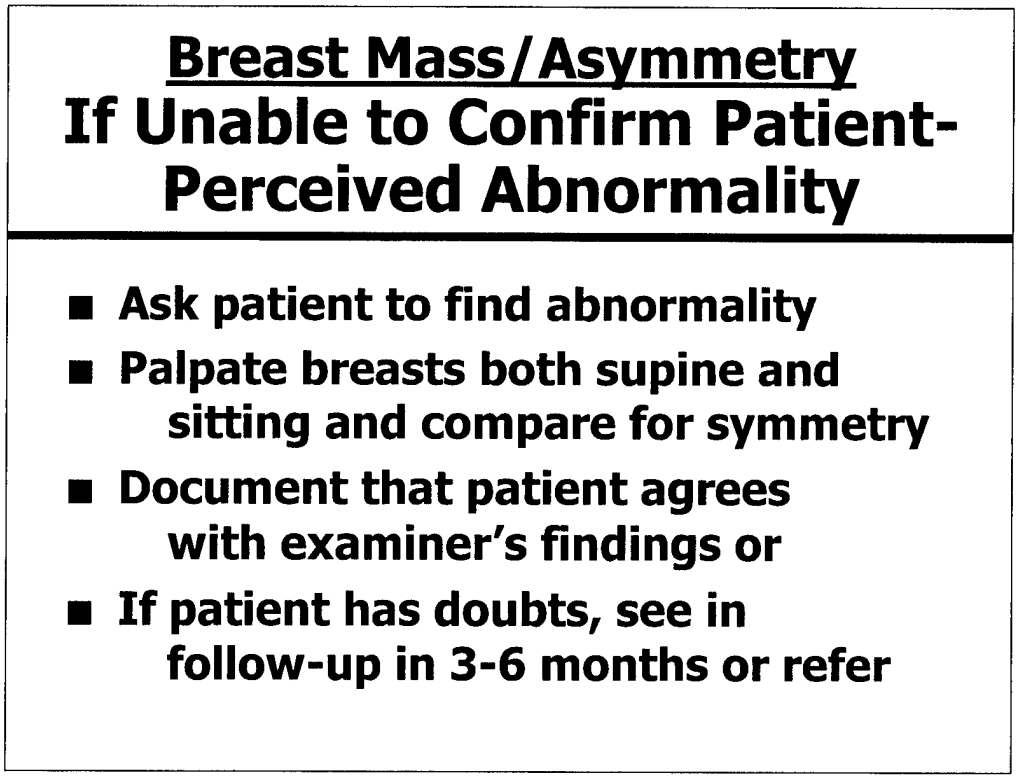
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 167

Since many women are fearful that they may have a mass but are not sure that they have one, it is important for the provider to document exactly where the woman perceives her breast mass to be located. This is most easily done by asking the patient to point to the lump with one finger. If CBE does not confirm the mass, ask the patient to palpate the abnormality herself.

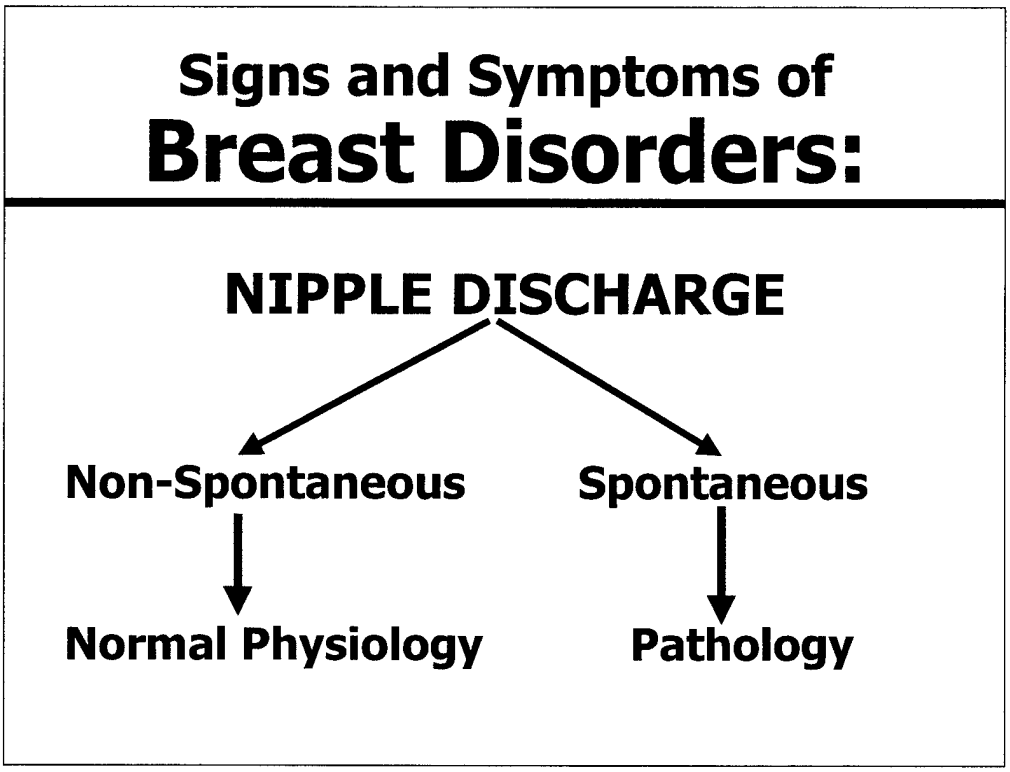
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 168

Many patients discover their abnormality in the shower. When this occurs, it is recommended that the provider palpate the breasts in the sitting position. Remember to examine the mirror-image area in the contralateral breast, and if the findings are similar have the patient perform her own comparison. If the patient remains concerned, see her in follow-up in 3-6 months or refer.

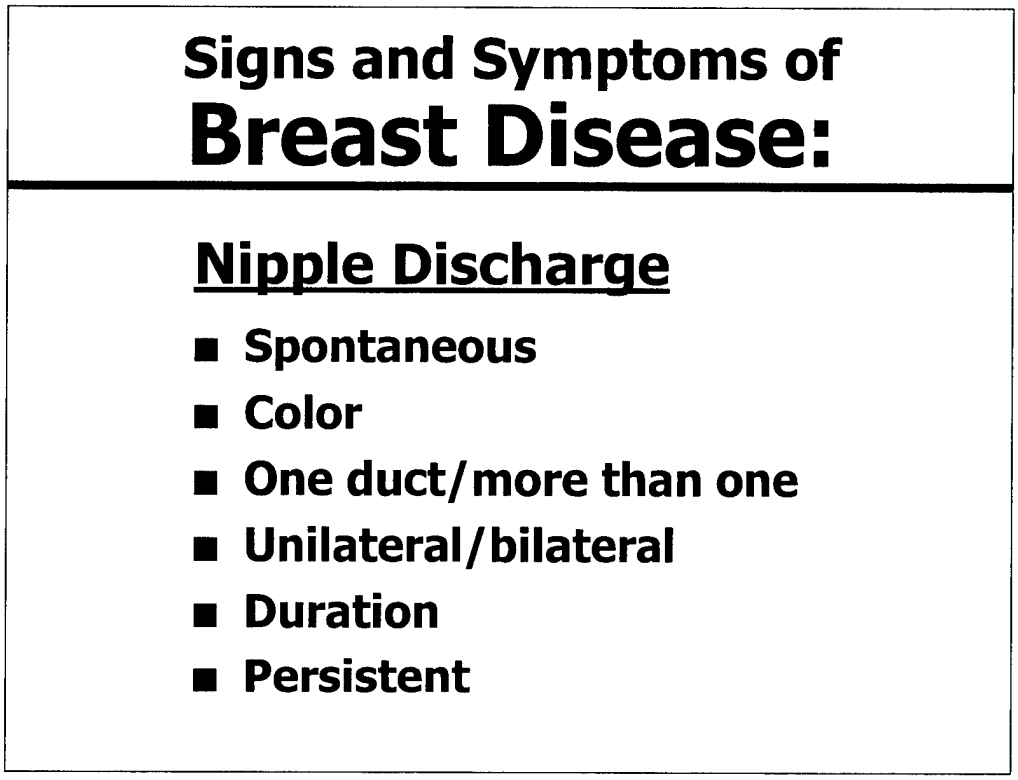
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health, 1998: Vol 3. No. 5. http://www.medscape.com (see instructions in Appendix 10).




SLIDE 169

We will next turn to the symptom of nipple discharge. It should be emphasized that non-spontaneous nipple discharge is a normal physiological phenomenon and of no clinical consequence. Women who present with this symptom require reassurance exclusively; any other work up is costly both financially and emotionally. The symptom of non-spontaneous nipple discharge resolves when nipple compression is avoided.

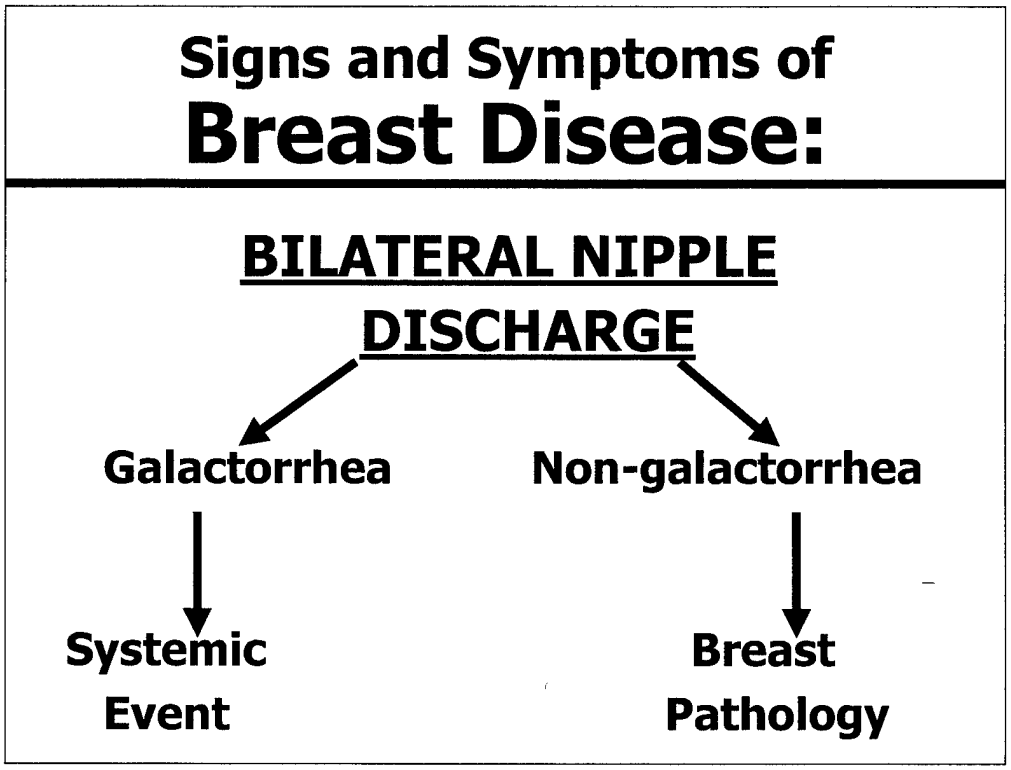
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.




SLIDE 170

To determine if the discharge is spontaneous, ask the patient if it stains her underclothing or bed clothing. If it does, it is significant and requires investigation. Ask about the color, whether one or more ducts is involved, whether it is unilateral or bilateral, when it was discovered, and whether it is persistent.

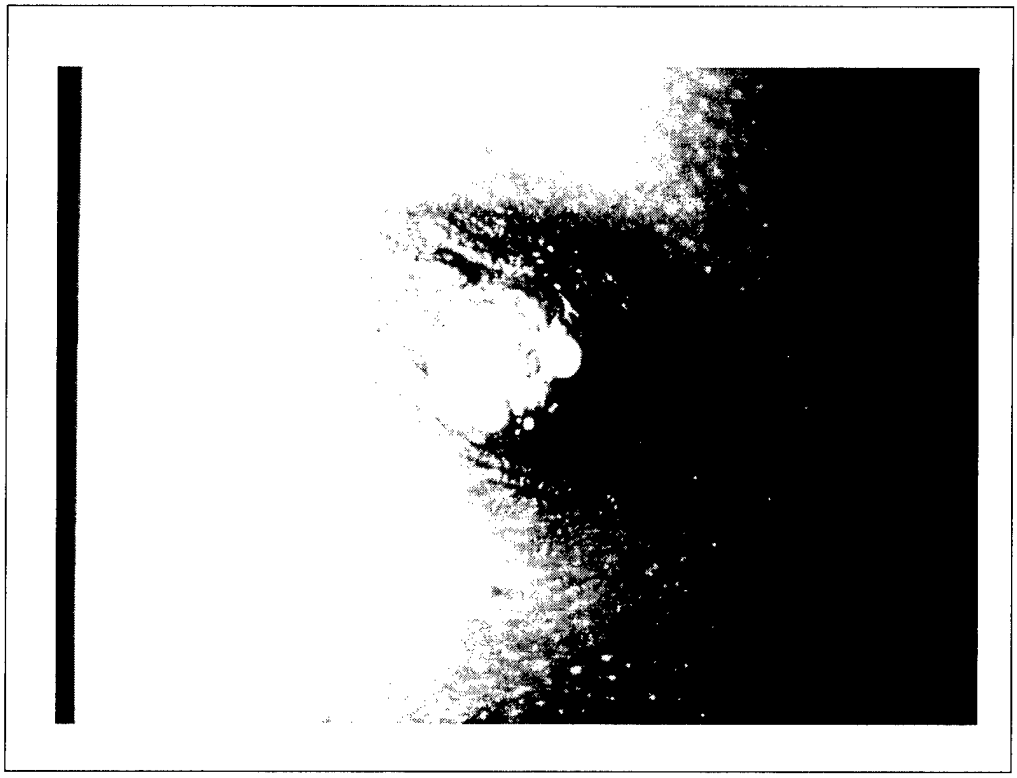
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.




SLIDE 171

If the discharge is bilateral, it is classified as galactorrhea versus nongalactorrhea. Both usually present as multiple duct discharge.

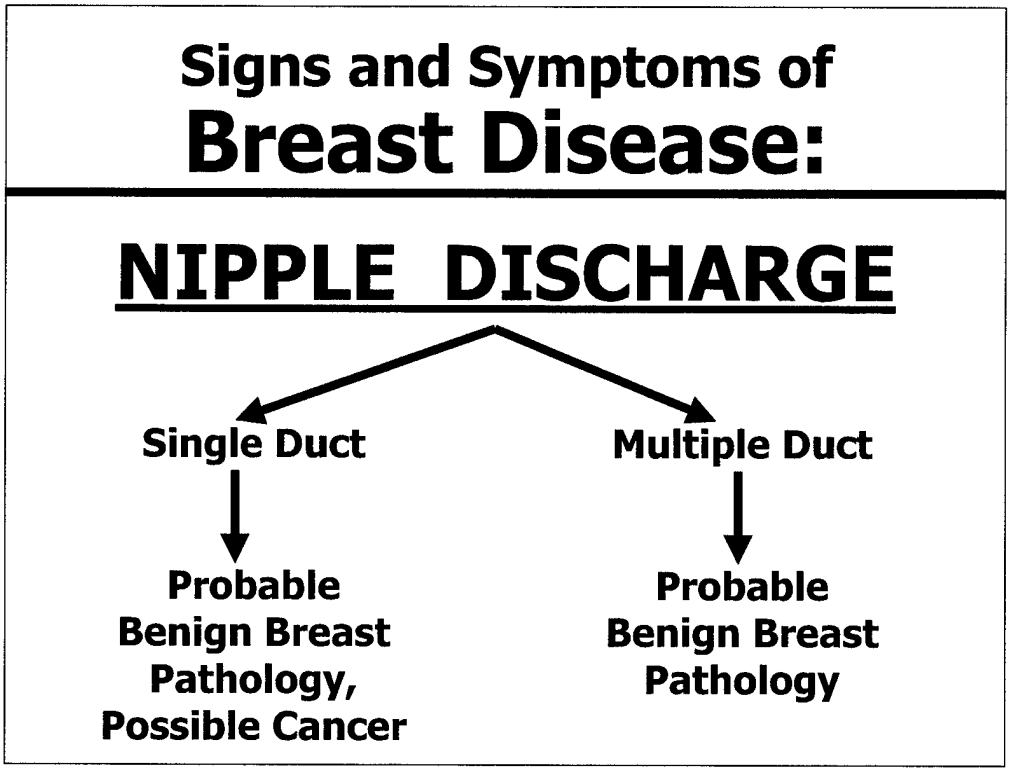
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



SLIDE 172

This is a typical appearance of galactorrhea. Nipple discharge of this type following cessation of lactation is very common and can continue for years as a normal phenomenon. Other etiologies include: drugs, pregnancy, presence of a pituitary adenoma, or other endocrine event. All of these conditions will be associated with an elevated prolactin level.

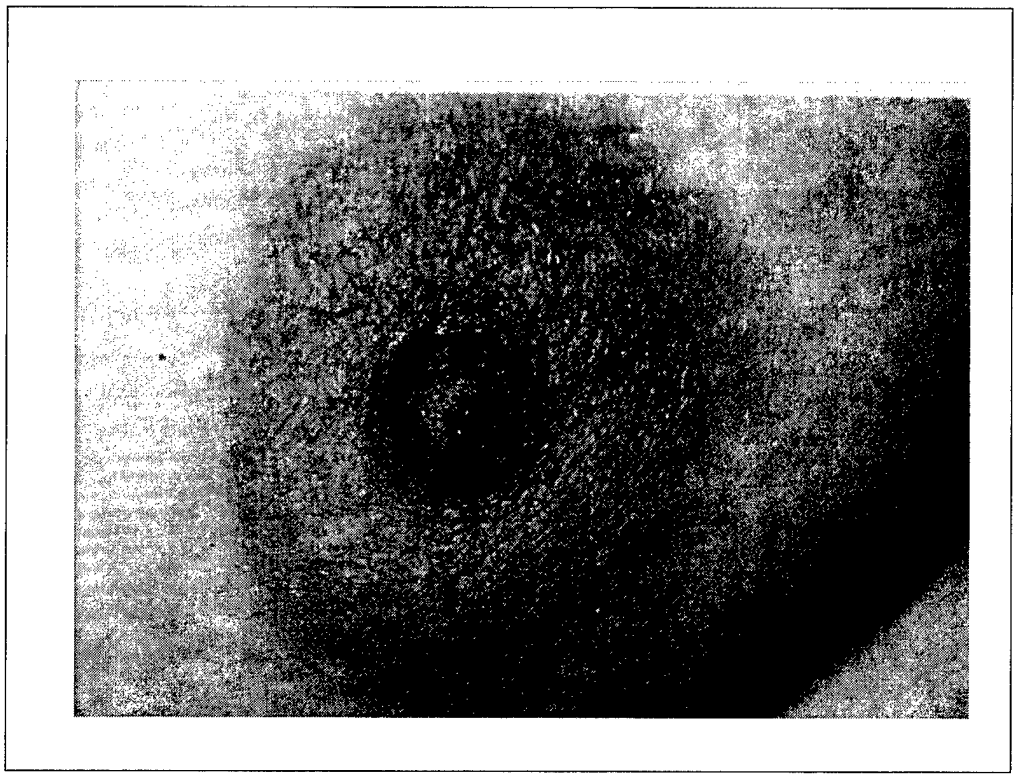
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.




SLIDE 173

Nipple discharge can originate from single or multiple ducts. Single-duct discharge indicates probable benign breast pathology, but also may represent cancer. Multiple-duct discharge is very unlikely to represent malignancy, particularly if it is bilateral. If the discharge is non-milky, duct ectasia is the most common diagnosis.

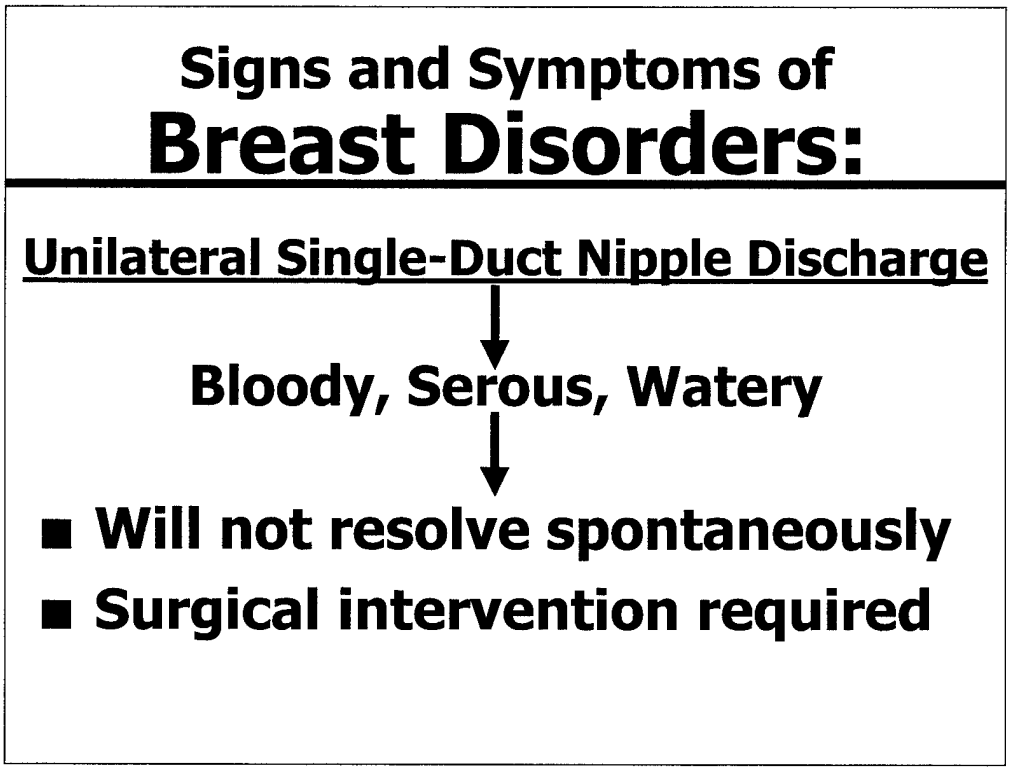
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



SLIDE 174

This is an example of duct ectasia. The discharge is usually of a yellowish-green or dark green character. This condition represents a dilatation of the subareolar ducts with accumulation of stagnant secretions which cause an obstruction and subsequent discharge. These symptoms are usually followed, with surgical intervention deferred unless they cause social embarrassment. If surgery is indicated, removal of the subareolar duct system is necessary. This results in inability of the woman to lactate.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.




SLIDE 175

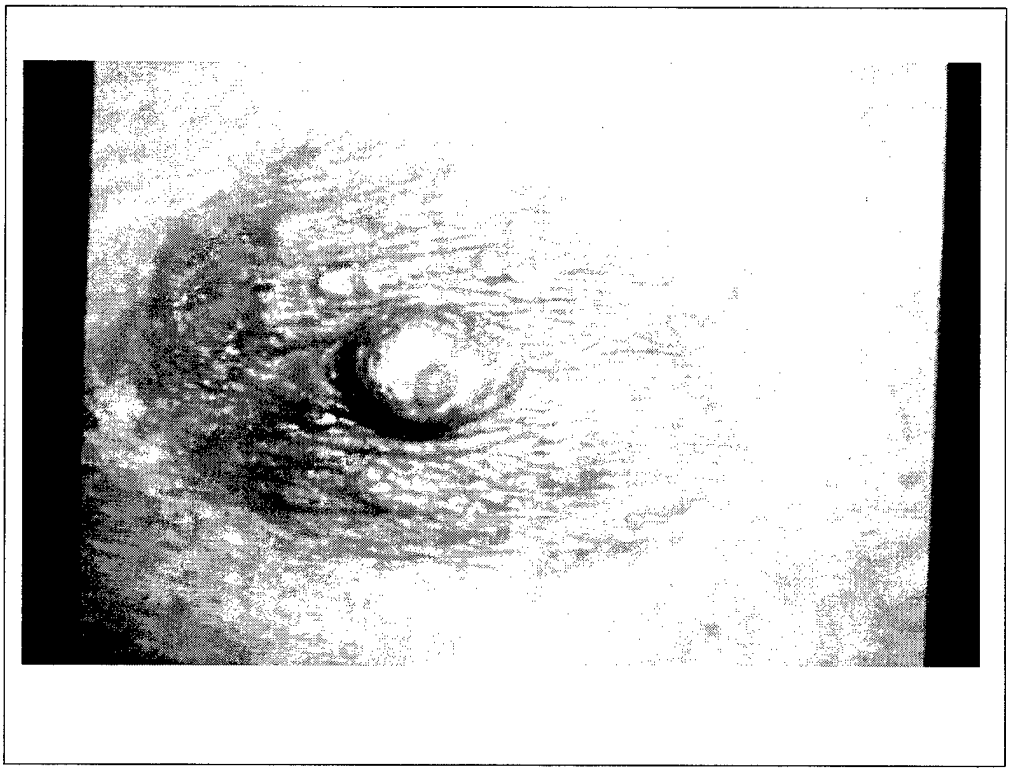
Nipple discharge that is spontaneous, unilateral, persistent, and from a single duct is an indication for referral. The symptom is unlikely to resolve without surgical intervention, and the differential diagnosis includes carcinoma. This is true whether the character of the discharge is bloody, watery or serous.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

SLIDE 176

Much attention has been paid to the symptom of bloody nipple discharge. The differential diagnosis includes intraductal papilloma, duct ectasia, and carcinoma. Seventy-five to eighty-five percent of cases represent a benign intraductal papilloma.

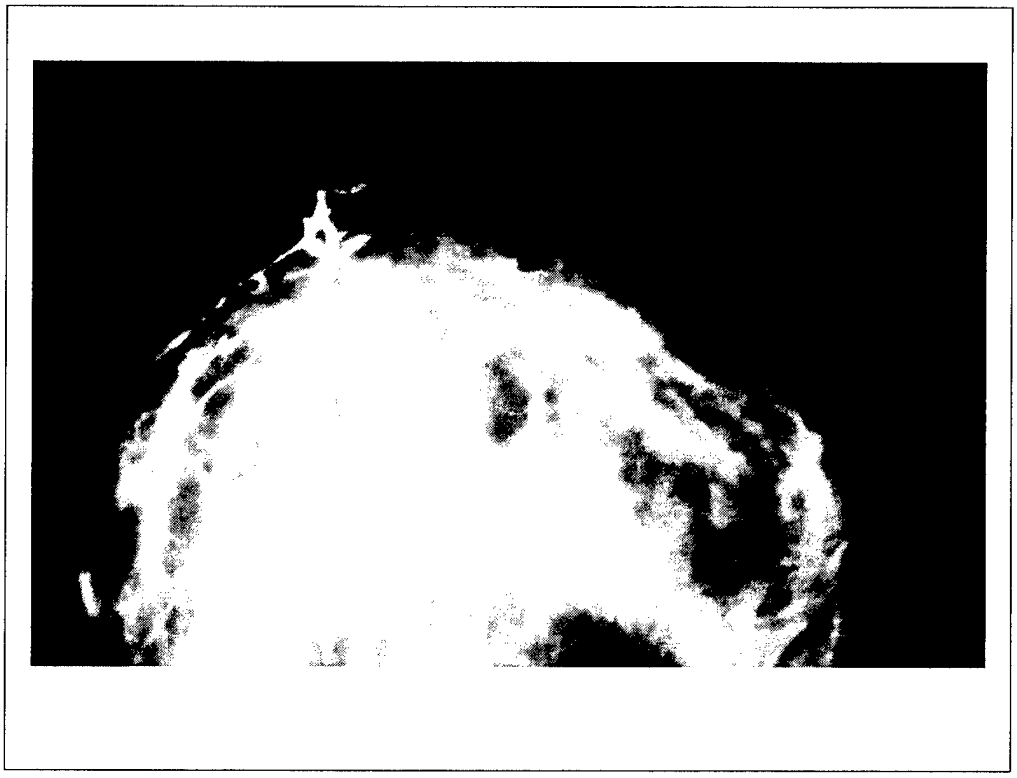
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health*. Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.



SLIDE 177

Any type of unilateral single-duct discharge is important, however. This slide demonstrates serous discharge. The differential diagnosis includes all of the conditions associated with bloody nipple discharge. Watery discharge, although uncommon, has the highest incidence of carcinoma.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.

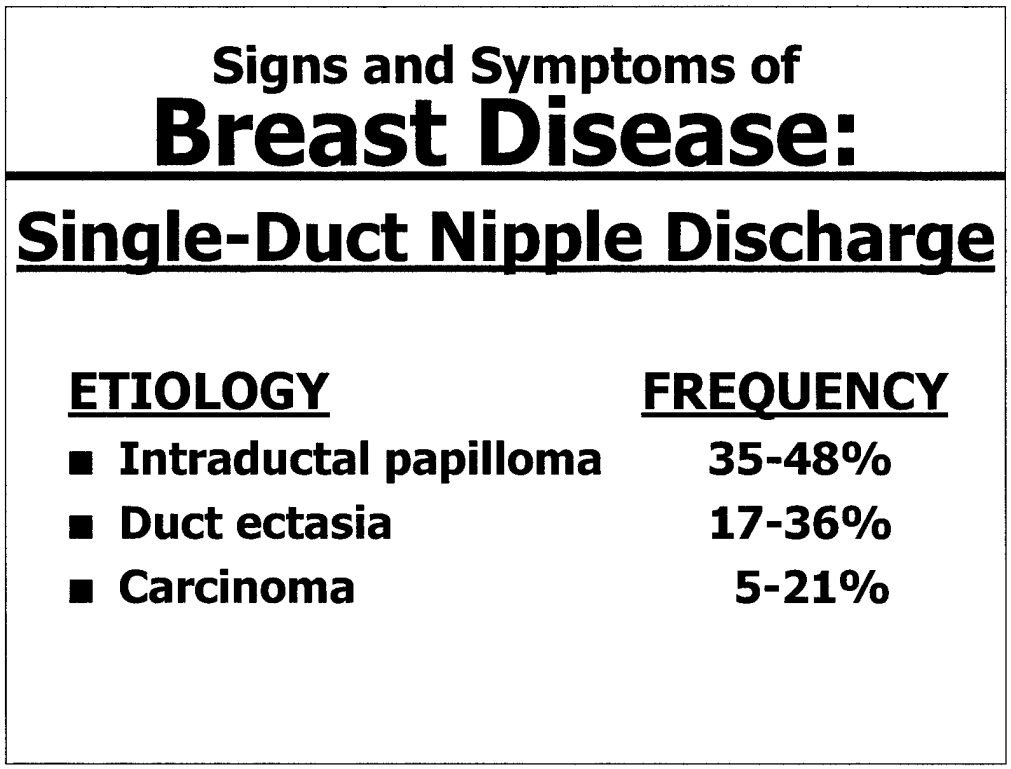


SLIDE 178

The work-up of the nipple discharge historically has included radiographic and laborative assessment and is uncomplicated. Mammography can be performed in age-eligible women, but is normal in most cases. Cytology of nipple discharge secretions has high false-positive and false-negative rates and is not recommended.

This is an example of a normal galactogram. This test involves the injection of radiocontrast material into the involved duct to demonstrate a filling defect on mammography. Galactography is helpful under some circumstances, especially when used for surgical localization. Galactography cannot differentiate benign from malignant duct lesions, and is generally not advocated. Surgical referral is necessary when a woman has unilateral, persistent single-duct nipple discharge.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.): *Textbook of Women's Health.* Philadelphia, PA: J.B. Lippincott, 1998, pp. 295-313.




SLIDE 179

The three most common causes of persistent, unilateral, single-duct nipple discharge are: intraductal papilloma, duct ectasia, and carcinoma. Five to 21% of women will have an underlying ductal cancer, depending on the age group, with older women much more likely to have cancer.

**Source:** Winchester DP. Nipple Discharge. In: Harris JR, Lippman ME, Morrow M, et al (Eds.), *Diseases of the Breast*. Philadelphia, PA: Lippincott-Raven, 1996, pp 106-110.

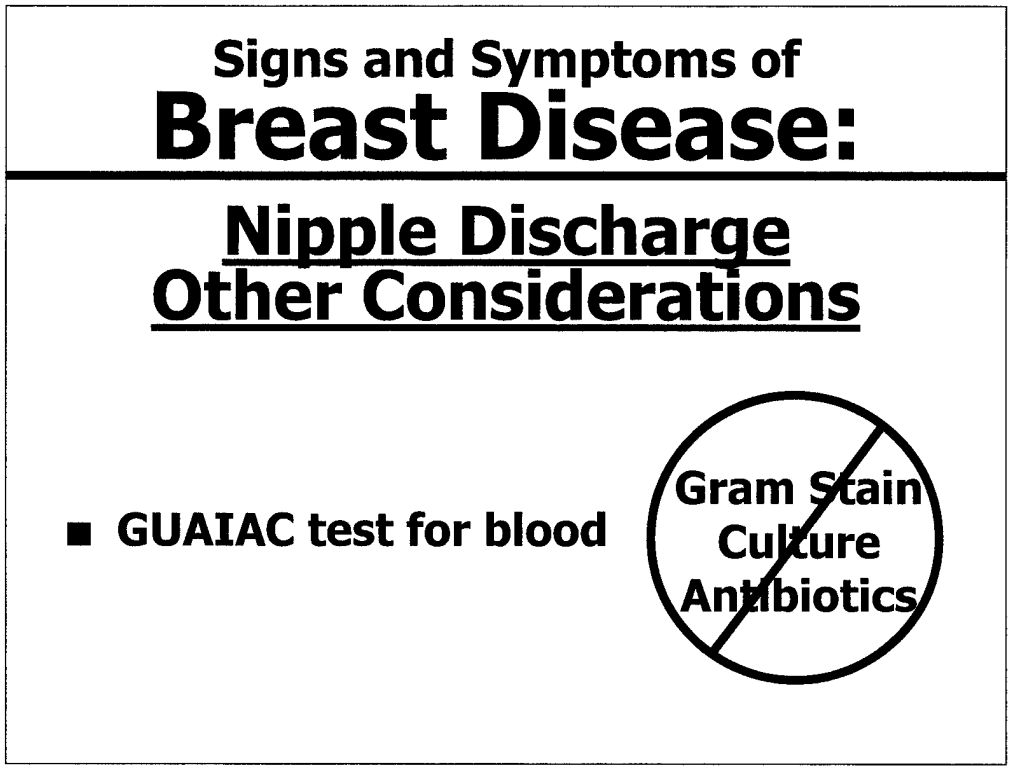
## Signs and Symptoms of
# Breast Disease:
## Single-Duct Nipple Discharge

| TYPE | Frequency of Cancer |
|---|---|
| Watery | - 45% |
| Bloody | - 25% |
| Serous | - 6% |

SLIDE 180

Although the most common type of single-duct nipple discharge is bloody, the etiology is malignant in only 25% of cases. Watery discharge is more likely to represent carcinoma, and is seen in 45% of women with this presentation. Only 6% of women who present with serous, single-duct nipple discharge will have cancer. Spontaneous nipple discharge is very unlikely to resolve without intervention. Diagnosis and treatment are one and the same - surgical excision. This is accomplished by passing a probe into the involved duct, raising a nipple-areolar flap, and removing the duct containing the probe. Lactation remains possible, and complications are minimal following this procedure.

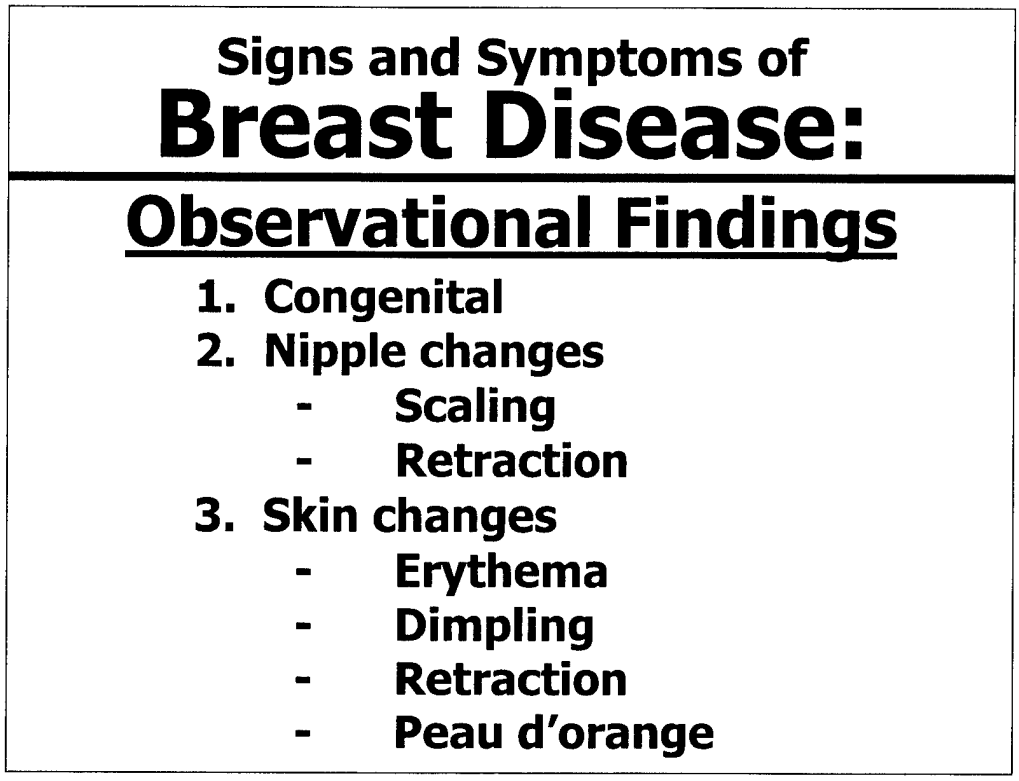
**Source:** Winchester DP. Nipple Discharge. In: Harris JR, Lippman ME, Morrow M, et al (Eds.), *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven, 1996, pp 106-110.




SLIDE 181

Guaiac testing of nipple discharge can be useful in determining whether blood is present, but work up will still be necessary. The etiology of nipple discharge is not infectious in nature. A culture will usually produce staph or strep from the surface of the nipple. Administration of antibiotics is not indicated. An algorithm summarizing the work up of nipple discharge can be found in Appendix 6.

**Source:** Morris LL, Osuch JR. *Breast Cancer Education for DoD Primary Care Managers.* American Medical Women's Association , Alexandria, VA, 1997.




SLIDE 182

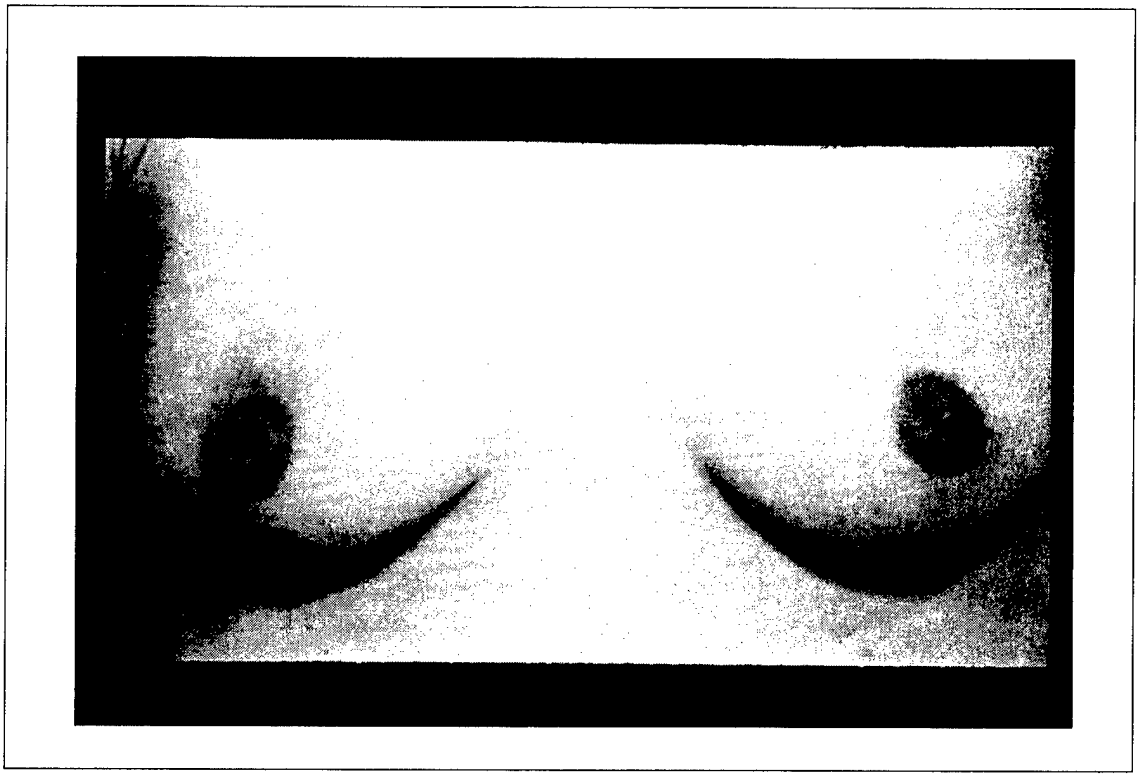
Clinical findings that may be detected on inspection including: congenital abnormalities, nipple scaling, nipple retraction, erythema, skin dimpling, retraction, and Peau d'orange. When inquiring about these symptoms, establish the location, the date the patient first noticed the symptoms, and whether there have been any changes since the date of symptom onset.

# Congenital Abnormalities on CBE

- Developmental nipple inversion
- Hypomastia
- Poland's Syndrome
- Supernumerary breast/nipples

SLIDE 183

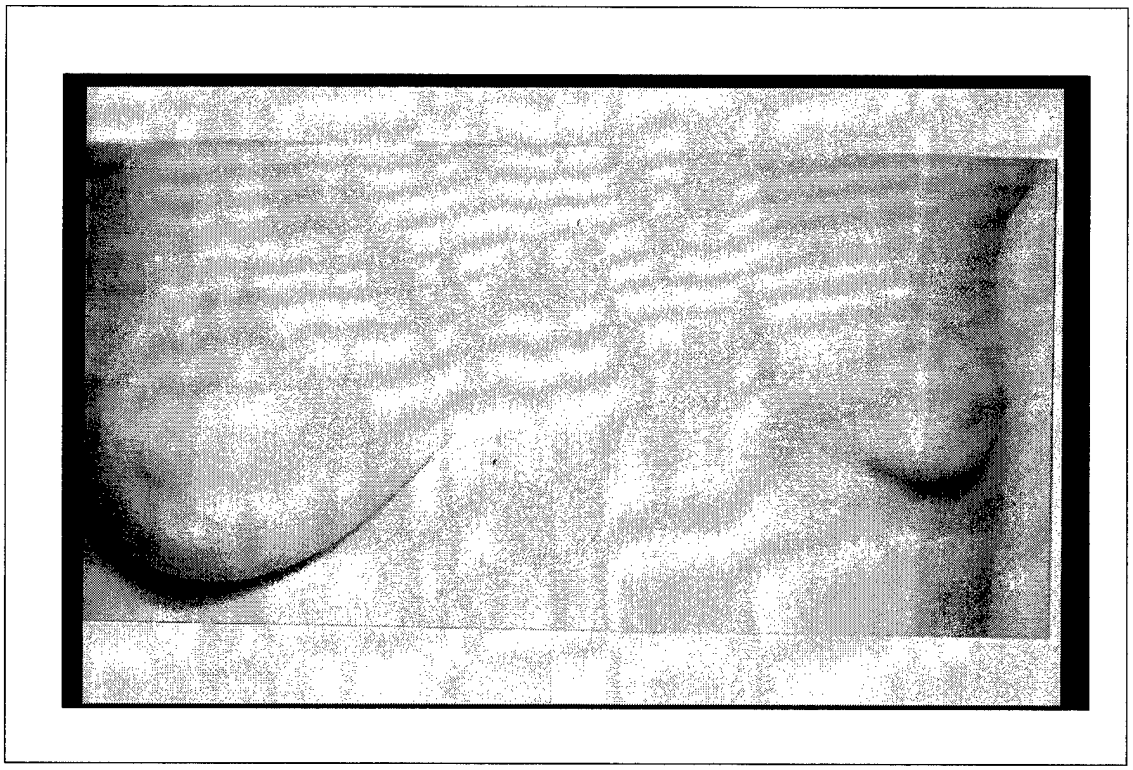
Congenital abnormalities include developmental nipple inversion, hypomastia, Poland's syndrome, and supernumerary breasts or nipples.



SLIDE 184

This is an example of inversion of the nipple. If the patient's history confirmed that this finding was present since adolescence, the abnormality is developmental. The nipples evert as one of the last steps in breast development, occurring at about age 12. The presence of nipple inversion predisposes to subareolar abscess. If a patient indicates that the nipple has been inverting slowly over time from a previously everted state, the differential diagnosis includes periductal mastitis vs subareolar carcinoma. This will be discussed in more detail later.

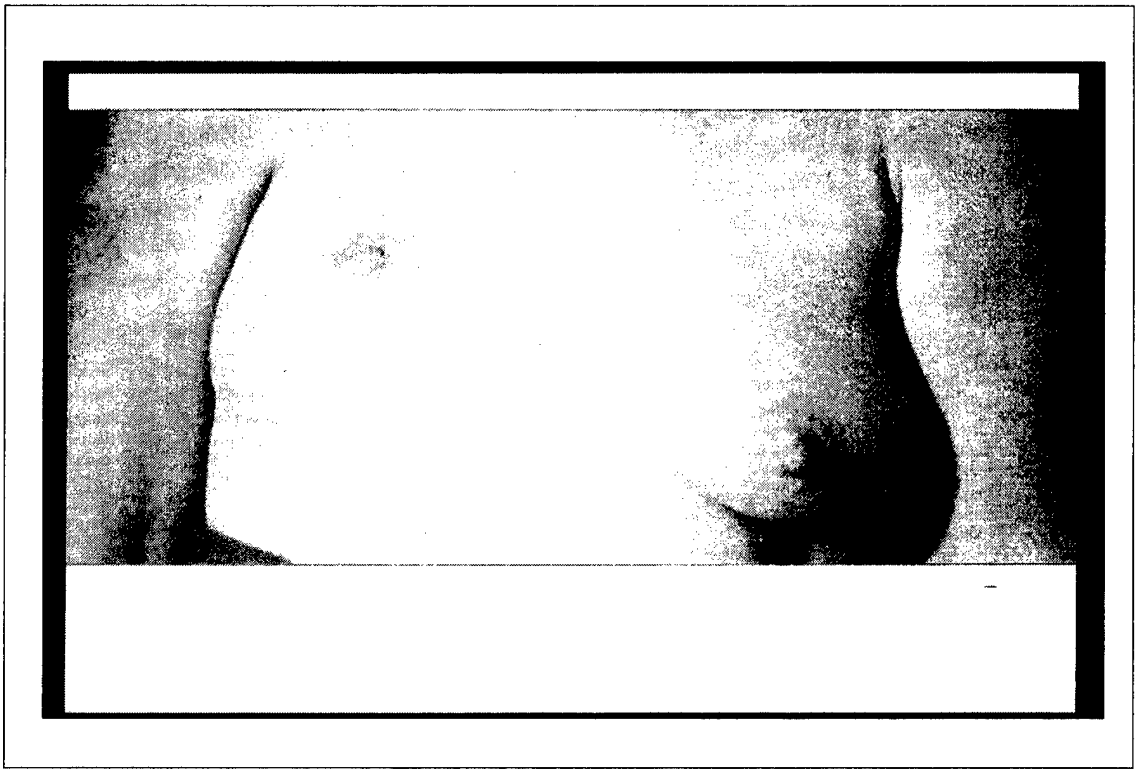
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.) *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, *1989*, pp. 107-131.



SLIDE 185

This is an example of breast hypoplasia. Correction of a visible asymmetry such as this would require plastic surgery. Hypomastia can be congenital or acquired. If the latter, it is usually iatrogenic, from ill-placed chest tubes in the neonatal period, chest wall radiation therapy prior to pubescence, or inappropriate surgical resection of the breast bud.

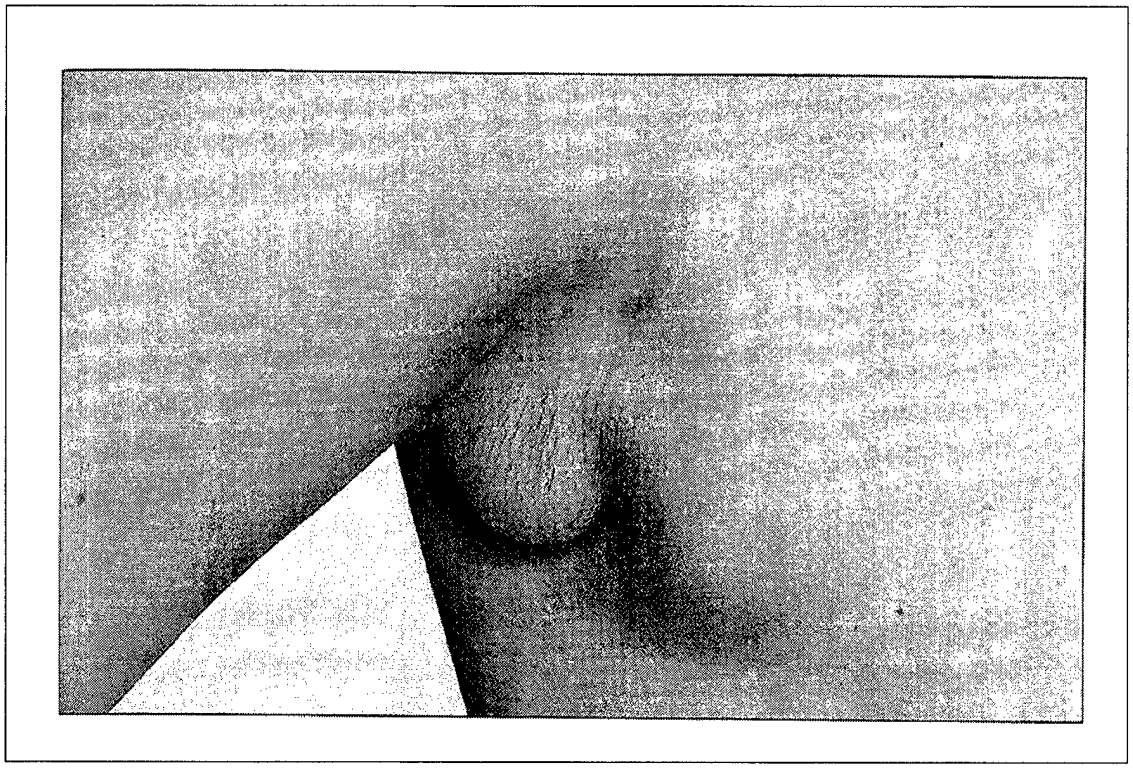
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.) *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, *1989*, pp. 107-131.



SLIDE 186

Poland's syndrome represents hypomastia of one breast, with absence of the pectoralis major muscle. This is not common. Cosmetic symmetry should be accomplished by plastic surgery.

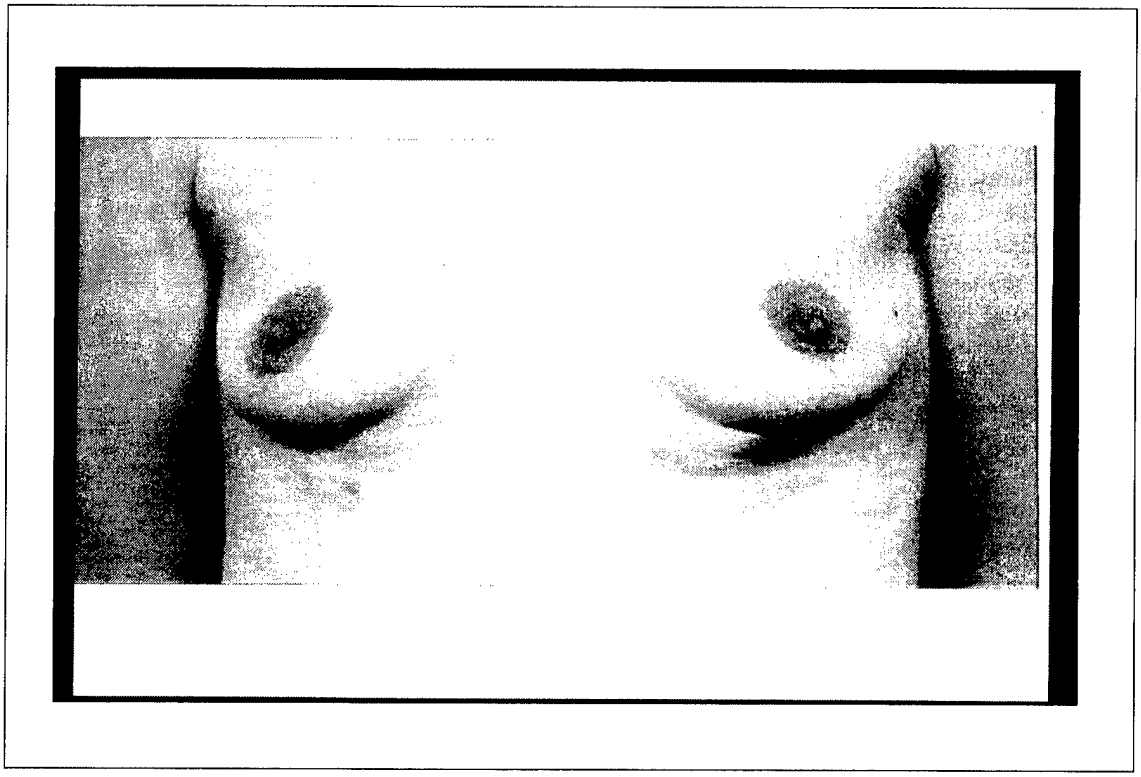
**Source:** Normal breast. In: Mansel RE, Bundred NJ (Eds.). *Color Atlas of Breast Diseases.* London: Mosby-Wolfe, 1995, pp. 7-20.



SLIDE 187

Supernumerary or extra breasts are common, and the most frequent site of presentation is the axilla. Developmentally, all mammals have the potential to develop breasts from the axilla to the groin, along the milk line. In human beings during normal embryological development, several breasts can form, but all but two usually recede by birth. However, residual supranumerary breasts or nipples occur in about 10% of the population, and because the condition is inherited as an autosomal dominant characteristic, it occurs in women and in men with equal frequency. Because the tissue is hormonally responsive, it can become engorged and painful during pregnancy and in cycling in women. If symptoms mandate, surgical excision is indicated.

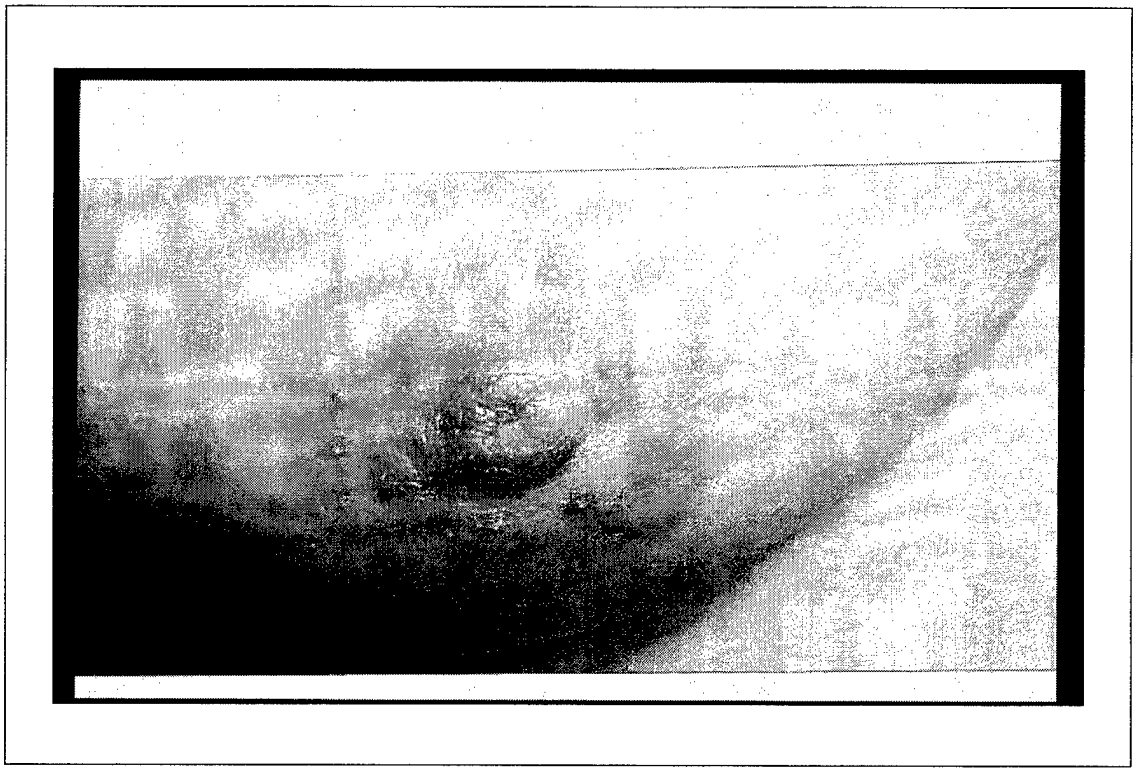
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, *1989*, pp. 159-166.



SLIDE 188

Polythelia, or extra nipples are also common, either associated with supranumerary breasts or occurring separately. This slide demonstrates both. On the right is a supernumerary breast and nipple complex. Some women can lactate from this structure. On the left is a supernumerary nipple. It most often occurs in an inframammary location, and is often mistaken for a skin tag or mole.

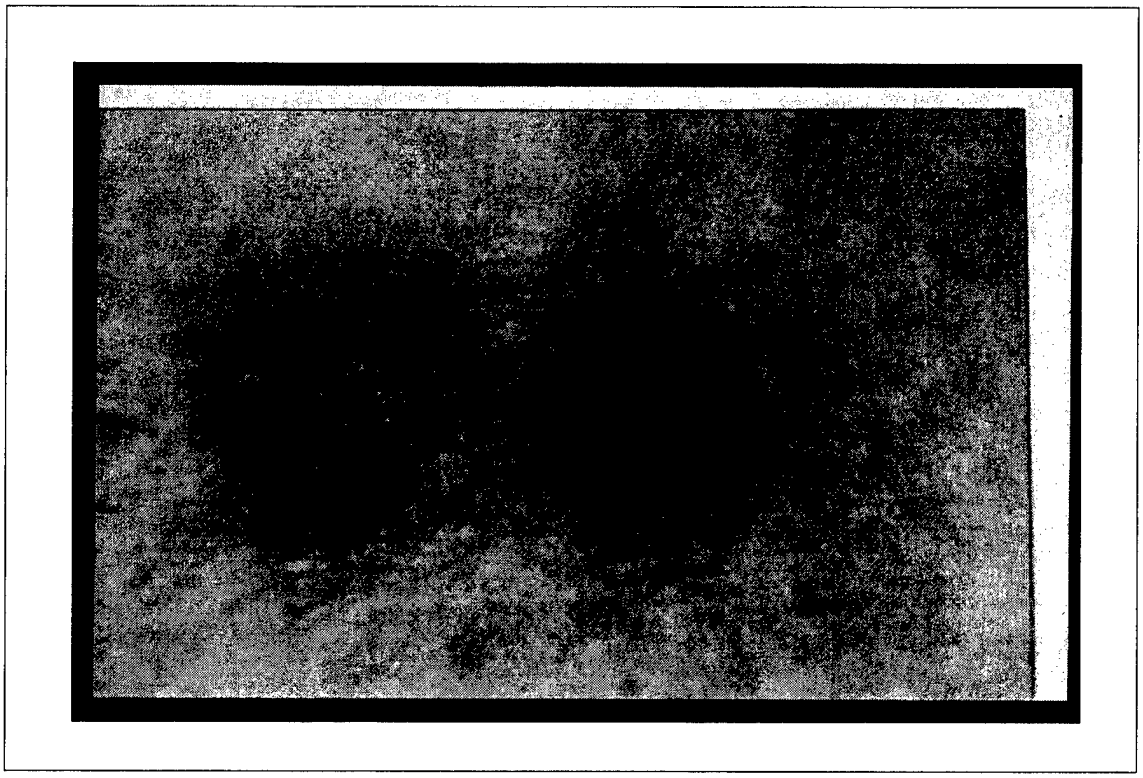
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, *1989*, pp. 159-166.



SLIDE 189

This is the normal appearance of the nipple-areolar complex. Montgomery glands are visible as bumps around the areola. These become more prominent during pregnancy.

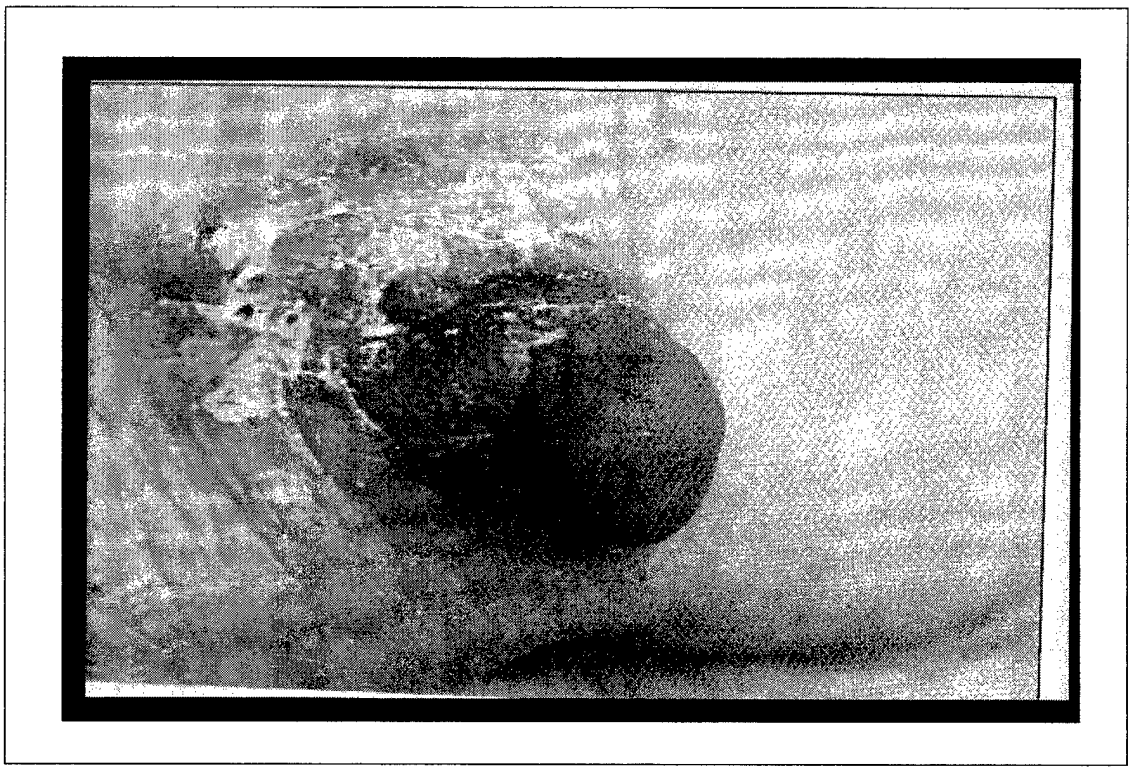
**Source:** Normal breast. In: Mansel RE, Bundred NJ (Eds.). *Color Atlas of Breast Diseases.* London: Mosby-Wolfe, 1995.



SLIDE 190

This slide demonstrates the appearance of eczema of the areola, which presents as pruritis and skin scaling. Notice that the nipple is not involved with the scaly hyperpigmented process present at the 6 o'clock position. Eczema rapidly responds to local hydrocortisone cream therapy.

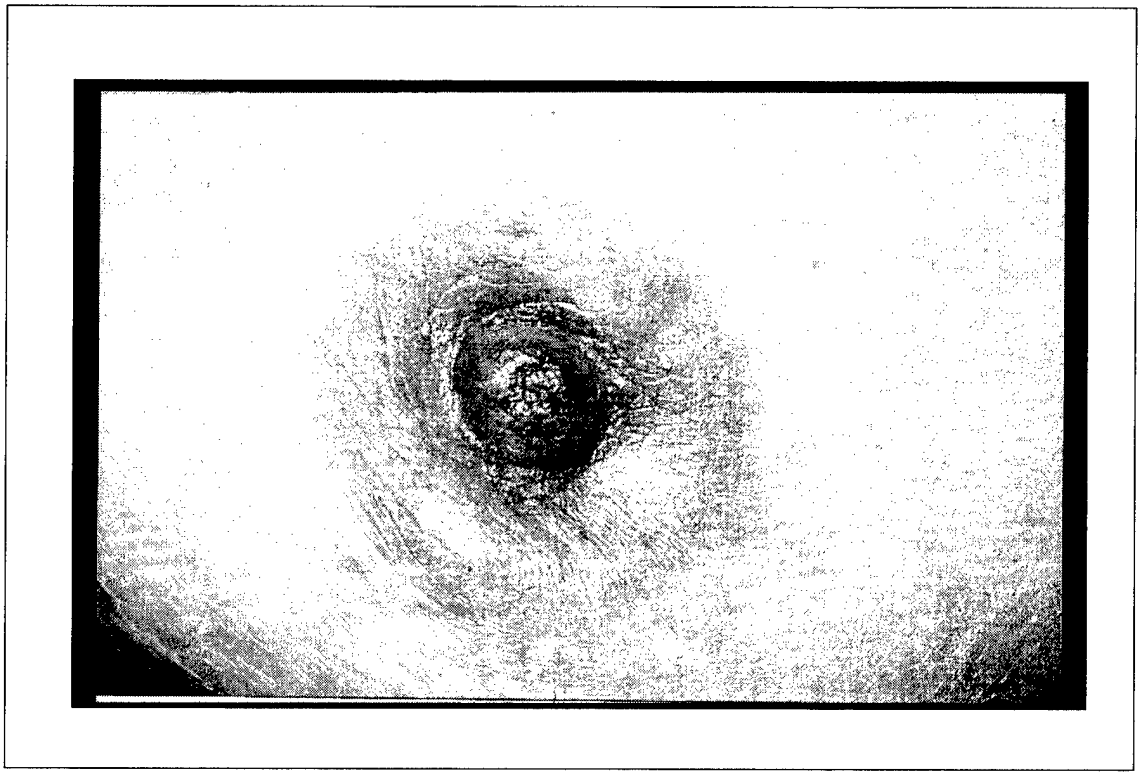
**Source:** Disorders of the Nipple and Areola. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, 1989, pp. 151-157.



SLIDE 191

This is an example of a more advanced case of areolar eczema. Sometimes the process can involve the nipple, but this is uncommon.

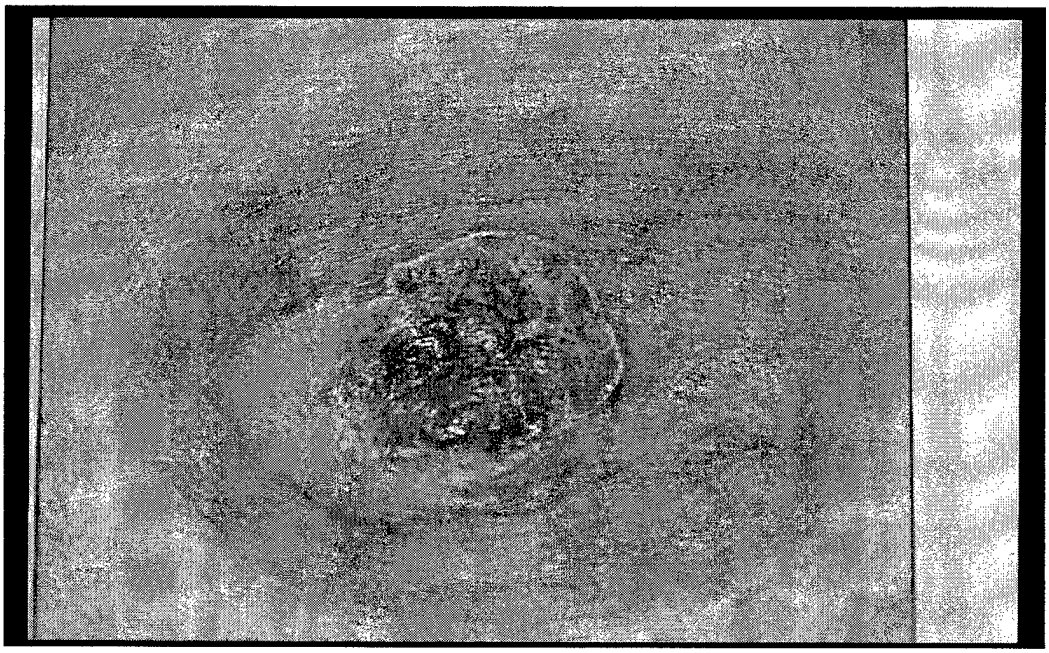
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, *1989*, pp. 151-157.



SLIDE 192

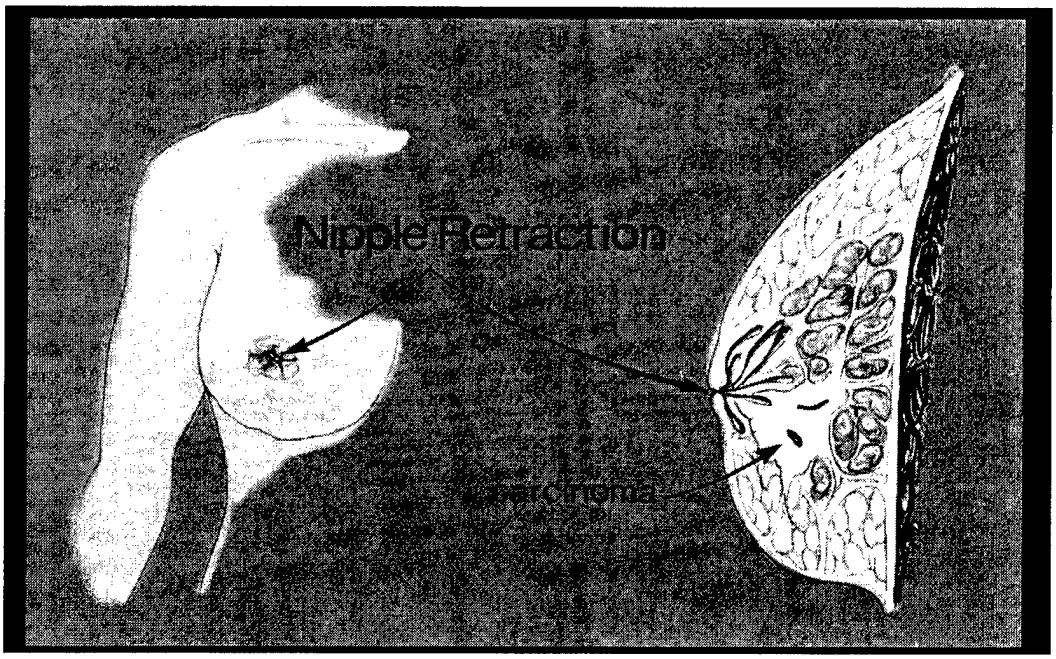
This slide demonstrates the appearance of early Paget's disease. Paget's disease represents cancer of the subareolar ducts and often is associated with no other findings on CBE or mammography. If the areola is involved in an eczematous process and the nipple is not, Paget's disease should not be part of the differential diagnosis. To differentiate between the two processes when uncertain, keep in mind that Paget's disease may respond to, but will not resolve with topical steroid creams. Misdiagnosis of Paget's disease is one cause of delayed diagnosis of breast cancer. Any patient who does not respond to topical treatment with hydrocortisone within 2 weeks of initiation needs a surgical referral.

**Source:** Disorders of the Nipple and Areola. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, 1989, pp. 151-157.



SLIDE 193

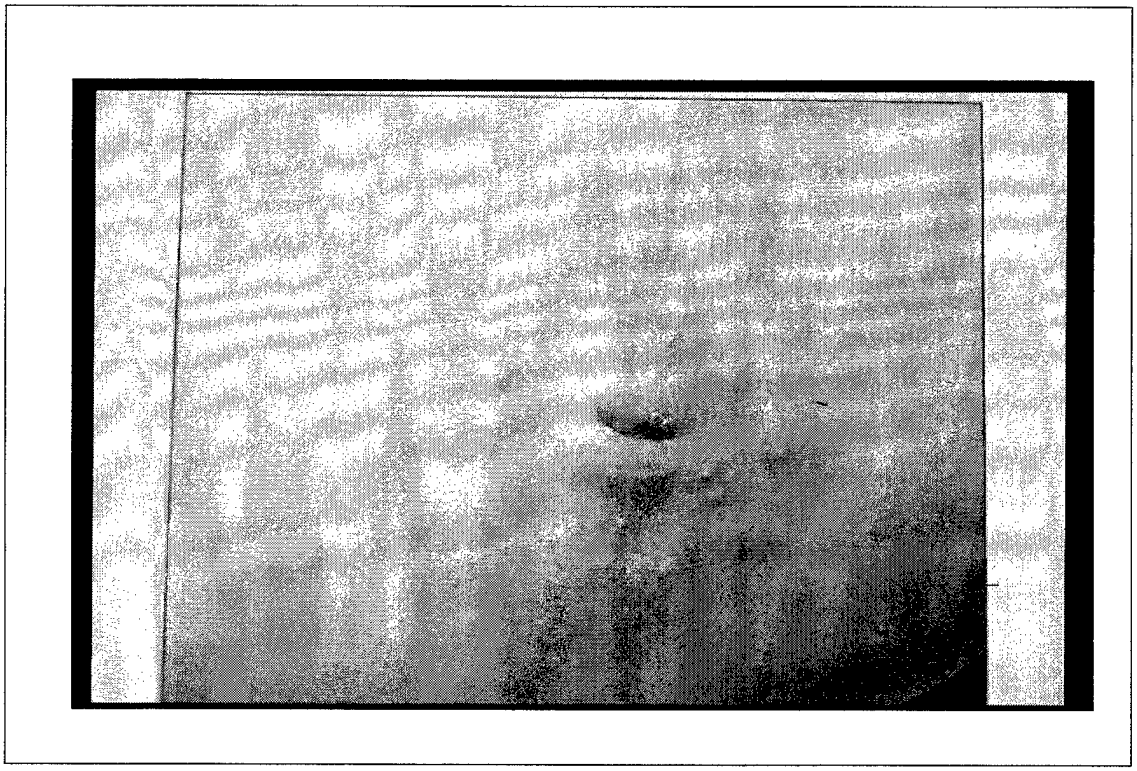
Paget's disease, as it advances, destroys the nipple. Even in this case, no underlying mass was palpable.




SLIDE 194

Nipple retraction, unlike nipple inversion, is a serious condition. Nipple retraction is the gradual onset of nipple inversion and is usually associated with broadening of the nipple and flattening of the nipple-areola complex. Until proven otherwise, nipple retraction implies that there is a carcinoma in the retro-areolar part of the breast. If a patient presents with new onset of nipple retraction, it requires surgical referral.

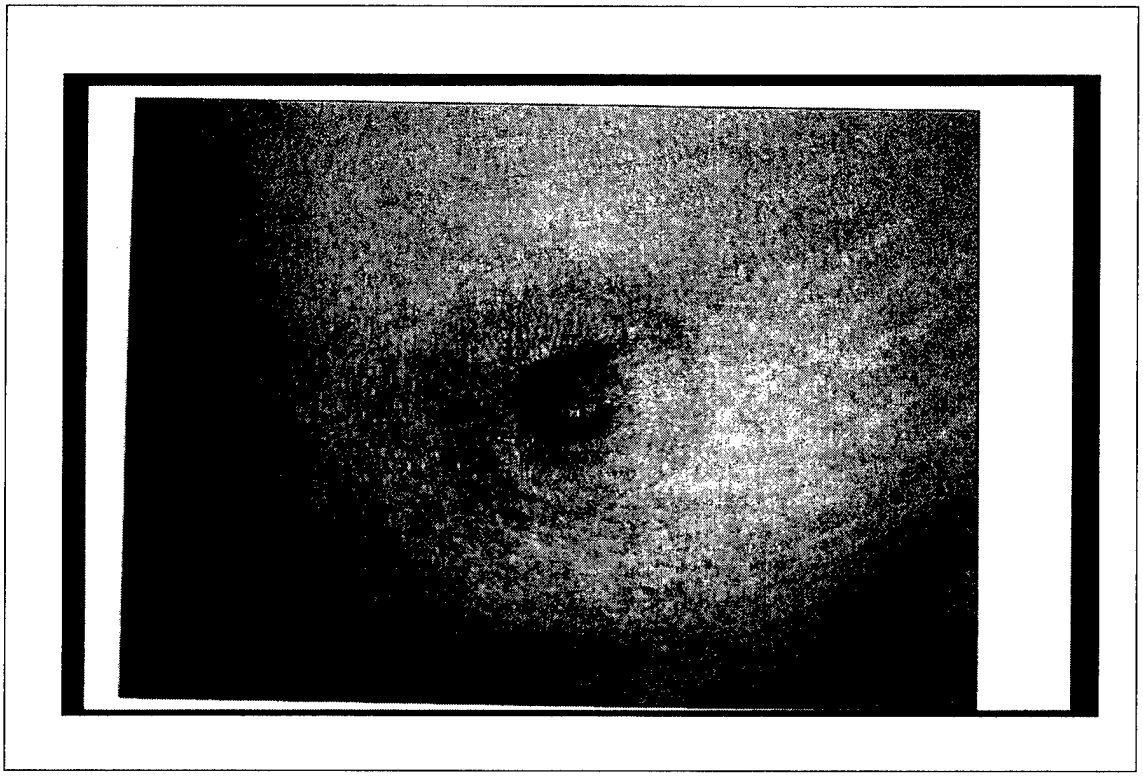
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 195

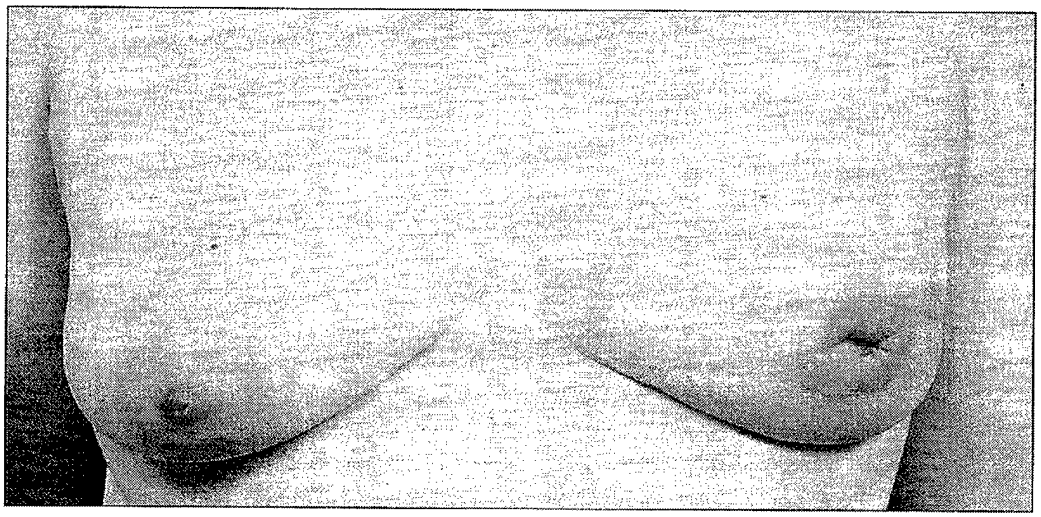
This is an example of acquired nipple inversion. Although the differential diagnosis in such cases includes carcinoma, this appearance is more consistent with the sequelae of periductal mastitis which occurs in association with duct ectasia. A history consistent with the latter, the commonly bilateral nature of the condition, and the presence of an otherwise normal CBE and mammogram will help differentiate the two. Referral is appropriate when uncertainty exists.

**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management*. London: Baillière Tindall, *1989*, pp. 107-131.



SLIDE 196

This slide illustrates the presentation of lateral retraction of the niple. The nipple is flattened and broadened. This woman has carcinoma in the retro-areolar location in her breast. A palpable thickening is present laterally.



SLIDE 197

This is a more advanced example of subareolar carcinoma, causing complete left nipple inversion.

## Signs and Symptoms of Breast Disease

# Observational Findings

## SKIN CHANGES

**Erythema**

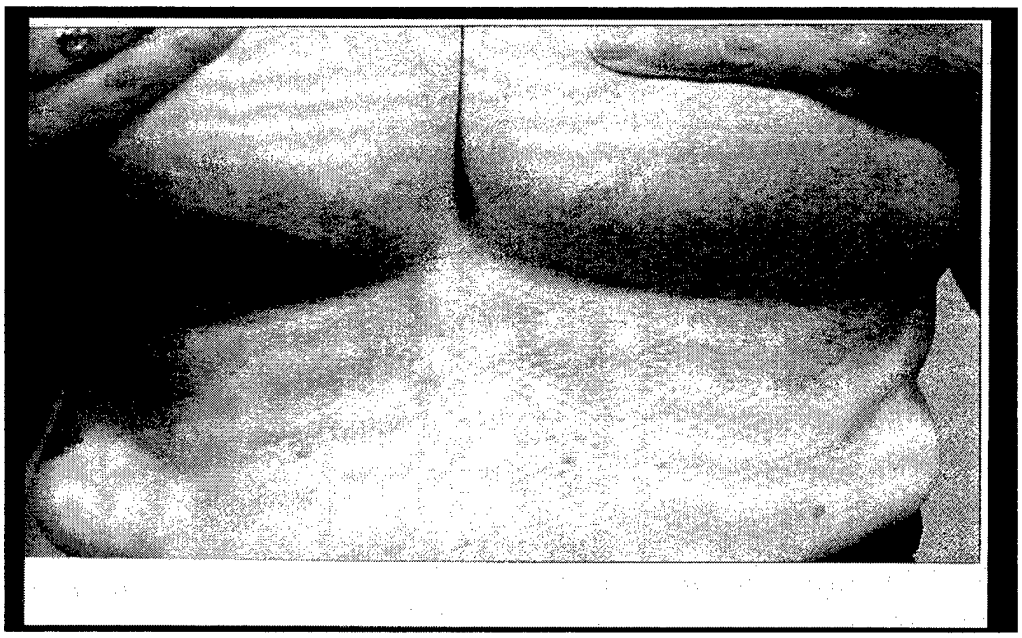
**Dimpling**

**Skin Retraction**

**Peau d'Orange**

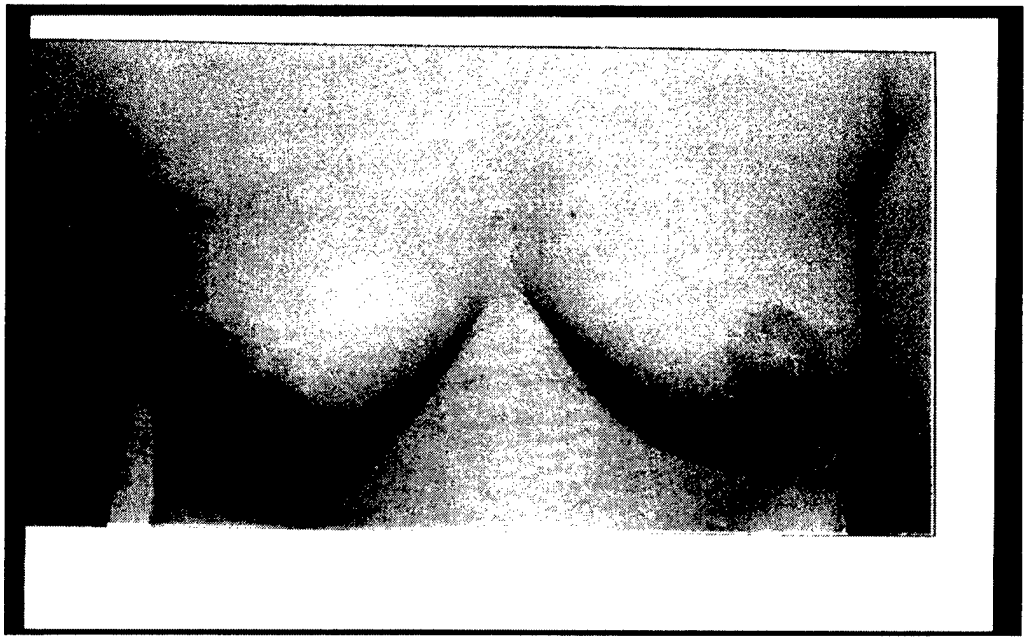
SLIDE 198

There are multiple causes for skin changes observed on CBE. Most of these have an etiology, like nipple changes, of either an inflammatory process or carcinoma. We will observe examples of each common skin change in the following slides.



SLIDE 199

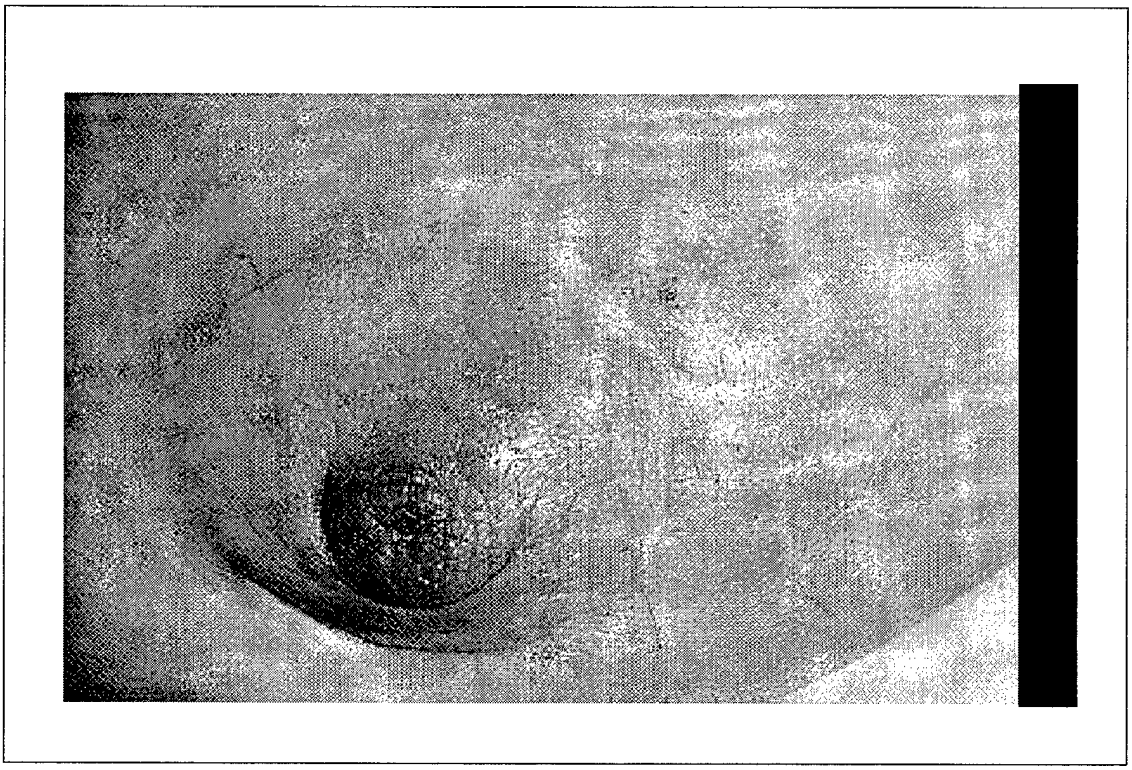
This is an example of intertrigo. It commonly occurs in older women in the folds of large pendulous breasts, and is not associated with carcinoma. Zinc oxide or talc to keep the area dry is helpful. The disease is of fungal origin, and can be treated with anti-fungal creams. The possibility of diabetes should be investigated in cases of intertrigo.



SLIDE 200

This example of mastitis of the right breast could be of lactational or non-lactational origin. Lactational mastitis is treated with warm compresses and if unresolved within 24 hours, with an antibiotic active against Staphylococcus aureus. Early treatment of the cellulitis is important to avoid abscess formation. Complete resolution is usual and referral is unnecessary unless an abscess develops.

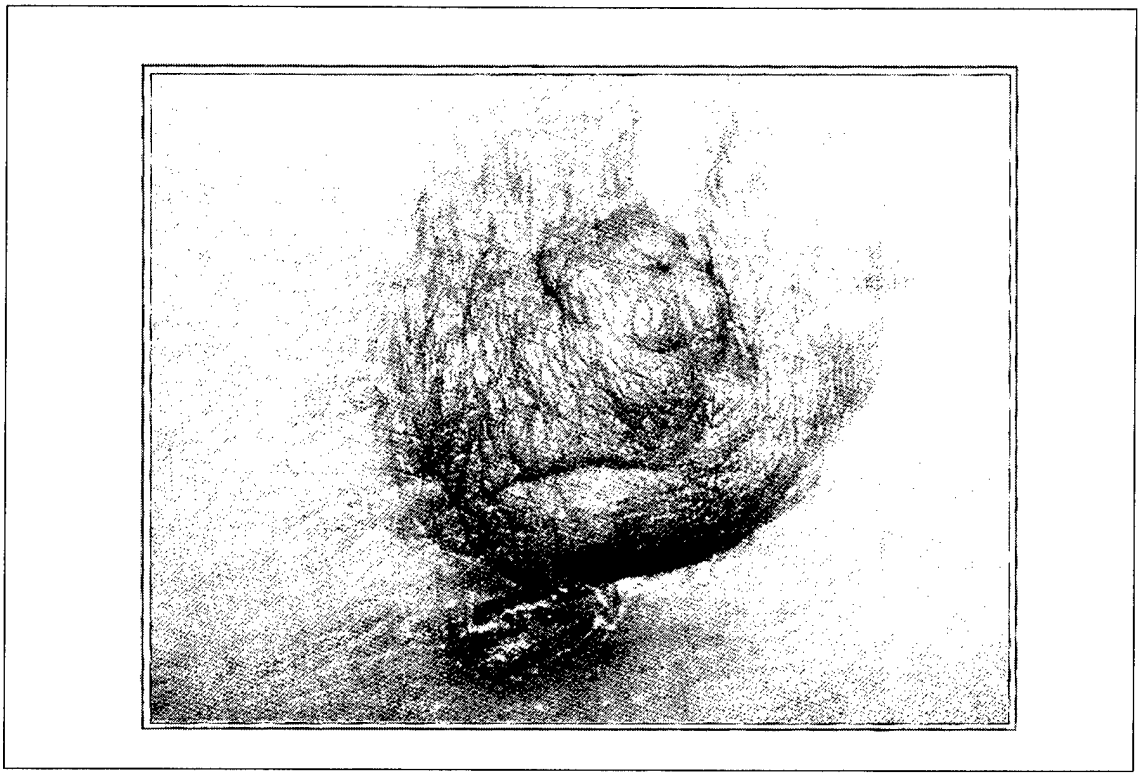
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 201

Periductal mastitis is secondary to duct ectasia and bacterial colonization of the subareolar ducts. It sometimes causes acute mastitis of the peri-areolar system. When it occurs, it needs to be treated with antibiotics active against Straphylococcus aureus and anaerobic organisms. If the condition progresses to abscess formation, incision and drainage followed by removal of the subareolar ductal system becomes necessary to prevent recurrence. This is a difficult condition to treat successfully, and recurrences are common, even with surgical intervention.

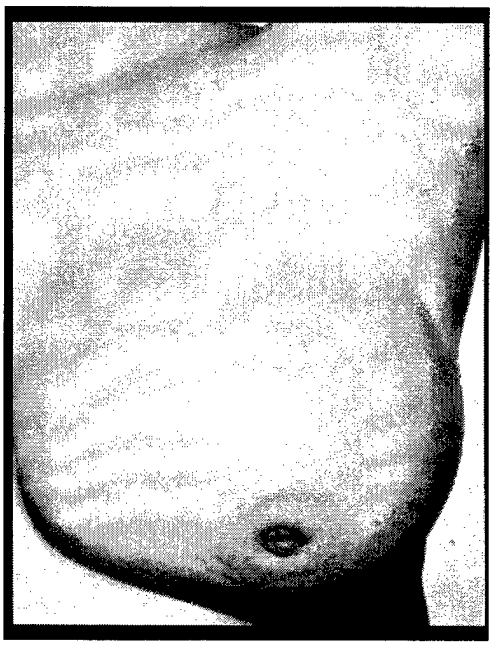
**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, *1989*, pp. 107-131.



SLIDE 202

Repeated recurrences of a peri-areolar abscess secondary to periductal mastitis can result in a mammary fistula, manifested by chronic peri-areolar drainage and distortion. Repeated incision and drainage will not resolve the problem. Instead, excision of the major ducts and fistulous tract will be necessary. This condition is much more likely to occur in smokers and smoking cessation will often be necessary to resolve the problem permanently after surgical treatment.

**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, *1989*, pp. 107-131.

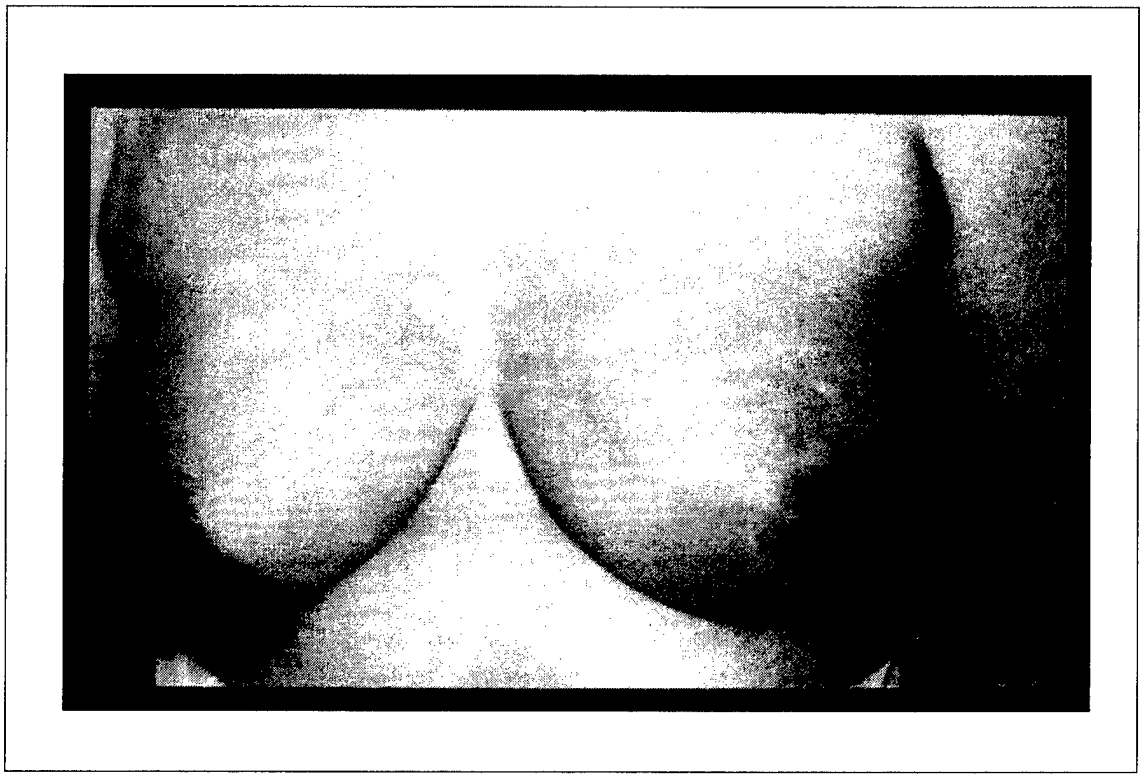


SLIDE 203

This is a case of erythema involving the entire breast and represents advanced inflammatory carcinoma. Note the nipple retraction.

Inflammatory breast cancer is an ominous condition associated with an extremely poor prognosis. Many times no mass can be palpated; mammography demonstrates skin thickening and increased density in the breast, but often no specific abnormalities.

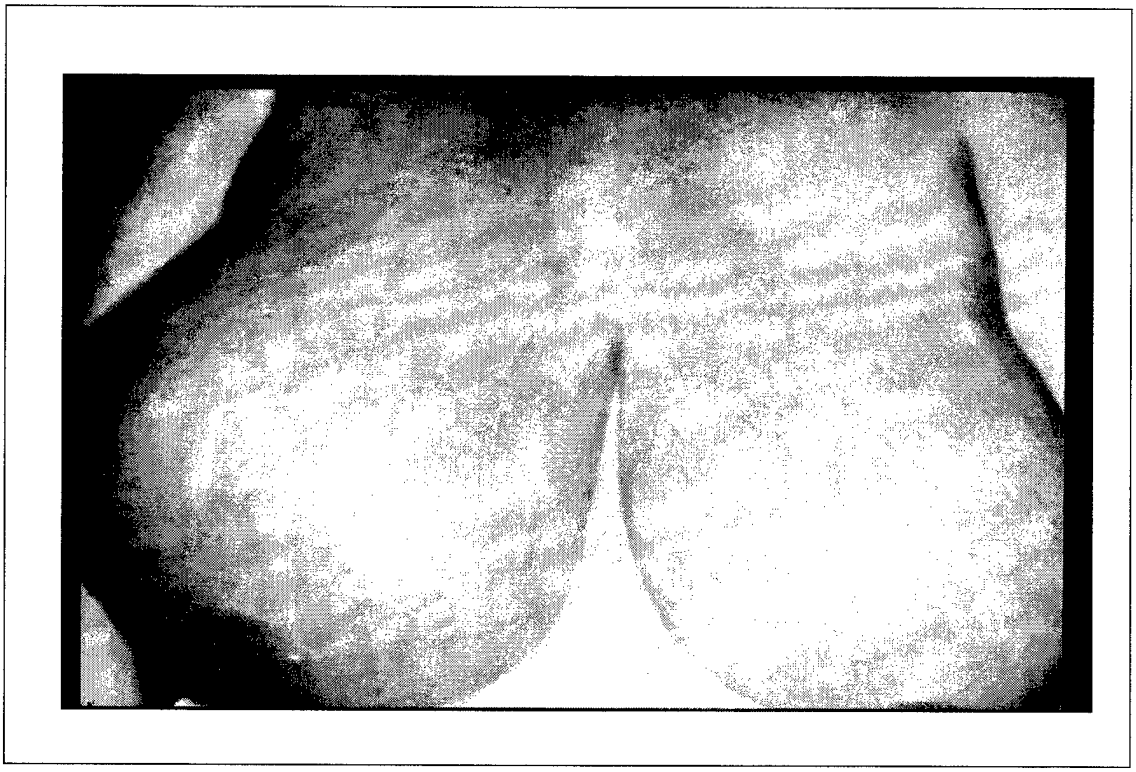
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 204

A more subtle presentation of inflammatory cancer is that of localized mastitis in a non-lactating woman. Usually pain and fever are absent, but the differential diagnosis can be challenging. Persistent mastitis beyond 2 weeks that does not resolve with antibiotics is a cause for grave concern, and an indication for surgical referral.

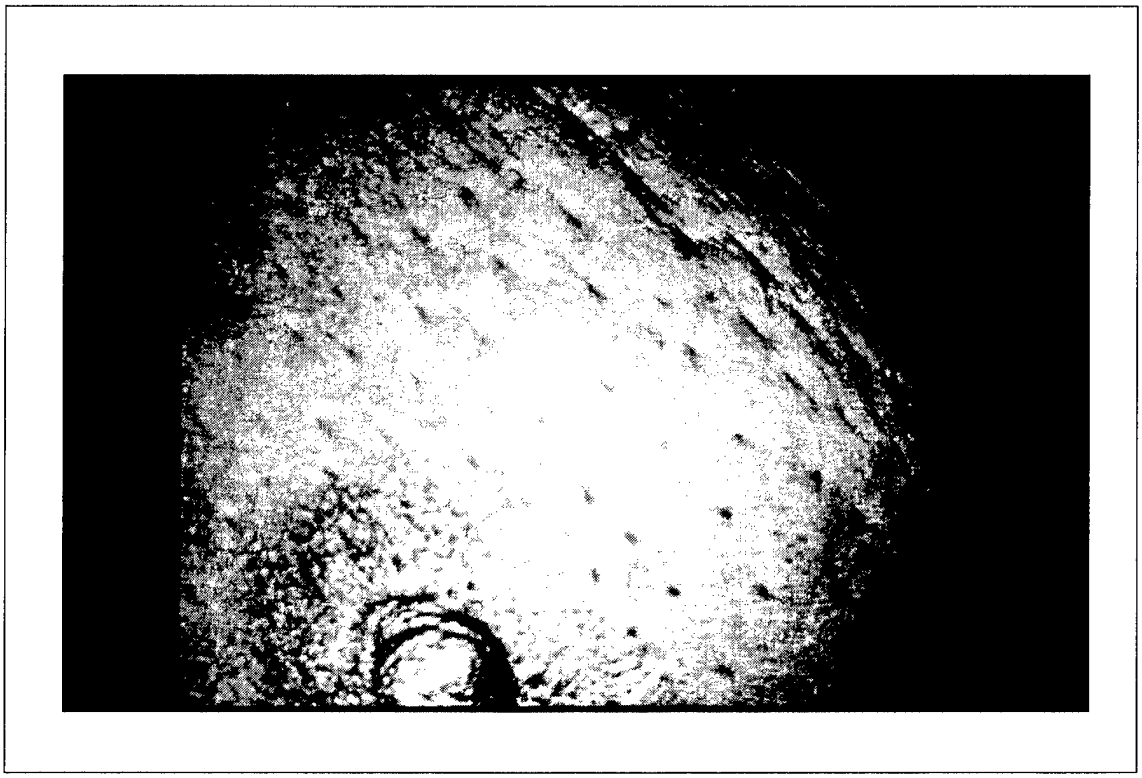
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health.* Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 205

Often accompanying breast erythema is peau d'orange, a term denoting skin thickening. This implies obstruction of the dermal lymphatics with inflammatory or malignant cells. Symptoms of erythema and peau d'orange that do not respond to antibiotic therapy within 2 weeks need referral to rule out inflammatory carcinoma.

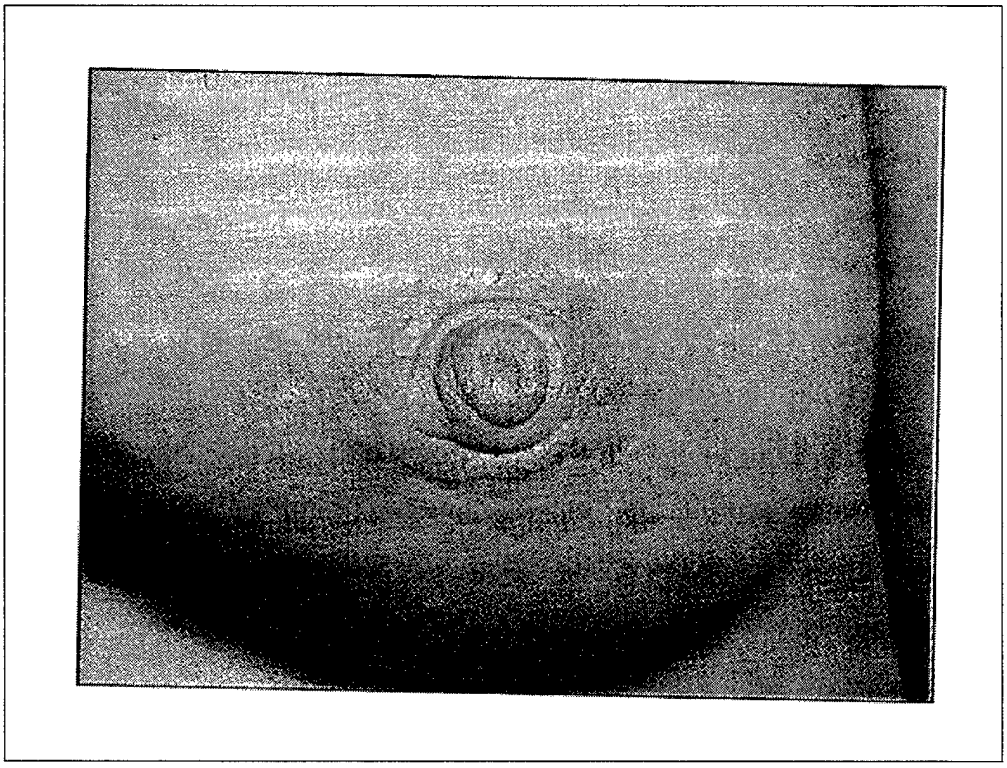
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 206

This close up view of peau d'orange makes the orange-peel description obvious. Diagnosis is made by punch biopsy of the skin; if this is negative, open biopsy to include skin should be performed.

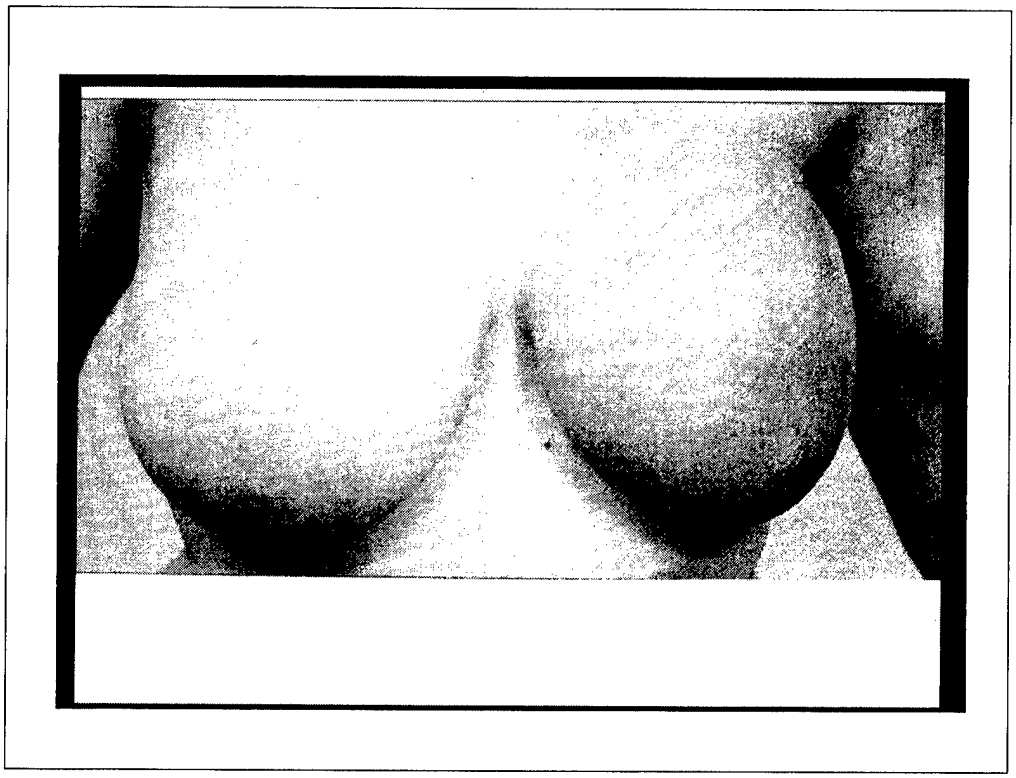
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 207

Note the erythema, nipple retraction, and peau d'orange present in this case. This patient's symptoms, which included pain, resolved after being treated with broad-spectrum antibiotics. If she had not resolved with antibiotics within 2 weeks, referral would have been necessary to rule out inflammatory carcinoma.

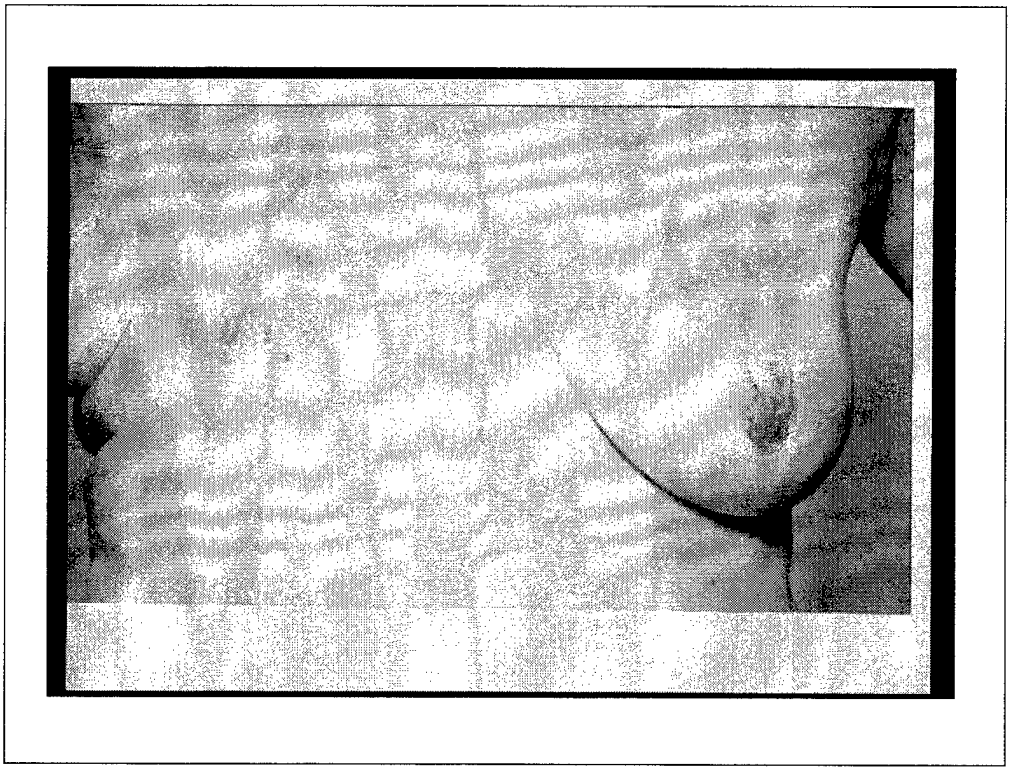
**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.



SLIDE 208

Acute erythema can, but does not always occur as a reaction to radiation treatments. This woman's left breast is showing some sunburn-like effect from radiation. This condition can last up to a year after radiation therapy. It is common to develop peau d'orange from radiation therapy as well. Sometimes it becomes difficult to distinguish the etiology of these reactions and consultation with the specialist may be necessary to rule out inflammatory carcinoma.

**Source:** Osuch JR. Breast health and disorders over the life phases. In: Wallis LA (Ed.), *Textbook Women's Health*. Philadelphia, PA: Lippincott-Raven, 1998, pp. 295-313.

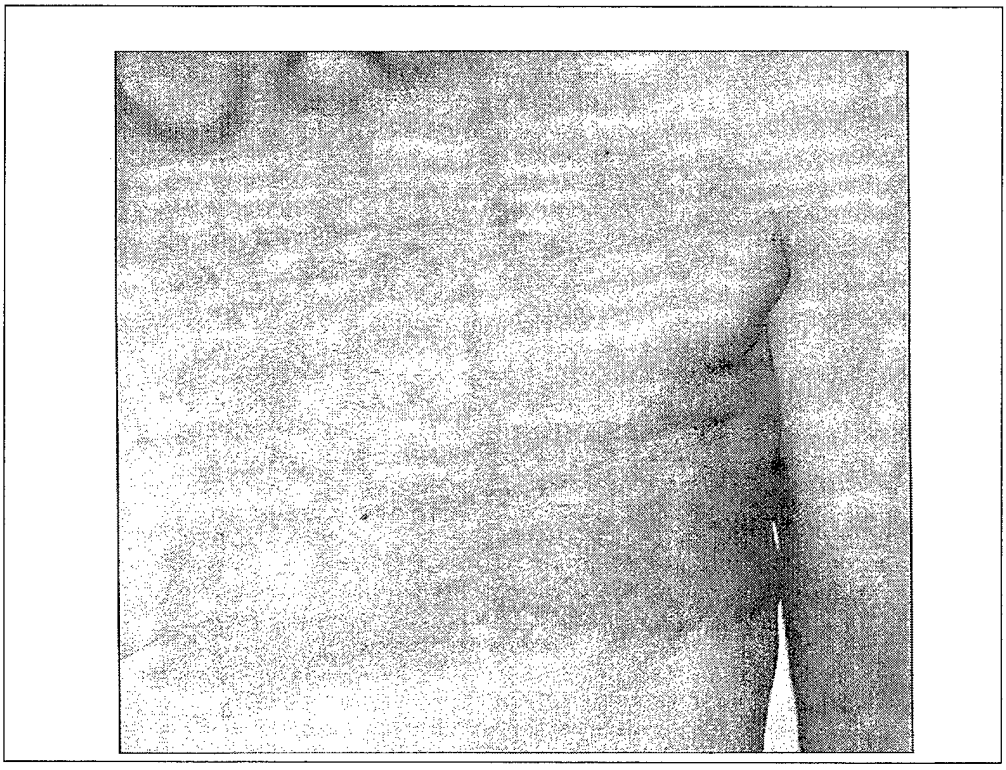


SLIDE 209

The appearance of erythematous nodules in a surgical site after breast cancer treatment is an ominous sign and usually represents a local recurrence. Post-treatment skin changes are often subtle. This event can occur years after primary treatment. Referral is indicated.

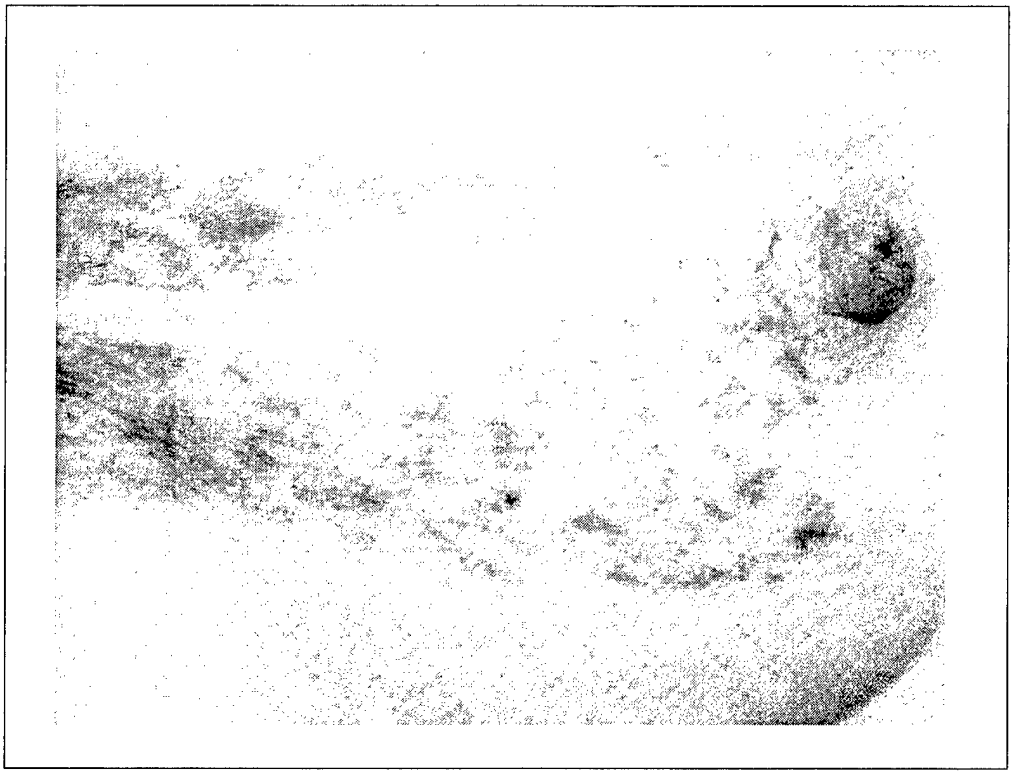
SLIDE 210

This slide demonstrates a chest wall recurrence that is a more advanced presentation of local recurrence.



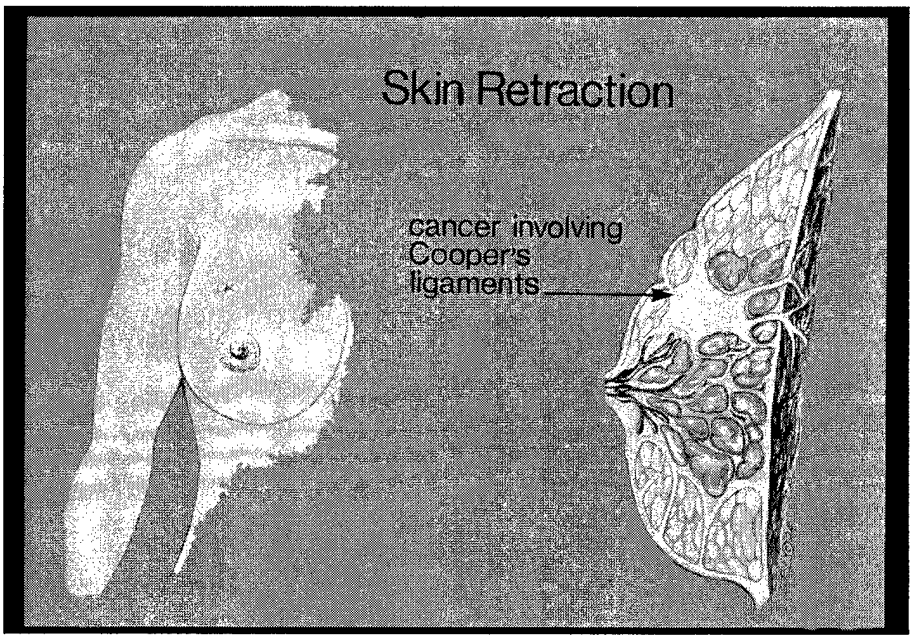
SLIDE 211

Sometimes a diffuse erythematous rash occurs at the site of previous breast cancer surgery. It often extends onto the back. This skin change represents a local recurrence and is very difficult to control.



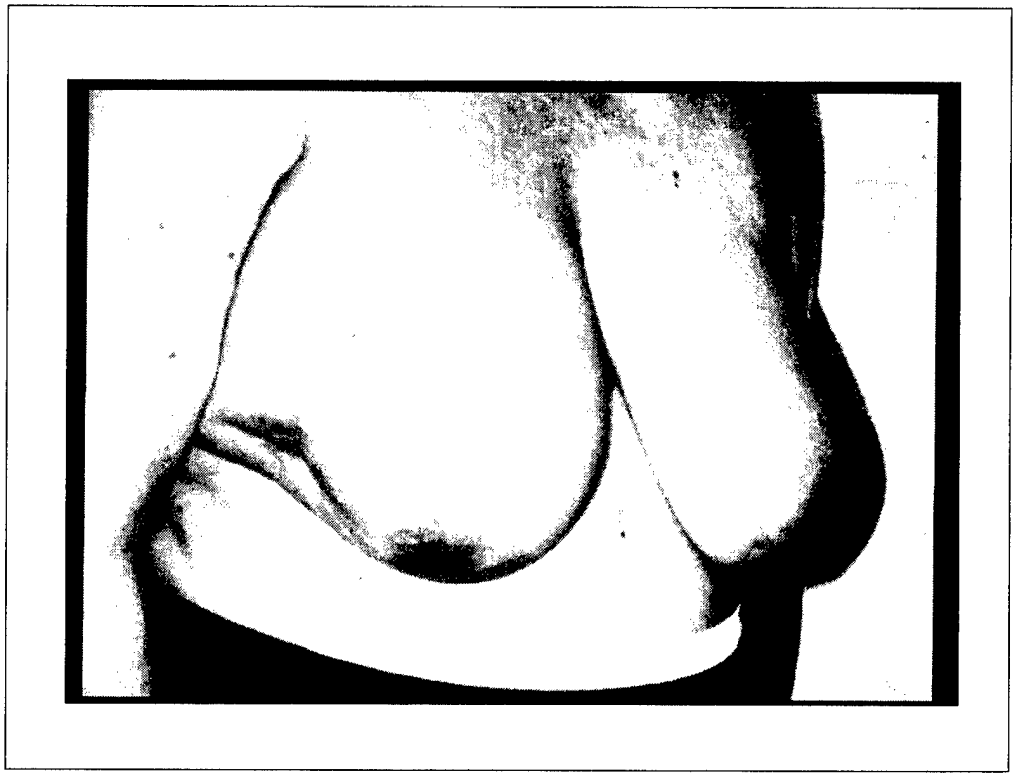
SLIDE 212

Sometimes radiotherapy can result in the proliferation of blood vessels known as telangiectasias. These are not raised and are harmless, although cosmetically unattractive. Telangiectasias often takes 4-5 years to develop.



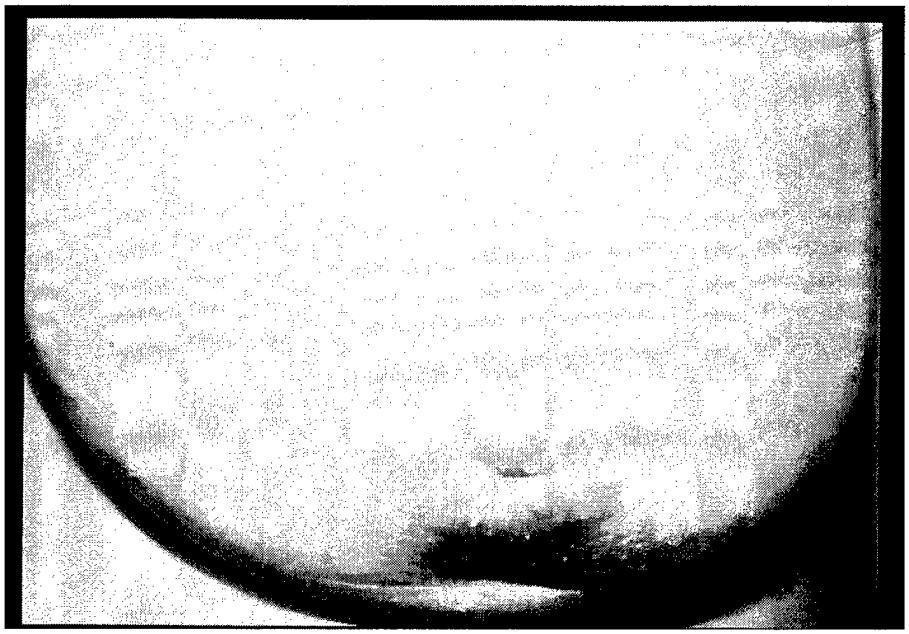

SLIDE 213

Skin retraction is almost always a sign of underlying carcinoma. It occurs secondary to involvement of Cooper's ligaments with carcinoma. Recall that Cooper's ligaments attach to both the skin and the pectoralis major muscle.



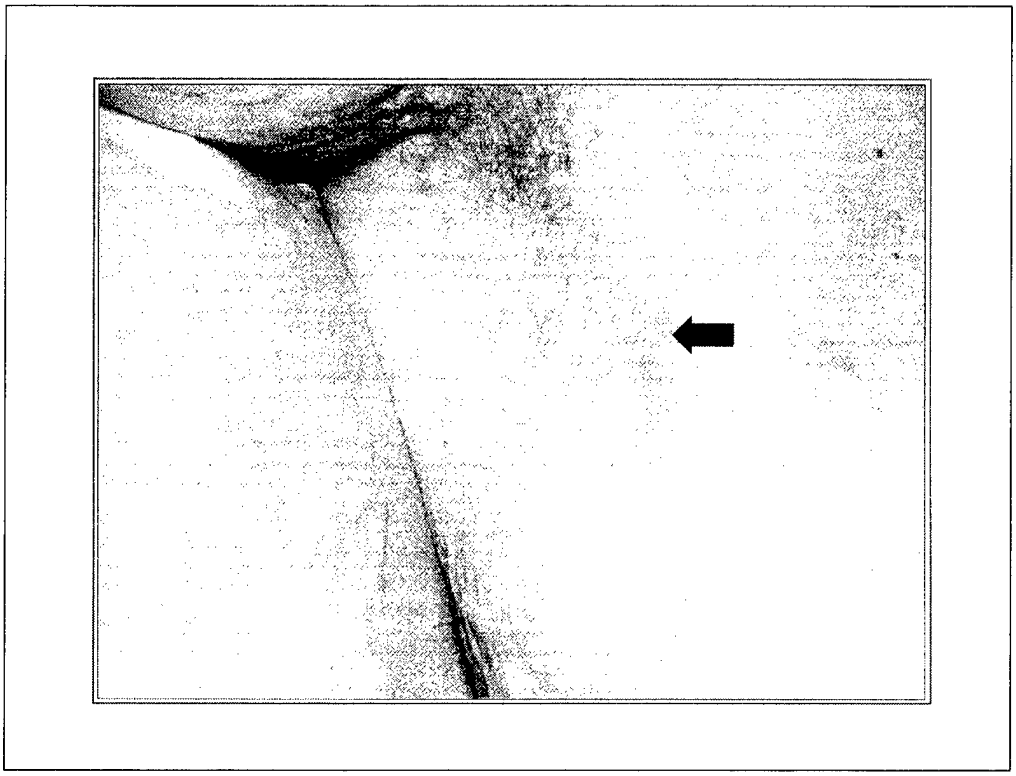
SLIDE 214

Advanced cases of skin retraction can be note with simple observation. This patient saw her doctor every 6 months for 8 years for hypertension, had never had a breast exam or a mammogram.



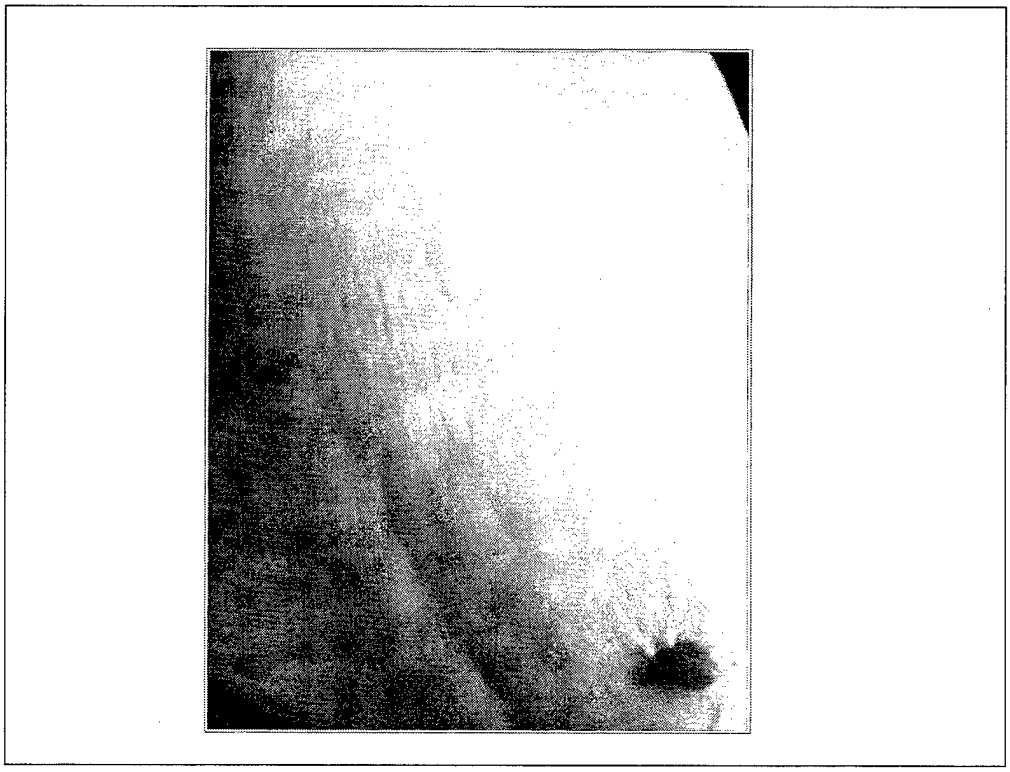
SLIDE 215

This is a picture of a woman with congenital nipple inversion who developed advanced subareolar skin retraction. This woman has cancer.



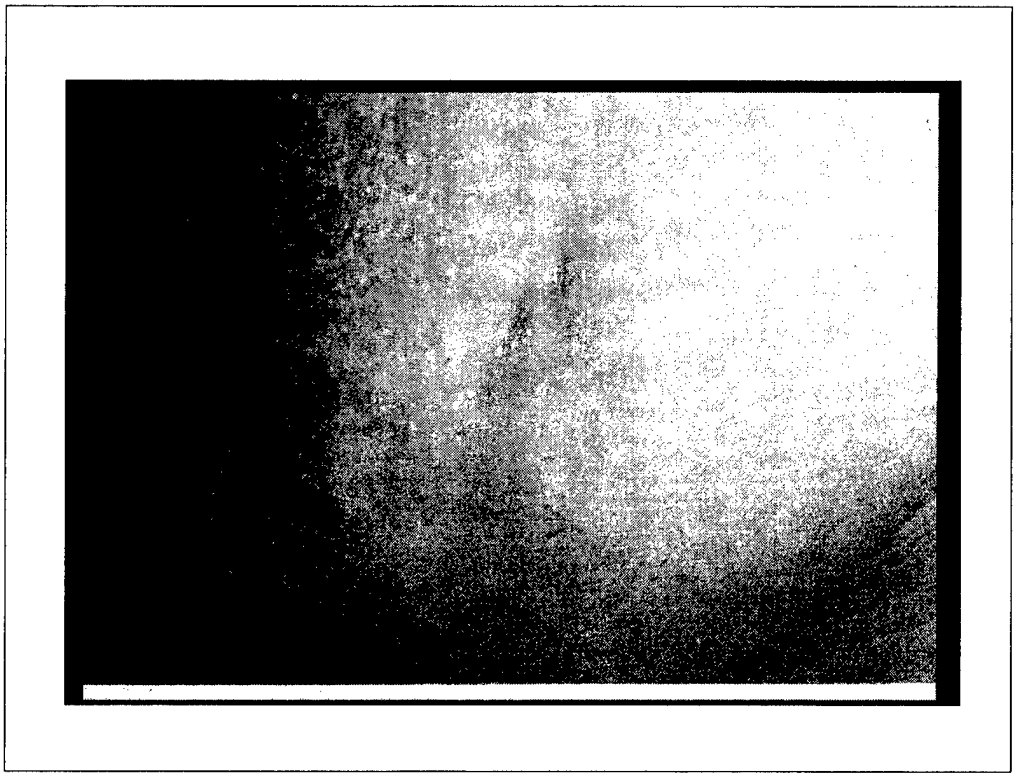
SLIDE 216

More subtle skin retraction may require arm raising, as shown here. The arrow shows the site of an underlying carcinoma.



SLIDE 217

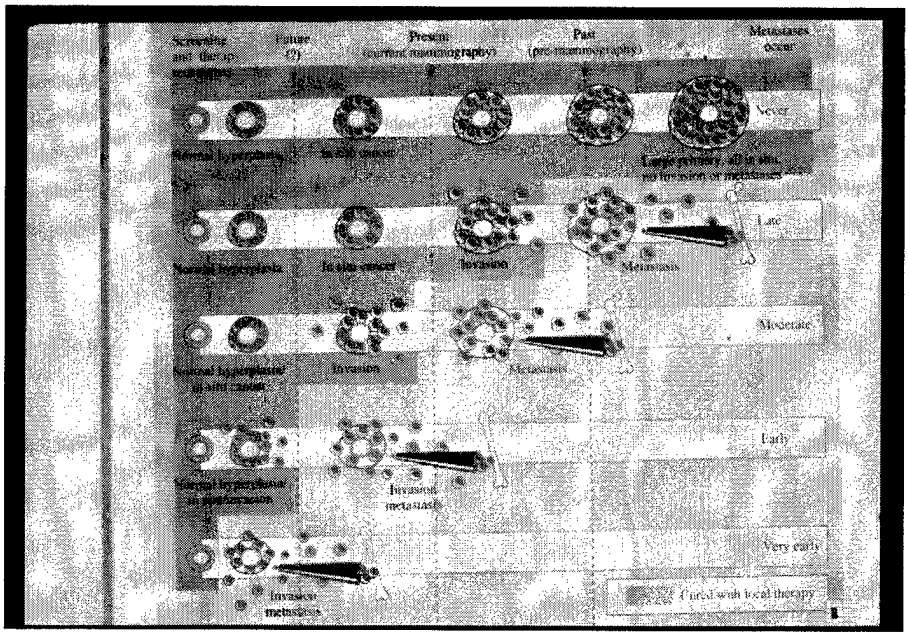
Contrast the previous slide with the skin retraction present along the course of a vein. This is an example of Mondor's Disease, or thrombophlebitis of the lateral thoracoepigastric vein in the breast, usually due to surgery or trauma. If painful, it can be treated with oral analgesics. It resolves spontaneously within 2-6 weeks. The differential diagnosis includes carcinoma.



SLIDE 218

Sometimes skin dimpling will be elicited only with pectoralis major muscle contraction. The differential diagnosis in this case is carcinoma vs. Mondor's disease of a short segment of the lateral thoracoepigastric vein. Carcinoma is much more common and referral should be considered when this change is present. An algorithm summarizing the management of patients with observational findings of breast disease can be found in Appendix 7.

**Source:** The duct ectasia /periductal mastitis complex. In: Hughes LE, Mansel RE, Webster DJT (Eds.). *Benign Disorders and Diseases of the Breast: Concepts and Clinical Management.* London: Baillière Tindall, 1989.




SLIDE 219

The whole goal of detection of breast cancer in the pre-clinical phase is to diagnose the disease prior to its ability to metastasize. This will not be possible in every patient. This slide reinforces the tremendous heterogeneity of breast cancer. The dark area represents those patients cured with local therapy, the light green represents those patients destined to die from metastatic breast cancer no matter when it is detected. The second dashed vertical line from the left represents the detection of occult breast cancer by mammography. The slide illustrates the principle that breast cancer has the ability to metastasize very early in some patients, long before the disease in the breast is detectable. This is illustrated in the bottom three rows of the slide. It becomes critical, therefore, that work up and follow up of breast problems follow standard protocols and that it be carefully documented.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. http://www.medscape.com. (See instructions in Appendix 10.)

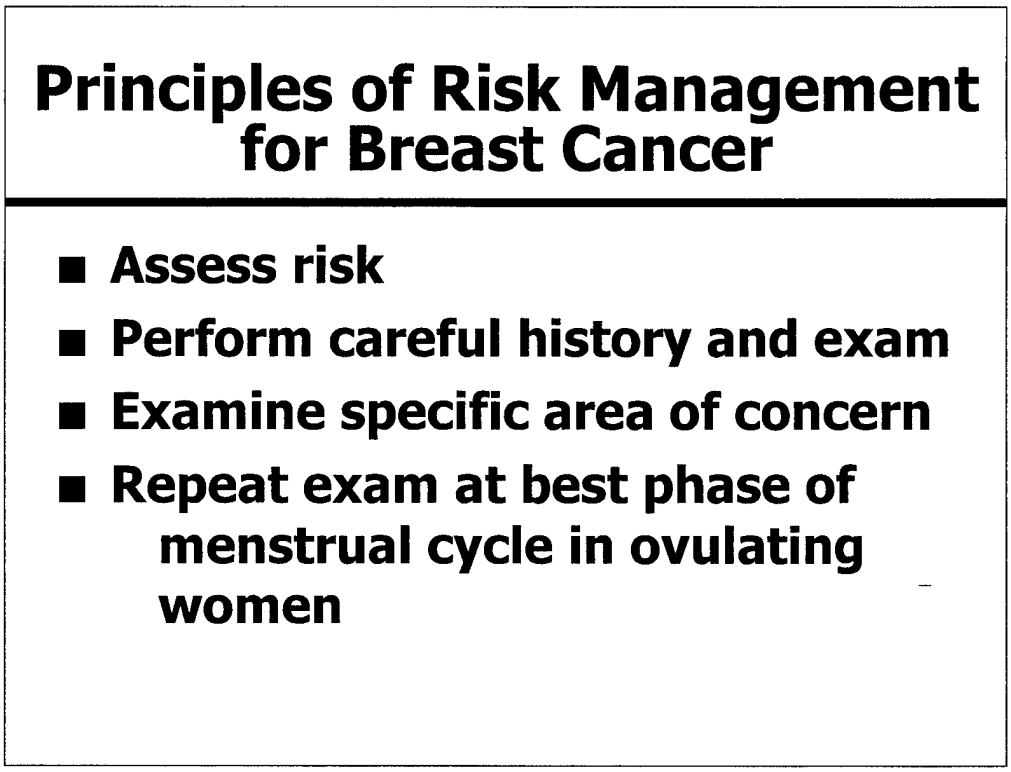
# Principles of Risk Management for Breast Cancer

## Screen According to Guidelines

SLIDE 220

Allegations of failure to screen for breast cancer are becoming increasingly common. Routine breast cancer screening through the use of mammography and CBE is universally recommended for women 50 and over. Evidence has accumulated to favor mammography use in women 40 and over on a routine basis as well. The screening schedule followed by the physician should be applied uniformly to the active patient population, with exceptions to the office's screening policy carefully documented. Documentation of assessment for breast cancer risk will become increasingly important in the future.

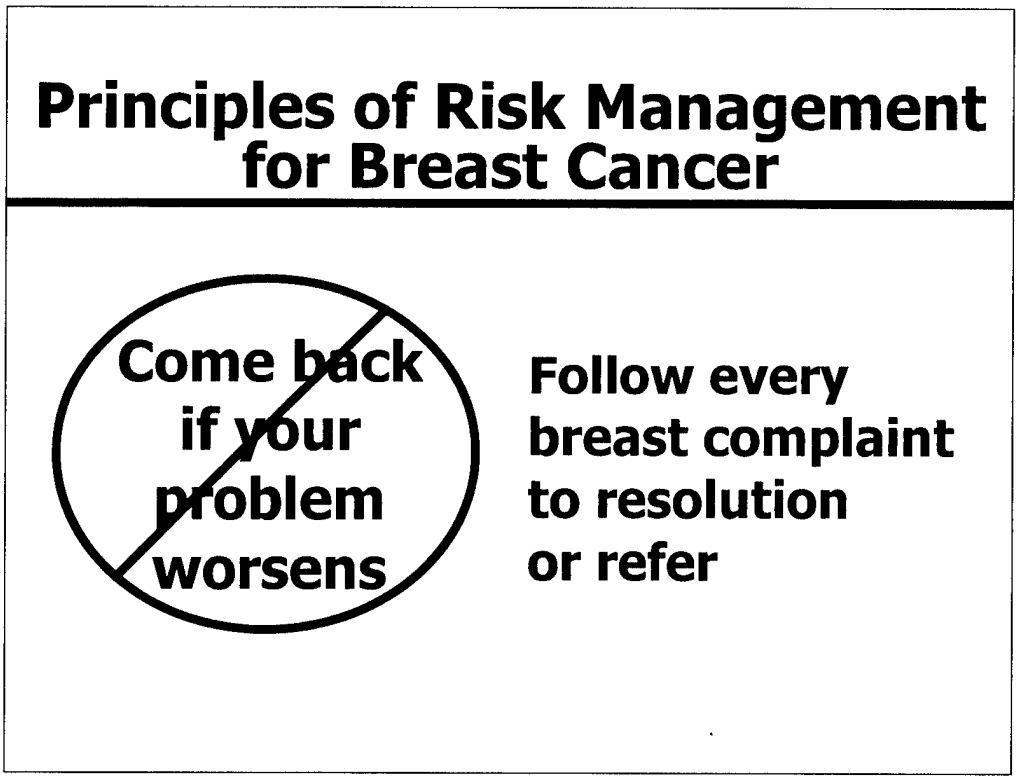
**Source:** Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.




SLIDE 221

The most common allegation for failure to diagnose breast cancer is failure to be impressed with clinical findings or to verify a patient's complaint. In addition to a risk assessment, it is important to document a thorough history and CBE, to document the findings on CBE if the patient has a specific area of concern, and if the findings are subtle, to be sure the exam is at the best phase of the cycle in premenopausal women.

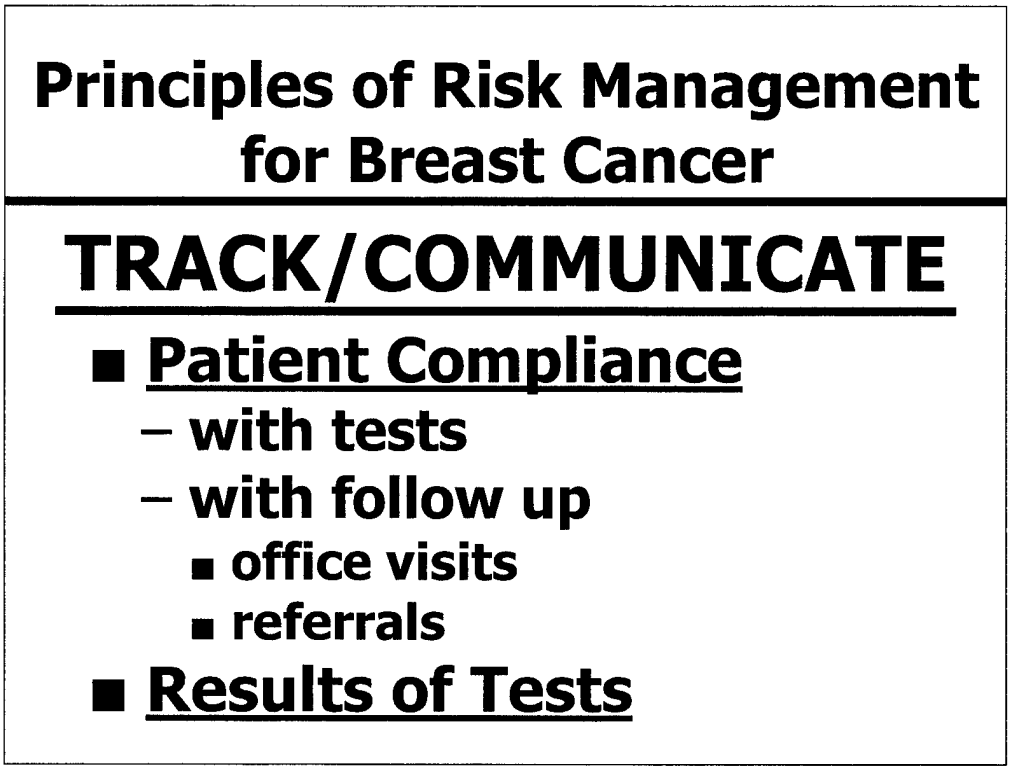
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. http://www.medscape.com. (See instructions in Appendix 10.)




SLIDE 222

Asking a patient to call if the problem worsens is a suboptimal office policy from a risk management standpoint, as some patients will unconsciously deny their problems until they become more advanced. Instead, specific follow-up or referral is advised.

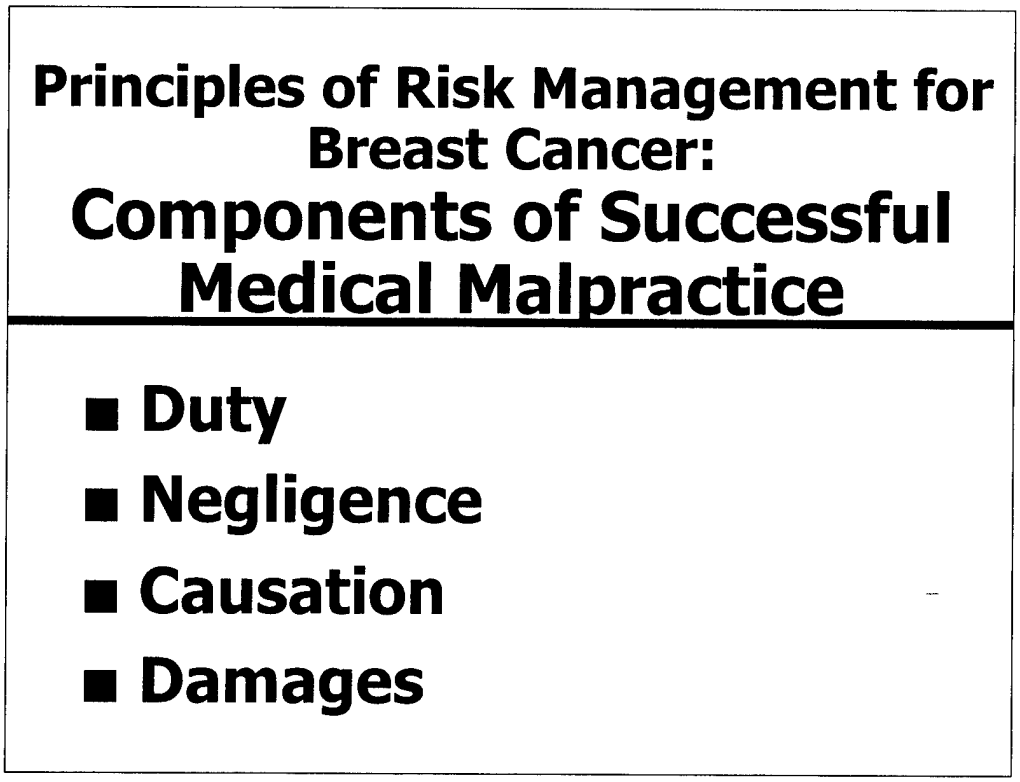
**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. http://www.medscape.com. (See instructions in Appendix 10.)




SLIDE 223

Tracking of test results and recommendations for tests or referrals is a critical component of the risk management process. Results of tests need to be received before they can be reviewed and recommendations communicated. This includes results of referrals to other physicians. A method for ensuring the timely receipt of all ordered tests or referrals, with chart documentation of recommendations for follow up, is a necessary component of sound risk management. Many practices also use tracking systems to remind patients that they are due for check-ups, and this policy promotes communication and good patient care.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. http://www.medscape.com. (See instructions in Appendix 10.)




SLIDE 224

The components of a successful medical malpractice lawsuit include issues related to duty, negligence, proof that the negligence caused harm to the patient, and that economic, non-economic, or punitive damages resulted. Especially important in the risk management of a non-compliant patient is the principle of duty.

**Source:** Dewar MA. Legal issues in breast disease. In: Bland KI, Copeland EM (Eds.) *The Breast-Comprehensive Management of Benign and Malignant Disease, 2nd Edition.* Philadelphia, PA: W.B. Saunders, 1998; pp. 1577-1587.

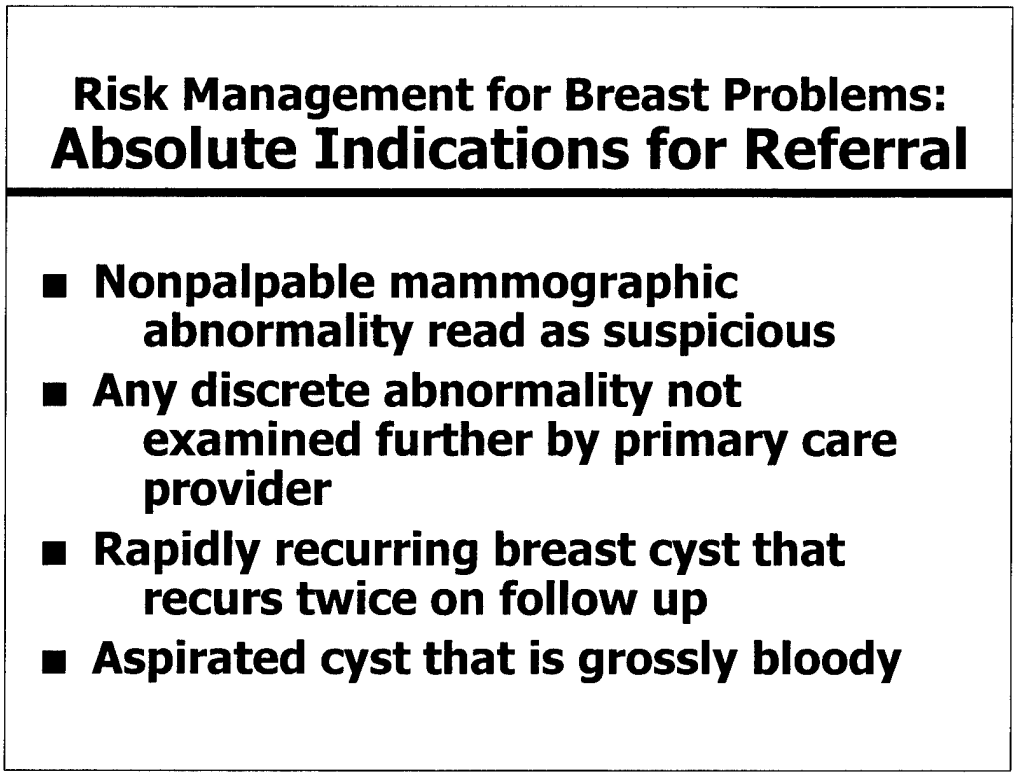
## Principles of Risk Management for Breast Cancer: The Non-Compliant Patient

# "What are my obligations?"

SLIDE 225

Duty refers to the legal responsibility that a doctor assumes whenever a patient is accepted into the practice. The responsibility assumes that both reasonable and appropriate care have been rendered to the patient. This is an impossible task if the patient does not follow recommendations for follow up. Most physicians are troubled to learn that non-compliance on the patient's part does not excuse the doctor's legal responsibility to the patient. It is at these times that tracking and follow up, in conjunction with careful chart documentation is critical. If the patient continues to be resistant to recommendations, it may be best to formally curtail the legal responsibility inherent in the doctor-patient relationship. Most physicians find this concept contrary to their ethical codes of conduct regarding patient care. It is important to realize, however, that good patient care implies mutual trust and that it may be in the best interest of the patient to refer her to a physician who may better meet her needs.

**Source:** Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Managing a Breast Mass: Step-by-Step Work-Up. Medscape Women's Health 1998; Vol. 3, No. 5. http://www.medscape.com. (See instructions in Appendix10.)




SLIDE 226

While many breast complaints can be followed and resolved by primary care providers, the following are absolute indications for a surgical referral:

- Nonpalpable mammographic abnormality read as suspicious
- Any discrete abnormality not examined further by the primary care provider
- Rapidly recurring breast cyst (within 4-6 weeks) that recurs a second time within 4-6 weeks
- Aspirated cyst that is grossly bloody

**Source:** Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

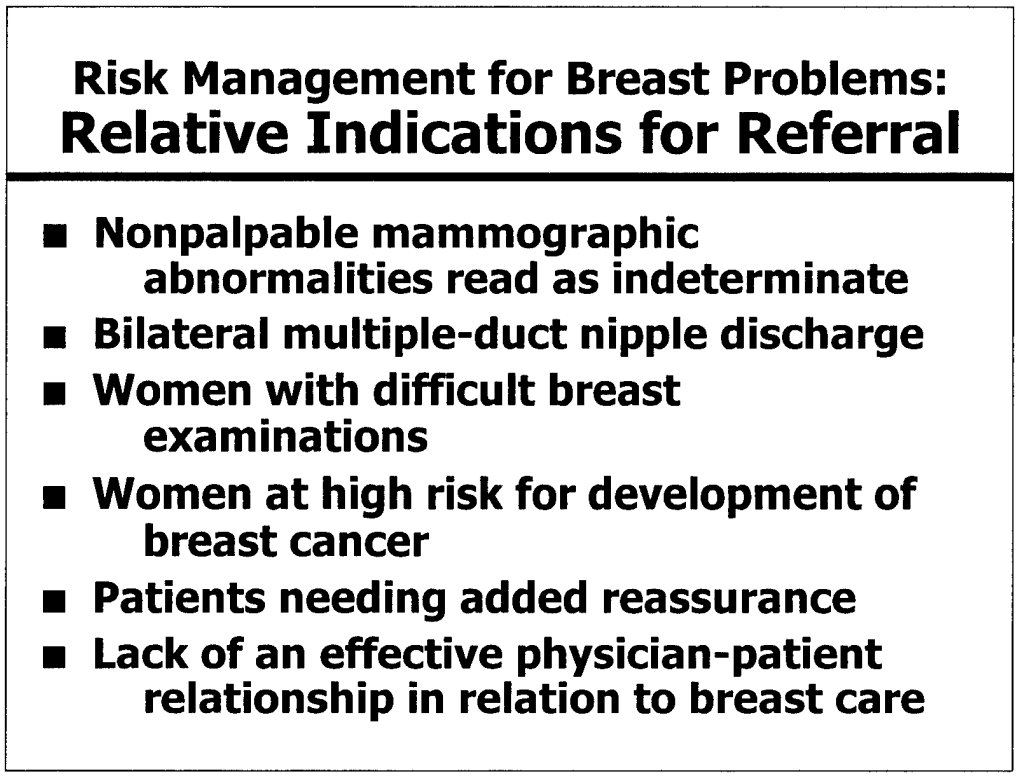
## Risk Management for Breast Problems:
# Absolute Indications for Referral

- **Palpable asymmetric mass or thickening solid after aspiration and either not evaluated or not benign by triple diagnosis**
- **Spontaneous unilateral single-duct nipple discharge**
- **Nipple scaling that does not respond to hydrocortisone treatment within 2 weeks**
- **Skin or nipple retraction**
- **Skin erythema that does not respond to antibiotic treatment within 2 weeks**

SLIDE 227

- Palpable asymmetric mass or thickening solid after aspiration and either not evaluated or not benign by triple diagnosis
- Spontaneous unilateral single-duct nipple discharge
- Nipple scaling that does not respond to hydrocortisone treatment within 2 weeks
- Skin or nipple retraction
- Skin erythema that does not respond to antibiotic treatment within 2 weeks.

**Source:** Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.




SLIDE 228

Relative indications for referral include:

- Nonpalpable mammographic abnormalities read as indeterminate
- Bilateral multiple-duct nipple discharge
- Women with difficult breast examinations
- Women at high risk for development of breast cancer
- Patients needing added reassurance
- Evidence of lack of an effective physician-patient relationship in relation to breast care.

A summary of risk management principles for common allegations of failure to diagnose breast cancer can be found in Appendix 9.

**Source:** Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer* 1994;74:271-278.

# Clinical Skills - CBE

## *The Clinical Breast Examination (CBE)*

SLIDE 229

Historically, the clinical breast exam (CBE) has been a neglected part of the physical examination. In the 1950s a survey was done indicating that 30% of women who requested a complete history and physical examination from their physician did not have even a cursory examination of their breasts.

Many physicians express concern regarding lack of adequate training of CBE in medical school. CBE is an often-skipped portion of clinical skills training, sometimes being allocated to OB/GYN clerkships, sometimes being included as an afterthought during pelvic and rectal exam training, and rarely reinforced during clerkship residency years in any formal way.

In addition, once formal training of CBE is done, many physicians complain that doing a proper exam requires an unrealistic amount of time. We must challenge ourselves, however, to consider the fact that breast cancer and breast disease are prevalent conditions that are often asymptomatic. Performing a thorough CBE will often lead to discovery of unsuspected disease, with higher yield than other parts of the routine physical exam, especially in the asymptomatic ambulatory patient.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.

# Clinical Skills - CBE

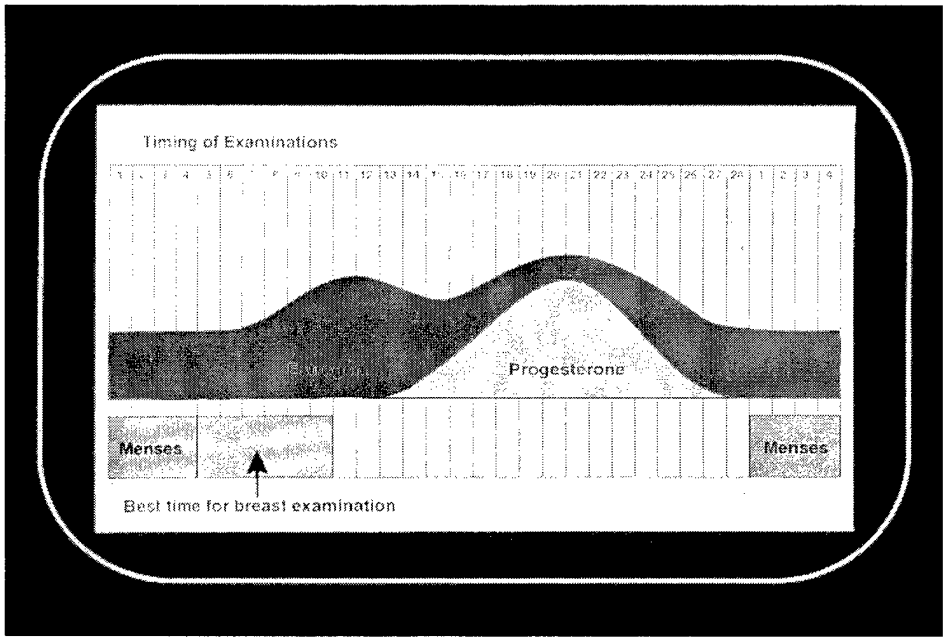
## *Normal CBE = Absence of Abnormality*

SLIDE 230

Interpretation of CBE can be challenging, and requires confidence for proficiency in interpretation. This is achieved as with any other skill--through practice. It is time to actively discourage the practice of reporting breast exam results as "deferred," or worse, of not even including the breasts as a portion of the physical exam deserving comment.

Consider the physical exam of the heart. When one places a stethoscope in the fifth intercostal space in the mid-clavicular line on the left side of the chest, the same heart sounds are auscultated in every normal patient. However, the breast exam is not so uniform. As we have discussed, the breast exam changes markedly throughout a woman's lifecycle. The exam is most challenging in women 35-55. Before this time, most women have dense breasts with a smooth but firm sensation on palpation. Between 35-55, the breasts are much more nodular, with a popcorn-like bumpy background. After menopause, the breasts should be smooth and soft, with little nodularity. Some women believe that their breasts "have always been lumpy". It is helpful to provide feedback during CBE regarding the relative nodularity of the breasts according to the woman's stage of the lifecycle.

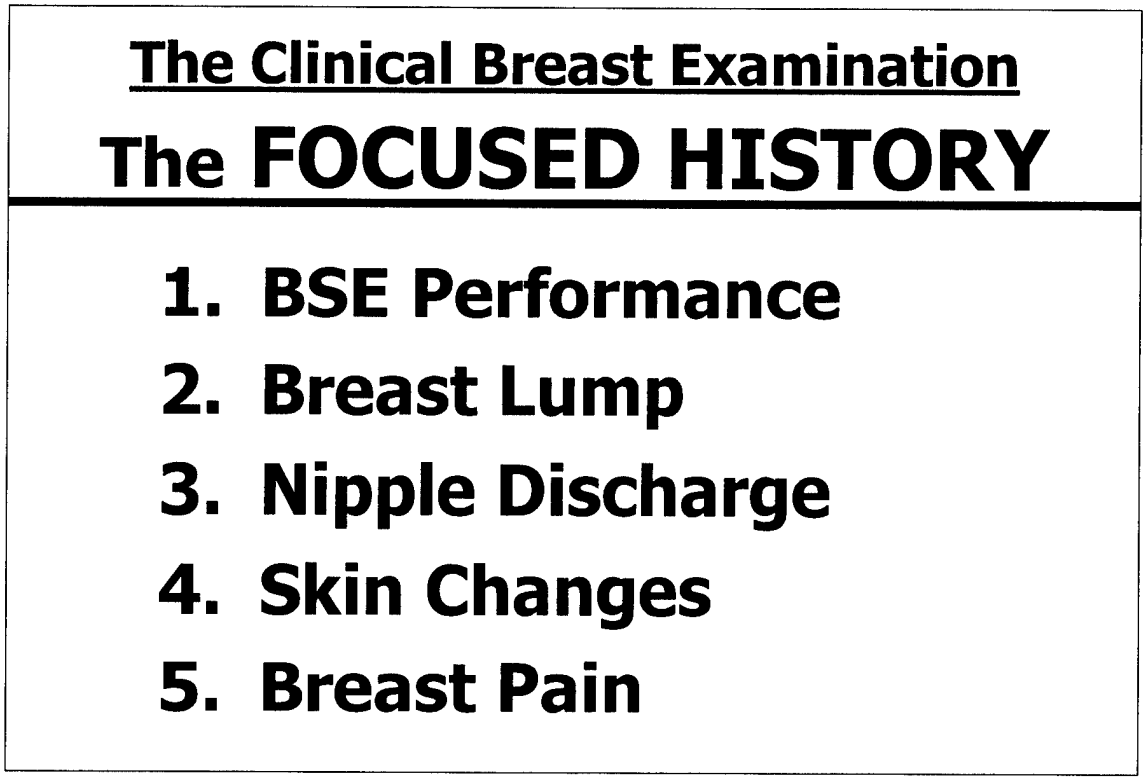
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.




SLIDE 231

Not only is the CBE interpretation different in every woman, but the exam can be different in the same woman if she is premenopausal. As previously discussed, the breast tissue responds to the secretion of progesterone in the latter half of the ovarian cycle with engorgement of tissue and increased nodularity. Consequently, the breasts may be tender and nodular during the luteal phase of the cycle. Interpretation of CBE may in turn be difficult and it is best to ask a woman to return for a repeat examination in the best phase of her ovarian cycle if there is any question of an asymmetry between one breast and the other. The optimal time to interpret the breast exam in a premenopausal woman is 3-10 days after the onset of menses. It can be difficult to determine optimal timing in a premenopausal woman who has had her uterus removed. Asking her to return in approximately 6 weeks to examine her in a different phase of her ovarian cycle is helpful if the CBE interpretation is difficult. It is not useful to ask a post-menopausal woman with an abnormal CBE to follow up for repeat exam, because she should not be undergoing dynamic breast changes because her ovarian function has ceased. Her abnormality needs immediate work up.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition*. Philadelphia, PA: W.B. Saunders Co., 1986.




SLIDE 232

As with any clinical examination, CBE begins with a focused history that should include a risk factor profile and questions regarding possible breast symptoms, as listed here. We have discussed these portions of the focused history during the morning session. The breast self-examination portion of the history is especially important when the patient presents with a breast complaint. Be sure to discuss with the patient how often she does BSE and at which phase of the menstrual cycle. Ask if she performs her exam in the shower, lying down, or both. The clinical breast exam is the ideal setting for teaching breast self-exam.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.

# Clinical Skills - CBE

## *Observation*

- Size
- Symmetry
- Shape
- Skin Color
- Skin Texture
- Nipple/Areola
- Skin Retraction

SLIDE 233

Physical examination of the breast begins with observation. It is important to assess size, symmetry between the two breasts, shape, skin color, texture of the skin, appearance of the nipple-areolar complex, and the presence or absence of skin retraction.

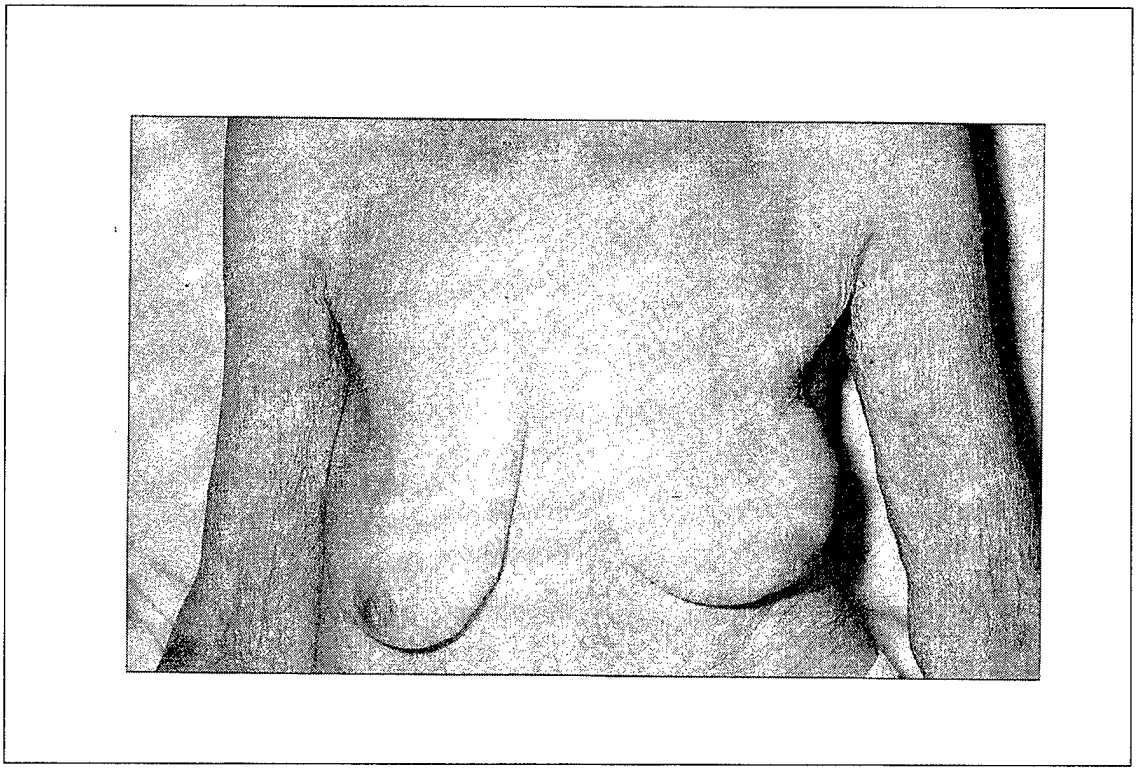
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.

SLIDE 234

Observe the patient from the front in the sitting position. Visualize the internal anatomy and location of the breast tissue over the pectoralis major and serratus anterior muscles.

Some physicians express concerns about embarrassing the patient with this and other maneuvers of observation. This portion of the exam lasts seconds and the patient is unlikely to feel uncomfortable if the physician approaches it with confidence and compassion. It is often helpful to have a third person present for the exam, be it a family member, friend, or office assistant.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



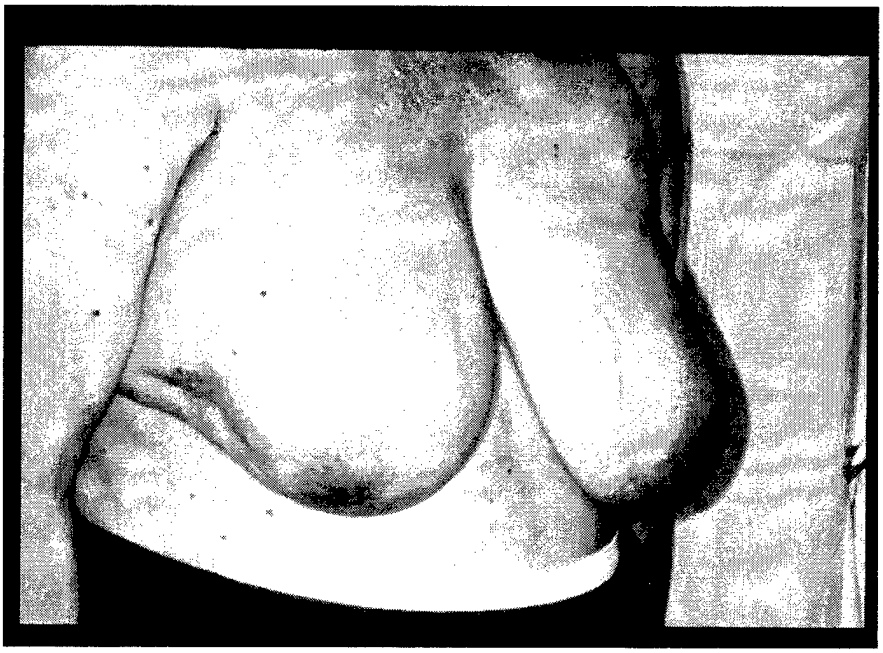
SLIDE 235

The exam of a woman in the sitting position provides important clues to the presence of carcinoma which may not be appreciated if the observation component of the exam is omitted. The changes in size, shape and symmetry of the left breast as compared to the right demonstrated on this slide are facilitated by simultaneous observation of the breast. Whenever the height of the nipple varies between breasts, carcinoma should be suspected.

**Source:** Mansel RE, Bundred NJ. *Color Atlas of Breast Diseases*. London: Mosby-Wolfe, 1995.

SLIDE 236

Observe the breasts on each side as well as from the front. Remember that when the patient's arms are at her sides, part of the skin of the breast is covered. Especially in larger breasted women, the breast tissue will extend over the serratus anterior muscle and be covered by the arm.



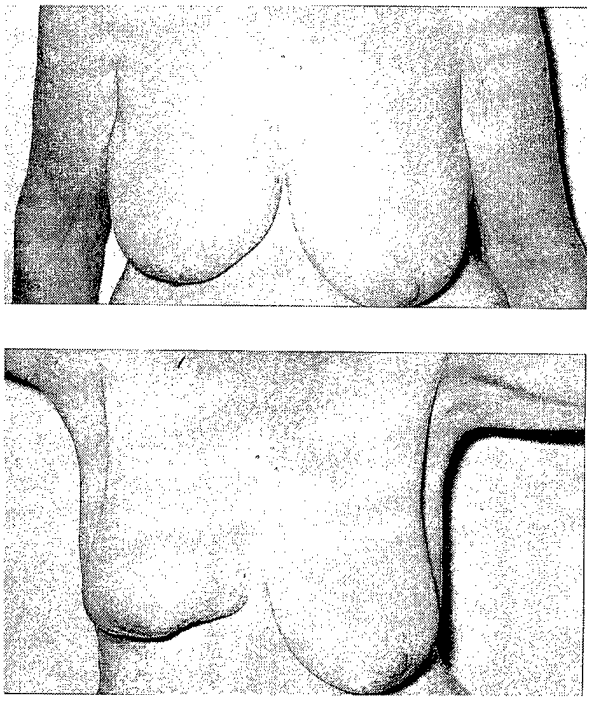
SLIDE 237

You have already seen this slide. It illustrates the findings, sometimes not subtle, than can be observed through a simple inspection of the lateral aspect of the breast.

SLIDE 238

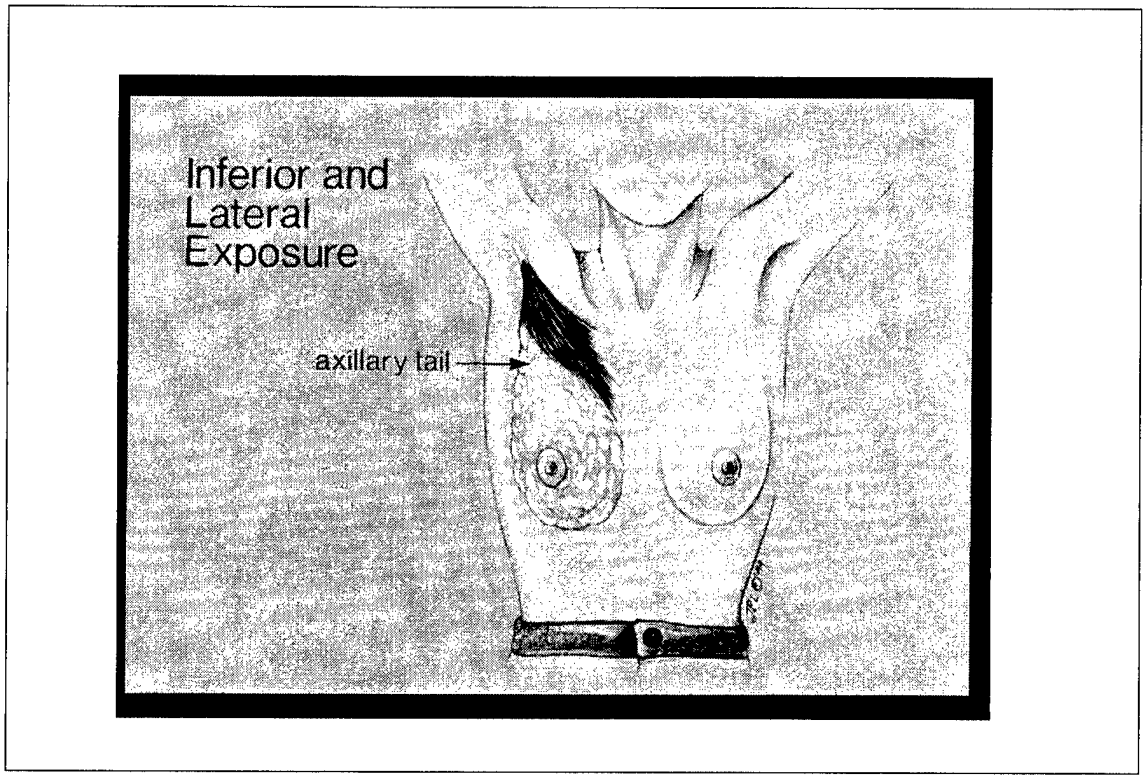
The next step in CBE is to have the patient lift her arms over her head. This exposes the lateral sides and inferior portions of the breast. Again, you will be observing size, symmetry, shape, skin color, skin texture, the appearance of the nipple-areolar complex, and the presence or absence of skin retraction. Remember to conduct this portion of the examination from the front and sides of the patient as well.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



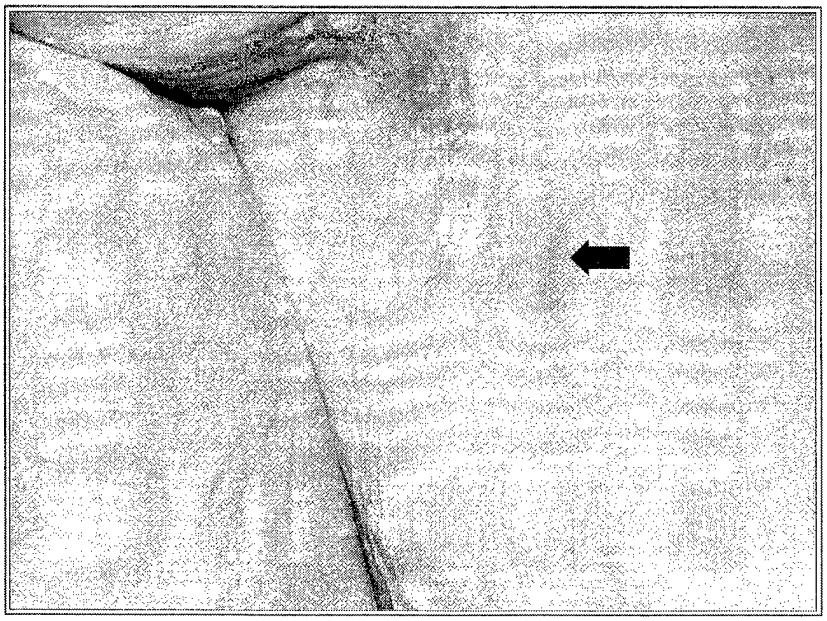
SLIDE 239

This slide illustrates the importance of the maneuver just discussed. In the sitting position with the arms at the sides, this patient's right breast is smaller than the left. In this setting, it is important to ask the patient if her breasts have been asymmetrical since adolescence. If she answers affirmatively, the finding is considered normal. If the patient indicates that the finding is new or of gradual onset, be prepared to search for an abnormality on CBE. Asking the patient to raise her arms above her head demonstrates obvious retraction of the lower inner portion of the breast in this slide.




SLIDE 240

Remember that arm raising exposes the surface anatomy of the axillary tail of the breast.



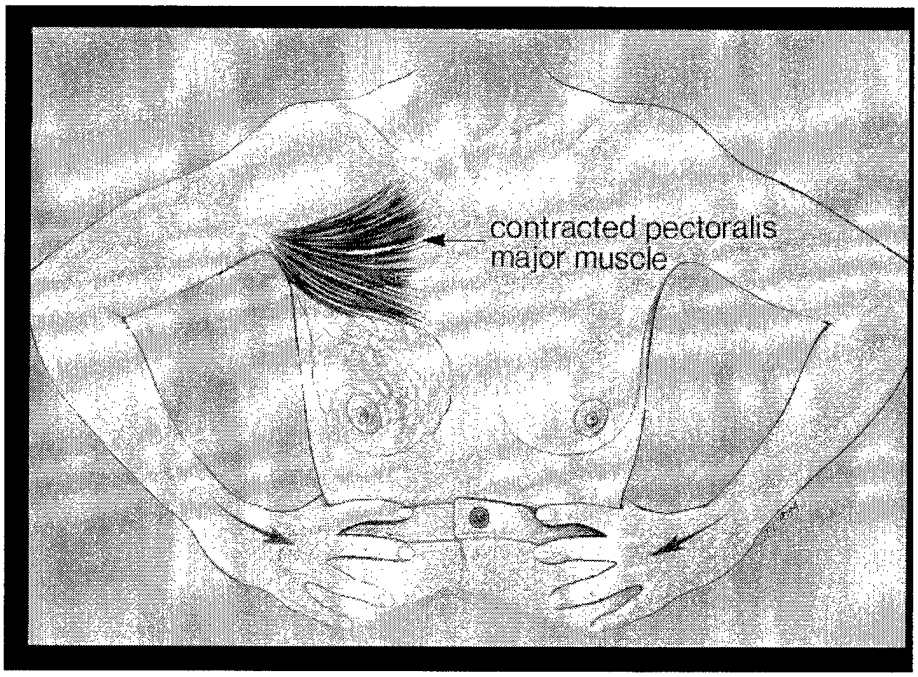
SLIDE 241

Arm raising alone can be enough to elicit the sign of skin dimpling. You have also seen this slide previously. It demonstrates skin retraction of the axillary tail of the breast, and would not be observed if the arm raising maneuver was omitted.

SLIDE 242

Next ask the patient to place her hands on her hips and to push in tightly. This causes contraction of the pectoralis major muscles.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.




SLIDE 243

If there is a tumor involving Cooper's ligaments, contraction of the pectoralis major muscle will cause skin retraction. The pathophysiology of this finding is related to breast anatomy. Contraction of the pectoralis major muscle results in shortening of Cooper's ligaments, which have attachments on the fascia of the muscle as well as the fascia under the skin.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.

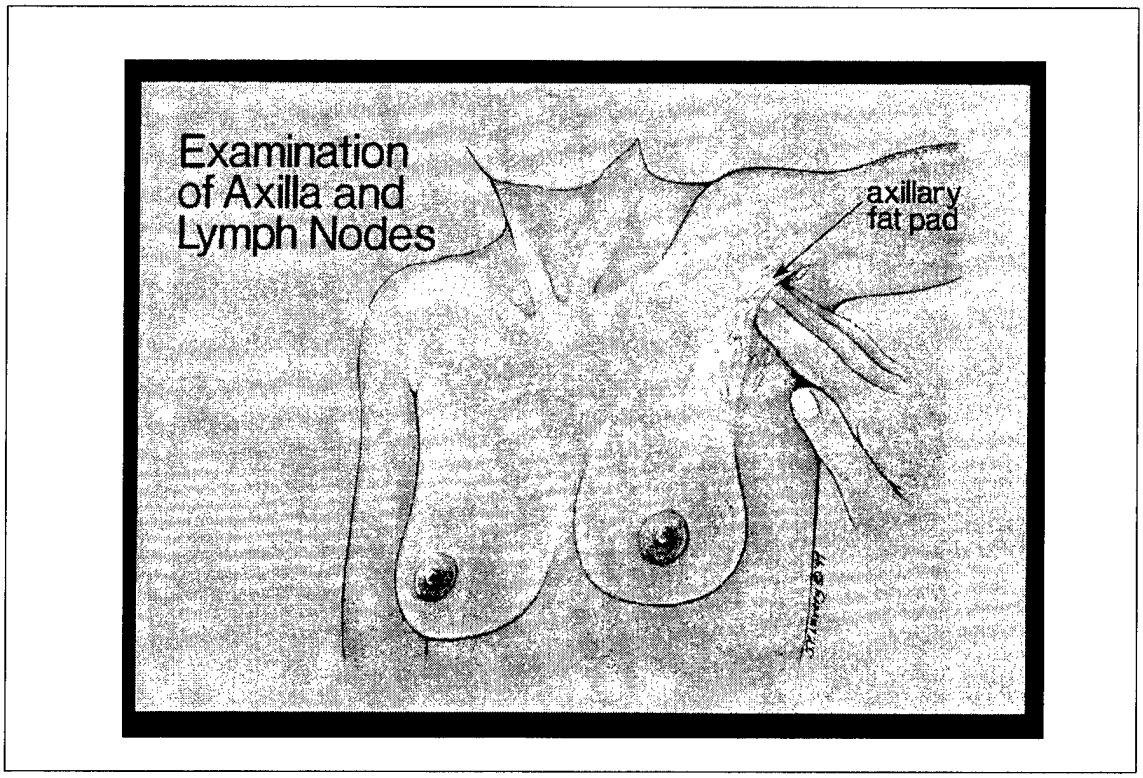
SLIDE 244

The next step is examination of the supraclavicular and infracavicular nodes by palpation. This is done by simultaneous bilateral palpation, first above the clavicle, and then below.

SLIDE 245

The next step is examination of the axillary lymph nodes. This is done in the sitting position. The physician should support the woman's arm at the elbow so that the arm and pectoralis muscles are relaxed. The examining hand can then palpate the axillary lymph nodes.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.




SLIDE 246

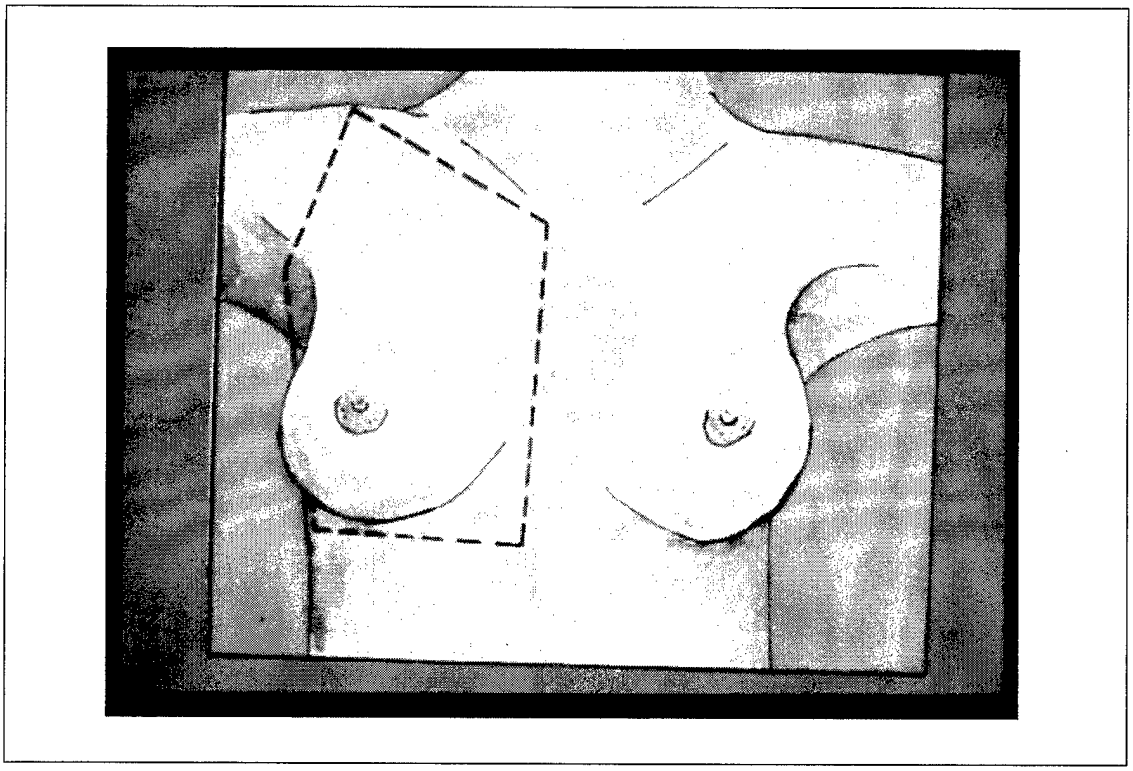
Many physicians skip the examination of the breast in the sitting position. There are three excellent reasons w this part of the exam should be done. First, when the woman is in a sitting position, the axillary fat pad moves forward, allowing access to the nodes. In the supine position, the fat pad falls back and up, making the lymph nodes less accessible to examination.

Second, many women palpate abnormalities doing BSE in the shower. If this is the case, the area of concern should be palpated with the patient sitting, especially if it cannot be felt with the patient supine.

Third, observation for skin retraction on pectoralis major contraction is difficult with the patient in a supine position.

An easy way to incorporate the sitting portion of the clinical breast exam during a routine physical exam is immediately before or after auscultation of the lungs. If done at this time, it should add only a matter of seconds to the exam.

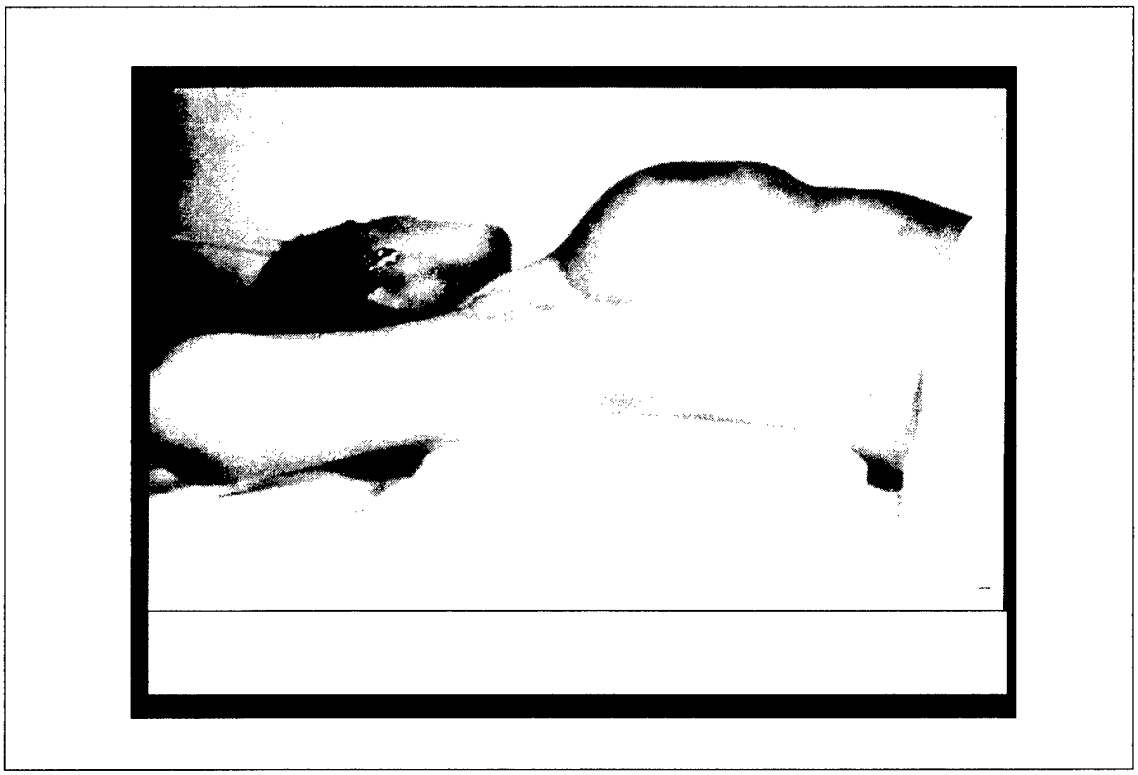
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 247

The breasts are then palpated in the supine position. In this position, the breast tissue will move toward the clavicles. This slide demonstrates the perimeter of the breast. Remember that a fascial sheath encompasses the whole breast, starting at the second rib and extending to the latissimus dorsi muscle laterally, the lateral edge of the sternum medially, and the inframammary crease inferiorly. Since the second rib is difficult to palpate accurately, the exam extends to the clavicle. Rather than a circle, then, CBE encompasses a pentagon-shaped area.

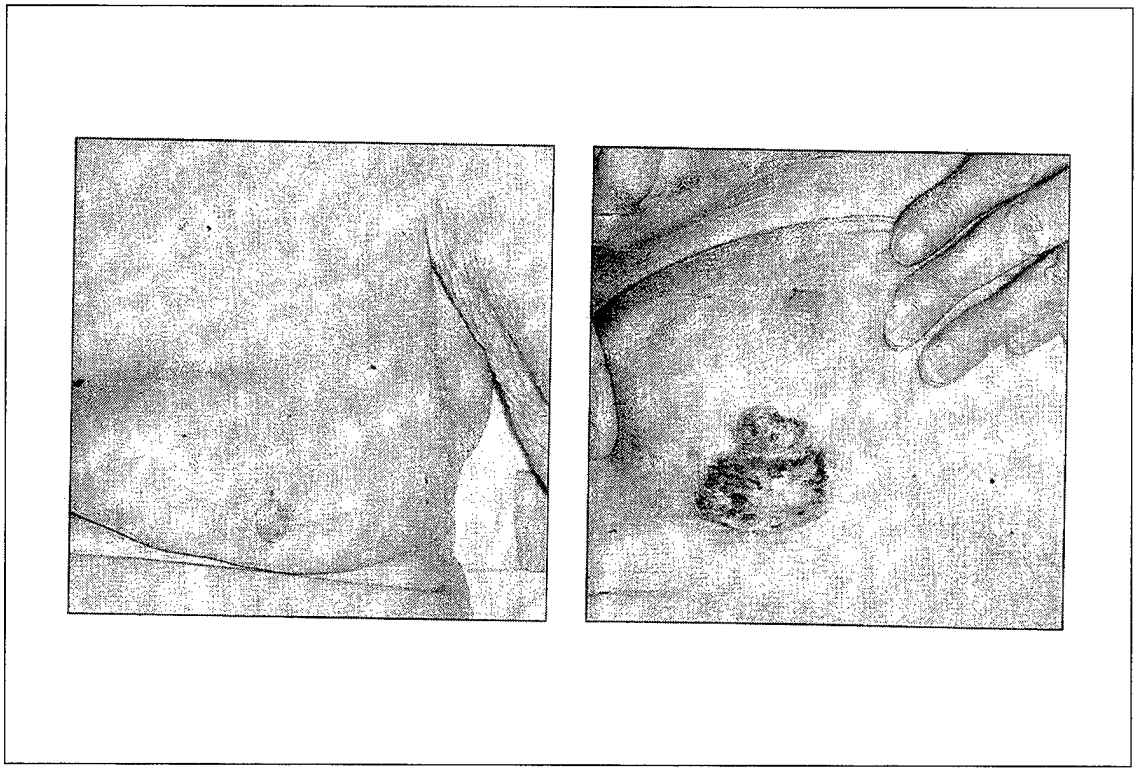
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 248

All patients should be examined with the ipsilateral arm over the head, as this maneuver spreads the breast tissue across the chest wall. If the breast continues to overlap the chest wall following this maneuver, the examiner should displace the medial portion of the ipsilateral breast toward the opposite side when examining the lateral portion of the breast. Alternatively, placing a pillow or towel underneath the patient's back and shoulders as shown in this slide will also help the breasts to fall medially against the chest wall so as to facilitate the exam. This maneuver adds time to the exam and is awkward for some, but manual medial displacement works very well as discussed above.

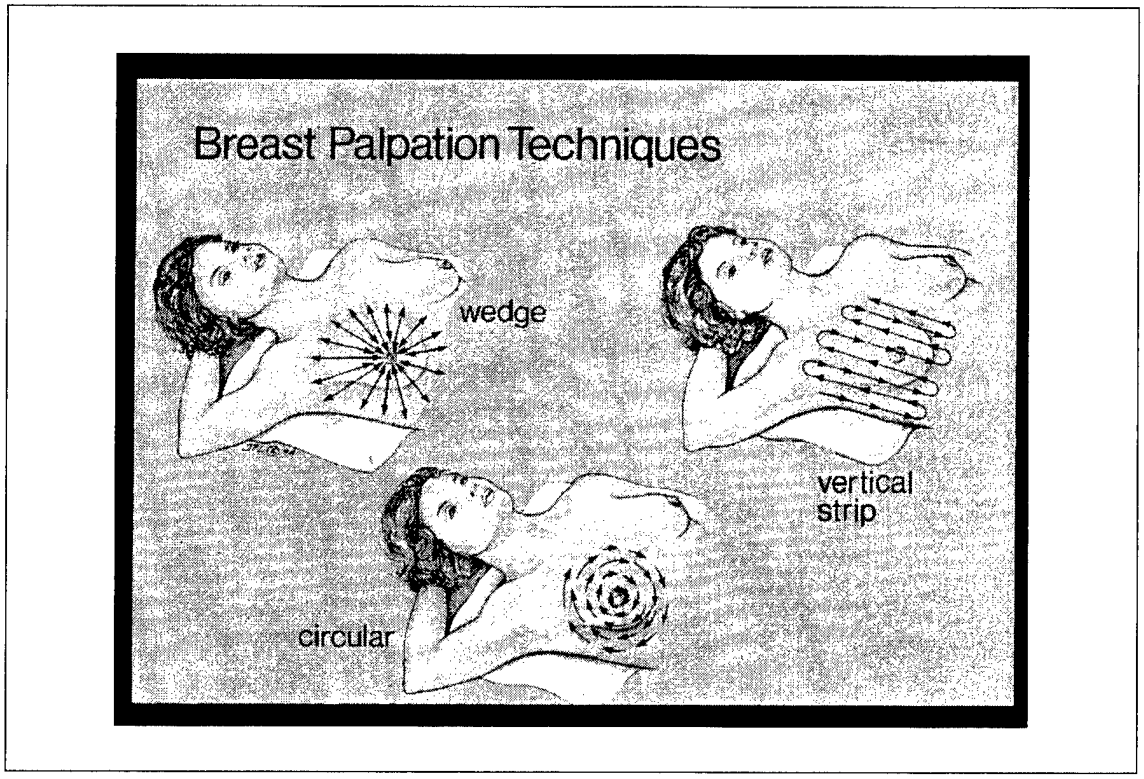
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 249

The inspection portion of the examination should continue in the supine position for any portion of the breast not previously examined in the upright position. This typically involves examination of the inframammary fold, especially in women with pendulous breasts. It is easy to imagine how a lesion as large as this one would be missed without proper maneuvers of inspection.

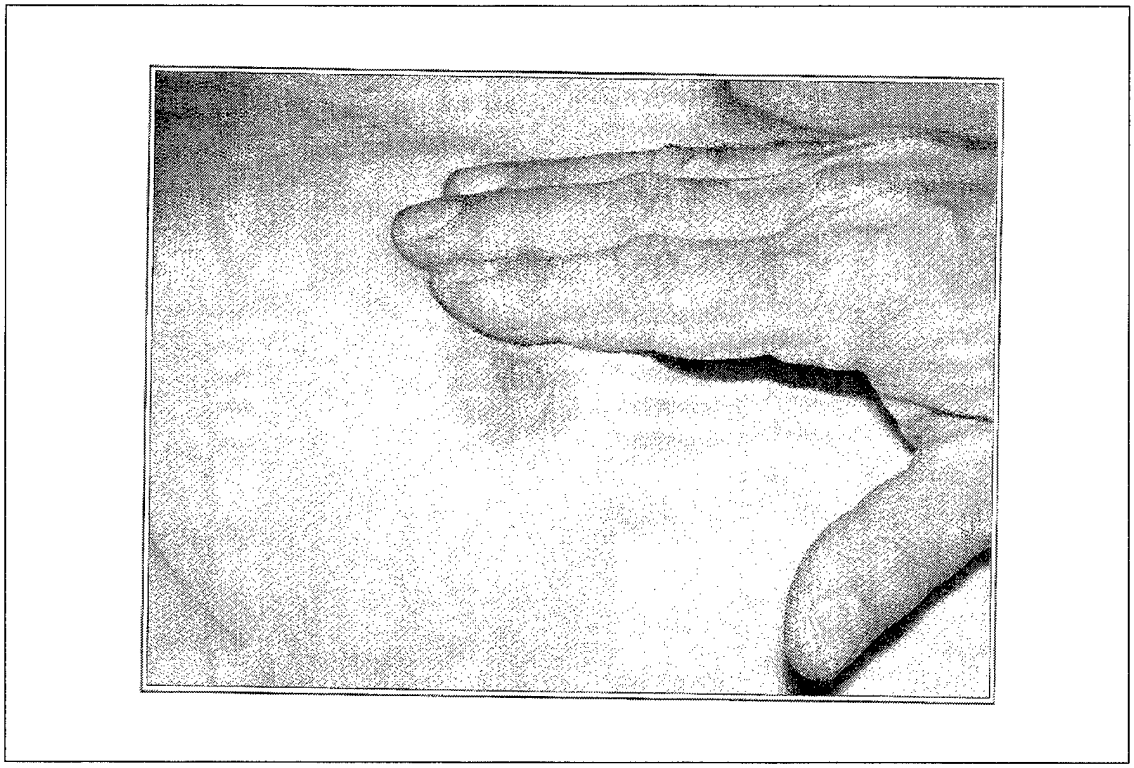
**Source:** Mansel RE, Bundred NJ (Eds). *Color Atlas of Breast Diseases.* London: Mosby-Wolfe, 1995.




SLIDE 250

There are three techniques for breast palpation: circular, vertical strip, and wedge. Any of these methods are appropriate as long as the entire pentagon-shaped area of the breast is examined.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 251

When palpating the breast, the pads of the first three fingers are used, covering an area about the size of a dime for each examining finger. The depth of palpation is done first with a light touch, then a medium, and a deep in order to examine the breasts completely. The breasts are systematically examined in overlapping fields (like mowing a lawn). The least examined portion of the breast is the retro-areolar area. It is often believed that palpation of this area will be painful. This is not the case, however. This region is the second most likely to develop breast cancer and it is important that the breast be examined all the way to the nipple.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.

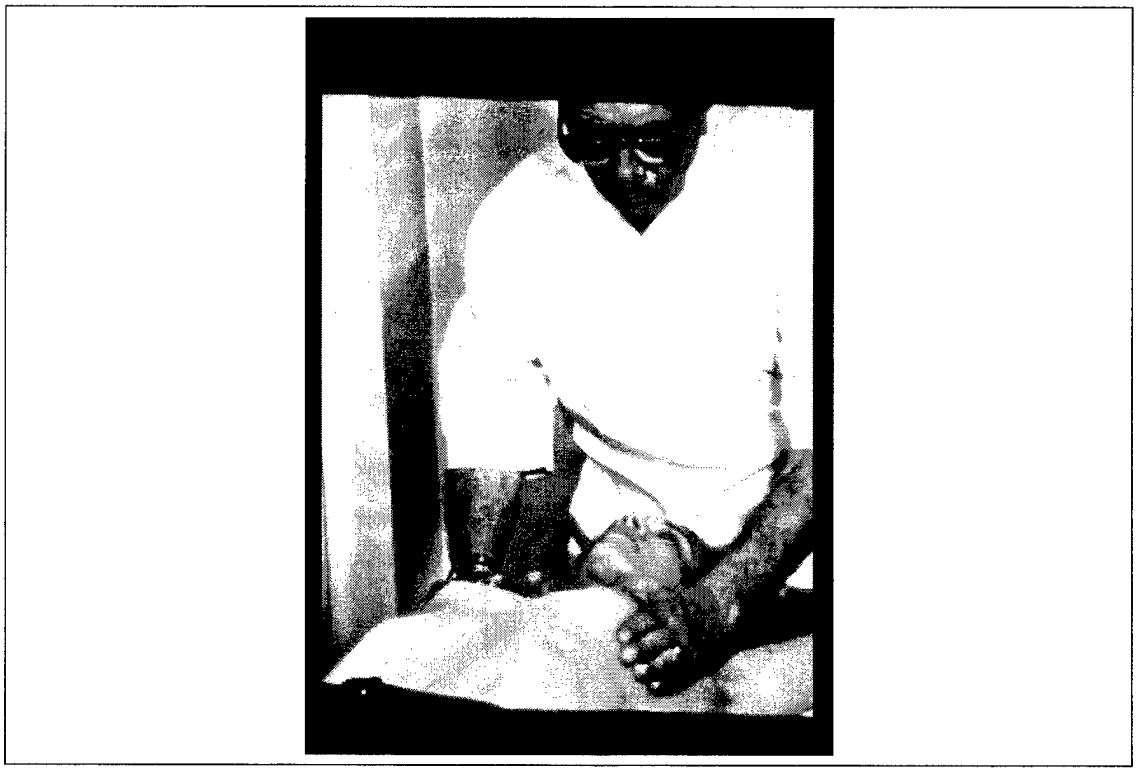
# Clinical Skills - CBE

- **Background nodularity**
- **Dominant mass/thickening**
- **Nipple compression with spontaneous nipple discharge**

SLIDE 252

When palpating the breast, assess the degree of nodularity and whether there is a dominant mass or thickening in the breast. Palpation of the nipple in a woman who does not have a history of persistent spontaneous nipple discharge is not recommended. Many physicians are surprised by this, as we have emphasized the importance of nipple compression to women performing BSE. Many needless work ups are prompted by the elicitation of nipple discharge that is not spontaneous. Remember that non-spontaneous nipple discharge is physiologic. CBE techniques in the presence of spontaneous discharge will be reviewed in an upcoming slide.

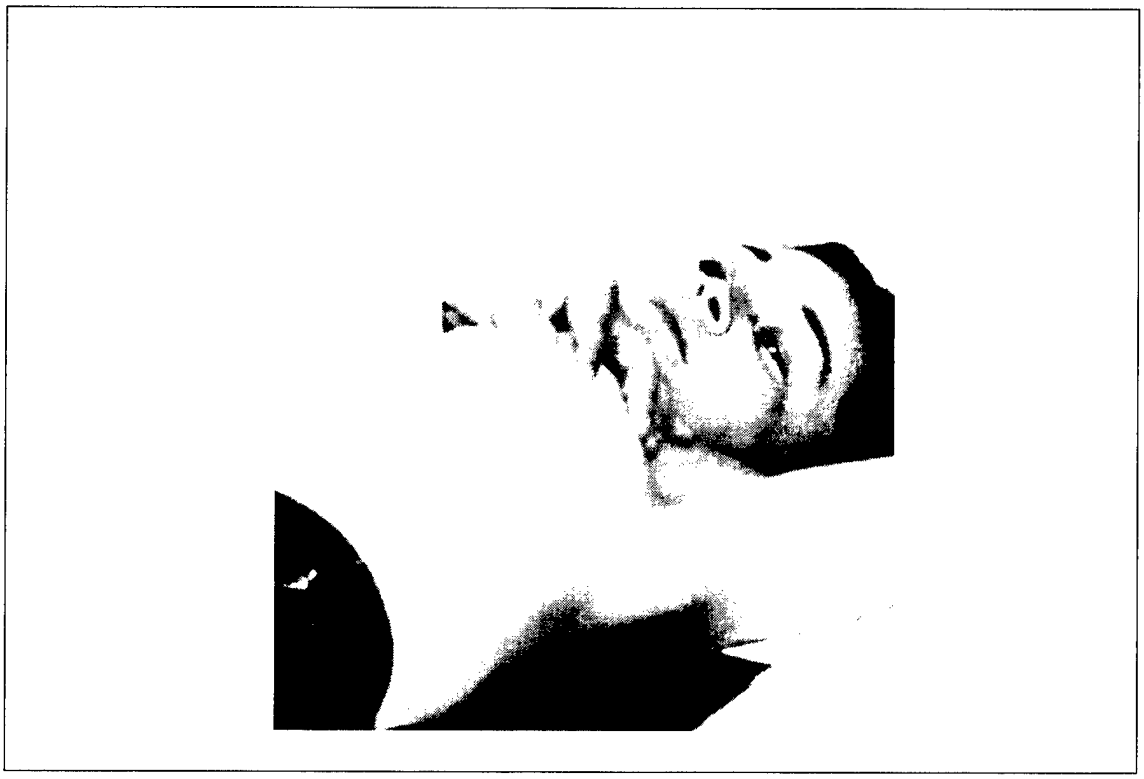
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 253

When assessing nodularity and tissue thickening, it is helpful to examine the symmetry between the two breasts. Subtle thickenings and ridges felt on palpation of one breast can be compared to the opposite breast in the mirror image location, to determine if there is symmetrical thickening or nodularity in the opposite breast. If the exam is symmetrical, this is usually an indication that the exam is normal. If there is asymmetry, even if only a thickened area, further work up is necessary. Note that the exam for symmetry need not be done from the head of the table.

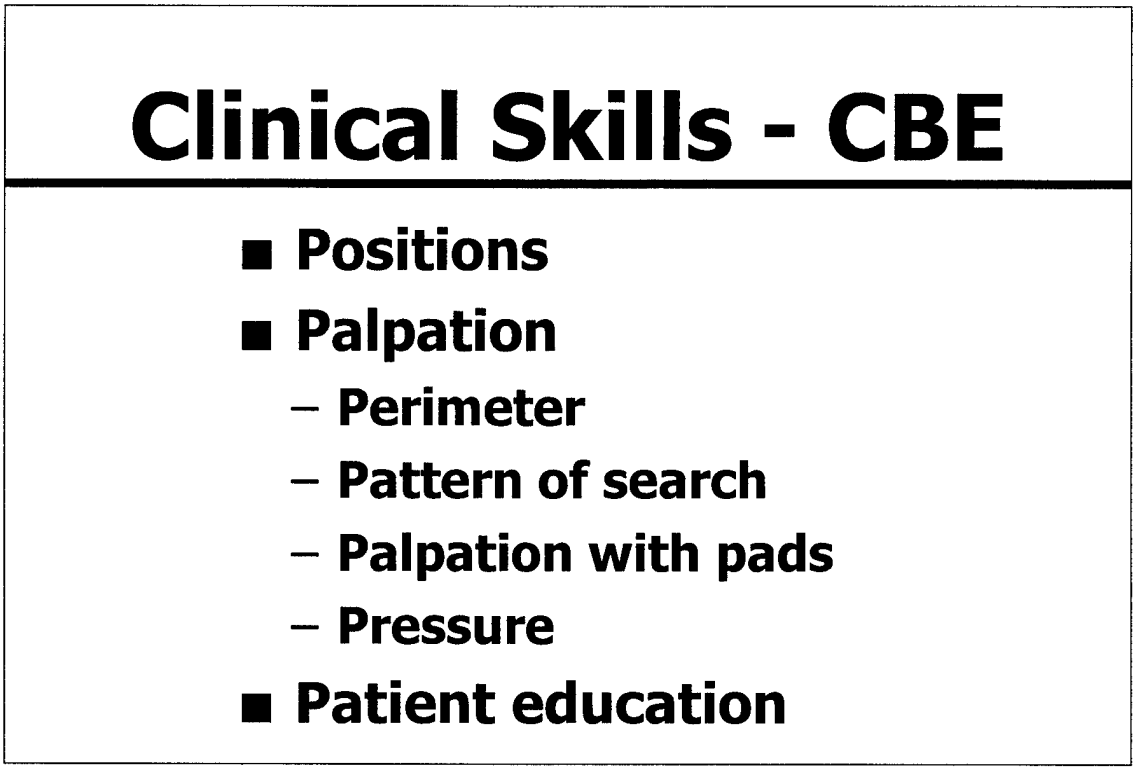
**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



SLIDE 254

In women with a history of persistent spontaneous nipple discharge, the nipple is compressed very gently in the horizontal and vertical directions to check for discharge. If this technique does not elicit the discharge, firm pressure should be applied from the periphery toward the nipple. Pressure should be distributed evenly so that the duct system is milked for each number on the clock.

**Source:** Physician's role in the detection and diagnosis of breast disease. In: Haagensen CD (Ed.), *Disease of the Breast, 3rd Edition.* Philadelphia, PA: W.B. Saunders Co., 1986.



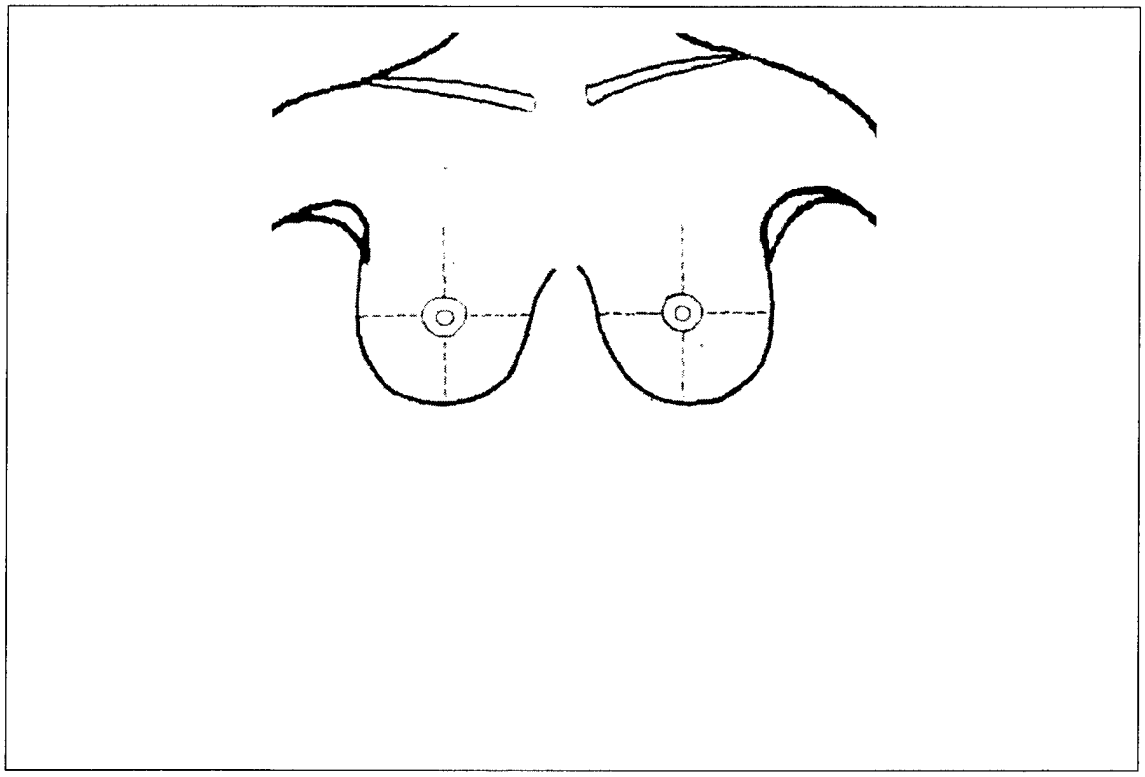

SLIDE 255

The steps in breast examination can be thought of in terms of seven P's. This includes:

- Positions
- Palpation
    - Perimeter
    - Pattern of search
    - Palpation with pads
    - Pressure
- Patient education

Appendix 8 lists a step-by-step approach to CBE using these seven P's.

**Source:** Modified from Clinical Breast Examination: Proficiency Criteria and Guidelines. American Cancer Society, California Division. (Reprinted with permission)



SLIDE 256

Documentation is an extremely important part of the clinical breast examination. This is an example of a pre-printed form, but drawing two circles will suffice. We will now watch a video tape and observe CBE in real time.

## SLIDE CREDITS

1-2. Osuch RJ, Barry HC, and Zuber TJ.

3. Osuch JR, Barry HC, and Zuber TJ, modified from a slide courtesy of American Cancer Society. Atlanta, GA, Public Domain.

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137. Courtesy of Janet Rose Osuch, MD, Michigan State University, East Lansing, MI (personal collection).

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213. Osuch J, Dell D, and Sighter S. *Breast and Cervical Cancer Education for Primary Care Providers.* Alexandria, VA: American Medical Women's Association, 1994, Slide No. 155.

214. Courtesy of Janet Rose Osuch, M.D., personal collection.

215. Blaney R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer.* Hampshire, UK: Merit Publishing International, 1994, figure 4.

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220-34. Osuch JR, Barry HC, and Zuber TJ.

235. Mansel RE, Bundred NJ (Eds.). Nipple disorder and disease. In: *Color Atlas of Breast Diseases.* London: Mosby-Wolfe, 1995.

236. National Cancer Institute, Public Domain.

237. Courtesy of Janet Rose Osuch, M.D., personal collection.

238. National Cancer Institute, Public Domain.

239. Mansel RE, Bundred NJ (Eds.). Nipple disorder and disease. In: *Color Atlas of Breast Diseases.* London: Mosby-Wolfe, 1995, figure 7.4-7.5.

240. Osuch J, Dell D, and Sighter S. *Breast and Cervical Cancer Education for Primary Care Providers.* Alexandria, VA: American Medical Women's Association, 1994, Slide No. 87.

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242. National Cancer Institute, Public Domain.

243. Osuch J, Dell D, and Sighter S. *Breast and Cervical Cancer Education for Primary Care Providers.* Alexandria, VA: American Medical Women's Association, 1994, Slide No. 89.

244-45. American Cancer Society, Public Domain.

246. Osuch J, Dell D, and Sighter S. *Breast and Cervical Cancer Education for Primary Care Providers.* Alexandria, VA: American Medical Women's Association, 1994, Slide No. 94.

247. Courtesy of Mammatech Corporation, Gainesville, FL.

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251. Blaney R, Evans A, Ellis I, et al. (Eds.). *Atlas of Breast Cancer.* Hampshire, UK: Merit Publishing International, 1994, figure 9.

252. Osuch JR, Barry HC, and Zuber TJ.

253. American Cancer Society, Public Domain.

254. National Cancer Institute, Public Domain.

255. Osuch JR, Barry HC, and Zuber TJ.

256. Courtesy of the Comprehensive Breast Health Clinic, Michigan State University, East Lansing, MI.

# APPENDICES

1. Screening Guidelines for Women in Different Risk Categories
2. ANDI Classification
3. Management of Breast Pain
4. Management of Occult Mammographic Abnormalities

5A. Management of Initial Evaluation of a Breast Mass/Asymmetrical Thickening

5B. Management of a Breast Cyst

5C. Management of a Solid Breast Mass by Triple Diagnosis

6. Management of Nipple Discharge
7. Management of Observational Findings
8. Clinical Breast Exam: A Step-by-Step Approach
9. Common Allegations for Failure to Diagnose Breast Cancer and Recommended Steps in Risk Management
10. Instructions for Access to Medscape
11. AstroZeneca Blank Risk Assessment Forms
12. The Use of the Gail Model. Risk Assessment Tools-Practice Session

# APPENDIX 1

## SCREENING GUIDELINES FOR WOMEN IN DIFFERENT RISK CATEGORIES:

| Risk Category | Lifetime Risk (%) | Clinical Breast Exam Schedule | Mammogram Schedule |
|---|---|---|---|
| **No risk factors** | 11-12 | Annual at and after age 30 | Annual at and after age 40 |
| **Two or more reproductive or hormonal risk factors and no family history** | 10-20 | | |
| **Weak family history** (one first-degree relative with postmenopausal breast cancer, or one or two more distant relatives with postmenopausal breast cancer) | 15-20 | | |
| **Strong family history** (three or more relatives at any age with postmenopausal breast cancer, or any second-degree relative with breast cancer before age 40) | > 20 | Annual at and after age 25; Twice yearly after age 30 | Annual at and after age 35 or 5 years younger than youngest affected relative |
| **Carrier of known breast cancer susceptibility gene** Or **Very strong family history** (two or more first degree relatives with breast or ovarian cancer, one or more first degree relatives with breast cancer before age 40, or any first degree relative with bilateral premenopausal breast cancer) | 20-85 | Twice yearly at and after age 25 | Annual at and after age 25 |
| **Atypical hyperplasia with a negative family history** | 15-20 | Annual at and after diagnosis | Age 40 or after diagnosis if earlier than age 40 |
| **Atypical hyperplasia with a positive family history** | > 20 | Twice yearly | |
| **Lobular carcinoma in situ** | 20-30 | | |

Modified after Garber JE and Smith BL. Management of the high-risk and the concerned patient. Table 9-3, page 329. In: Harris JR, Lippman ME, Morrow M, and Hillman S. *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven Publishers, 1996.

# APPENDIX 2

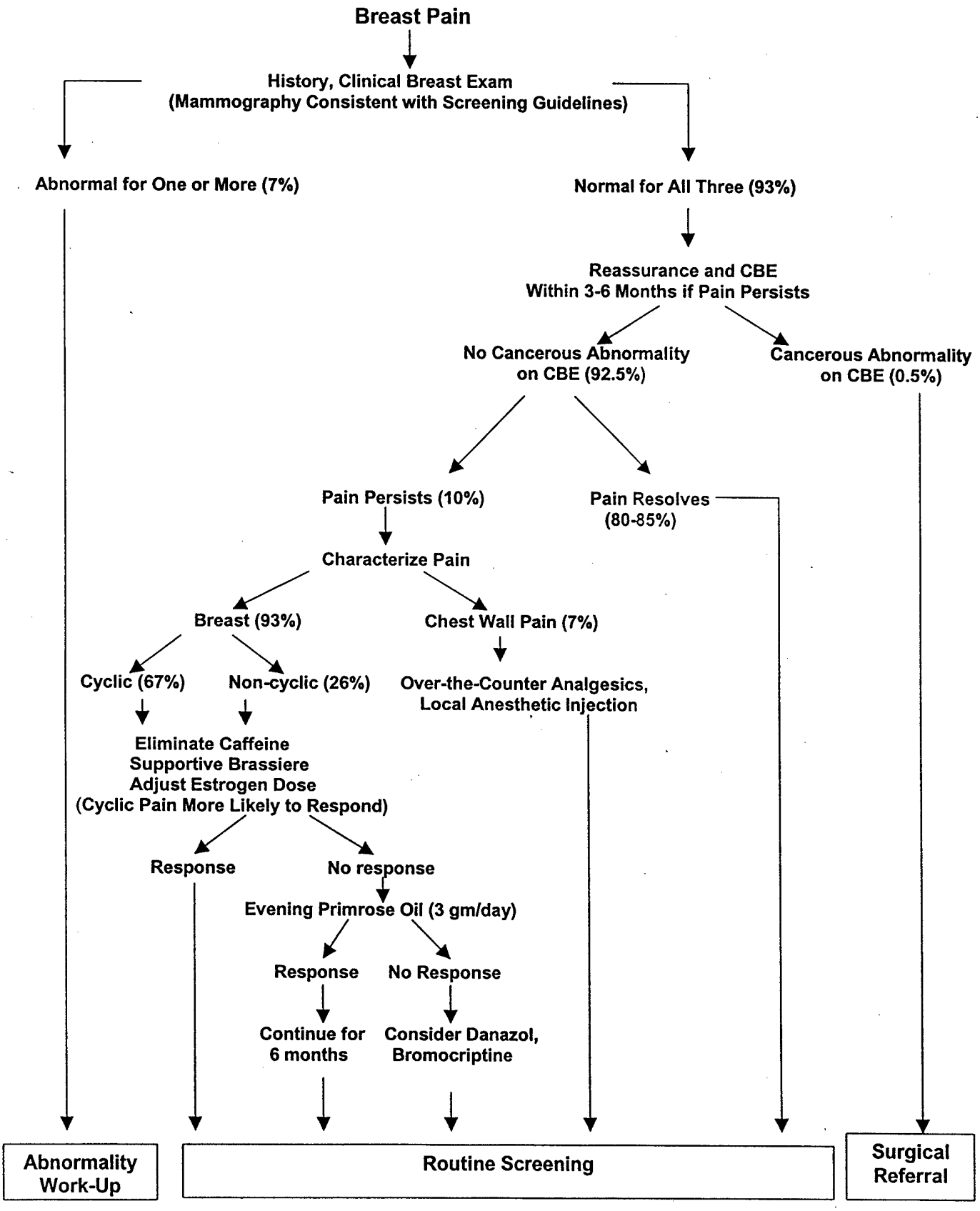
## THE ANDI CLASSIFICATION of BENIGN BREAST DISEASE

| Stage (Peak Age) | Normal Process | Aberration | | |
|---|---|---|---|---|
| | | Underlying Condition | Clinical Presentation | Disease State |
| Early reproductive period (15-25 yr) | Lobule formation | Fibroadenoma | Discrete lump | Giant fibroadenoma<br>Multiple fibroadenomas |
| | Stroma formation | Juvenile Hypertrophy | Excessive breast development | |
| Mature reporductive period (25-40 yr) | Cyclic hormonal effects on glandular tissue and stroma | Exaggerated cyclic effects | Cyclic mastalgia and nodularity, generalized or discrete | |
| Involution (35-55 yr) | Lobular involution (including microcysts, apocrine change, fibrosis and adenosis) | Macrocysts<br>Sclerosing lesions | Mastalgia<br>Lumps<br>Mammogram abnormalities | |
| | Ductal Involution (including periductal round cell infiltrates) | Duct dilation<br>Periductal fibrosis | Nipple discharge<br>Nipple retraction | Periductal mastitis with bacterial infection and abscess formation |
| | Epithelial turnover | Mild epithelial hyperplasia | Histological report | Epithelial hyperplasia with atypia |

Modified from Hughes LE. A Unifying Concept for Benign Disorder of the Breast: ANDI. In Donegan WL, Spratt JS (eds): Diseases of the Breast. Philadelphia: WB Saunders; 1995.

# APPENDIX 3

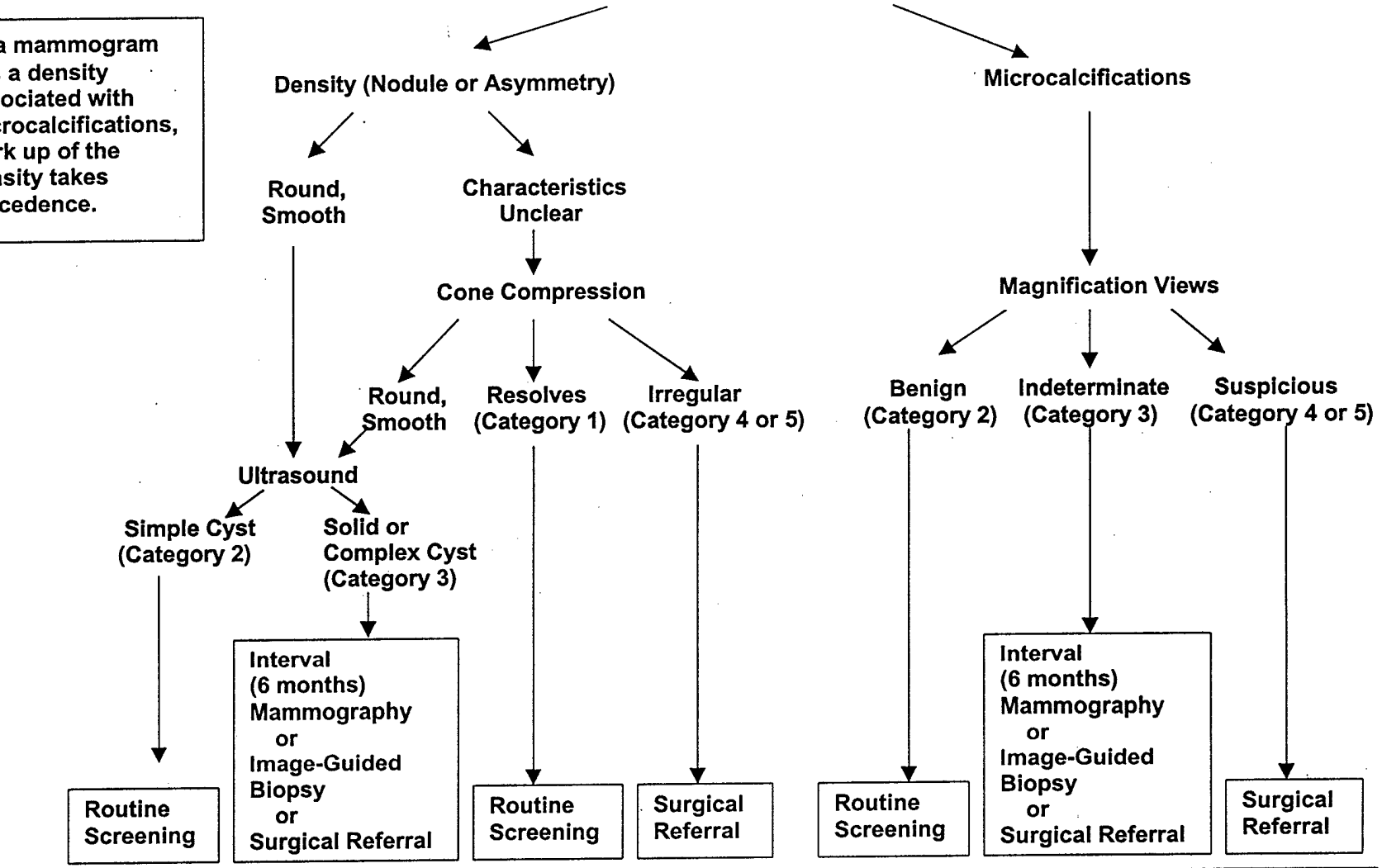
## MANAGEMENT OF BREAST PAIN



# APPENDIX 4

## MANAGEMENT OF OCCULT MAMMOGRAPHIC ABNORMALITY*

*If a mammogram has a density associated with microcalcifications, work up of the density takes precedence.



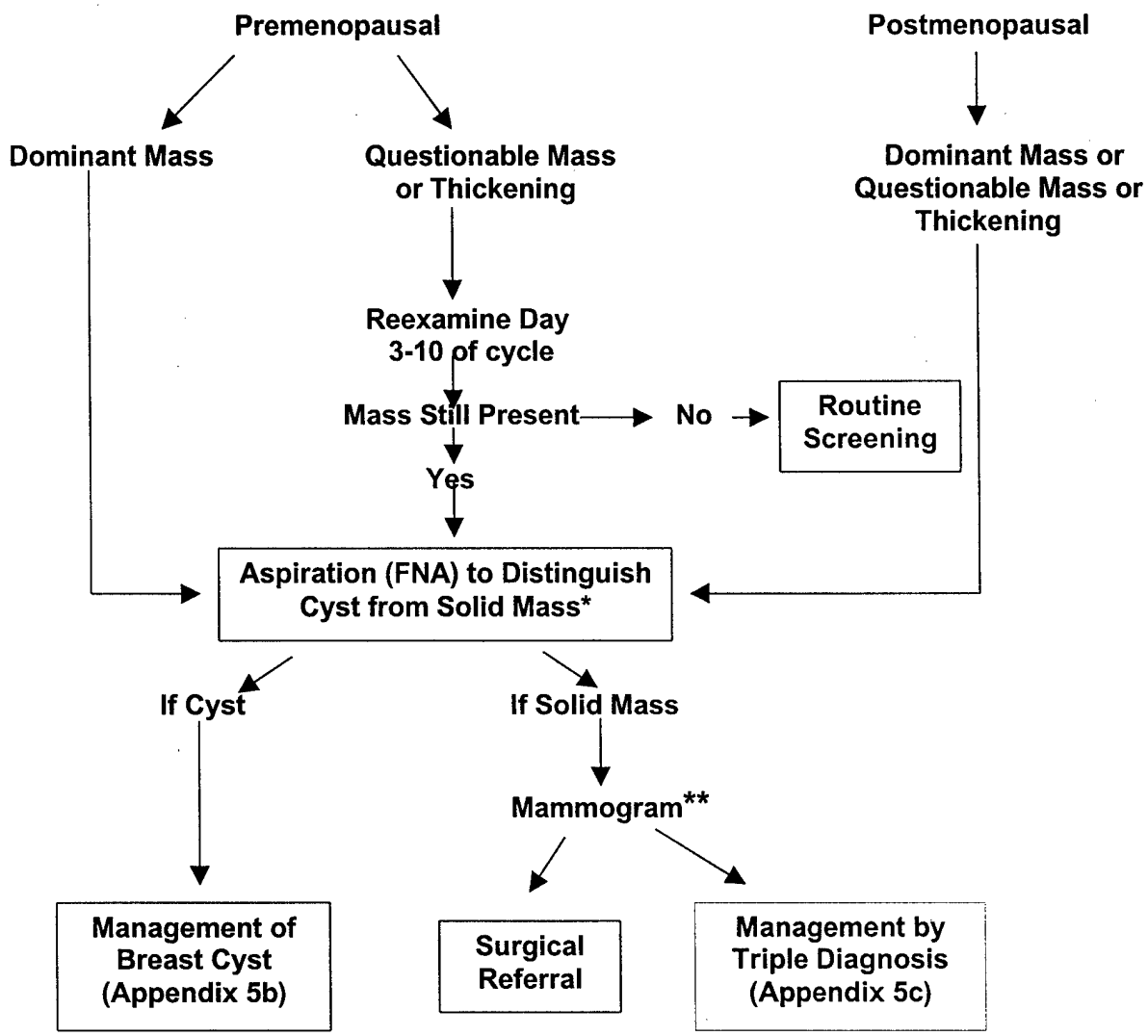

Category 1=Normal; Category 2=Benign-appearing abnormality; Category 3=Probably benign/Possibly malignant, Indeterminate
Category 4=Suspicious for malignancy; Category 5=Malignant until proven otherwise

Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

## APPENDIX 5A

## INITIAL APPROACH

## MANAGEMENT OF BREAST MASS/ASYMMETRICAL THICKENING

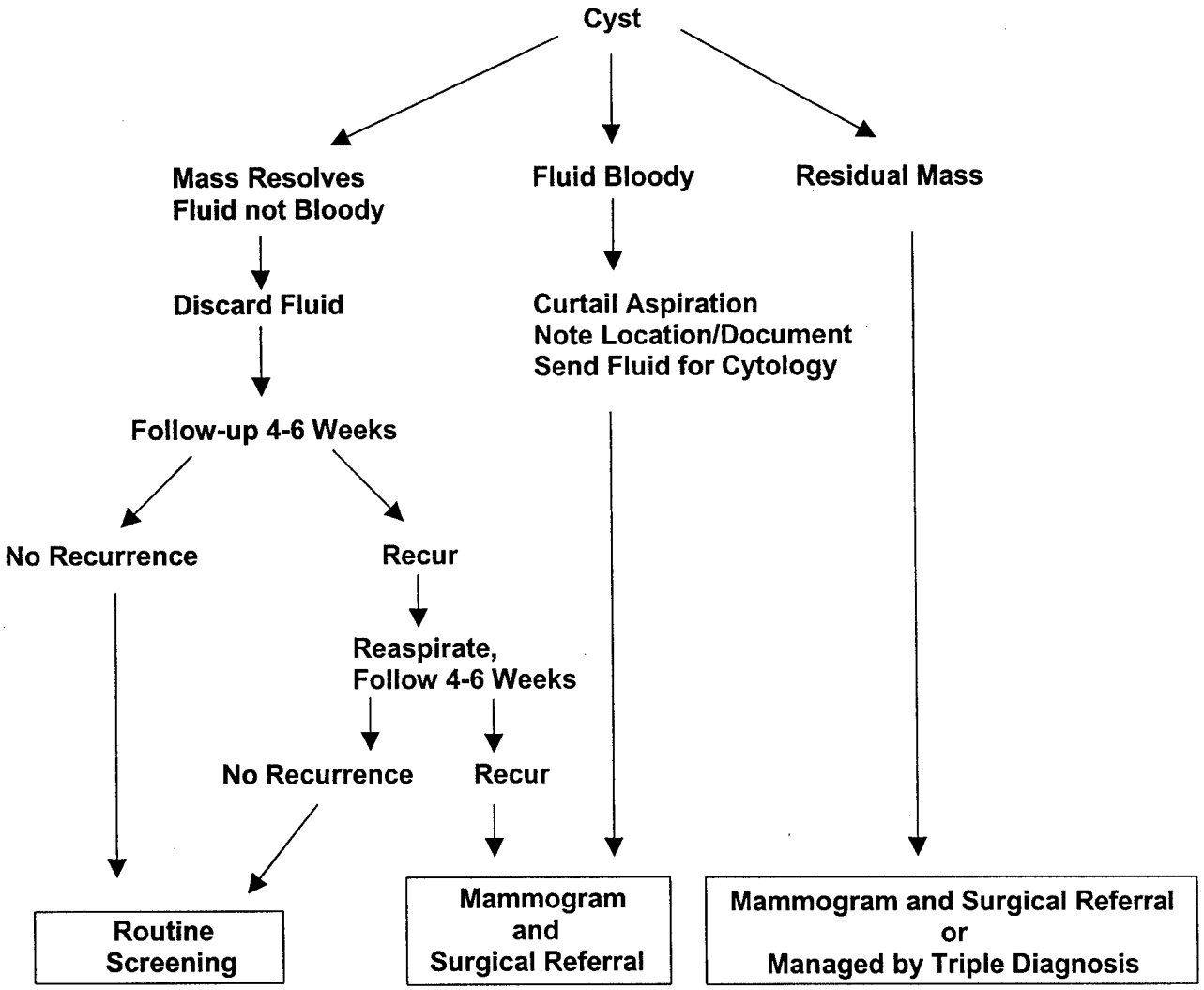



*** Mammography**
**a) could be done prior to Fine Needle Aspiration (FNA)**
**b) should be avoided in women less than 30 years old and pregnant women**
**** Mammography should be ordered 2-3 weeks following aspiration to avoid false positive**

Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. Diseases of the Breast. Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

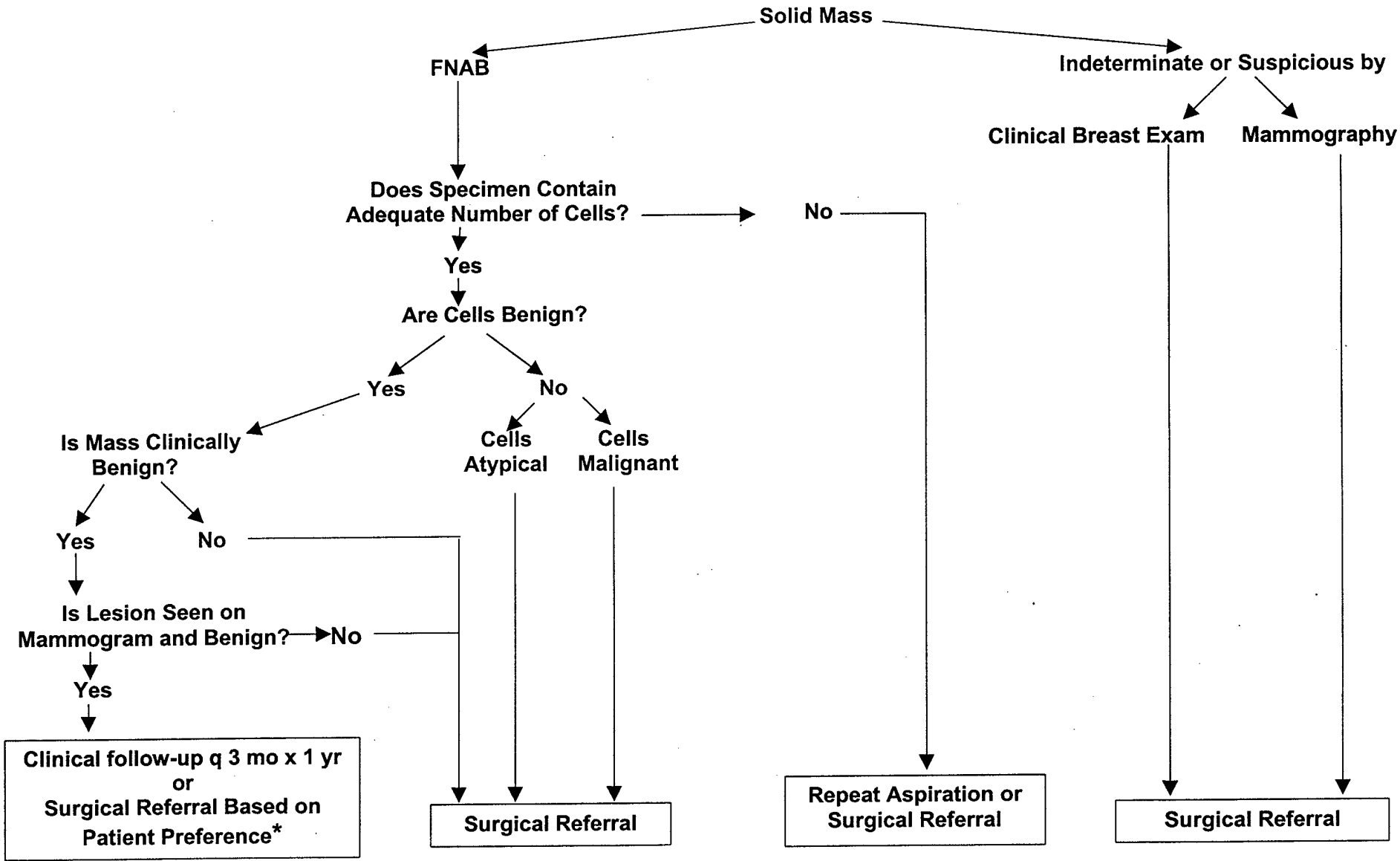
# APPENDIX 5B

## MANAGEMENT OF A BREAST CYST




Modified from: Osuch JR, Dell D, Sightler S. Breast and Cervical Cancer Education for Primary Care Providers. Alexandria, VA: American Medical Women's Association, 1994.

## APPENDIX 5C
## MANAGEMENT OF SOLID MASSES BY TRIPLE DIAGNOSIS

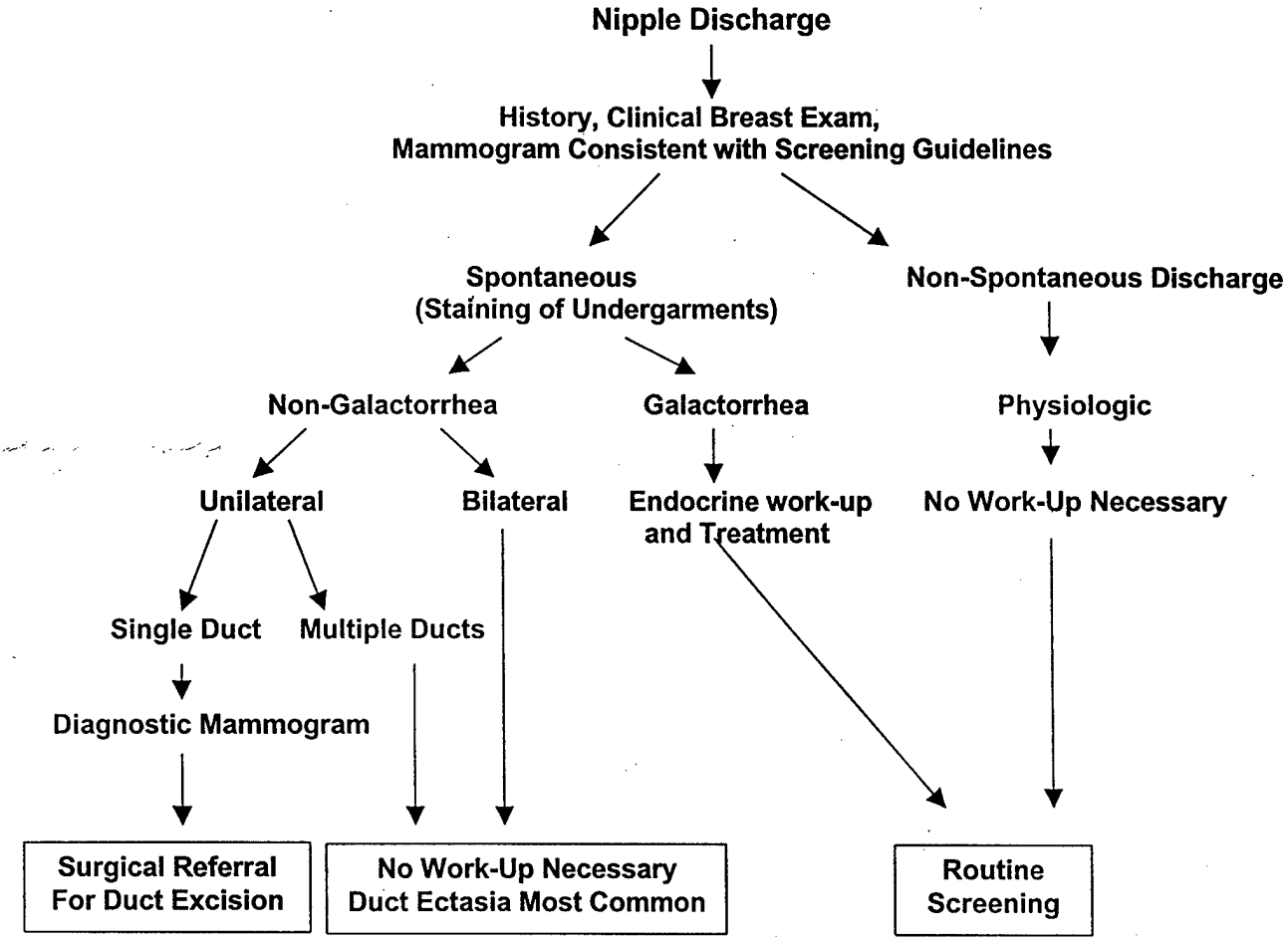



*All three elements must be benign. Cancer detected at follow-up exam in 1% of women.

Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. *Diseases of the Breast.* Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

# APPENDIX 6

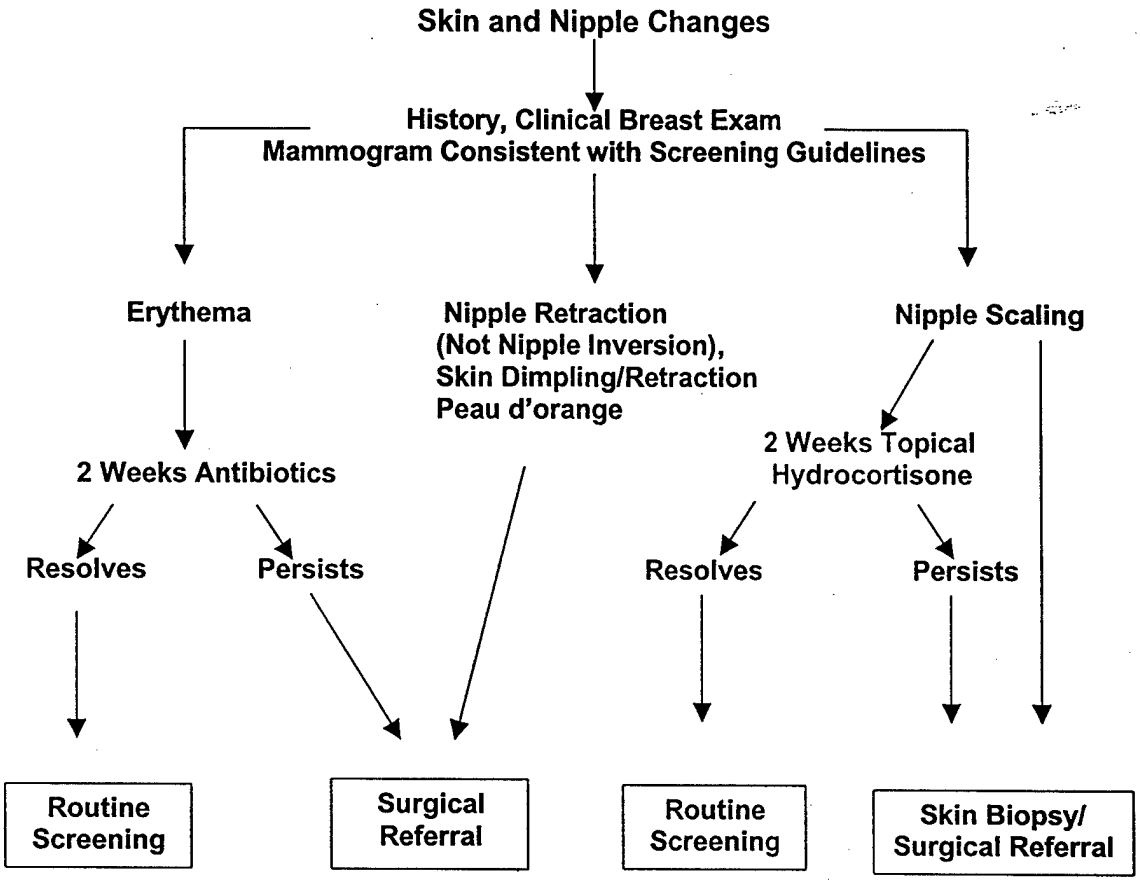
## MANAGEMENT OF NIPPLE DISCHARGE




Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

# APPENDIX 7

## MANAGEMENT OF SKIN AND NIPPLE CHANGES ON OBSERVATION




Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

# APPENDIX 8

## CLINICAL BREAST EXAM: STEP-BY-STEP APPROACH

### A Step-by-Step Approach

A useful approach to systematically perform CBE includes use of the "7 P's".

1. Ask patient to remove her gown. Visually inspect the breasts with the patient sitting and with arms at sides. Include frontal and lateral views. Look at SIZE, SHAPE, SYMMETRY, COLOR, TEXTURE, CONDITION OF NIPPLES **(POSITION).**

2. Repeat step 1 with arms overhead **(POSITION).**

3. Repeat step 1 with hands on hips, contracting pectoralis major. Look especially for skin dimpling with this maneuver **(POSITION).**

4. Palpate axillary and supraclavicular and infraclavicular lymph nodes with patient sitting **(POSITION, PALPATION).**

5. Help patient lie supine. Cover breast not being examined. Place ipsilateral arm overhead **(POSITION).**

6. Examine from ipsilateral side of table **(POSITION).**

7. Centralize the breast (manually or with a towel under the shoulder) **(POSITION).**

8. Visualize the perimeter of the breast **(PERIMETER).**

9. Choose a pattern of search. This should be either vertical strip, radial, or circular. Note that the circular method does not always cover the entire perimeter of the breast unless a conscious effort is made to do so. **(PATTERN OF SEARCH).**

10. Use pads of 3 middle fingers and examine in overlapping dime-sized circles **(PADS/PALPATION).**

11. Palpate the entire breast using the appropriate palpation techniques and sequential depths of pressure; light, medium and deep **(PALPATION, PRESSURE).**

12. During the process, the patient should be asked **(PATIENT EDUCATION)**
    a. if she is comfortable
    b. if the pressure is causing any discomfort
    c. if she performs BSE, how often, and her level of confidence
    d. if she has any questions or concerns

13. Emphasize to the patient the importance of the triad of Clinical Breast Examination, Breast Self Examination, and Mammography for early detection of breast problems **(PATIENT EDUCATION).**

**Source:** Osuch JR, Bonham VL, Morris LL. *Primary Care to Managing A Breast Mass: Step-by-Step Work Up.* Medscape Women's Health, 1998; Vol 3. No.5. http://www.medscape.com (See instructions in Appendix 10).

American Cancer Socity, California Division-Clinical Breast Exam: Proficiency Criteria and Guideline, February 1988.

# APPENDIX 9

## COMMON ALLEGATIONS FOR FAILURE TO DIAGNOSE BREAST CANCER AND RECOMMENDED STEPS IN RISK MANAGEMENT

| Allegation | Recommendation for risk management |
|---|---|
| • Failure to screen | • Perform clinical breast exam according to guidelines<br>• Order mammography according to guidelines<br>• Teach patients breast self exam<br>• Communicate recommendations<br>• Document each step above |
| • Failure to have knowledge of abnormal mammogram results | • Track results of tests<br>• Communicate abnormal results and recommendations to patient<br>• Document each step above |
| • Failure to follow up on complaint; failure to take patient complaint seriously | • Perform focused history and clinical breast exam<br>• Follow complaint to resolution or refer<br>• Communicate findings/recommendations<br>• Track patient follow-up appointments<br>• Document each step above |
| • Failure to verify a patient complaint on physical exam | • Perform careful history and clinical breast exam<br>• Compare and confirm results of clinical breast exam with results of breast self-exam.<br>• Repeat exam at best phase of menstrual cycle if ovulating<br>• Follow complaint to resolution or refer<br>• Communicate findings/recommendations<br>• Track patient follow-up appointments<br>• Document each step above |
| • Failure to follow up on a physical exam with abnormal findings | • Follow physical finding to resolution or refer<br>• Communicate findings/recommendations<br>• Track patient follow-up appointments<br>• If referred, establish follow-up responsibility with referring provider and patient<br>• Document each step above |
| • Failure to refer | • Refer any persistent breast abnormality to a specialist, no matter what the mammogram result<br>• Communicate area of concern to patient and specialist<br>• Establish follow-up responsibility<br>• If surgical intervention deferred, establish clear follow-up plan<br>• Document each step above |

Modified from Osuch JR, Bonham VL. The timely diagnosis of breast cancer. *Cancer.* 1994;74:271-8.

# APPENDIX 10

## INSTRUCTION TO MEDSCAPE

**To view the article, *Osuch JR, Bonham VL, and Morris LL. "Primary Care Guide to Managing a Breast Mass: Step-by-Step Workup"*, one must first sign in as described below in 1 and 2 and then proceed by either Option 1 or Option 2.**

1. www.medscape.com
2. If your objective is to view an article, you must register. There will be a box in the upper left hand corner with the selections "Register" and "Sign In" and "Search". Click on Register and follow the directions.

---

**Option 1**

3. On the left hand side you will see a column of selections. Scroll down until you see: **Women's Health.** Click on it.
4. Again, on the left hand side you will see columns with headings. Scroll down until you see **Journal Room.** Click on it.
5. You will come to a page with a variety of Journal names. Click on **Medscape Women's Health.**
6. It will ask you for your UserID and password. Enter the following which you chose when you registered.
7. You will open to a variety of articles. Look for the above "Osuch" article, Vol. 3, No. 5.

**OR**

**Option 2**

3. Return to the homepage after you have registered and in the upper left hand box where you see the search option, type in "Osuch".
4. It will bring you to a screen which you click on "Sign in and remember password" or "Sign in and do not remember password". Click on either one and Dr. Osuch's articles will come up, from which you may pick the appropriate one.

Use as a guide:

www.medscape/Medscape/Womenshealth/journal/1998/vo3.n05/wh3026.osuc/wh3026.osuc-01.html.

# APPENDIX 11

**Health care provider:**
Please photocopy this form.

# Personal risk assessment

Date _____

Name _____ Doctor _____

*Please answer the following questions to help your doctor determine your risk factors for developing breast cancer.*

*Have you ever had breast cancer?* ❑ yes ❑ no

*If you checked "yes," you have completed the survey. Please give the survey to your health care provider.*

**1.** *Have you ever had a breast biopsy that showed lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS)?* ❑ yes ❑ no or don't know

**2.** *How old are you?* _____

**3.** *How old were you when you had your first menstrual period?* _____

**4.** *How old were you when your first child was born? (If you've never had a child, write "0.")* _____

**5.** *How many of your sisters, daughters, or mother have had breast cancer?* _____

**6.** *Have you ever had a breast biopsy? (In a breast biopsy, the doctor removes tissue from your breast to test for cancer.)* ❑ yes ❑ no ❑ don't know

**6a.** *If yes, how many breast biopsies have you had?* _____

**6b.** *Did the doctor ever tell you that one of your biopsies showed atypical hyperplasia (a precancerous condition)?* ❑ yes ❑ no ❑ don't know

**7.** *What is your race?* ❑ White ❑ Black ❑ Asian

*Now please return this form to your doctor for calculation of your risk.*

**Health care provider:**
Please use this form with the Breast Cancer Gail Model Risk Assessment Tool.

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**Health care provider:**
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# Interpreting your risk assessment score

Date

Name

Doctor

*Based on calculation of your risk factors, your risk of developing breast cancer in the next 5 years as well as over your lifetime is as given below. The average risk for a woman your same age and race with no risk factors is included for comparison.*

| | |
|---|---|
| *My personal 5-year risk:* | _____% |
| *Average 5-year risk for woman of same age and race with no risk factors:* | _____% |
| *My personal lifetime risk:* | _____% |
| *Average lifetime risk for woman of same age and race with no risk factors:* | _____% |

***If your 5-year score is 1.67% or higher,*** *you are considered at high risk of developing breast cancer. Please discuss these results with your doctor. Only your doctor can help you decide whether NOLVADEX may be right for you, based on discussion of the benefit and risk involved. Your next steps are to:*

- *Schedule a counseling discussion with your doctor*
- *Complete* ***About the benefit and risk,*** *a form that your doctor can give you*
- *Read an information sheet called* ***Weighing the options: important considerations*** *and a booklet called* ***Assessing your risk for breast cancer...there is something you can do,*** *which your doctor can give you*

***If your 5-year score is under 1.67%,*** *you are not currently considered at high risk. Your next steps are to:*

- *Continue monthly breast self-exams, periodic office exams, regular mammograms, and ongoing breast cancer risk assessments*

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**Health care provider:**
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# About the benefit and risk

Date

Name

Doctor

*Please answer the following questions. Then give this form to your doctor, so you can have a thorough discussion of the benefit and risk involved with NOLVADEX therapy.*

1. *Am I at high risk of developing breast cancer—that is, do I have lobular carcinoma in situ (LCIS) or a 5-year score of 1.67% or higher on the Breast Cancer Gail Model Risk Assessment Tool?* ❑ yes ❑ no
2. *Do I plan to become pregnant during the next 5 years?* ❑ yes ❑ no
3. *Am I taking anticoagulants such as coumarin?* ❑ yes ❑ no
4. *Have I ever had a blood clot in the lung (pulmonary embolism) or in a major vein (deep-vein thrombosis)?* ❑ yes ❑ no
5. *Have I had a hysterectomy?* ❑ yes ❑ no
6. *Am I taking hormone replacement therapy, or HRT, for menopause?* ❑ yes ❑ no
7. *Am I taking hormonal contraceptives such as the "Pill," injections, or implants?* ❑ yes ❑ no

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# APPENDIX 12

# The Use of the Gail Model Risk Assessment Tool –

# Practice Session

# ***The Use of the Gail Model Risk Assessment Tool:***
# Practice Session

- **Calculate the risk for an average risk Black woman who is 51 years old according to the following steps:**

  Calculation of Risk for a 51 year old Black woman of average risk:

  1. Press the "on" button on the Gail Model Risk Assessment Tool
  2. Press B for Black race.
  3. Enter 51 for the age of the patient. The number at the left of the calculator's screen represents the question number as listed on the left-hand panel of the calculator.
  4. Press the green enter button.
  5. Enter 14 for the age at first menses.
  6. Press the green enter button.
  7. Enter 18 for the age of the first live birth.
  8. Press the green enter button.
  9. Enter zero for the number of first-degree relatives with breast cancer.
  10. Press the green enter button.
  11. Enter zero for the number of previous breast biopsies.
  12. Press the green enter button.
  13. Press the blue result button.

  Use the form entitled "Interpreting your risk assessment score" to enter the pertinent data (blank form found following this page).

- **Calculate the risk for an individual Black woman who is 51 years old**

  Calculation of risk for an individual 51 year old Black woman:

  1. Use Teaching form A to find the appropriate data for entry into the Risk Assessment Tool (last page).

  2. Follow the same steps as for data entry for an average-risk woman, making it specific to the individual woman presented in Teaching Form A.

  3. After entering '1' for breast biopsy, press the "Y" to designate a finding of atypical epithelial hyperplasia.

  4. Press the blue result button.

  Use the same form entitled "Interpreting your risk assessment score" to enter the pertinent data for the individual woman

**Health care provider:**
*Please photocopy this form.*

# Interpreting your risk assessment score

Date

Name

Doctor

*Based on calculation of your risk factors, your risk of developing breast cancer in the next 5 years as well as over your lifetime is as given below. The average risk for a woman your same age and race with no risk factors is included for comparison.*

| | |
|---|---|
| *My personal 5-year risk:* | _____% |
| *Average 5-year risk for woman of same age and race with no risk factors:* | _____% |
| *My personal lifetime risk:* | _____% |
| *Average lifetime risk for woman of same age and race with no risk factors:* | _____% |

***If your 5-year score is 1.67% or higher,*** *you are considered at high risk of developing breast cancer. Please discuss these results with your doctor. Only your doctor can help you decide whether NOLVADEX may be right for you, based on discussion of the benefit and risk involved. Your next steps are to:*

- *Schedule a counseling discussion with your doctor*
- *Complete* ***About the benefit and risk,*** *a form that your doctor can give you*
- *Read an information sheet called* ***Weighing the options: important considerations*** *and a booklet called* ***Assessing your risk for breast cancer...there is something you can do,*** *which your doctor can give you*

***If your 5-year score is under 1.67%,*** *you are not currently considered at high risk. Your next steps are to:*

- *Continue monthly breast self-exams, periodic office exams, regular mammograms, and ongoing breast cancer risk assessments*

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- **Using the form entitled "Interpreting your risk assessment score", interpret the results of the calculation of risk for the individual patient in Teaching Form A and compare it with a patient of average risk:**

The first number on the form represents the **patient's 5-year absolute risk** for breast cancer, meaning her chances of being diagnosed with breast cancer over the next five years expressed as a percentage. This number represents the 5-year absolute risk for all 51 year-old Black women with the risk profile entered. The average 5-year absolute risk for breast cancer for the individual patient in Teaching Form A is 2.6%. You should have entered the number **2.6%**.

Interpretation:
**Twenty-six of 1000** 51-year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over the next 5 years.

The second number on the form represents the **average woman's 5-year absolute risk** who is of the same race and age as the patient to whom she is being compared and whom has no other risk factors. The average-risk 51 year old black woman's 5-year absolute risk for breast cancer is 0.4%. You should have entered the number **0.4%**.

Interpretation:
Four of 1000 51-year old average-risk Black women with no risk factors will be diagnosed with invasive breast cancer over the next 5 years.

The third number on the form represents the **patient's lifetime absolute risk** for breast cancer, meaning her chances of being diagnosed with breast cancer over a lifetime, assuming life expectancy to age 90. This number represents the lifetime absolute risk for breast cancer for all 51 year-old Black women with the risk profile entered. The average lifetime absolute risk for breast cancer for the individual patient in Teaching Form A is 19.6%. You should have entered the number **19.6%**.

Interpretation: **One hundred ninety-six of 1000** 51 year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

The fourth number that appears on the form the **lifetime absolute risk** for breast cancer for an average risk woman of the race and age designated. The average-risk 51-year-old black woman's absolute lifetime risk for breast cancer is 3.2%. You should have entered the number **3.2%**.

Interpretation: **Thirty-two of 1000** average-risk 51 year-old Black women will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

- **Use the form entitled "About the benefit and risk" (following page) to assess indications, contraindications, and risks associated with the use of Tamoxifen as an agent to reduce the risk of breast cancer.**

## ***Remember:***

**Contraindications:**

**Medical contraindications include:**

- Current anticoagulant therapy
- History of deep vein thrombosis
- History of pulmonary embolism
- History of stroke

**Lifestyle contraindications include:**

- Pregnancy
- Lactation
- Hormonal contraception
- Hormone replacement therapy

**Side Effects*:**

**Statistically significant side effects include:**

- Endometrial carcinoma in postmenopausal women with a uterus
- Pulmonary embolism
- Cataracts and need for cataract surgery

**Reported side effects not measured for statistical significance:**

- Hot flashes
- Vaginal discharge

**Possible other side effects include:**

- Venous thromboembolism
- Stroke

*Premenopausal women were less likely to experience side effects than postmenopausal women were.

**Indications**

The P-1 Trial assessed Tamoxifen use in women 35 and over with a 5-year absolute risk of 1.67% or above, or women 35 and over with a history of lobular carcinoma in-situ. It reduced breast cancer incidence in women at all levels of high risk, ranging from categories of less than or equal to 2% to greater than or equal to 5%. The average risk assessed in the trial was 3.2%.

Tamoxifen use is not indicated in average-risk women for breast cancer, nor is it indicated in every high-risk woman. However, after considering the contraindications and side effects, women at high risk should be offered the choice of taking Tamoxifen to reduce the risk of breast cancer.

**Health care provider:**
*Please photocopy this form.*

# About the benefit and risk

Date

Name

Doctor

*Please answer the following questions. Then give this form to your doctor, so you can have a thorough discussion of the benefit and risk involved with NOLVADEX therapy.*

1. *Am I at high risk of developing breast cancer—that is, do I have lobular carcinoma in situ (LCIS) or a 5-year score of 1.67% or higher on the Breast Cancer Gail Model Risk Assessment Tool?* ❑ yes ❑ no
2. *Do I plan to become pregnant during the next 5 years?* ❑ yes ❑ no
3. *Am I taking anticoagulants such as coumarin?* ❑ yes ❑ no
4. *Have I ever had a blood clot in the lung (pulmonary embolism) or in a major vein (deep-vein thrombosis)?* ❑ yes ❑ no
5. *Have I had a hysterectomy?* ❑ yes ❑ no
6. *Am I taking hormone replacement therapy, or HRT, for menopause?* ❑ yes ❑ no
7. *Am I taking hormonal contraceptives such as the "Pill," injections, or implants?* ❑ yes ❑ no

ONCE-DAILY
20 mg TABLETS
Nolvadex®
TAMOXIFEN CITRATE

ZENECA Pharmaceuticals

Roche Pharmaceuticals

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# ***The Use of the Gail Model Risk Assessment Tool***

- The data entered into the risk assessment tool is dependent on the individual patient's history and is compared with that of an "average risk" woman of the same race and age to whom the patient is being compared.

- **"Average risk" is age-dependent and means:**

  - No history of in-situ or invasive breast cancer
  - Age at menarche 14
  - Age at first birth 18
  - No family history of breast cancer
  - No breast biopsy history

- AstroZeneca has provided **preprinted forms** to assist in the process of risk assessment. These are intended for office use and include forms entitled:

  - **Personnel risk assessment**
  - **Interpreting your risk assessment score**
  - **About the benefit and risk**

  Blank copies of each are included in the manual. Either patients can fill out the forms themselves or this can be done by an office assistant or by the physician.

- **If none of the race designations are applicable in your patient:**

  1. Explain to the patient that the risk assessment tool does not apply to her race.
  2. Offer her a calculated estimate of risk based on the highest risk that is used in the Gail model.
  3. If she is comfortable with this, press the A button.
  4. Explain that the patient's actual risk may be lower than the number calculated.

**Practical Tips:**

- The calculator is programmed to turn off automatically if not used continuously.

- The "C" button will clear the previous entry for a given case. Pushing the "C" button again will clear the previous entry for that same patient. To correct or restart the data entry on a specific patient, it may be easier to simply press the "on" button twice. This will cancel all previously made entries and prepare the calculator for a new case.

**Health care provider:**
*Please photocopy this form.*

# Personal risk assessment

Date July 1999

Name TEACHING FORM A

Doctor Osuch-Barry-Zuber

*Please answer the following questions to help your doctor determine your risk factors for developing breast cancer.*

*Have you ever had breast cancer?* ☐ yes ☒ no

*If you checked "yes," you have completed the survey. Please give the survey to your health care provider.*

1. *Have you ever had a breast biopsy that showed lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS)?* ☐ yes ☒ no or don't know
2. *How old are you?* 51
3. *How old were you when you had your first menstrual period?* 12
4. *How old were you when your first child was born? (If you've never had a child, write "0.")* 24
5. *How many of your sisters, daughters, or mother have had breast cancer?* 1
6. *Have you ever had a breast biopsy? (In a breast biopsy, the doctor removes tissue from your breast to test for cancer.)* ☒ yes ☐ no ☐ don't know
   - 6a. *If yes, how many breast biopsies have you had?* 1
   - 6b. *Did the doctor ever tell you that one of your biopsies showed atypical hyperplasia (a precancerous condition)?* ☒ yes ☐ no ☐ don't know
7. *What is your race?* ☐ White ☒ Black ☐ Asian

*Now please return this form to your doctor for calculation of your risk.*

**Health care provider:**
*Please use this form with the Breast Cancer Gail Model Risk Assessment Tool.*

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# APPENDIX 3

# Documentation of the Clinical Breast Exam

## HOW TO DOCUMENT

- Many physicians believe that they instinctively know how to document a medical record appropriately, but in retrospect find they have failed to do so.

- The medical record becomes a guide for physician and for subsequent providers.

- To ensure quality of care and manage the risk of liability it is necessary to throughly document:
  - Patient's health history
  - Symptoms and complaints
  - Clinical examination
  - Clinical decision making

**Breast Disorders can be classified into one of five signs or symptoms: (Slide 87)**

- Breast Pain
- Breast Mass or Asymmetrical Thickening
- Nipple Discharge
- Skin and Nipple Changes on Observation

- Occult (non-palpable) Mammographic Abnormalities

A **Focused history** for each of these common presenting complaints has been discussed in the curriculum; the first four of these are summarized below.

- **Breast Pain (Slide 89)**
  1) Location
  2) Duration
  3) Unilateral/Bilateral
  4) Rank on 10-point scale
  5) Relation to hormones
  6) Lifestyle-altering
  7) Worry

- **Breast Mass or Asymmetrical Thickening (Slide 143)**
  1)Location
  2)Method of discovery
  3) Size
  4) Duration
  5) Hormonal influences
  6) Characteristics of tenderness

- **Nipple Discharge (Slide 170)**
  1) Spontaneous
  2) Color
  3) One duct/more than one
  4) Unilateral/bilateral
  5) Duration
  6) Persistent

- **Skin and Nipple Changes on Observation (Slide 182)**
  1) Location
  2) Date first noticed
  3) Have there been any changes since the date of symptom onset

**DOCUMENTATION OF THE CLINICAL BREAST EXAM SHOULD INCLUDE MENTION OF:**

1) Inspection
2) Palpation
3) Lymph node examination

- **Statement if findings are Normal vs Abnormal**

- **IF ABNORMAL**

- A basic diagram of the breast should be incorporated into the medical record using a prepared form or a simple drawing to document the location of patient's complaints and findings on CBE. Written documentation should specify:

  - **For Breast Pain**
    1) Breast vs Chest Wall Pain
    2) If Breast Pain -- Cyclic vs Non-cyclic
    3) *Document work-up to resolution or referral*

  - **Breast Mass or Asymmetrical Thickening**
    1) When the lump was detected
    2) Location and Size of lump
    3) Associated changes in the breast (eg, nipple discharge, nipple or breast skin abnormality, skin erythema, dimpling, pain)
    4) Patient's findings -- location of the lump or the change in the breast should be fully documented
    *5) Document work-up to resolution or referral*

  - **Nipple Discharge**
    1) Is there a history of spontaneous discharge
    2) Is it elicited on physical examination
    3) Is it from one or multiple ducts
    4) Location
    *5) Document work-up to resolution or referral*

  - **Skin and Nipple Changes on Observation**
    1) Congenital
    2) Nipple changes -- a)Scaling, b)Retraction
    3) Skin Changes -- a)Erythema, b)Dimpling, c) Retraction, d) Peau d'orange
    *4) Document work-up to resolution or referral.*

**Occult (non-palpable) Mammographic Abnormalities -** *Document Initial Work-up* **(Slide 109)**

1) Had diagnostic mammogram been ordered -- a) Cone or Spot compression, b) Magnification
2) Had Ultrasound been ordered
*3) Document Work-up to resolution or referral.*

**REMEMBER THE IMPORTANCE OF DOCUMENTING EVERY STEP IN THE CLINICAL DECISSION PROCESS.**

**Modified from Osuch JR, Bonham VL, Morris LL. Primary Care Guide to Manging a breast Mass: A Legal Perspective on Risk Management. Medscape Women's Health, 1998: Vol 3.No.5. http://www.medscape.com (see instructions in Appendix 10).**

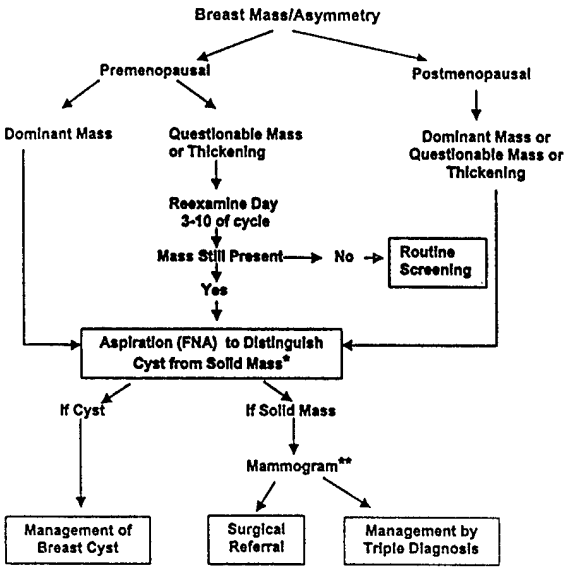
# APPENDIX 4

## A- Guidelines for Follow-up of Breast Abnormalities
## B- Summary of Breast Care
## C- Reminder Sticker

# Appendix 4A GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

INITIAL APPROACH:

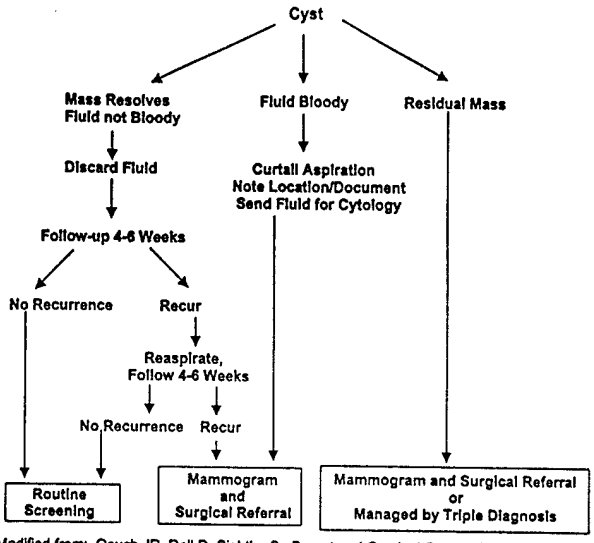
MANAGEMENT OF BREAST MASS/ASYMMETRICAL THICKENING




* Mammography
a) could be done prior to Fine Needle Aspiration (FNA)
b) should be avoided in women less than 30 years old and the pregnant women
** Mammography should be ordered 2-3 weeks following aspiration to avoid false positive results.

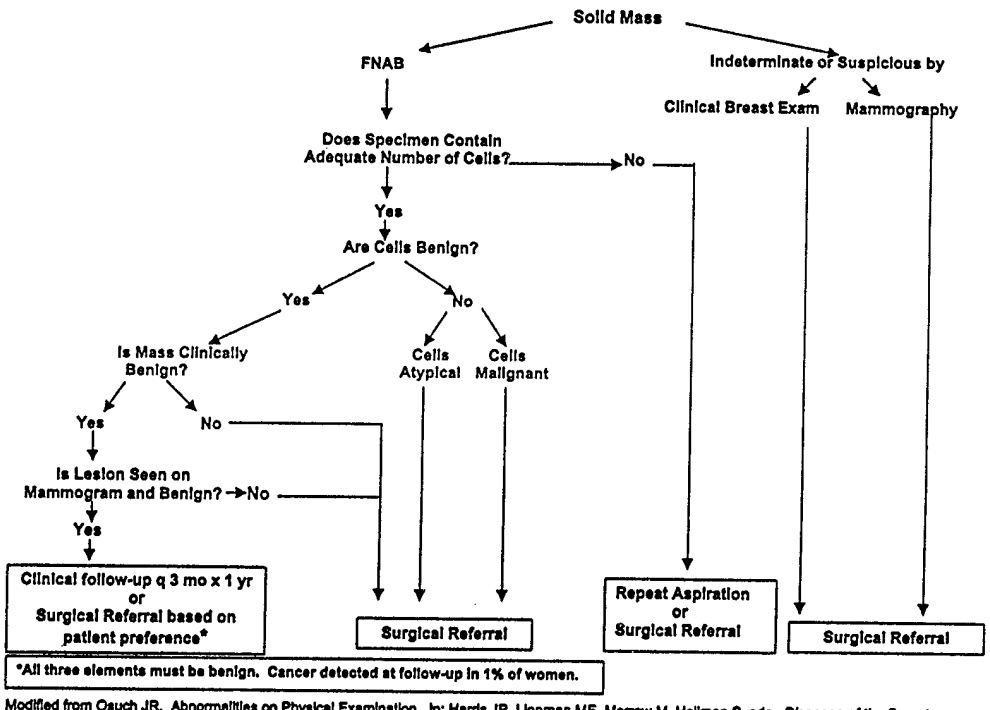
Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. Diseases of the Breast. Philadelphia: Lippincott-Raven, 1996:110-114. Reprinted with permission.

MANAGEMENT OF A BREAST CYST




Modified from: Osuch JR, Dell D, Sightler S. Breast and Cervical Cancer Education for Primary Care Providers. Alexandria, VA: American Medical Women's Association, 1994.

MANAGEMENT OF A SOLID MASS BY TRIPLE DIAGNOSIS

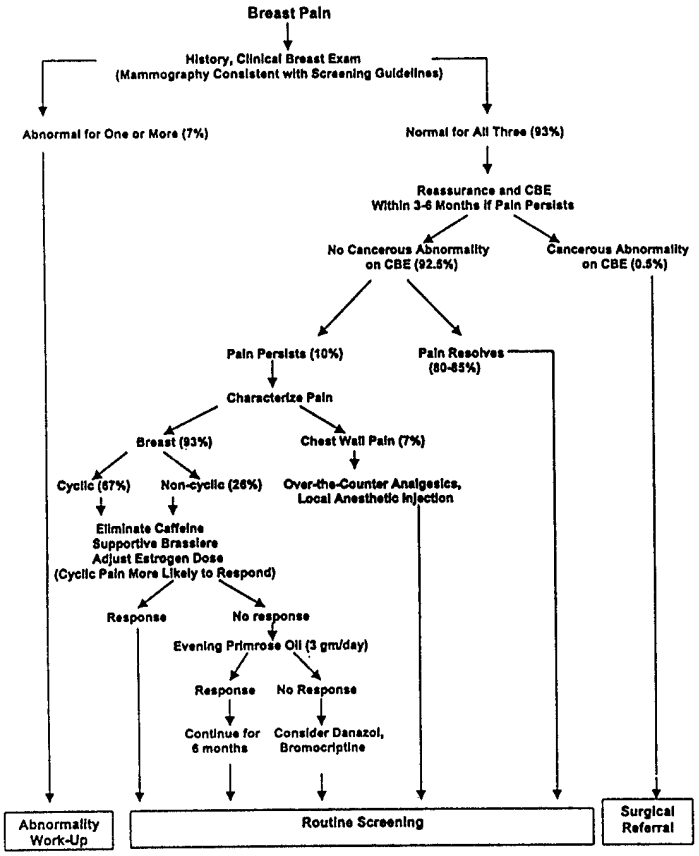



*All three elements must be benign. Cancer detected at follow-up in 1% of women.

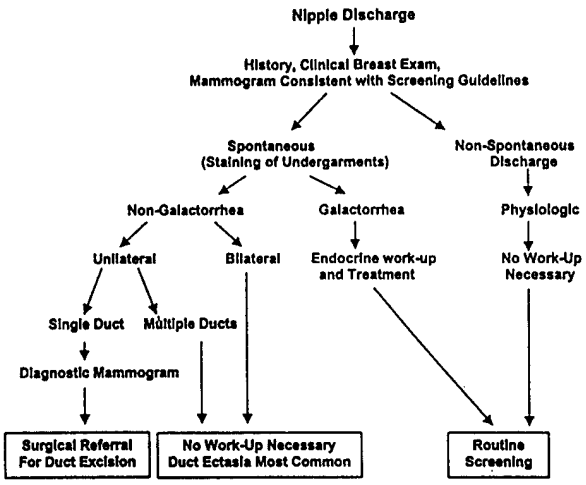
Modified from Osuch JR. Abnormalities on Physical Examination. In: Harris JR, Lippman ME, Morrow M, Hellman S, eds. *Diseases of the Breast.* Philadelphia, PA: Lippincott-Raven, 1996:110-114. Reprinted with permission.

# GUIDELINES FOR FOLLOW-UP OF BREAST ABNORMALITIES

## MANAGEMENT OF BREAST PAIN

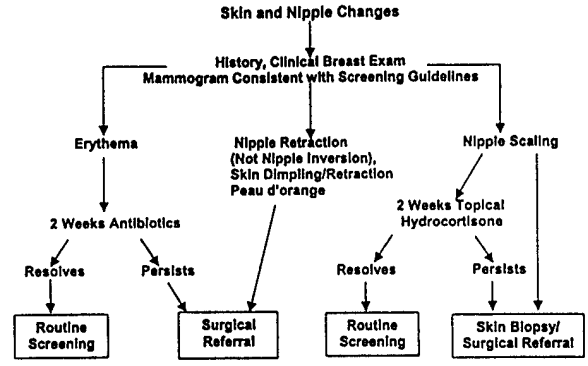



## MANAGEMENT OF NIPPLE DISCHARGE



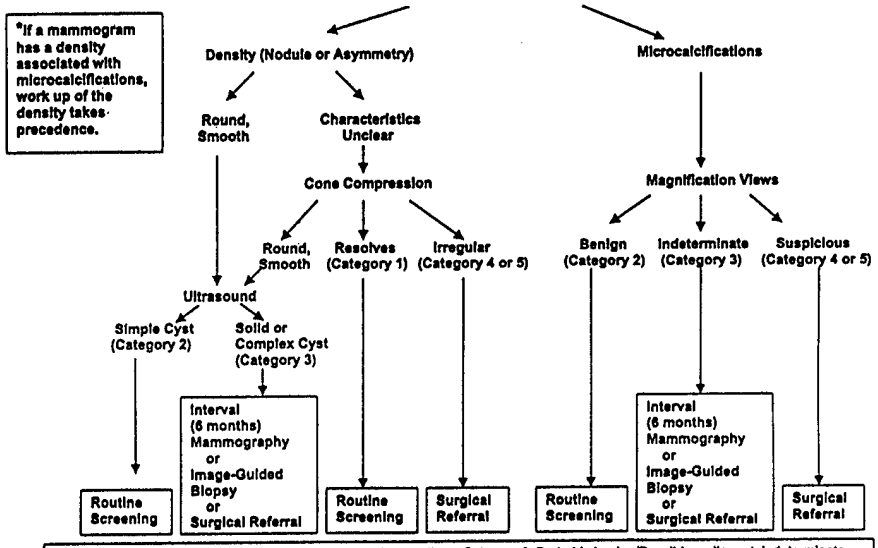

Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

## MANAGEMENT OF SKIN AND NIPPLE CHANGES ON OBSERVATION




Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

## MANAGEMENT OF OCCULT MAMMOGRAPHIC ABNORMALITY*




Modified from Morris LL and Osuch JR: Breast Cancer Education for Department of Defense Primary Care Managers. American Medical Women's Association. Alexandria, VA. 1998.

Appendix 4C

Appendix 4B

# SUMMARY OF BREAST CARE

Last visit prior to edit __ /__ / __ End date for review (15 months) __ / __ / __

**BREAST CARE**:

**None** during this time period _____

| **Date:** | **Type of Breast Care** |
|---|---|
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |
| __/__/__ | _____ |

**Codes for Type of Breast Care:**

**Normal CBE** –N CBE

**Abnormal CBE** – Abn CBE
- Lump
- Nipple Discharge
- Skin Changes
- Breast Pain
- Other

**Normal Mammogram** –N Mammo
**Abnormal Mammogram**--Abn Mammo

**Other Test results**
FNA
FNAB
Ultra Sound – U/S
Surgeon's Letter –SL
Biopsy report
**Other (specify)**

# APPENDIX 5

# Nurse Abstractors Training Manual

# AGENDA
# Nurse Abstractor Training

Training Leader: Barbara Given, Ph.D., R.N.

August 9, 1999

9:00 Refreshments and registration

9:30 Project Overview; Role of Nurse Abstractor; Importance of standards/guidelines

10:30 Break

10:45 Review and discussion of key items in charts;
Rationale for items abstracted from chart

12:00 Working lunch

1:00 Review of abstractor instructions and eligibility criteria

2:00 Introduction to the laptop; How to use the laptop; Email and FTP

4/4:30 Conclusion/End of Day One

August 10, 1999

9:00 Mock case

11:00 Break

11:15 Practice cases

12:30 Lunch

1:00 Practice cases; Review of practice cases; Discussion

3:00 Employment paperwork; Assignments at Residency Sites

4/4:30 Conclusion of Training

# Nurse Abstractors
# Training Manual

Table of Contents


I. Overview of the project

II. Responsibilities of the position

III. Employment information

IV. Key contacts

V. Abstracting Instructions

VI. Paper Audit

VII. Practice cases

VIII. Quality Assurance

# PROJECT OVERVIEW

# Overview of the Project

**"Improved Follow-up of Breast Abnormalities Through Comprehensive Breast Care in Women 40 to 70 Years of Age"**

## Purpose of the Study

Breast cancer is an important preventable cause of illness and death among women. Unfortunately, physicians may misinterpret findings from women's history, physical and mammogram, resulting in delayed diagnosis or prolonged waits for reassurance. The focus of this study is to improve the knowledge, physical examination skills, and management skills of physicians.

The intervention will include three components:

1) Educational Session designed to enhance physicians' skills in appropriate follow-up and risk assessment of breast abnormalities and to improve the physicians' knowledge of the epidemiology of breast cancer and benefits of screening;
2) Clinical Skills Course teaching the optimal technique of clinical breast exam and interpretation of findings; and
3) Chart Reminder/Guideline System designed to improve recording, tracking and follow-up of women.

We hope to demonstrate that, for women 40 to 70 years of age, physicians receiving the special training will demonstrate a significantly greater increase in the rate of screening and improvement in the appropriateness and timeliness of follow-up of abnormal findings.

## What residency programs are involved in the study?

The residency program sites include:

1) MidMichigan Regional Medical Center (Midland)
2) Saginaw Cooperative Hospitals
3) McLaren Regional Medical Center (Flint)
4) Genesys Health Systems (Flint)
5) Sparrow/MSU (Lansing)
6) Kalamazoo Center for Medical Studies
7) Munson Medical Center (Traverse City)
8) Providence Hospital (Southfield).

Four sites will be randomly selected to be intervention sites and the remaining four will be control.

**What will be happening at each site?**

At both intervention and control sites - Nurse abstractors will be performing chart audits on the charts of female active patients age 40-70 years of age. These nurses will be regularly sending information to MSU via the use of a laptop computer, which will be kept at the site for the duration of the project. Nurses will be abstracting charts during August through October 1999 and same months in 2000.

Intervention sites – Health care providers will receive the one day training in the summer of 1999 and are encouraged to use the chart reminder and follow-up form during the year after training. This chart reminder and follow-up form will be included in charts.

Control sites – Health care providers will receive a one day training (if they choose) in the summer of 2000 and have the option to use the chart reminder and follow-up system at that time.

This project is funded by the Department of Defense.

# POSITION RESPONSIBILITIES

# Responsibilities of the Position

This section describes the responsibilities and expectations for the Nurse Abstractor position.

GENERAL RESPONSIBILITIES

## Training

1. Complete required two day training session to be held in East Lansing, Michigan in August.
2. Read and utilize the procedures outlined in the Nurse Abstractor Training Manual.
3. Actively work with Project Coordinator and Nurse Trainer to clarify procedures as needed.
4. Acknowledge the importance of ongoing training, in the form of regular quality assurance meetings with Project Coordinator and Nurse Trainer.

## Public Relations

1. Be flexible and courteous to other personnel in the Family Practice Center. You represent the MSU Essentials of Breast Health for Primary Care Physicians Project. The continued support and assistance of the Family Practice Center staff is crucial for the success of this project.
2. Keep an identification letter from the study with you, in case of request.

## Quality Assurance

1. Conduct system quality assurance reviews of your own work, being thorough and reading through **all** records provided. Remember that errors can often be avoided by considerable attention to detail, careful thought, regular review, and asking questions when uncertain.
2. Participate in quality assurance reviews of audits done by others.
3. Participate in regular quality assurance meetings with Project Coordinator and or Nurse Trainer, noting problems and revising or modifying approach as needed.

## Confidentiality

1. Maintain confidentiality for all audited information. Refer to patients by their ID numbers, rather than by name, whenever possible. If there is a need to discuss a particular case outside of the project areas, the Project Coordinator or Nurse Trainer should be contacted. Remember that the right of patient confidentiality should always be protected.
2. To insure confidentiality in your absence be certain no files or audit notes are left out or scattered about. All audits should be kept covered, in closed folders, or envelopes. All identifiers must be kept confidential whenever possible.

## Security

1. You will be provided with a laptop computer for use with data entry. It will be your responsibility (with assistance from the site contact) to identify a secure place the laptop can be stored after working hours and when not in use. The laptop will need to be stored in this place when not in use.
2. As well, it is important that use of the laptop be secured with a password. Using a password will prevent others from accessing the data. It is your responsibility to assign (with assistance from the data manager) a password and utilize it for entry into the data screens.

3. Project goals and hypotheses. It is important that we not jeopardize the study by letting others know specifically what data we are abstracting. Although important at intervention sites, this is especially true at control sites. It is your responsibility to not divulge the specific aims of the project. If others inquire, refer them to the Project Coordinator or Principle Investigator.

Employment

1. Complete hiring packet information.
2. Complete weekly timesheets and turn in to the Project Coordinator by the date specified.
3. Notify the Project Coordinator in advance if total hours per week will not be met (i.e. sickness or vacation prohibits 19 hours/week).

## SPECIFIC RESPONSIBILITIES

Identification and "Pulling" of Patient Medical Records (Charts)

At some locations, it may be necessary to pull charts of patients for the study. This will include the following tasks:

1. Locating patient medical records area
2. Identifying process for pulling medical records
3. Learning method of records organization and how to identify selected patient's records.
4. Identifying locations where medical records may be abstracted
5. Identifying proper procedure for use and returning medical records.

*These tasks will be explained by your site coordinator at your orientation meeting.

Eligibility Determination

It is important that you audit charts for patients that are eligible for the study. Auditing charts of patients that are not eligible will causes errors in our data. The following tasks are included in this process:

1. Gathering report of all potential eligible patients (criteria: female, 40-70, active patient). This will be provided to you by the site as you begin.
2. Determining eligibility for various aspects of the study (ineligible, eligible for guideline insertion and eligible for guidelines and abstracting). There is a specific form that you will be completing (on the laptop) which will help you to determine eligibility.

Audits

1. Complete audits each week, as assigned and FTP on Fridays to data manager.
2. Complete and return reports to Project Coordinator as needed.
3. Notify Project Coordinator of any problems that occur, for example, with chart availability, documentation, personnel, or audit assignments.
4. If uncertain of anything, ask Project Coordinator for clarification.
5. Accuracy in abstracting data will be checked twice by a quality assurance auditor. It is important that you achieve and maintain a 90% or higher accuracy rate.

# EMPLOYMENT

# Employment Through MSU

## Employee Status

In this position, you are hired as a temporary, on-call employee.

## Period of Employment

You will be employed for the following periods of time:

- MSU training to be held August 9 and 10, 1999 (includes travel time)
- Time at family practice site abstracting
  - Begins August 16 (or that week) and end October 29, 1999 (potentially longer or shorter depending on need)
  - 19 hours per week

## Getting Paid

As an MSU Employee, you will need to regularly complete Time sheets in order to get your check. Included in this section are:

- MASTER copy of a timesheet. Use this to make copies to complete and send in.
- LISTING OF SUBMISSION AND PAY DATES. This lets you know when we need to receive your timesheet and when you should receive your paycheck, if submitted on time.

Probably the best way to get time sheets in is by fax. Please fax to:
Jodi Holtrop, PhD, CHES
(517) 355-7700

Address (FYI) is:
Jodi Holtrop, PhD, CHES
Department of Family Practice - MSU
B101 Clinical Center
East Lansing, MI 48824

Jodi will sign your time sheet and forward on to the appropriate individual at the University.

If you do not receive a check, please contact Maria Struck. She will check into the status of your pay check.

Please remember that it is important that you send in your time sheets and they are received by or before the dates listed on the enclosed listing of submission dates!

# KEY CONTACTS

## Key Contacts

Dorothy Pathak, Ph.D., M.S. – Principle Investigator and Professor, Family Practice and Epidemiology
(517) 353-0772 ext. 441; pathak@pilot.msu.edu
Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Jodi Holtrop, Ph.D., CHES – Project Manager and Residency Network Director
(517) 353-3544 ext. 432; jodi.holtrop@ht.msu.edu
Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Barbara Given, Ph.D., R.N. – Co-Investigator, Professor of Nursing, and Research Director, Institute for Managed Care
(517) 432-4326; bgiven@pilot.msu.edu
Institute for Managed Care – MSU, D133 West Fee Hall, East Lansing, MI 48824

Maria Struck – Support for grant
(517) 432-2794 ext. 458; maria.struck@ht.msu.edu
Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

Suiying Huang - Data Coordinator
(517) 353-8623 ext. 149; huangsu1@msu.edu
Dept. of Epidemiology

Ping He, M.D. – Data Manager
(517) 353-8623 ext. 128; hejianp2@msu.edu
Dept. of Epidemiology

Janet Osuch, M.D. – Co-Investigator, Professor of Surgery and Director of the MSU Comprehensive Breast Health Clinic
(517) 353-3140; osuch@pilot.msu.edu
Dept. of Surgery, B424 Clinical Center, E. Lansing, MI 48824

Henry Barry, M.D., M.S. – Co-Investigator, Associate Professor of Family Practice
(517) 353-0851 ext. 456; henry.barry@ht.msu.edu
Dept. Family Practice - MSU, B100 Clinical Center, E. Lansing, MI 48824

G. Marie Swanson, Ph.D., M.P.H. – Co-Investigator, Professor of Family Practice and Director of the Cancer Center at MSU
(517) 353-3843 ext. 452; swansong@pilot.msu.edu
Dept. Family Practice – MSU, B108 Clinical Center, E. Lansing, MI 48824

# ABSTRACTING INSTRUCTIONS

# Instruction for Data Entry

This section will provide instruction on entering data onto data entry forms provided on your laptop computer.

**To Do's in Chart Familiarity:**

It is first important to familiarize yourself with how the medical record (chart) is organized. Each Residency Program will have it's own system. It is important to be familiar with the medical record so that you may quickly find the information you are looking for, as well as not miss anything important. Here are some things to think about when doing so:

- General chart organization.
  - In what sections do you find a record of office visits?
  - Where are examination results (are they typed or hand-written)?
  - Determine what forms are used for phone calls so that you can distinguish phone calls from visits.
  - Mammogram reports?
  - Ultrasound reports? (Make sure you are clear whether you are reviewing mammogram reports or ultrasound reports, as they can look very similar).
  - Pathology reports
  - Surgeon's letters

- Determine if the chart begins with the most recent visits (i.e. they are on top) or the most recent visits are toward the back of the chart.

- Get list of who is a resident, faculty member and PA or Nurse practitioner so when you see a name you will know what category they go in. Ask if there are any people who were residents and are now faculty. There are some cases where this occurs, so you'll need to find out what year they were in which position.

- Become familiar with common abbreviations and symbols such as PH meaning Personal History.

- ACS guidelines are a 12 month mammogram and 12 month CBE for ages 40 and over. If you see this noted in follow-up plan as "Follow ACS Guidelines" this, you'll know that's what it means. However, we also provided you with an option of "ACS guidelines". So, all you need to do is to chose that option.

**Getting Into the Program:**
To open the program, follow these steps:

1. Turn on the computer
2. Double click on the icon that says 'Breast Care'
3. The database designed for this study contains **four** forms for you to work on.
4. The first form '**Form I-Front-End**' will automatically open. It contains patient's general information, eligibility criteria, and part of chart review form (Questions 1-5).
5. The second form '**Form II-Visit Entry**' is connected to the Form I through linking buttons. The purpose of the visit, presenting symptoms, and CBE documentation need to be recorded in this form.
6. The third from '**Form III-Test Result Entry**' is connected to the Form II and Form IV through linking buttons. All types of tests results, such as mammogram, FNA, FNAB, ultrasound, Biopsy, are recorded in this form
7. The forth form '**Form IV-Follow-up Entry**' is connected to the previous Forms through linking buttons. This form collects all the assessment and recommended follow-ups.

**The information you see on the screen corresponds with the first data form in the computer. Before you proceed with entering data, there are few key things to keep in mind:**
As you begin using the program, keep in mind these points to help you enter information and find your way around.

**Scrolling**–You may use the arrows in the vertical bar on the right-hand of the screen to move up and down to the beginning or end of the form.

**Navigating**—

**FOR MOVING BETWEEN FORMS OR NAVIGATING WITHIN FORM I AND II, USE ONLY THE NAVIGATING BUTTONS PROVIDED ON TOP OR BOTTOM OF EACH FORM. DO NOT USE THE ARROW BUTTONS ON THE BOTTOM OF THE DATABASE. THIS DOES NOT CARRY THE STUDY ID TO THE NEW FORM.**

When you are in Form I, **the horizontal bar at the bottom** of the screen gives you the information as to how many individuals are in your database. You can

move between patients but be careful. Similarly when you are in Form II, the horizontal bar tells you how many encounters you have for that person. Again you can move between encounters if you are careful, **but make sure you do not use that method to add a new visit. Navigating with the horizontal bar buttons does not carry Study ID to the next encounter form.**

**Closing Form or Database**—At the top of the screen, you see two sets of 3 small buttons with the following symbols:

1) an underline for minimizing the screen;
2) a two overlaid little squares for restoring the screen to smaller size; one little square for maximizing the screening; either one will appear.
3) a "X" symbol for closing the screen.

The upper set corresponds to the screen of the current ACCESS database; the lower set to the screen of the current object, such as forms, tables, etc.
To close the ACCESS application, click "X" in the upper set; To close the form you are currently working on, click "X" in the lower set.

**Entering Information** – Can be performed by using either the [Enter] or [Tab] keys, or moving the mouse to the appropriate field and click.
There are three types of data entry.

1) When you see a rectangular box, you will need to type in the required information;
2) When you see a rectangular box with an arrow at the end of it, click on the arrow, it will give you pull-down options for this field. Select the appropriate option.
3) When you see a little square, you will need to click on this square and a check mark will appear indicating 'Yes'.

**Correcting Information** – If you make an error,

1) in the rectangular box, put your cursor at the beginning and hold the left mouse button and drag the cursor to select all the information. This will make the selected area shaded. Then release your left mouse button and hit the delete button on your keyboard. Then type the new information.
2) in the rectangular box with arrow, click the arrow and select the appropriate option. It will overwrite the previous choice.
3) in the little square, click once to de-select your previous choice (the check mark will disappear).

**Required Data Entry Fields**

- **On the Form I**, there are two required fields--Study ID and Today's Date
  1) If you do not fill out study ID, or have a duplicate ID number, or you did not enter today's date, a warning message box will appear when you click the button in the first form, titled 'Click here to continue', or click the button titled 'Continue to record visit info.'. You should click 'OK' on the massage box, it will always take you back to the Study ID box. If the study ID field is empty, fill in appropriate study ID; if there is a study ID, but the field 'Today's date is empty, fill in today's date; if both study ID and Today's date are filled, that implies this study ID is duplicate. Please check and correct.
  2) If you try to exit the form by clicking "X" symbol in the lower set but these required fields are not appropriately entered, you will see two messages. The first will give you a warning indicating information is missing; when you click 'OK' on this message box, the second message box appears. If you click 'Yes', you will exit this form without saving that record. If you click 'No', you will have a chance to enter/correct the missing/duplicate information.
- **On the Form II-Visit Entry form,** there is one required field--Question 6. Date Breast Care Activity was recorded.
  1) If you do not fill out the date of visit in this field, a warning message box will appear when you click the button titled 'Add new visit' or 'Add new patient'. You should click 'OK' on the massage box; it will always take you back to the Question 6 box.
  2) If you try to exit the form by clicking "X" symbol in the lower set, but this required field is missing, you will see two messages. The first will give you a warning indicating information is missing; when you click 'OK' on this message box, the second message box appears. If you click 'Yes', you will exit this form without saving that record. If you click 'No', you will have a chance to enter the missing information.

**Saving Information** – You do not need to select 'save' anywhere to save data. After you enter the information for each field it automatically saves it. When you exit, it saves the data. The only exception is that when the information in the required fields is missing and you exit that form.

**Searching Information** – When you see the binoculars, this means you may search. You must first click on the field that you wish to search and then move the to binoculars and click on it.

**Blue shaded boxes** – These boxes are automatically filled out based on the information you provided previously. You have no access to change this information.

**Disabled fields**—appear faded on the screen. When a leading category has been checked, these fields will be enabled and represent options that will need to be selected.

**Skip Pattern**—Certain fields when selected will trigger a message box indicating a skip pattern. Click 'OK' on that message box and you will be automatically taken to that question.

**Note:**

- Currently when you choose in Type of Contact (Question 6) any one of the test results, you will be taken directly to Form III-Test Result Form by clicking the button on the right.
- Similarly, if you choose Surgeon's letter, you will be taken directly to Form IV-Follow-up Form at "Assessment/Recommended Follow-up From Surgeon's Letter".

**FPC**– This stands for 'Family Practice Center.' This means the care was provided by a provider from the Family Practice Center rather than another institution.

**FPCP**—This stands for Family Practice Center Provider.

**The following steps describe how to add new patient and visit.**
Start entering information beginning with the first screen.

Last name – Insert patient last name

First name – Insert patient first name

Medical record number – Enter. This field will accept either number or letters. If no information is available, leave it blank.

Date of birth – All date type of fields are entered as 3 sets of numbers starting with month, day, and year, such as 08/10/99 indicating August 10, 1999. Slashes automatically pop-up when you go to enter. When you start entering the date, make sure your cursor at first place-hold, i.e. at the first digit for the month entry. To avoid errors, enter all leading 0's, such as '08'. You will notice after you entered date and move to the next field, the leading '0' for month and day will not show on the screen.

Abstractor ID – You will be given an 2-digit ID number. Enter that number here. Please fill in your 2-digit abstractor ID here: |____|____|

For your information, the following table lists the site number and abstractor ID.

| **Site** | | | **Abstractor ID** | |
|---|---|---|---|---|
| 1 | Intervention | Sparrow (includes Mason) | 11=P. McAfee | 12=S.E. Bonfiglio |
| 2 | Intervention | St. Lawrence | 21=A. Quitos | 22=C.A. Dobias |
| 3 | Intervention | Kalamazoo | 31=G. Peterson | 32=C. Aaron |
| 4 | Intervention | Midland | 41=S.J. Leibfritz | 42=E. Horvath |
| 5 | Intervention | Saginaw | 51=S.K. Davis | |
| 6 | Control | Genesys | 61=M. Debernardi | 62=N. Kale |
| 7 | Control | McLaren | 71=M. Taylor | 72=C. Farella |
| 8 | Control | Traverse city | 81=M.K. Wilmot | 82=D. Doggins |
| 9 | Control | Providence | 91=C. Dworman | 92=J. Rotthoff |

**Eligibility Criteria Section:**

1. Complete each of the questions # 1 through 5. Click the arrow on the right of the field for a pull-down of choices. Point your mouse arrow and click on the choice you wish to select.

2. After completing all 5 questions, click the button 'determine eligibility code.' To the right, in a blue shaded field, a code will appear of 1, 2 or 3. For your information, the computer comes up with the eligibility code based on your answers to questions 1 through 5:
   - Eligibility code=1 when the answers are: FEMALE to criteria 1; YES to 2 and 3; FPC Provider to 4; and YES to 5
   - Eligibility code=2 when the answers are: FEMALE to criteria 1; YES to 2 and 3; FPC Provider to 4; and NO to 5
   - Eligibility code=3 for all others

**Eligibility codes and actions:**

Eligibility code =1: Eligible for abstracting, guideline and breast care summary sheet insertion

Eligibility code =2: Eligible for guideline and breast care summary sheet insertion but not abstracting

Eligibility code =3: Not eligible; No further action is needed.

**Assign a study ID**—Study ID is a 6-digit number. Using this guide to assign a study ID as follows:

| Digit | 1st | 2nd | 3rd | 4th | 5th | 6th |
|---|---|---|---|---|---|---|
| Study ID= | Site Number | Eligibility Code | Assigning consecutive number | | | |

Site numbers and eligibility code see above.

If you are at a control site (site 6, 7, 8, 9), there are only two categories really: These are 1 = eligible for abstracting and 2 & 3 = not eligible. Because we are not inserting guidelines in the chart, category 2 is not applicable. Thus, those in category 2 become category 3's. Keep the study ID as 2 for the second digit, however, know that they are essentially ineligible.

The 6-digit study ID is a unique identifier for each patient. Patients at your site have the same 1st digit. If they have the same status of eligibility, they will also have the same 2nd digit. But the last four consecutive numbers should be incremented. Look at the last 4 numbers entered for the category

(1, 2 or 3) of eligibility code you are in. Under study ID, there two boxes: one explains how to assign a study ID number, the other (blue shaded) shows the last study ID number assigned in each category of eligibility. After you enter first two digits of study ID number, You should find out what was the last 4 digit number assigned for that specific eligibility category. Use the next consecutive number.
Same study ID number cannot be assigned twice – it will not be accepted.

Today's date – Same instructions as date of birth. It is a required field.

At this point, you are given two choices:

1) If this patient is eligibility code 2 or 3, after you assigned study ID and entered today's date, you can click button 'Add New Patient' and start with a blank screen to do your next patient.
2) If this patient is eligibility code 1, after you assigned study ID and entered today's date, then you click button 'Click here to continue' (This button will check if you assigned appropriate study ID and filled in today's date) and then you simply continue abstracting and adding to this form.

**FORM I:**

1. Date of most recent visit – Enter in. Again, remember to put in two digits for each month, day and year.

2. Date of last eligible visit for audit—This date is automatically calculated for you. It tells you how far back to go and audit this chart (15 months). Review all records including office visits, breast care phone consultation, mammogram, and other test results in this chart from that date forward.

3. Enter the total number of visits—

   - Count all family practice office visits (These are all types of visits, not just breast care).
   - In addition, count all phone calls for breast care.
   - Do not count phone calls for other concerns.
   - Do not count visits to oncologists, radiologists, etc, even if that information is available in the chart.

- Do not count phone calls to family practice physicians regarding refills of Tamoxifen/Nolvadex, if it is for treatment of breast cancer. However, if it is specified that tamoxifen is prescribed for prevention, then it will be counted as an encounter. You would then record that information in the general comment box provided in the follow-up form (Form IV)

4. Was breast care performed?--During the time period, was there any breast care performed? Select yes or no. If the answer is NO, the patient is not eligible for further abstracting. You are done with this patient. If you wish to continue to next patient, click button 'Add New Patient'. Otherwise, you click 'X' to exit.

5. Personal/Family History of Breast Cancer--Select choice from:
   - None - Select if there is documentation that the patient has no personal / family history
   - Yes – Select if noted personal/family history

     **For age at diagnosis,** You should:
     - Fill in exact age when information is available;
     - Fill in '777' if only known Pre-menopausal, less than or equal to 50 years old;
     - Fill in '888' if only known Post-menopausal or greater than 50 years old;
     - Enter 999 for don't know;

     **If in self:**
     - If available, document type of surgery
     - If available, specify all treatments
   - Undocumented – Select if not mentioned if there is family history or not.
   - Patient Don't Know – Select if documented that patient doesn't know family history.

   Note: There might be times as you review the chart, that the family members' age at diagnosis will be mentioned in, say, mammogram report, Please go back than to Form I and record that information.

**At the bottom of the Form I, four navigating buttons can be used to move from patient to patient within the first form:**

- **Go to first patient**
- **Go to previous patient**
- **Go to next patient**
- **Go to last patient**

To continue record information for individual visits, click the button 'Continue to record visit info.', it takes you to the Form II

**FORM II:**

After you click the button 'Continue to record visit info.' on Form I, Form II will appear for you to enter patient's visit or related phone consultation information. On this form you also enter in the "type of contact" whether it is a test result or surgeon's letter. For these two options you will be prompted that you can go directly to the "Test results form" or "Surgeon's letter form". To whatever form you go the **study ID number in the first form will be automatically carried over to this form.**

6. Date any breast care performed – Enter in the date following the same rules as for date of birth;

For VISITS or PHONE CONSULTATIONS enter the date it occurred.
For TEST RESULTS or SURGEON'S LETTER use the date it was received in the FP files (if stamped) as the date of the encounter. If that is not available but the date FPCP reviewed the results is available use that date. If neither date is available use the date the test was done as the date for the encounter.

**Type of contact**: Select choice from a pull down list.

- **If you choose office visit or phone call consultation,** you should go on and fill out the rest of Form II.
- **If you choose any of the test results listed,** a message box will appear to inform you that you will be taken to Form III-Test Result Form by clicking the button on the right. You will skip the rest of Form II.
- **If you choose 'Surgeon's letter' from the pull down list,** a message box will appear to inform you that you will be taken to Form IV directly.

7. Purpose of visit/call--Select choice from pull-down.
   If you selected choice 2, 3, 4, 5, or 8, you have to specify in the box underneath.

8. Who performed breast care-- On several charts, you will see the name of a resident and a faculty physician. If there is a resident name, select resident even if there is a faculty name. Faculty must sign off on resident records for billing purposes. If the faculty physician is seeing the patient without a resident, then select Faculty physician.

9. Presenting symptoms--Check all that apply.
   - If purpose of this visit is "Presenting Symptom", then specify which breast and check the appropriate abnormality category. The options under 'Skin/nipple change' will be enabled if 'Skin/nipple change' has been checked. Same is true for the option 'Occult Mammographic Abnormality'.
   - If the purpose of this visit is "Screening/Well Women Exam/Annual Exam", or any other health problem, but a problem related to breast abnormality is mentioned by the patient, then it should also be recorded as a presenting symptom.
   - However, if the purpose of this visit is "Screening/Well Women Exam/Annual Exam", and there is no mention of a problem in the history, but during the examination, the physician discovers an abnormality, then this will be recorded as "none" for presenting symptoms and the details about the abnormality will go under "CBE findings".

10. CBE Documentation--Check 'Documented' (you can find documentation in chart) or 'Not done/undocumented' (if you cannot).

11. CBE Findings--Remember that this question relates to CBE and not to mammograms. Question 11 asks about CBE findings only.
- Check 'Bilateral Implants' if there is mention in the chart
- Check 'Previous abnormality resolved' if on the follow-up visit there is documentation indicating that the problem resolved.

**CBE NORMAL**

- **Note re: QUALITY OF WRITTEN CBE DESCRIPTION.** The quality of written documentation for CBE appears separately under NORMAL findings and separately under ABNORMAL findings.

You will check 'Inspection', 'Palpation' or 'Lymph Node Examination' if at least one of the criteria, following these components of CBE has been mentioned in the chart. Notice that the default at the moment for each of the criteria is 'undocumented'. Please check each of the findings mentioned in the chart.

**CBE ABNORMAL--** If there was an abnormality found, answer the question under Q11 regarding which breast(s) has abnormal finding? (a pull-down screen), then proceed to complete the pertinent information under the breast(s) with the noted abnormality.
**Note –** If you cannot determine which breast – follow the instructions noted on the screen and enter information under the left breast category. If both breasts have abnormalities, you need to record the information for each side.

**There are four types of abnormalities** that can be entered directly
1) Lump(s)/Mass(es)/Asymmetric breast thickening/Asymmetric Fibrocystic
2) Nipple discharge with no lump
3) Observational findings with no lump
4) Pain

Underneath each one additional detail about findings should be specified if available in the chart.

**Location**– Write in exactly as it is in the chart. Sometimes it will be written as clock position. Otherwise, simply type in the written descriptor of the location of the abnormality.

**Specifically for each type of abnormality**

*Lump(s)/Mass(es)/Asymmetric breast thickening/Asymmetric Fibrocystic*--You need to specify the lump size, depth, hardness, mobility, shape, and texture if available. If there are additional findings associated with Lump(s), such as observations on skin changes or nipple changes, these should be recorded in the appropriate boxes provided. Use the pull-down menu to select 'Yes' or 'No'

based on the information on the chart. Note: The default entries for these fields are 'undocumented'.

*Nipple discharge with no lump*--Specify if Spontaneous, Color of discharge, Unilateral or bilateral, single vs multiple ducts.

*Observational findings with no lump*--Check all that apply

*Pain*—Check whether breast or chest wall or unspecified

*Other*--If the abnormality described does not fit into one of the four categories, check 'Other, specify' at the end of this box and write in the description from the chart.

**Quality of written description of CBE documentation for Abnormal Findings** – The three components of CBE 'Inspection', 'Palpation', 'Lymph node examination', should be checked if at least one of the criteria that follows each component is mentioned in the chart. Additional information can be recorded in 'other, specify' box.

**FORM III:**

12. Mammogram Documentation – Click to pull down your answer choice. If on a particular visit, there is documentation in the chart that FPCP recommended or ordered mammogram, mark that the mammogram was ordered and the date. DO NOT include the results of the mammogram on this visit report, since they will be recorded separately under 'Mammogram results'. For 'Test results' enter the date stamped at the bottom of the report, that says when the results were obtained by the FPC. For 'results reviewed by FPCP' this is when the results were reviewed by the FPCP. It is okay to record any one or combination of the choices 1-4 if that is all that is available in the chart.

13a, 13b, 13c: Mammogram findings – Remember to fill in **which breast** was recorded on this specific mammogram result.
*In Section 13a* report the Category or description of the Final Impression, separately for each breast. Sometimes, especially for Category I, there will not be a separate mention of each breast, but only a mention of a Bilateral mammogram. Then the findings would apply to both breasts and you need to check Category I under each breast.
*In Sections 13b* we have provided you with options that are most often mentioned as mammogram findings so you do not have to write in the specific findings. If none of the categories provided can be checked, you still have the option of writing under 'Other'. Select all the categories that apply based on the result.
*Section 13c* needs to be filled out only when mammogram finding was dictated as Category II and up. Sometimes even for Category II you will not have location specified. It is O.K. under such circumstances not to record location.

14. Patient notified of mammogram findings--You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

15.Cyst-Fine Needle Aspiration (FNA) —Specify who performed this procedure by selecting the option provided in the pull down menu for the field 'Done by'. Also fill in the date done. If done by FPCP at the time of the visit when the lump was

identified, enter for 'Date done' as the date of the visit. If this information is obtained from a Cytology report following fluid sent for analysis, either by FPCP or Surgeon, all the information should be entered as a separate contact under 'FNA results' and the provider should be specified if information available. Report results from Cytology report in the appropriate categories or write in 'Other'.

16. Patient notified of FNA findings and date?.
You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

17.Solid Mass-Fine Needle Aspiration Biopsy. (FNAB).
Specify who performed this procedure by selecting the option provided in the pull down menu for the field 'Done by'. Also fill in the date done. If done by FPCP at the time of the visit when the lump was identified, enter for 'Date done' as the date of the visit. If this information is obtained from a Pathology report following specimen sent for analysis, either by FPCP or Surgeon, all the information should be entered as a separate contact under 'FNAB results' and the provider should be specified if information available. Report results of FNAB in the appropriate categories, or write in 'Other'.

18. Patient Notified of the FNAB findings from Path Report and date?
You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned.

19. Ultrasound findings.
If on a particular visit, there is documentation in the chart that FPCP recommended or ordered ultrasound, mark that it was ordered and the date. DO NOT include the results of the ultrasound on this visit report, since they will be recorded separately if there is an actual report in the chart.

20. Patient Notified of the Ultrasound Findings and date?
You can say 'yes' only if there is documentation on the test result that a card was sent, or patient was called, or some other comment that indicates that communication between patient and FPCP occurred. Provide date if mentioned

21. Image-Guided Biopsy/Open Biopsy Results

*For Results received*:--enter the date stamped at the bottom of the report that says when the results were obtained by the FPC. For '*results reviewed by FPCP*' record the date when the results were reviewed by the FPCP if indicated. It is okay to record any one or combination of the choices 1-4 if that is all that is available in the chart.

Based on the results from the Pathology Report check all that apply for findings. If the provided categories do not include the description in the report write the findings in 'Other'.

**FORM IV:**

22.Recommended follow-ups(s)—If there is no documentation of any follow-up, check 'Undocumented'. Otherwise,

There are two sections here:

- **Follow-Up for Normal CBE and Mammogram (or one of them undocumented)**:

  Select the appropriate follow-up options provided in the box. If you checked 'Following Other Guidelines', you need to specify what was written in the chart and write in the space provided. You can always write other recommendations in the 'Comments' field.

- **Follow-Up for Abnormalities:**

  Notice these are two sets of follow-up choices. On the left-hand side, you have follow-up options for specific abnormalities; on the right, you have follow-up options that can be recommended for any abnormality.

Please always check **ALL** the recommended follow-up options mentioned in this visit or test result.

Note the large box on the bottom right called 'Other recommendations or comments concerning Abnormality(ies).' Use this space to describe any additional recommendations / comments concerning this abnormality that does not fit into the categories described. Please make sure to make information in this section very clear as to what breast problem or abnormality is being addressed (such as pain, lump, etc.) and what was found. You can type in at most 250 characters in this box.

**General Comments About this Visit**

An additional box for comments was created at the end of Follow-up but before the Surgeon's letter follow-up. You should write overall comments regarding this visit in this box. For example if you have 'Other health visit' that mentions that CBE is due on a certain date, you would have an encounter where the only information recorded would be in that box. '

**Surgeon's letter:**

**There is a big change in the way we will be recording information from Surgeon's letter. Much less detail.**

- Rather than record everything that was described in the letter, we have created in the Follow-up Form, a section called Assessment/Follow-up From Surgeon's Letter. After you enter on Form II in "Type of Contact" Surgeon's Letter, you will be taken to this section directly, after you click O.K in the message box. You will have to check whether the referral diagnosis is confirmed or not. Whether additional tests were done/ordered by surgeon, and what is the recommended follow-up. This should shorten the time you have to enter data based on the Surgeon's letters

**What to do next after you entered information for one visit, or test result?**

**YOU ALWAYS HAVE TO GO THROUGH FORM IV-FOLLOW-UP FORM**

**FOR MOVING BETWEEN FORMS OR NAVIGATING WITHIN FORM I AND II, USE ONLY THE NAGIVATING BUTTONS PROVIDED ON TOP OR BOTTOM OF EACH FORM. DO NOT USE THE ARROW BUTTONS ON THE BOTTOM OF THE DATABASE. THIS DOES NOT CARRY THE STUDY ID TO THE NEW FORM.**

In Form II and IV, you may:

- Click 'Add new visit' – Use this if there are other visits/test results for breast care within the auditing time frame. You will be given a blank screen to start over to fill in information from the next visit. *You will start again with Q 6.*

In Form IV, you may also:

- Click 'Add new patient'—Use this if you go on to record new patient. After clicked this button, this form will be closed and you will be taken back to the Form I.
    - If you are at intervention site (site 1-5), you will be reminded to summarize breast care activity for this patient on a summary sheet.

By now we have taken you through the steps involved in **Situations: I—Add New Patient; II—Add New Visit.**
Suppose you want to update, please follow the steps described below:

**Situation III**—Update information on Form I for an existing patient:
(You are on Form I.)

1. Move your mouse to the box titled 'Please assign study ID' and click inside of it. You should see your cursor inside the box.
2. Now move your mouse to the binocular button on the upper left-hand corner and click.
3. A dialog box titled 'Find in Field: 'Study ID" will appear on the screen. In the line titled 'Find What', type in the study ID for the patient you are searching.
4. Click the button at the end of the line titled 'Find First'. The patient's record will appear on the screen.

5. You need to **overwrite today's date** (please follow the instructions for 'correcting information' to type in today's date),
6. You can now proceed with the update.

If you would like to search by patient's last name rather than by Study Id, in step 1, you would move your mouse to the box titled 'Patient Name (Last)' and click inside of that box. Then proceed with step 2. At step 3, the title of the dialog box is 'Find in field: Lname'. Type in the patient's last name in line titled 'Find What' and hit the button 'Find First'. The patient's record will appear.

We have given you two examples of how to search by a given field of interest. You can also search by patient's medical record number, or date of birth.

**Situation IV**—Update information on Form II, III, or IV for an existing patient:
(You are on Form I)

1. Move your mouse to the box titled 'Please assign study ID' and click inside of it. You should see your cursor inside the box.
2. Now move your mouse to the binocular button on the upper left-hand corner and click.
3. A dialog box titled 'Find in Field: 'Study ID" will appear on the screen. In the line titled 'Find What', type in the study ID for the patient you are searching.
4. Click the button at the end of the line titled 'Find First'. The patient's record will appear on the screen.
5. You need to overwrite today's date (please follow the instructions for 'correcting information' to type in today's date).
6. Click the button, on the bottom of the form, 'Continue to record visit info.', it takes you to the second form.
7. Move your mouse to the box of Question 6-Date of Breast Care Activity Was Recorded' and click inside of it. You should see your cursor inside the box.
8. Now move your mouse to the binocular button on the upper left-hand corner and click.
9. A dialog box titled 'Find in Field: 6. Date of Breast Care Activity...' will appear on the screen. In the line titled 'Find What', type in the date for the visit you are searching.
10. Click the button at the end of the line titled 'Find First'. The patient's visit will appear on the screen. You can now proceed with the update.

**Possible Error Messages and Their Interpretation**

1. "*The changes you requested to the table were not successful, because they would create duplicate values in the index, primary key or relationship. Change the data in the field or fields that contain duplicate data, remove the index, or redefine the index to permit duplicate entries and try again.* "

   This message means you have a duplicate study ID or the study ID field is left empty. It's a protective device to make sure you assigned a correct study ID. Please go back and check if study ID was properly assigned.

2. "*You can't save this record at this time. Microsoft Access may have encountered an error while trying to save a record. If you close this object now, the date changes you made will be lost. Do you want to close the database object anyway?*"

   This message usually appear after message 1, after you click ok to make message1 disappear. If you choose YES (close the database object anyway), and not to make changes in the study ID field, this record is not saved. If you choose NO, you get a chance to go back and change study ID field, and make it either not empty, or not duplicated.

3. "*You can't go to the specified record: you may be at the end of a recordset*"

   This message can be caused by two reasons: first, you maybe at the end or the frontmost of a recordset. You may have clicked "Go To Previous Record" while you are already on the first record. Second, this message could mean study ID field is left empty or duplicated, or if the field for today's date (which is right next to the field for studyid) is not filled in.

4. "*The field 'tblFront-End.Date' can't contain a null value because the required property for this field is set to true. Enter a value in this field*"

   This message appeared because the field for today's date (which is next to the field for studyid) is not filled in. This is another protective device to make sure you entered today's date. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

5. "*The field 'tblFront-End.StudyID' can't contain a null value because the required property for this field is set to true. Enter a value in this field*"

   This message appeared because the field for study ID is not filled in. Study ID is required for each patient. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

6. " *The field 'tblSecB.date' can't contain a null value because the required property for this field is set to true. Enter a value in this field"*

   This message appeared because the field for "Date of Visit", or Question 6 On the second form was not filled. This is a required field in order to save the particular record. If you want to save this message, click OK to this message, then click NO to the next message box, which will give you a chance to go back and correct the incorrectly filled fields. If you do not want to save this particular record, click ok to this message, then YES to the next message.

**Special Cases/Questions:**

Q: What do I do if pages are missing and data is not there?
A: Put in what you can determine from what *is* there.

Q: What do I do with transposed dates?
A: If you are *sure* that it is a transposition, then put it in as it should be. If you are not sure, put it in as it is stated.

Q: What do I do with lots of missing dates?
A: Put in what you can, leave blank missing dates.

Q: Do I count phone calls as visits?
A: Generally, no as part of the count of overall number of visits However, count phone calls for the number of visits if they have to do with breast care. It is a good idea to familiarize yourself with the forms used at your site for phone calls so you may easily identify phone consultations versus regular visits.

Q: What do I do with prophylactic mastectomy?
A: Write this information in the 'General Comments about this visit' box that has been provided in the Follow-up Form. Do not forget to do this, since that box appears at the end.

# Additional Information To Consider

1. Suppose you worked on the visit form and want to go back to the first or front-end form, you can do this by clicking the button "Go Back to Front-end" on the top of the visit form.

   However, when you do this, we have secured the visit you are working on is connected to the specific patient. Therefore, you will notice on the bottom bar of the screen, 1 of 1 (Filtered) on the first or front-end form. To go back to your full data set, you need to click on the highlighted funnel/filter on the top of the first or front-end form. After clicking the funnel/filter, notice you will be taken to the very first patient existing in your data set. It will say on the bottom bar 1 of n, where n is the number of patients in your database. If you want to search now, click on the field you want to use for searching, and click the binocular and fill in the requested information in the message box appeared afterward.
2. Keep in mind to fill in today's date, if you are updating a record!

3. Open only one application. If you accidentally opened two applications by double clicking, you will see the message stating: you can not save the record, and out of memory. You have to go back and close the leftmost application with the same name on the bottom bar by maximizing the leftmost application form and clicking on the X on the top of the screen.

4. Log into MSU by using pilot account (one per site). Log into MSU health team by using ht.msu.edu account.

5. You need to properly shut down your application, otherwise it will give you an error message when you turn it on next time. To properly shut down, you need to close all the applications, then go to "Start" on the left bottom of your screen. Scroll up to "Shut Down" and click it. You have to confirm that you want to shut down the computer. Wait until you see the message: it is safe to turn off your computer now. Then the laptop is automatically turned off. You can close it and store it properly.

# QUALITY ASSURANCE

# Quality Assurance

**What is meant by Quality Assurance?**
Quality assurance is checking to make sure that what you are abstracting accurately reflects what is truly in the medical record. It is important that we determine your accuracy to make sure that the data being collected truly reflects what has been documented in the medical record.

**What is Involved in Quality Assurance?**
At two points during the early and middle point of your auditing time, Barbara Given, PhD, RN, or her designee, will visit your program site. She will select randomly 10 medical records that you have audited. She will then audit these records on her own without looking at how you have audited the record. A comparison will be made between the data collected when you audited the records and when she audited the records. A statistic called a Kappa will be used to determine the degree of consistency between the two sets of collected data. If there is low consistency, this may indicate a problem with accuracy.

**What happens if I am found to have low accuracy?**
The quality assurance auditor will then look over the cases and compare. Clarifications as to how to handle certain cases will be discussed. This process is called remediation. The quality assurance auditor will then return at a later time to do another quality assurance comparison. If there continues to be a problem with accuracy of audited information, other steps may need to be taken.

**What do I do If I have questions regarding how to audit a record?**
Contact Barbara Given, PhD, RN. The best way to contact her is by email. Her address is bgiven@msu.edu. Keep in mind that Dr. Given has MANY responsibilities. However, your questions are important. Just remember it might take a few days for her to return your email with a response. Sometimes it might mean that she has to ask someone else what the answer is. Simply keep track of your questions and continue auditing. Return to answer that question at a later time when you receive your answer.

If it is a particularly urgent question, you may try calling her at (517) 432-4326 or Jodi Holtrop, PhD, at (517) 353-3544 ext. 432.

# APPENDIX 6

## Essentials of Breast Care
## Patient Instructor Responsibilities

# ESSENTIALS of BREAST CARE

## *PATIENT INSTRUCTOR RESPONSIBILITES*

## I. Attend an initial orientation session and receive a clinical breast examination by a licensed health care professional.

A. Review packet of orientation materials.
B. Complete the consent form and health history after they are explained to you.
C. View a video on clinical breast examination.
D. Learn how to:
    1. Trace the area of breast tissue (perimeter) on yourself, noting landmarks of anatomy.
    2. Answer questions about your health history based on your responses on the history form.
    3. Provide verbal feedback to course participants on selected communication skills.
    4. Provide verbal feedback to course participants on their palpation pressures during the examination, noting if/when pressures are uncomfortable.
    5. Recognize your own breast tissue characteristics, and provide feedback to participants on their assessment.

## II. During the course:

A. Arrive at the appointed time and commit to several examinations per session.
B. Pretest:
    1. complete the evaluation form labeled "Pretest" after being examined
    2. do not discuss the examination technique with the learner
C. Practice session
    1. provide feedback to the learner
    2. not all learners will have this session
D. Posttest:
    1. complete the evaluation form labeled "Posttest" after being examined
    2. do not discuss the examination technique with the learner
E. During all three components
    1. clarify information about your health history
    2. evaluate their skills in palpation, communication and patient education.

## III. Tips for the day of the examination

A. Wear a two-piece outfit since you only need to remove clothing above the waist.
B. Since there will be periods when you are waiting for your session, you might want to bring something to read or do (for example, knitting).
C. Sometimes the exam rooms are cool, so bring a sweater or jacket- we will try to provide blankets.

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

### *Scoring Instructions*

- Start timing when the participant begins palpating
- Check the pattern of search used
- Place an "S" to indicate start of pattern
- Place a tick mark in each square that represents an area the participant palpates, following the pattern that is used
- Place an "F" at the finish point
- If the participant goes back to cover an area that may have been missed or not done well, indicate with an "x"
- Proficiency checklist: mark performance for each item, noting comments for feedback (only during the practice session)
- When the participant is finished, record the time.

### *Feedback (During the practice sessions only)*

- The patient instructor can share observations with the participant during the practice session.
- Point out areas on the grid that may have been missed.
- Discuss their performance on each of the Ps and on the sequential depths of pressure.

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

## CONSENT FORM FOR PATIENT INSTRUCTORS

I, _____, consent to participate as a patient instructor in this training course to demonstrate clinical breast examination techniques to Physicians, Advanced Practice Nurses and Physician Assistants.

As part of the course, I will have an initial screening examination by a licensed healthcare professional and complete a short health history. The faculty member will help me understand the type of feedback and information I should discuss with the course participants assigned to me. This examination is for the purpose of this training course only and not for personal screening or diagnostic purposes. I understand that the clinical breast examination techniques being used by participants may not detect all lumps or irregularities in my breasts and that this examination does not substitute for an examination by my usual health care provider. Should any of the course faculty or participants find or suspect any new irregularities or lumps in my breasts, it is my responsibility to bring it to the attention of my usual healthcare provider.

I will be interviewed about my breast health history and have my breasts examined in a private room by one course participant for several sessions using techniques of visual observation and manual palpation. I have been informed that repeated exams may cause some breast tenderness and that if the tenderness persists for more than a few days I should consult with my usual healthcare provider.

I have been given the opportunity to ask questions about the examination technique and the course, and I feel I understand the purposes and my role as a patient instructor.

Occasionally facilities allow for observation of the examination by other course instructors or selected participants through a one-way mirror. If this situation is planned, I will be told in advance who will be observing. I will __, will not __allow observation. _____
(Initials)

Signature _____ Date:_____

Witness Signature _____ Date:_____

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

# ESSENTIALS OF BREAST CARE

## PATIENT INSTRUCTOR SCREENING HEALTH HISTORY

Thank you for agreeing to be a patient instructor for this course. Please answer the following questions and discuss the information with the course faculty and the selected participants who will be examining you. All of your answers are confidential.

Name _____Age_____Today's Date _____/_____/_____

**1. Have you ever had any of the following examinations of your breast?**

Physical breast exam by a doctor or nurse:

- ❑ no
- ❑ yes most recent exam was_____
  results: ❑normal ❑abnormal ❑don't know
  other _____
- ❑ don't know

Mammogram-an x ray of your breasts (different from a chest x ray):

- ❑ no
- ❑ yes most recent one was: results: ❑normal ❑abnormal ❑don't know
  other _____
- ❑ don't know

Other tests on your breasts (ultrasound, fine needle aspiration, biopsy):

- ❑ no
- ❑ yes which breast(s)?__right__left
  test done: _____
  how long ago? _____
  results: ❑normal ❑abnormal ❑don't know
  other _____
- ❑ don't know

**2. Do you ever check your own breasts (breast self--exam)?**

- ❑ no
- ❑ yes About how often? _____
  How did you learn to do a breast self-exam? (check all that apply)
  ❑course ❑healthcare provider ❑video ❑pamphlet ❑self-taught

**3. Are you currently having any breast tenderness?**

- ❑ no
- ❑ yes is it ❑premenstrual ❑from hormones ❑other _____?

**4. Have any members in your immediate family (sister, mother, daughter) had breast cancer? If you are adopted and don't know, please check that box.**

- ☐ no
- ☐ don't know
- ☐ adopted-don't know
- ☐ yes

If so, which family member(s) had breast cancer and note if they are living or deceased.

Relationship

_____ ☐living ☐deceased
_____ ☐living ☐deceased
_____ ☐living ☐deceased

**5. How would you rate your risk for developing breast cancer sometime during your lifetime?**

- ☐ low
- ☐ medium
- ☐ high
- ☐ don't know

**6. Do you have any concern about your breasts you would like the faculty or participants to know?**

# ESSENTIALS of BREAST CARE

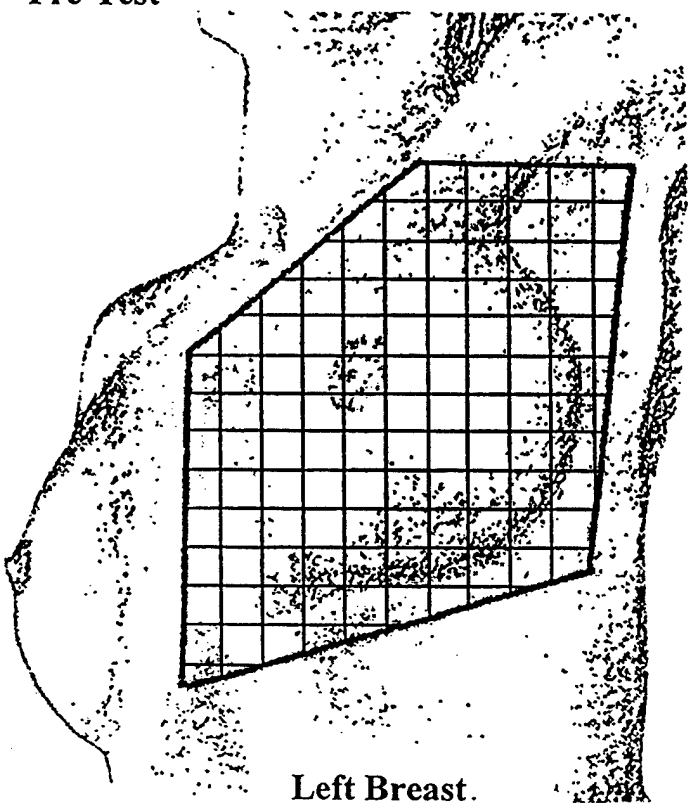
## Pre-Test

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

**Pattern:**
- ☐ vertical
- ☐ wedge
- ☐ circular
- ☐ other

**Scoring:**
- ☐ S at start
- ☐ Check each box palpated
- ☐ F at finish
- ☐ X for going back to area

**Remember: DO NOT GIVE FEEDBACK!**



Left Breast.

**COMMUNICATION**
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Reviews health history
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

**POSITIONS**

Patient Sitting

Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ hands on hips

Palpates lymph nodes
- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine
- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

**PERIMETER**
- ☐ Palpates entire area within perimeter

**PATTERN OF SEARCH**
- ☐ Uses consistent pattern
- ☐ Adequate amount of overlap

**PALPATION**
- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

**PRESSURE**
- ☐ 3 sequential depths

____superficial ____medium ____deep

**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reinforces BSE pattern and frequency
- ☐ Reviews early detection triad intervals
- ☐ Checks for understanding and agreement

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

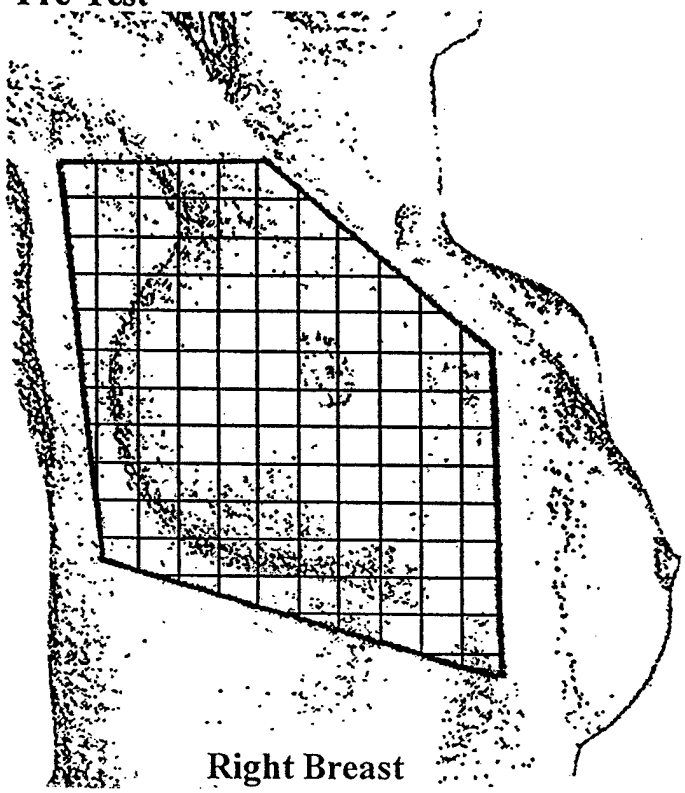
# ESSENTIALS of BREAST CARE

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

**Pattern:**
- ☐ vertical
- ☐ wedge
- ☐ circular
- ☐ other

**Scoring:**
- ☐ S at start
- ☐ Check each box palpated
- ☐ F at finish
- ☐ X for going back to area

## Pre-Test



Right Breast

## Remember: DO NOT GIVE FEEDBACK!

**COMMUNICATION**
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Reviews health history
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

**POSITIONS**

Patient Sitting

Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ hands on hips

Palpates lymph nodes
- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine
- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

**PERIMETER**
- ☐ Palpates entire area within perimeter

**PATTERN OF SEARCH**
- ☐ Uses consistent pattern
- ☐ Adequate amount of overlap

**PALPATION**
- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

**PRESSURE**
- ☐ 3 sequential depths

____superficial ____medium ____deep

**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reinforces BSE pattern and frequency
- ☐ Reviews early detection triad intervals
- ☐ Checks for understanding and agreement

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

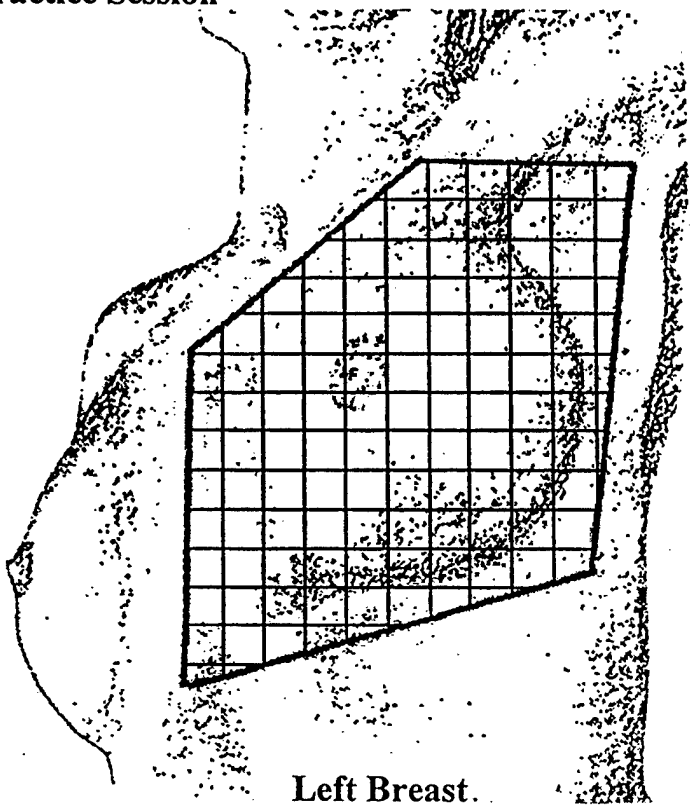
# ESSENTIALS of BREAST CARE

## Practice Session

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

**Pattern:**
- ☐ vertical
- ☐ wedge
- ☐ circular
- ☐ other

**Scoring:**
- ☐ S at start
- ☐ Check each box palpated
- ☐ F at finish
- ☐ X for going back to area



Left Breast.

**PLEASE, Give Feedback during this session.**

**COMMUNICATION**
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Reviews health history
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

**POSITIONS**

Patient Sitting

Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ hands on hips

Palpates lymph nodes
- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine
- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

**PERIMETER**
- ☐ Palpates entire area within perimeter

**PATTERN OF SEARCH**
- ☐ Uses consistent pattern
- ☐ Adequate amount of overlap

**PALPATION**
- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

**PRESSURE**
- ☐ 3 sequential depths

____superficial ____medium ____deep

**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reinforces BSE pattern and frequency
- ☐ Reviews early detection triad intervals
- ☐ Checks for understanding and agreement

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# ESSENTIALS of BREAST CARE

## Practice Session

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

**Pattern:**
- ☐ vertical
- ☐ wedge
- ☐ circular
- ☐ other

**Scoring:**
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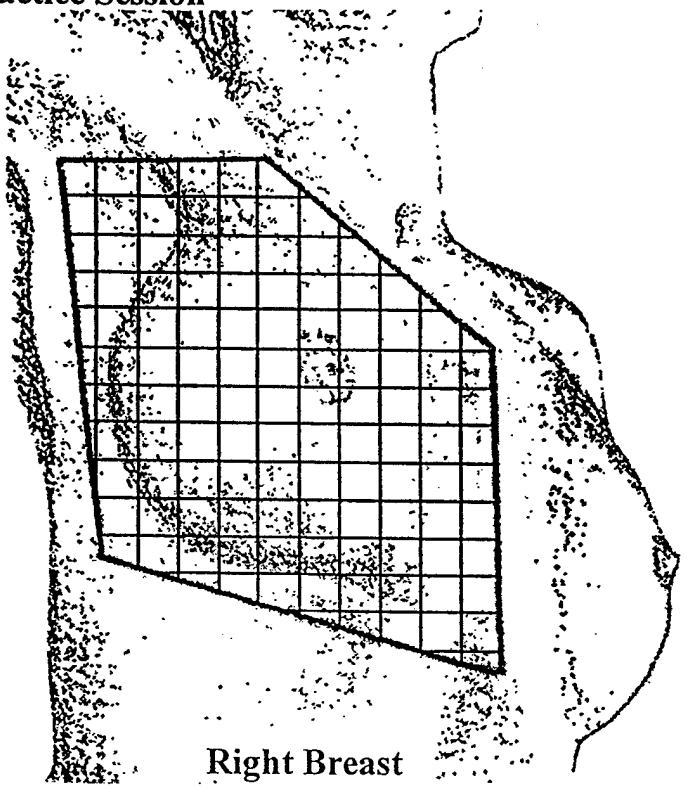
- ☐ Check each box palpated
- ☐ F at finish
- ☐ X for going back to area

**PLEASE, give feedback during this session.**



Right Breast

**COMMUNICATION**
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Reviews health history
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

**POSITIONS**

Patient Sitting

Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ hands on hips

Palpates lymph nodes
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- ☐ axillary

Patient Supine
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**PERIMETER**
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**PRESSURE**
- ☐ 3 sequential depths

____superficial ____medium ____deep

**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reinforces BSE pattern and frequency
- ☐ Reviews early detection triad intervals
- ☐ Checks for understanding and agreement

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# ESSENTIALS of BREAST CARE

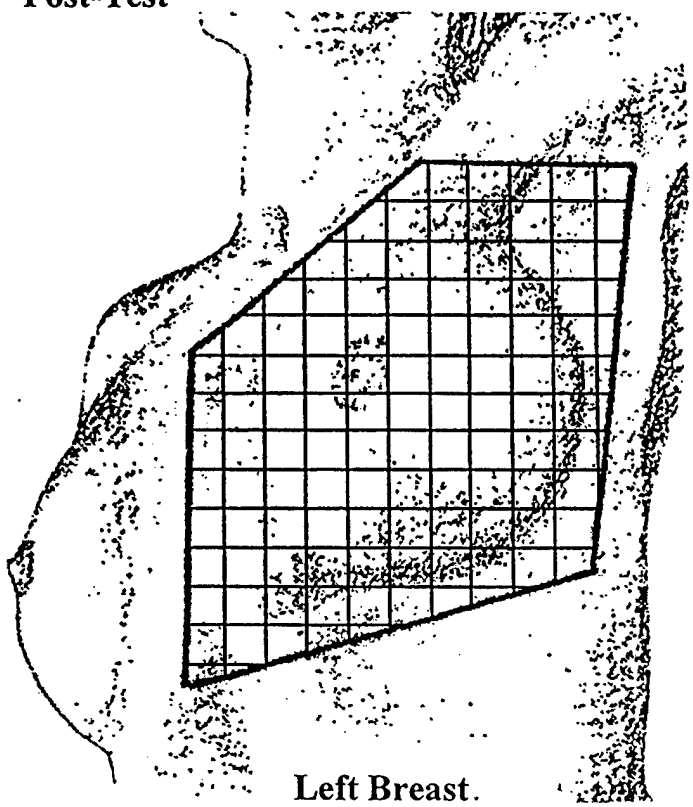
## Post-Test

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

**Pattern:**
- ☐ vertical
- ☐ wedge
- ☐ circular
- ☐ other

**Scoring:**
- ☐ S at start
- ☐ Check each box palpated
- ☐ F at finish
- ☐ X for going back to area

**Remember: DO NOT GIVE FEEDBACK!**



Left Breast.

**COMMUNICATION**
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**PRESSURE**
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**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reinforces BSE pattern and frequency
- ☐ Reviews early detection triad intervals
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Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

# ESSENTIALS of BREAST CARE

## Post-Test

DATE: _____
PARTICIPANT: _____
PATIENT INSTRUCTOR: _____
Total Time: _____ minutes

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- ☐ circular
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**Scoring:**
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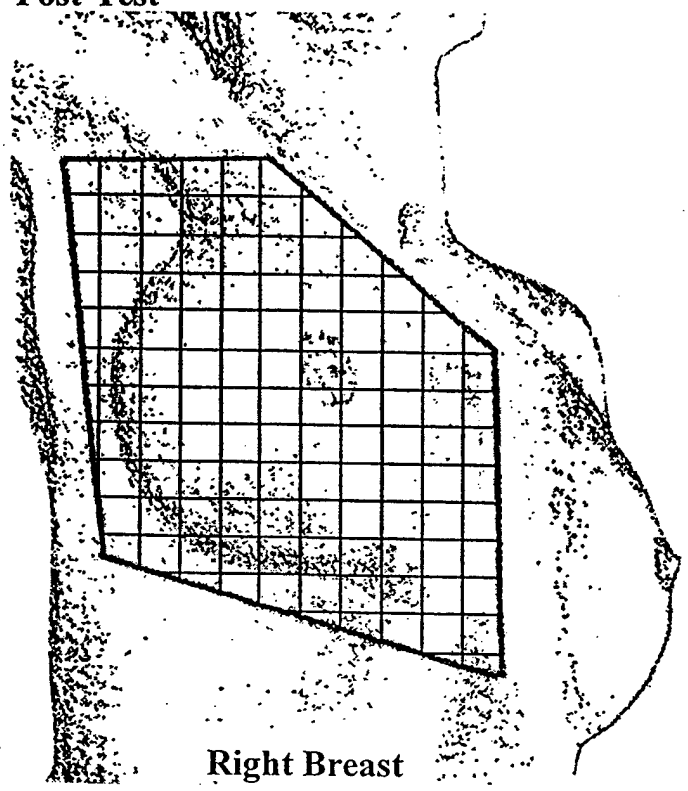

Right Breast

## Remember: DO NOT GIVE FEEDBACK!

**COMMUNICATION**
- ☐ Introduces self
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# APPENDIX 7

## Essentials of Breast Care for Primary Care Physicians
## Outline of the Day

# Essentials of Breast Care for Primary Care Physicians – Outline of the Day

| Time | What Covered | Who Does What | Room | What Needed |
|---|---|---|---|---|
| 7:45 – 8:00 | Refreshments | | | Beverages ☺ |
| 8 – 8:20 | Consent form<br>"Knowledge" Pre-test | Physician Instructors | Lecture room | Pre-tests<br>Pencils |
| 8:20 – 12:15 | Lecture content | Physician Instructors | Lecture room | Slides & Projector/Training manuals/Handouts/Microph./ |
| 12:30 – 1:15 | LUNCH | | | Food ☺ |
| 1:15 – 2:15** | 3 – 20 minute stations<br>1. "Knowledge" Post-test<br>2. Patient models Pre-eval.<br>3. Silicone breast Pre-eval. | Coord. – Overall flow<br>Physician Instructors<br>Patient models<br>Observers* | Lecture room<br>Clinic exam rooms<br>Stations | Post-tests/pencils<br>Forms for Patient models<br>Silicone breasts<br>Silicone breast forms |
| 2:15 – 3:30 | Slides<br>Video<br>Breast model teaching | Physician Instructors | Lecture room | TV/VCR<br>Teaching breast models |
| 3:30 – 3:45 | BREAK | | | Refreshments ☺ |
| 3:45 – 4:00 | Practice | Patient models<br>Observers* | Clinic exam rooms<br>Stations | Silicone breasts<br>Silicone breast forms |
| 4:00 – 5:00** | 3 – 20 minute stations<br>1. Patient models Post-eval.<br>2. Silicone breast Post-eval.<br>3. Gail Model | Coord. – Overall flow<br>Physician Instructors<br>Patient models<br>Observers* | Clinic exam rooms<br>Stations | Forms for Patient models<br>GAIL models<br>Silicone breasts<br>Silicone breast forms |
| 5:00 – 5:10 | Distribute Certificates and Obtain Evaluations | | Lecture room | |

*Observers are witnesses to the live model exams.

**We have three activities and 3 groups. We have allocated 20 min for each activity and moving from one type of station to the other.

JH/ 7/1/99

# APPENDIX 8

## Essentials of Breast Care Workshop
## Assessment of CBE Technique by Patient Instructor

# ESSENTIALS of BREAST CARE

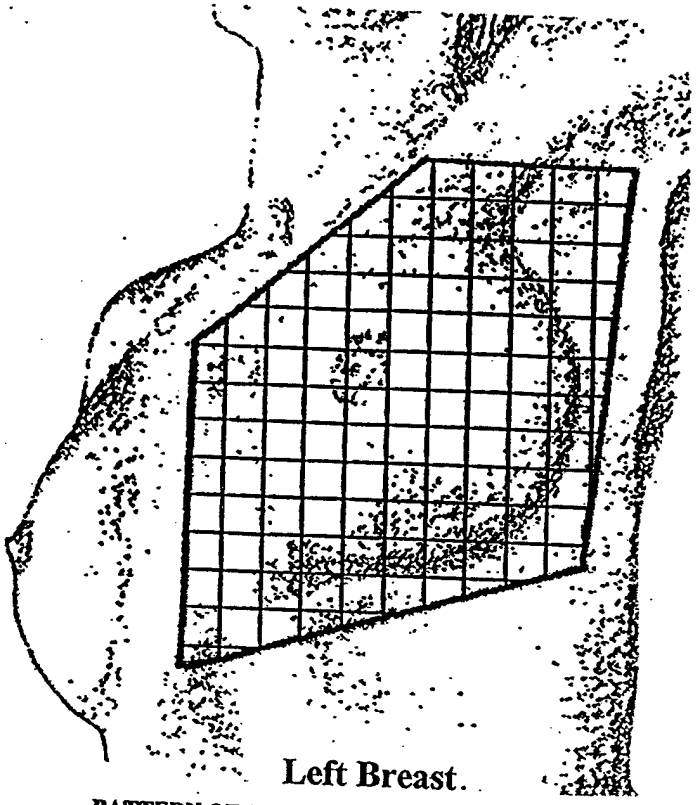
## Practice Session

DATE: _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

LEFT BREAST EXAMINATION TIME
_____ minutes

DOCTOR/PATIENT ENCOUNTER TIME
_____ minutes

**Scoring:**
- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ March "X" for each area NOT palpated



Left Breast.

**PLEASE GIVE FEEDBACK during this session. Circle areas where feedback is given.**

**COMMUNICATION**
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

**POSITIONS**

Patient Sitting

Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ pressure on hips with hands

Palpates lymph nodes
- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine
- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

**PERIMETER**
- ☐ Palpates entire area within perimeter

**PATTERN OF SEARCH**
- ☐ Uses consistent pattern
  - ☐ vertical
  - ☐ wedge
  - ☐ circular
  - ☐ other
- ☐ Adequate amount of overlap

**PALPATION**
- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

**PRESSURE**
- ☐ 3 sequential depths

____superficial ____medium ____deep

**PATIENT EDUCATION**
- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
  - ☐ Monthly BSE
  - ☐ Annual CBE
  - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

*Rev. 7/21/99-mrs*

Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

# ESSENTIALS of BREAST CARE

## Practice Session

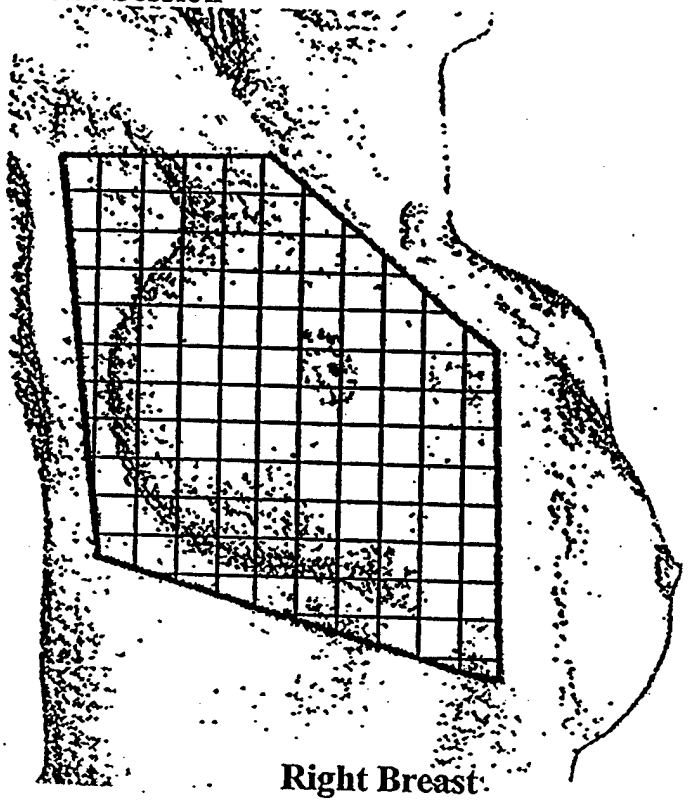
DATE _____
EXAMINER ID _____
PATIENT INSTRUCTOR _____

RIGHT BREAST EXAMINATION TIME
_____ Minutes

PATIENT/DOCTOR ENCOUNTER TIME
_____ minutes

Scoring:
- ☐ Mark "S" at start
- ☐ Mark "F" at finish
- ☐ Thorough exam (ALL areas covered)
- ☐ Mark "X" for each area NOT palpated

**PLEASE GIVE FEEDBACK during this session. Circle areas where feedback is given.**



Right Breast

COMMUNICATION
- ☐ Introduces self
- ☐ Establishes rapport
- ☐ Checks on comfort
- ☐ Elicits/responds to questions/concerns

POSITIONS
Patient Sitting
Visual inspection
- ☐ arms at sides
- ☐ arms above head
- ☐ pressure on hips with hands

Palpates lymph nodes
- ☐ supraclavicular
- ☐ infraclavicular
- ☐ axillary

Patient Supine
- ☐ Centralizes each breast
- ☐ Arm behind or at right angle to head

PERIMETER
- ☐ Palpates entire area within perimeter

PATTERN OF SEARCH
- ☐ Uses consistent pattern
  - ☐ vertical
  - ☐ wedge
  - ☐ circular
  - ☐ other
- ☐ Adequate amount of overlap

PALPATION
- ☐ 3 middle fingers
- ☐ Pads, not tips
- ☐ Hand bowed upward
- ☐ Sliding motion, doesn't lift fingers
- ☐ Overlapping, dime size circles

PRESSURE
- ☐ 3 sequential depths

____superficial ____medium ____deep

PATIENT EDUCATION
- ☐ Points out anatomic landmarks
- ☐ Reviews early detection triad intervals
  - ☐ Monthly BSE
  - ☐ Annual CBE
  - ☐ Mammogram every 1-2 years
- ☐ Checks for understanding and agreement

*Rev. 7/21/99-mrs*

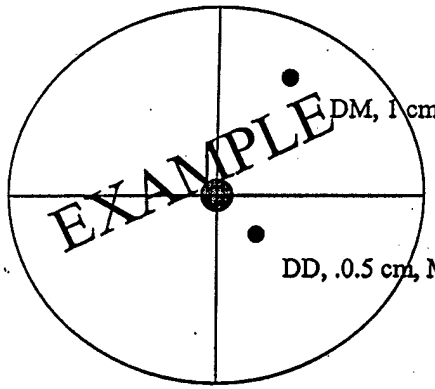
Modified from: Clinical Breast Examination: Proficiency and Risk Management A Continuing Education Program of the California Department of Health Services

# APPENDIX 9

## Essentials of Breast Care Workshop
## Silicone Breast Models Exam

# *Essentials of Breast Care*
# *Clinical Breast Examination Form*
# *<u>Post-test</u> Silicone Breast Models*

July 15, 1999




These breasts simulate the breast tissue of a 50 year old woman.

**INSTRUCTIONS:** Draw each lump in the appropriate location and indicate in the following order:

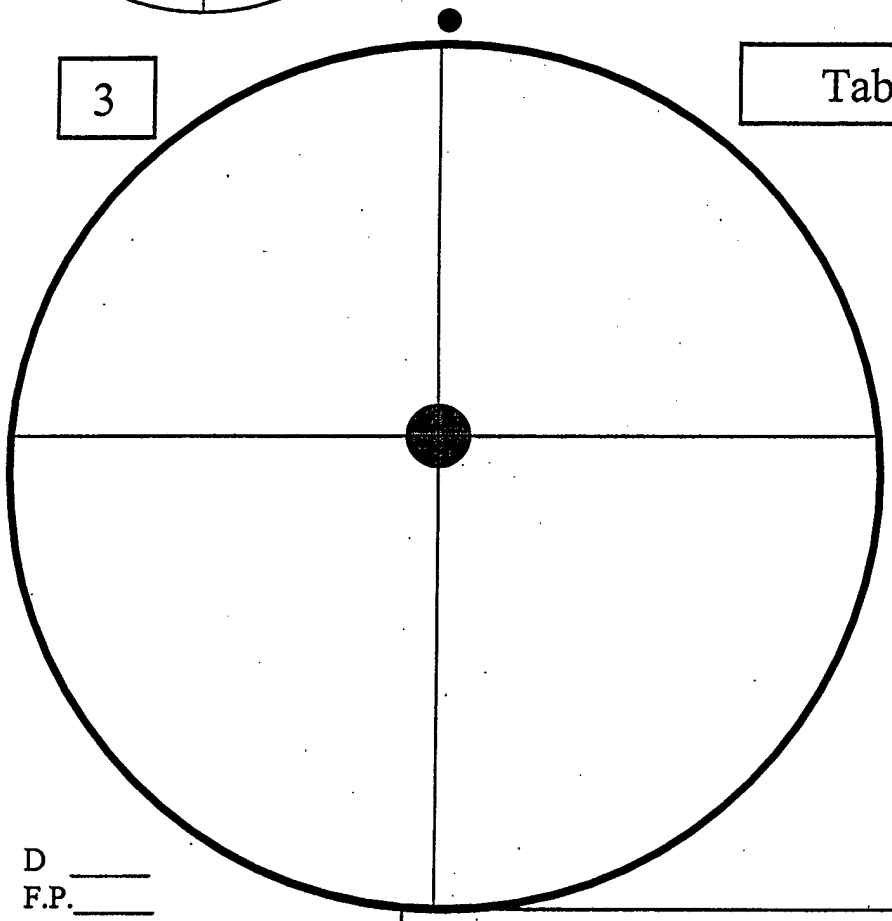
**1. Depth:** Medium (DM), Deep (DD)

**2. Size:** 0.3 cm, 0.5 cm, 1.0 cm

**3. Hardness:** Hard (H), Medium (M), Soft (S)

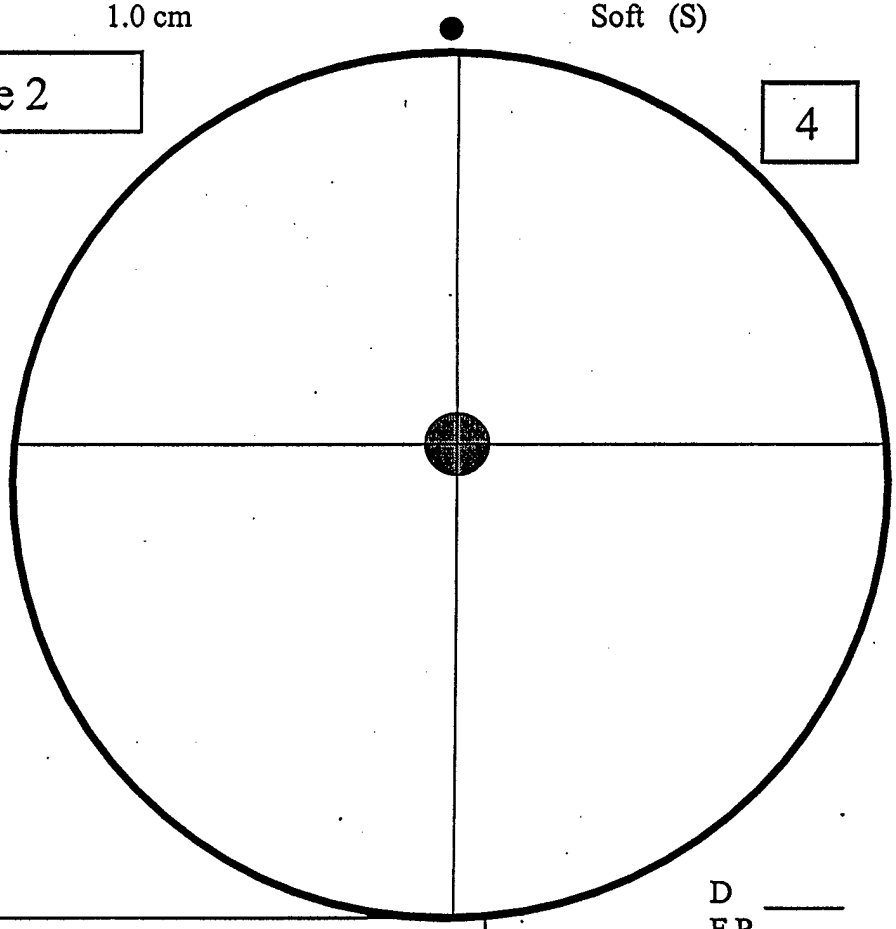
Table 2

3



D _____
F.P._____

4



D _____
F.P. _____

Total D _____ Total F.P. _____ Sensitivity _____% Specificity _____%

# APPENDIX 10

## Essentials of Breast Care Workshop
## Physician's Survey

# Essentials of Breast Care

Physician Survey: POST
Educational Component

**Choose the best answer:**

1. In the United States Breast Cancer occurs:

   a. In over 170,000 women and 1,000 men each year
   b. Most commonly per 100,000 women in the age group 55-60 years old
   c. In fewer than 5,000 women under the age of 50, annually
   d. In one in eight women at age 50

2. When Dr. Jones examines a pre-menopausal woman, the best time to perform a clinical breast examination is:

   a. During the luteal phase of her menstrual cycle.
   b. At the onset of menses.
   c. Days 3-10 of her menstrual cycle.
   d. The timing of the exam doesn't matter.

3. Regarding the risk factors for breast cancer, which of the following is TRUE?

   a. Seventy-five percent of women diagnosed with breast cancer have no risk factors other than age and gender.
   b. A 75-year old woman is at lower risk than a 65-year old woman.
   c. The majority of women diagnosed with breast cancer have a family history of the disease.
   d. Most women with fibrocystic changes have an increased risk.

4. A 52-year old woman has screening mammography. A small group of microcalcifications are found. The next step in her management should be:

   a. A 6 month follow-up mammogram
   b. An ultrasound examination
   c. Cone compression mammography
   d. Magnification mammographic views

5. All of the following statements about "abnormal" screening mammography interpretations are true EXCEPT:

   a. 35% of screening mammograms are termed abnormal and require patient "call back" for additional diagnostic views.
   b. Current follow-up of reported abnormal mammograms is sub-optimal because women often are not notified of the results.
   c. Following the recommendation for additional imaging studies is cost-effective and limits unnecessary specialty referral.
   d. Over 50% of women will have the abnormality resolved by further diagnostic studies.

6. A 38-year old woman who has no known risk factors for breast cancer discovers a right breast mass on breast self-examination. On CBE, a 1 cm. mass in the upper outer quadrant of the right breast is found. You interpret the mass as benign. All of the following are appropriate management options EXCEPT:

   a. Have her return 3-10 days after the onset of her next menstrual cycle for a repeat breast examination.
   b. A surgical referral
   c. A fine needle aspiration
   d. Reassurance

7. The single most important duty of a clinician when presented with a patient with a breast mass is:

   a. To order a bilateral mammogram
   b. To document the location of the mass in the chart and make timely referral to a breast specialist
   c. To inquire about family history and risk factors for the development of breast cancer
   d. To establish the etiology of the lesion as a cystic or solid

8. The performance of mammography in a woman with a breast mass

   a. Should be postponed until days 3-10 of the menstrual cycle
   b. Is mainly used to exclude occult lesions in the non-involved breast tissue.
   c. Is an effective means to rule out breast cancer in the palpable lesion
   d. Must occur before any attempt is made to perform fine needle aspiration of the breast.

9. Which of the following is **TRUE** of breast masses?

   a. It is possible to distinguish cysts from solid masses by palpation.
   b. A palpable breast mass in a 25-year old woman is most likely a cyst.
   c. A palpable breast mass in a 40-year old woman is most likely a fibroadenoma.
   d. A palpable breast mass in a postmenopausal woman should be considered carcinoma until proven otherwise.

10. The color of the fluid removed from a breast cyst

   a. Generally reflects the age of the cyst
   b. Is lighter when the epithelial lining of the cyst degenerates
   c. Is more often serous in older cysts
   d. Should only appear yellow if the lesion is benign

11. A patient elicits nipple discharge which is reproducible during her clinical breast examination. The patient has never experienced spontaneous nipple discharge. Which of the following is appropriate:

   a. A Prolactin level
   b. Culture and sensitivity testing of the discharge
   c. Cytologic examination of the discharge
   d. Reassurance

12. Which of the following is **TRUE** regarding spontaneous nipple discharge in a 35-year old non-lactating woman?

    a. If bilateral, greenish-brown, and from multiple ducts, the likelihood of cancer is high enough to warrant surgical intervention.
    b. If single duct and bloody, the diagnosis is likely to be cancer
    c. If unilateral and persistent, it is unlikely to resolve without surgical intervention.
    d. If unilateral, persistent, and clear, carcinoma is unlikely.

13. Risks of screening mammography include all of the following except:

    a. Overdiagnosis of subclinical disease
    b. Delays in diagnosis from false positive results
    c. Discomfort associated with the performance of the procedure
    d. Hypothetical radiation risk

14. The cost of screening mammography per year of life saved is about the same as that for which of the following interventions?

    a. Lung cancer screening
    b. Cholesterol screening
    c. Hormone replacement therapy
    d. Seat belts/Airbags

15. The most common barrier cited by women for not having a screening mammogram is:

    a. The high cost of the screening is not covered by their insurance
    b. Patients did not have any symptoms and didn't need the test
    c. The marked discomfort that was experienced during a prior mammogram
    d. The provider didn't inform the patient that a screening exam was needed

16. Aberrations of Normal Development and Involution (ANDI) have been classified into developmental stages. Benign breast disorders commonly occur during all of the developmental phases except:

    a. Postmenopausal phase (age 55 and above)
    b. Early reproductive period (age 15 to 25)
    c. Involutional phase (age 35-55)
    d. Mature reproductive period (age 25-40)

17. Fibrocystic changes in the breast

    a. Can be clinically distinguished from cancer by the nodularity noted on physical examination
    b. Occur most often in women aged 20 to 30
    c. Generally are not found in women over the age of 50
    d. Are easily distinguished from cancer on the basis of radiological examination

18. For women with an average life expectancy of 85, which of the following percentages most closely approximates their lifetime risk as calculated from birth for developing breast cancer? (Mark the best answer.)

    a. > 20%
    b. 16-20%
    c. 10-15%
    d. < 10%

19. Which statement about risk interpretation is correct?

    a. Absolute risk and relative risk are the same
    b. Multiplying two scores of relative risk can give an accurate appraisal of risk.
    c. Relative risk and absolute risk can change over time.
    d. Relative risk expresses the underlying probability of disease

20. How often do you recommend that women in the following age groups receive mammograms? (Mark one for each age category.)

    ➢ Women aged 40-49 ....
    a. Never
    b. Annually
    c. Every 2 years
    d. Other (Please describe) _____

    ➢ Women aged 50-64 ....
    a. Never
    b. Annually
    c. Every 2 years
    d. Other (Please describe) _____

    ➢ Women aged 65-79 ....
    a. Never
    b. Annually
    c. Every 2 years
    d. Other (Please describe) _____

    ➢ Women aged 80+ ....
    a. Never
    b. Annually
    c. Every 2 years
    d. Other (Please describe) _____

21. Indicate your level of agreement with each of the following statements. (Mark one box for each statement.)

    ➢ It is not important to spend much time on screening clinical breast exams because mammograms identify most early cancers ....

    *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

    ➢ Performing regular screening clinical breast exams on my female patients is important to avoid malpractice claims .....

    *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

- The average woman aged 80 or older does not benefit from screening mammograms .....

  *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

- In general, primary care physicians need more education about how to manage suspicious mammogram findings .....

  *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

- I would usually not order a screening mammogram for a 70 year old woman with multiple medical problems .....

  *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

- The risk of breast cancer as a result of radiation exposure from screening mammograms is a concern for me.....

  *a) Disagree Strongly* *b) Agree* *c) Agree Strongly*

22. A 60 year old woman who has been in your practice for several years comes in for the evaluation of a new acute problem (productive cough and fever). You diagnose bronchitis and prescribe an antibiotic. She has not had a mammogram for three years. How likely are you to recognize that she is overdue for a mammogram, and recommend one during this acute visit? (Mark the best answer.)

    *a) Very unlikely* *b) Somewhat unlikely* *c) Somewhat likely* *d) Very likely*

23. For each of the topics below indicate how well prepared you are to counsel your patients and answer their questions?

    - Individual risk of breast cancer

      *a) Not well prepared* *b) Somewhat prepared* *c) Well prepared*

    - The risks of getting a mammogram

      *a) Not well prepared* *b) Somewhat prepared* *c) Well prepared*

    - The benefits of getting a mammogram

      *a) Not well prepared* *b) Somewhat prepared* *c) Well prepared*

    - The patient's fears and concerns about breast cancer

      *a) Not well prepared* *b) Somewhat prepared* *c) Well prepared*

    - The effectiveness of mammograms

      *a) Not well prepared* *b) Somewhat prepared* *c) Well prepared*

24. Counseling patients to change negative behaviors is not helpful because they usually do not change. (Mark the best answer)

    *a) Strongly disagree* *b) Disagree* *c) Agree* *d) Strongly agree*

# APPENDIX 11

## Gail Model

# The Use of the Gail Model Risk Assessment Tool –

# Practice Session

# ***The Use of the Gail Model Risk Assessment Tool:***
## Practice Session

- **Calculate the risk for an <u>average risk Black woman</u> who is 51 years old according to the following steps:**

  <u>Calculation of Risk for a 51 year old Black woman of average risk:</u>

  1. Press the "on" button on the Gail Model Risk Assessment Tool
  2. Press B for Black race.
  3. Enter 51 for the age of the patient. The number at the left of the calculator's screen represents the question number as listed on the left-hand panel of the calculator.
  4. Press the green enter button.
  5. Enter 14 for the age at first menses.
  6. Press the green enter button.
  7. Enter 18 for the age of the first live birth.
  8. Press the green enter button.
  9. Enter zero for the number of first-degree relatives with breast cancer.
  10. Press the green enter button.
  11. Enter zero for the number of previous breast biopsies.
  12. Press the green enter button.
  13. Press the blue result button.

  <u>Use the form entitled "Interpreting your risk assessment score" to enter the pertinent data (blank form found following this page).</u>

- **Calculate the risk for an <u>individual Black woman</u> who is 51 years old**

  <u>Calculation of risk for an individual 51 year old Black woman:</u>

  1. Use Teaching form A to find the appropriate data for entry into the Risk Assessment Tool (last page).

  2. Follow the same steps as for data entry for an average-risk woman, making it specific to the individual woman presented in Teaching Form A.

  3. After entering '1' for breast biopsy, press the "Y" to designate a finding of atypical epithelial hyperplasia.

  4. Press the blue result button.

  <u>Use the same form entitled "Interpreting your risk assessment score" to enter the pertinent data for the individual woman</u>

***Health care provider:***
*Please photocopy this form.*

# *Interpreting your risk assessment score*

Date

Name

Doctor

*Based on calculation of your risk factors, your risk of developing breast cancer in the next 5 years as well as over your lifetime is as given below. The average risk for a woman your same age and race with no risk factors is included for comparison.*

*My personal 5-year risk:* _____%

*Average 5-year risk for woman of same age and race with no risk factors:* _____%

*My personal lifetime risk:* _____%

*Average lifetime risk for woman of same age and race with no risk factors:* _____%

***If your 5-year score is 1.67% or higher,*** *you are considered at high risk of developing breast cancer. Please discuss these results with your doctor. Only your doctor can help you decide whether NOLVADEX may be right for you, based on discussion of the benefit and risk involved. Your next steps are to:*

*Schedule a counseling discussion with your doctor*

*Complete* ***About the benefit and risk,*** *a form that your doctor can give you*

*Read an information sheet called* ***Weighing the options: important considerations*** *and a booklet called* ***Assessing your risk for breast cancer...there is something you can do,*** *which your doctor can give you*

***If your 5-year score is under 1.67%,*** *you are not currently considered at high risk. Your next steps are to:*

*Continue monthly breast self-exams, periodic office exams, regular mammograms, and ongoing breast cancer risk assessments*

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- **Using the form entitled "Interpreting your risk assessment score", interpret the results of the calculation of risk for the individual patient in Teaching Form A and compare it with a patient of average risk:**

The first number on the form represents the patient's 5-year absolute risk for breast cancer, meaning her chances of being diagnosed with breast cancer over the next five years expressed as a percentage. This number represents the 5-year absolute risk for all 51 year-old Black women with the risk profile entered. The average 5-year absolute risk for breast cancer for the individual patient in Teaching Form A is 2.6%. You should have entered the number 2.6%.

Interpretation:
Twenty-six of 1000 51-year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over the next 5 years.

The second number on the form represents the average woman's 5-year absolute risk who is of the same race and age as the patient to whom she is being compared and whom has no other risk factors. The average-risk 51 year old black woman's 5-year absolute risk for breast cancer is 0.4%. You should have entered the number 0.4%.

Interpretation:
Four of 1000 51-year old average-risk Black women with no risk factors will be diagnosed with invasive breast cancer over the next 5 years.

The third number on the form represents the patient's lifetime absolute risk for breast cancer, meaning her chances of being diagnosed with breast cancer over a lifetime, assuming life expectancy to age 90. This number represents the lifetime absolute risk for breast cancer for all 51 year-old Black women with the risk profile entered. The average lifetime absolute risk for breast cancer for the individual patient in Teaching Form A is 19.6%. You should have entered the number 19.6%.

Interpretation: One hundred ninety-six of 1000 51 year old Black women with the risk factor profile entered will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

The fourth number that appears on the form the lifetime absolute risk for breast cancer for an average risk woman of the race and age designated. The average-risk 51-year-old black woman's absolute lifetime risk for breast cancer is 3.2%. You should have entered the number 3.2%.

Interpretation: Thirty-two of 1000 average-risk 51 year-old Black women will be diagnosed with invasive breast cancer over a lifetime, assuming a life expectancy of 90 years.

- **Use the form entitled "About the benefit and risk" (following page) to assess indications, contraindications, and risks associated with the use of Tamoxifen as an agent to reduce the risk of breast cancer.**

## ***Remember:***

**Contraindications:**

**Medical contraindications include:**

- Current anticoagulant therapy
- History of deep vein thrombosis
- History of pulmonary embolism
- History of stroke

**Lifestyle contraindications include:**

- Pregnancy
- Lactation
- Hormonal contraception
- Hormone replacement therapy

**Side Effects*:**

**Statistically significant side effects include:**

- Endometrial carcinoma in postmenopausal women with a uterus
- Pulmonary embolism
- Cataracts and need for cataract surgery

**Reported side effects not measured for statistical significance:**

- Hot flashes
- Vaginal discharge

**Possible other side effects include:**

- Venous thromboembolism
- Stroke

*Premenopausal women were less likely to experience side effects than postmenopausal women were.

**Indications**

The P-1 Trial assessed Tamoxifen use in women 35 and over with a 5-year absolute risk of 1.67% or above, or women 35 and over with a history of lobular carcinoma in-situ. It reduced breast cancer incidence in women at all levels of high risk, ranging from categories of less than or equal to 2% to greater than or equal to 5%. The average risk assessed in the trial was 3.2%.

Tamoxifen use is not indicated in average-risk women for breast cancer, nor is it indicated in every high-risk woman. However, after considering the contraindications and side effects, women at high risk should be offered the choice of taking Tamoxifen to reduce the risk of breast cancer.

**Health care provider:**
*Please photocopy this form.*

# About the benefit and risk

Date

Name

Doctor

*Please answer the following questions. Then give this form to your doctor, so you can have a thorough discussion of the benefit and risk involved with NOLVADEX therapy.*

1. *Am I at high risk of developing breast cancer—that is, do I have lobular carcinoma in situ (LCIS) or a 5-year score of 1.67% or higher on the Breast Cancer Gail Model Risk Assessment Tool?* ❑ yes ❑ no
2. *Do I plan to become pregnant during the next 5 years?* ❑ yes ❑ no
3. *Am I taking anticoagulants such as coumarin?* ❑ yes ❑ no
4. *Have I ever had a blood clot in the lung (pulmonary embolism) or in a major vein (deep-vein thrombosis)?* ❑ yes ❑ no
5. *Have I had a hysterectomy?* ❑ yes ❑ no
6. *Am I taking hormone replacement therapy, or HRT, for menopause?* ❑ yes ❑ no
7. *Am I taking hormonal contraceptives such as the "Pill," injections, or implants?* ❑ yes ❑ no

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# ***The Use of the Gail Model Risk Assessment Tool***

- The data entered into the risk assessment tool is dependent on the individual patient's history and is compared with that of an "average risk" woman of the same race and age to whom the patient is being compared.

- **"Average risk" is age-dependent and means:**

  - No history of in-situ or invasive breast cancer
  - Age at menarche 14
  - Age at first birth 18
  - No family history of breast cancer
  - No breast biopsy history

- AstroZeneca has provided **preprinted forms** to assist in the process of risk assessment. These are intended for office use and include forms entitled:

  - **Personnel risk assessment**
  - **Interpreting your risk assessment score**
  - **About the benefit and risk**

  Blank copies of each are included in the manual. Either patients can fill out the forms themselves or this can be done by an office assistant or by the physician.

- **If none of the race designations are applicable in your patient:**

  1. Explain to the patient that the risk assessment tool does not apply to her race.
  2. Offer her a calculated estimate of risk based on the highest risk that is used in the Gail model.
  3. If she is comfortable with this, press the A button.
  4. Explain that the patient's actual risk may be lower than the number calculated.

**Practical Tips:**

- The calculator is programmed to turn off automatically if not used continuously.

- The "C" button will clear the previous entry for a given case. Pushing the "C" button again will clear the previous entry for that same patient. To correct or restart the data entry on a specific patient, it may be easier to simply press the "on" button twice. This will cancel all previously made entries and prepare the calculator for a new case.

**Health care provider:**
*Please photocopy this form.*

# Personal risk assessment

Date July 1999

Name TEACHING FORMA

Doctor Osuch-Barry-Zuber

*Please answer the following questions to help your doctor determine your risk factors for developing breast cancer.*

*Have you ever had breast cancer?* ☐ yes ☒ no

*If you checked "yes," you have completed the survey. Please give the survey to your health care provider.*

1. *Have you ever had a breast biopsy that showed lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS)?* ☐ yes ☒ no or don't know
2. *How old are you?* 51
3. *How old were you when you had your first menstrual period?* 12
4. *How old were you when your first child was born? (If you've never had a child, write "0.")* 24
5. *How many of your sisters, daughters, or mother have had breast cancer?* 1
6. *Have you ever had a breast biopsy? (In a breast biopsy, the doctor removes tissue from your breast to test for cancer.)* ☒ yes ☐ no ☐ don't know
   - 6a. *If yes, how many breast biopsies have you had?* 1
   - 6b. *Did the doctor ever tell you that one of your biopsies showed atypical hyperplasia (a precancerous condition)?* ☒ yes ☐ no ☐ don't know
7. *What is your race?* ☐ White ☒ Black ☐ Asian

*Now please return this form to your doctor for calculation of your risk.*

**Health care provider:**
*Please use this form with the Breast Cancer Gail Model Risk Assessment Tool.*

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# APPENDIX 12

# Summary of Workshop Evaluations

# Essentials of Breast Care for Primary Care Physicians Training Summary

*St. Lawrence, Sparrow, Midland, Kalamazoo, Saginaw*

*31 Faculty + 84 Residents = 115 Total Evaluations*

**MSU Department of Family Practice; MSU Department of Surgery; Department of Defense**

**Program Evaluation and Attendance Record**

**Office of Continuing Medical Education, College of Human Medicine**

*This activity has been planned and implemented in accordance with the Essential Area and Policies of the Accreditation Council for Continuing Medical Education (ACGME) through the joint sponsorship of Michigan State University, College of Human Medicine and the US Department of Defense. Michigan State University, College of Human Medicine is accredited by the ACGME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of the CME activity.*

*Michigan State University, College of Human Medicine designates this educational activity for a maximum of 8 hours in category I credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.*

Key- Items 1-15 tabulations = Faculty(F) – Resident /Staff answers (R)

Please place one check for each evaluation item in the chart below.

| Item for Evaluation | Poor | | Satisfactory | | Good | | Excellent | |
|---|---|---|---|---|---|---|---|---|
| | F | R | F | R | F | R | F | R |
| 1. Accuracy and timeliness of the content. | | | 4 | 5 | 1 | 30 | 26 | 49 |
| 2. Relevance to your daily practice. | | | | | 3 | 15 | 28 | 69 |
| 3. Impact on your professional effectiveness. | | | 1 | 3 | 9 | 19 | 21 | 62 |
| 4. Relevance of content to learning objectives. | | | 1 | 1 | 4 | 19 | 26 | 64 |
| 5. Objective of understanding breast cancer incidence and prevalence. | | | | | 5 | 35 | 25 | 49 |
| 6. Objective of understanding the national guidelines for screening. | | 1 | | 9 | 12 | 41 | 19 | 33 |
| 7. Objective of understanding risk factors for breast cancer. | | | | 4 | 9 | 33 | 22 | 47 |
| 8. Objectives of the rationale for breast cancer screening. | | | 1 | 3 | 7 | 28 | 23 | 52 |
| 9. Objective of understanding steps to take in a workup of abnormal findings. | | | | 2 | 6 | 21 | 25 | 62 |
| 10. Objective of utilizing the GAIL model to predict individual patients' risk. | 1 | | 1 | 9 | 5 | 34 | 24 | 40 |
| 11. Objective of using proper technique in performing a CBE. | | | 1 | 3 | 7 | 22 | 22 | 60 |
| 12. Objective of including all the steps to a complete breast health examination. | | | 1 | 4 | 4 | 21 | 25 | 60 |
| 13. Objective of identifying breast lumps in silicone breast models. | | | 1 | 6 | 9 | 34 | 21 | 44 |
| 14. Objective of utilizing a chart reminder/guideline system for screening and follow-up of breast abnormalities as part of practice. | | 1 | 5 | 17 | 10 | 33 | 16 | 33 |
| 15. Overall evaluation of this training. | | | 1 | 2 | 3 | 20 | 26 | 62 |

(One Faculty did not rate #15)

**OVER PLEASE**

(General Comments (Highlighted sections are from faculty evaluations.)

1) **HOW COULD THE ABOVE SEMINAR OBJECTIVES HAVE BEEN MET MORE EFFECTIVELY?**

- **Statistics/epidemiology**
- **Would have liked more discussion of screening guidelines.**
- **I am skeptical about the chart reminder system – we already have a dozen other pet project reminders and not all can be foremost in our minds.**
- **It was too long; I am brain dead. Clinical work interrupted by thought process (own patient crisis). Went thru algorithm at end quite *tired??***
- **Shorten time period. Most information is basic and may be excluded. Possibly integrating(sic) hands on with lectures**
- **Charting not explicitly covered**
- **It was overall an excellent overview. I wouldn't change a thing. I especially appreciated the use of silicone models.**
- **State the objectives more clearly at the beginning of the day.**
- **A long day but worthwhile**
- **I think all of you did a fine job in presenting a lot of material in a short period of time. I have no suggestions.**
- **I know that a pre-post test methodology helps in your data analysis and research design, but even though I probably demonstrated an "increase" in knowledge I couldn't say I have learned enough to impact my practice. Perhaps a case-based approach based on evidence would help. Greater emphasis on algorithms and processing patients with problems as well as screening rationales.**
- **No change.**
- **Did a great job.**
- **Excellent course – ½ day seminar would be more beneficial.**
- **Run close to schedule – 1 hour break for lunch to re-charge.**
- **I would like to know more about how to use, and apply, the Gail system for *st?? tax??*/assessment/screening.**
- **Has finding different lumps in silicone breast models ever been equated with finding them on real women? I sort of doubt it – if not, then question the success of effectively teaching the silicone breast. Exam may not be worth the time.**
- **Feedback on silicone model testing station**
- The day is very long but all material relevant. So somehow getting more time without having to do something during lunch.
- The seminar was <u>too</u> long. Need to decrease length or split into a 2-day session. Live models were excellent addition to learning.
- Very well done!
- As always: brevity is the soul of wit: although all information is good, try to pare down to <u>essentials</u>! Nine hours is a <u>long</u> time.
- No improvements. It was great.
- Less basic science.
- Well done as is.
- Less info.
- Give us 2 sessions, instead of 1 long session.
- Time crunch wouldn't have been a problem if everyone knew <u>where</u> to be @ 0745 (Sparrow's fault)

- Less time didactic. More time "hands on"
- 1) *D???* chart reminder system. 2) Less palpation of silicone models – fatigue factor
- 1) It was great. 2) Laminate algorithm cards?
- No suggestions
- Well delivered. Can't think of anything right now.
- More breaks!
- No specific suggestions or comments; excellent seminar. Very applicable to daily practice. Manual provided with seminar excellent resource.
- I found this day to be extremely helpful.
- Help stratify risk assessment – more.
- Done quite well - I would like to have seen examples of chart reminder/tracking forms.
- Clarify the setting of the model breast exam, e.g., "take no history" or "Do only exam" was unclear what the goal was initially in the exam.
- Simply need to condense the didactic material to 2 hours maximum. You need to allow time for lunch breaks. Most of the first 2 hours could have been combined into 45 minutes or one hour. Too much time on simple material. Give examples of good (and maybe even bad) documentation. Algorithms should be skeleton of lectures not afterthought at end.
- The medico-legal arguments aren't compelling for me to the extent which they were presented.
- If possible to include FNA into course – possibly weekend – 2 days.
- The seminar was great
- Very well organized and presented. No specific suggestions
- It was very effective
- More specifics (anonymous) with actual cases that went to court, i.e., chronology of events
- Break up portions of PM section into AM
- Overall fantastic, maybe more frequent but shorter breaks would help keep audience sharp.
- More specific guidelines for different age groups and risk factors; more specifics on risk factor; more information and emphasis/example on effectiveness and side effects of Tamoxifen therapy.
- Excellent Conference
- More time could be allocated to explain "risk" calculations and perhaps fewer cases?? to complete in the 20 on post test. A bit more detail on tamoxifen therapy would be helpful. I'm not well versed in it yet.
- Speed up morning session, possibly examine different models.
- Good job. Just a very long day.
- Went very well, long day though.
- It was great.
- Everybody was good. Maybe less time on practice models; get to (the) testing right away after first run on models?
- Instant feedback on Gail Model Risk exercise.
- Teaching is most effective technique in teaching self exam.
- They were well presented and accomplished.

2) **WHAT ARE YOUR SUGGESTIONS FOR IMPROVING THE ORGANIZATION OF THE COURSE?**

- **½ day vs. whole day**
- **None**
- **As above** (see 2nd bullet in Q1) **integration *of* skills and lecture**
- **Do two ½ days**
- **Work at allowing a break sometime in the afternoon**
- **One day-long seminar does seem long – perhaps break it up into 2 half-day sessions.**
- **Silicone breast model was long and repetitious.**
- **Try and cut (to) 1 hour of lecture time. This will be hard because it is all important, there is just too much lecture in this day.**
- **Well organized. Lots of material for one day.**
- **Alternate lectures/workshops if possible.**
- **More time by 1 hour**
- **My only recommendation is to start/stay on time.**
- **See above: Excellent course – ½ day seminar would be more beneficial**
- **Same as above: Run close to schedule – 1 hour break for lunch to re-charge.**
- **Organized well.**
- **Nice job currently.**
- **Less silicone model practice. I'm not sure it helps real exams.**
- **Need to give guidelines for examining live models before we go in to the rooms.**
- **It was well organized.**
- **Excellent!**
- Gail Calculators
- As above
- More room – more breaks – more hands-on
- Start promptly
- Spend less time on basics, i.e., anatomy; more time on subjects like use of Tamoxifen, Gail model
- Hands-on FNA on *oroze?!?*
- See above: Overall fantastic; maybe more frequent shorter breaks would keep audience sharp.
- See above: The day is very long but all material relevant. So somehow getting more time without having ot do something during lunch
- Course is organized well, just decrease the time playing with rubber models.
- See above: As always: brevity is the soul of wit: although all information is good, try to pare down to <u>essentials</u>! Nine hours is a <u>long</u> time Consider deleting or curtailing use of silicone models.
- All very good.
- It was a bit long and tiring – could possibly be compacted into a shorter time period.
- None
- Be clear about meeting location.
- Probably do not need to repeat silicone breast exams.
- Less info
- Give us 2 sessions, instead of 1 long session.
- Not sure what the objective of the "documentation" section was. Possibly eliminate?
- Well organized.
- Well done.

- Very well organized. Appreciated you staying on time/on track
- If possible, break up practice/test sessions and lecture. Probably less efficient, but easier to stay awake, keep fingers from falling off.
- More breaks.
- None
- None
- Condense the didactics (breast exam teaching could also be condensed). Leave adequate time for lunch and answering phone calls at breaks. Add FNA training!! Add video of cyst aspiration beginning to end.
- Very good course
- Way too long in the afternoon – I would prefer just once with the real patient models p lecture with feedback.
- Very well organized and very practical.
- Break up the morning lectures into one hands on (like maybe the silicon models).
- None
- AV failure
- Did good with no changes.
- See above
- Well structured (& delivered!) Range of answers in pre & post test are a bit restrictive (strongly disagree – then agree) without much middle ground. It does force a commitment to answer. But, not necessarily the participants' "true" opinion.
- Make it little shorter

3) **PLEASE IDENTIFY ADDITIONAL NEEDS/TOPICS FOR FUTURE EDUCATIONAL OFFERINGS.**

- **Additional lectures/workshops for FNA**
- **Breast aspiration/Biopsy workshop**
- **New drugs for prevention of breast cancer in high risk patients**
- **A "hands-on" workshop to take the place of 1 hour of lecture time**
- **Fine needle aspiration**
- **Assessment of local standards: 1) ob/gyn approach, 2) surgical approach, 3) local faculty vs. residency**
- **Fine needle aspiration**
- **Procedural workshops on injections.**
- **Use of natural progesterones.**
- **Fine needle aspiration**
- **None**
- **FNAB skills instruction**
- **Find most 1st year male residents can't do an adequate pelvic exam**
- **Would love a session on FNA aspiration of breast lesions**
- Clarification of when to use tamoxifen therapy.
- FNA
- How to do FNA
- Not more effective but maybe quicker
- HTN, Smoking cessation, DM, Pap & cervical cancer.
- Other GYN screening/prevention issues; other women's health issues (i.e., how do we do screening women for cardiac disease.
- Performing FNA.
- More info needed re FNA
- Male testicular exam; pap & pelvic exams
- Fine needle aspiration training.
- Would be interested in future workshop on FNAB
- Procedure for FNA and FNAB
- More literature data worldwide
- FNA
- FNA techniques/equipment
- Patient counseling when abnormalities are found
- Brief word on surgical options
- The exact consistency or feel of a mass, i.e, how to tell if it is suspicious or not; *( B/c the triple felt states it mass look benign on all then the 99% benign?!?*, but how do we know when we are palpating if it was benign.
- Prostate care – similar format
- More specific info on Tamoxifen
- More specific information regarding management of Paget's disease, inflammatory carcinoma, lymph nodes biopsy.
- Procedure like FNB, *Torcut ??*, etc.
- None
- More discussion of cases involving using tamoxifen

- **Give us calculators!**
- **None**
- **Good handouts. Will probably use the flow sheets**
- **More advance notice on agenda could be helpful in planning coverage**
- **Virtually everyone uses mammograms to rule out cancer. Perhaps more emphasis on this change of thinking would be helpful.**
- **Excellent course**
- **Very helpful**
- **Great Program**
- **Include checklist for CBE – something that might be included in the chart.**
- **Thanks. Please publish results and send me a copy!!**
- **Breaks *q/o??* are helpful**
- **Lecture portion very good/informative**
- **Drs. Osuch and Zuber: excellent instructors and motivators**
- Use of the patient/instructors was very helpful - gave great feedback.
- Thanks for coming. The teaching was great.
- This was a remarkable course.
- Silicone models too "stiff" – hurt fingers. Less greasy food.
- Lectures-excellent speakers! Nice job all the way around.
- Much appreciated. – Thank you!
- Thank you for coming and reemphasizing this very important aspect of primary care.
- Thanks for a <u>great</u> day.
- This was a much needed topic and <u>I enjoyed the course</u>.
- The course can be done yearly or every other year
- Emphasize that the order of CBE exam is not as important as completing all components. Overall excellent course – learned a great deal
- <u>Excellent presentation</u>!
- It was an excellent and wonderful course.
- It was an excellent course and I've learned a lot. Thank you. I hope you will do it next year with some changes.
- A disclosure statement is needed with pharmaceutical contributions or sponsorship and +*??* conflict of interest of speakers.
- I do not feel it was necessary to do a breast exam on the same person 3 times. By the time I did the post test it just seemed so rehearsed. I would not spend so much time on FNB info.
- The cause is good but I'm concerned about the outcome of the study being flawed by the length of the program. Many people grew tired and irritable late in the day and the post-test information may not be as good if people quit trying. Maybe split it into two ½ day sessions.
- Feedback from patient before final encounter very effective, in aiding correction and instant feedback on Δ in style.
- Take-out food next time.

Compiled & tabulated the composite results of all 5 agencies
02/11/00 By M.R. STRUCK

# APPENDIX 13

# Knowledge, Attitudes and Beliefs Survey - Database

# Physician's survey: PRE

PhysianID: | Site: | Date: 7/2[illegible]/1995

Question 1: In the United States Breast Cancer occurs [illegible]

1

Question 2: When Dr. Jones examines a pre-menopausal women, the best time to preform a clinical [illegible] breast examination is: [illegible]

3

Question 3: Regarding the risk factors for breast cancer, which of the following is TRUE: [illegible]

1

Question 4: A 52-year old woman has screening mammography. A small group of [illegible] microcalcifications are found. The next step in her management should be: [illegible]

1

Question 5: All of teh following statements about "abnormal" screening mammography [illegible] foundations are true EXCEPT: [illegible]

1

Question 6: A 38-year old woman who has no known risk factors for brest cancer discovers a right breast mass on breast self-examination. On CBE, a 1cm. mass in the upper-outer quadrant of teh right breast is found. You interpret the mass as benign. All of the following are appropriate management options EXCEPT: [illegible]

1

Question 7: The single most important duty o the clinician when presented with a patient with a breas mass is: [illegible]

1

Question 8: The performance of mammography in a woman with a breast mass [illegible]

1

Question 9: Which of teh following is TRUE of breast masses? [illegible]

4

Question 10: The color of teh fluid remove from a breast cyst [illegible]

1

Question 11: A patient el[illegible] nipple discharge which is reproducible during her clinical breast [illegible] examination. The patient has never experienced spontaneous nipple discharge. Which of the [illegible] is appropriate: [illegible]

Question 12: Which of teh following is TRUE regarding spontaneous nipple discharge in a 35-year old non-lactating woman?

3

Question 13: Risks for screening mammography include all of the following EXCEPT:

2

Question 14: The cost of screening mammography per year of life saved is about the same as that for which of the following interventions?

2

Question 15: the most common barrier cited by women for not having a screening mammogram is:

4

Question 16: Aberrations of Normal Development and Involution (ANDI) have been classified into developmental stages. Benign breast disorders commonly occur during all of the developmental phases EXCEPT:

1

Question 17: Fibrocystic changes in the breast

3

Question 18: For women with an average life expectancy of 85, which of teh following percentages most closely approximates their lifetime risk as calculated from birth for developing breast cancer? (Mark the best answer.)

2

Question 19: Which statement about risk interpretation is correct?

3

Question 20: How often do yu recomend that women in the following age groups recieve mammograms? (Mark one for each catagory)

>Women age 40-49

4

>Women age 50-64

2

>Women age 65-79

2

>Women age 80+

2

Question 21: Indicate your level of agreement with each of teh following statements: (Mark one box for each statement.)

It is not important to spend time to spend much time on screening clinical breast exams because mammograms identify most early cancers.

1

Performing regular sreening clinical breast exams on my female patients is important to avoid malpractice claims.

2

The average woman age 80 or older does not benefit from screening mammograms.

1

In general, primary care physicians need more education about how to manage suspicious mammogram findings...

2

I would usually not order a screening mammogram for a 70 year old woman with multiple medical problems.....

1

The risk of breast cancer as a result of radiation exposure from screening mammograms is a concern for me.....

Question 22: A 60 year old woman who has been in your practice for several years comes in for the evaluation of a new acute problem (productive cough and fever). You diagnose bronchitis bronchitis and prescribe an antibiotic. She has not had a mammogram for three years. How likely are you to recognize that she is overdue for a mammogram, and recomend one during this acute visit? (Mark the best answer.)

3

Question 23: For each of the topics below indicates how well prepared are you to counsell your patients and answer their question?

>individual risk of breast cancer

2

>The risk of getting a mammogra

2

> the benifits of getting a mammogra

2

>patients fear and concern about breast cancer

2

>effectiveness of a mammogra

2

Question 24: Counseling patients to change negative behaviors is not helpful because thay usually do not change. (Mark the best answer)

2

Comments

# APPENDIX 14

## Assessment of CBE Technique by Patient Instructor - Database

# PRE BREAST EXAM: LIVE MODE

| Date | Physician # | Pateint instructor | Time per breast | total time | Site |
|---|---|---|---|---|---|
| 8/5/99 | r12 | ch | 0:45 | 03:30 | sp |

Which Breast is this form for: right breast

| | # of filled in boxes | Percentage of area MISSED |
|---|---|---|
| Peri/retro areola | 0 | 0.0000 |
| Upper Inner Quadrant | 1.5 | 0.1667 |
| Lower Inner Quadraant | 9.5 | 0.2969 |
| Upper Outer Quadrant | 4 | 0.1250 |
| Lower Outer Quadrant | 2.5 | 0.0781 |

Remaining Common information was NOT filled out on form ☐

**COMMUNICATIONS**

- ☑ Introduced self
- ☑ Establishes rappor
- ☑ Checks on comfort
- ☑ Elicits/Responds to questions/Concerns

**POSITIONS**

Patient Sitting

Visual inspection

- ☐ Arms at side
- ☐ Arms above head
- ☐ Pressure on hips with hand

Palpates lymph nodes

- ☐ Supraclavicular
- ☐ Infraclavicular
- ☑ Auxillary

Patient Supine

- ☑ Centralizes each breast
- ☑ Arm behind at right angle

**PERIMETER**

- ☐ Palpates entire area within perimeter

**PATTERN OF SEARCH**

- [x] Uses consistant pattern
- [ ] Vertical
- [ ] Wedge
- [ ] Circular
- [x] Other
- [ ] Adequate overlap

**PALPATION**

- [x] 3 middle fingers
- [ ] Pads, not tips
- [x] Hand bowed upward
- [ ] Sliding motion, doesn't lift finger
- [ ] Overlapping, dime size circle

**PRESSURE**

- [ ] 3 sequential depths
  - [ ] superfic
  - [ ] medium
  - [ ] deep

**PATIENT EDUCATION**

- [ ] points out landmarks
- [ ] Review interval
  - [ ] MonthBSE
  - [ ] AnnCBE
  - [ ] Mammoyr
- [ ] Check understanding

Comment::

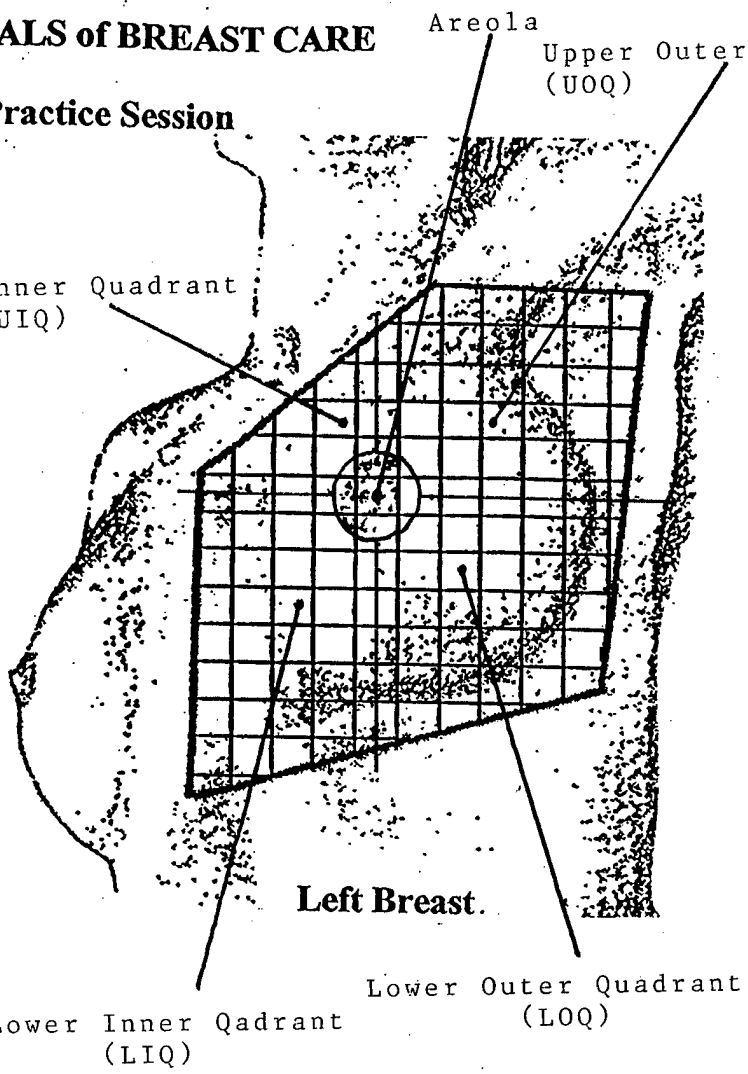
# APPENDIX 15

# Assessment of Palpated Area of the Breast

**ESSENTIALS of BREAST CARE**

**Practice Session**

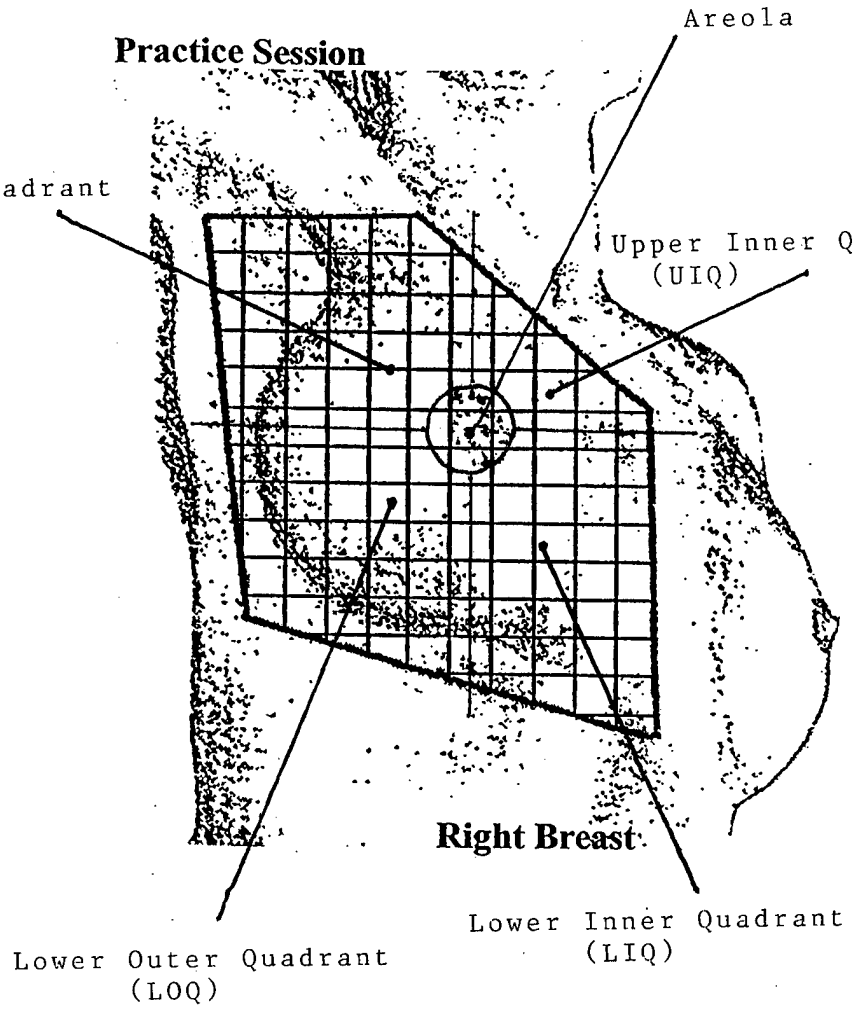
REGIONS OF THE BREAST
AFTER SEGMENTATION



# ESSENTIALS of BREAST CARE

## Practice Session

REGIONS OF THE BREAST
AFTER SEGMENTATION



# APPENDIX 16

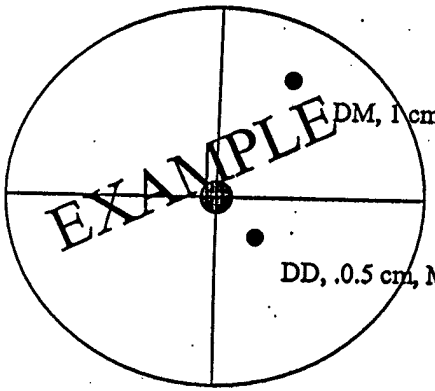
# Assessment of Lump Detection in Silicone Breast Models

A 5

# *Essentials of Breast Care*
# *Clinical Breast Examination Form*

July 15, 1999

## *Pre-test Silicone Breast Models*



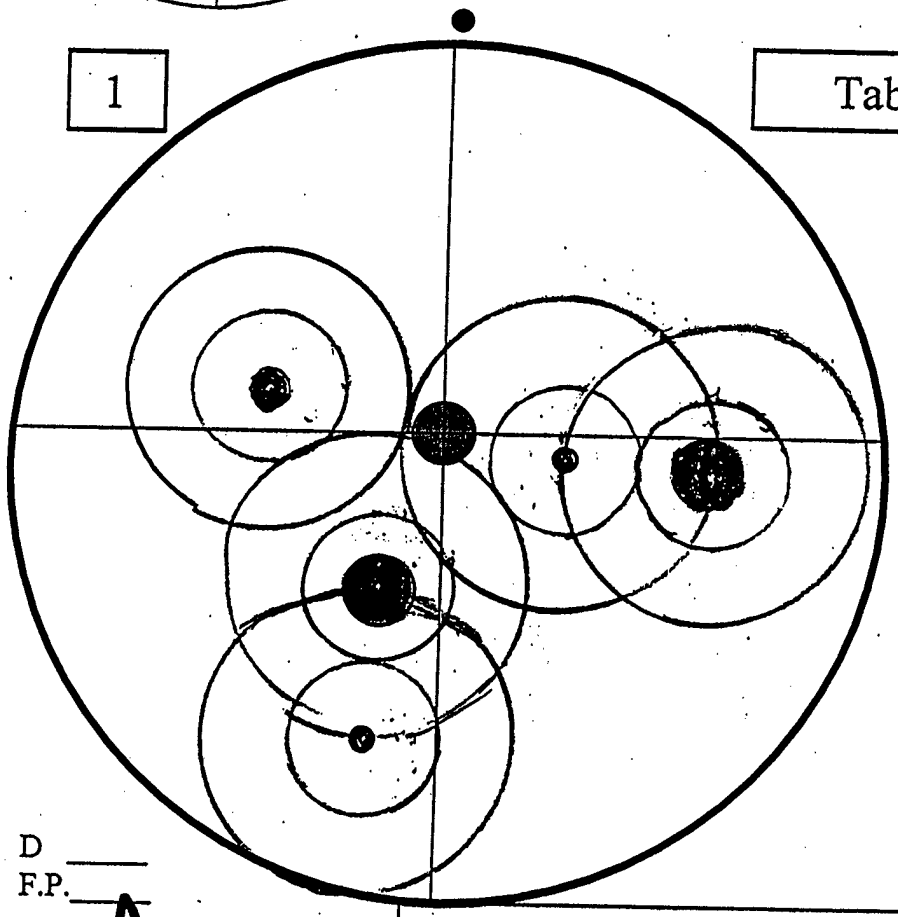

These breasts simulate the breast tissue of a 50 year old woman.

**INSTRUCTIONS:** Draw each lump in the appropriate location and indicate in the following order:

1. **Depth:** Medium (DM), Deep (DD)
2. **Size:** 0.3 cm, 0.5 cm, 1.0 cm
3. **Hardness:** Hard (H), Medium (M), Soft (S)

Table 1

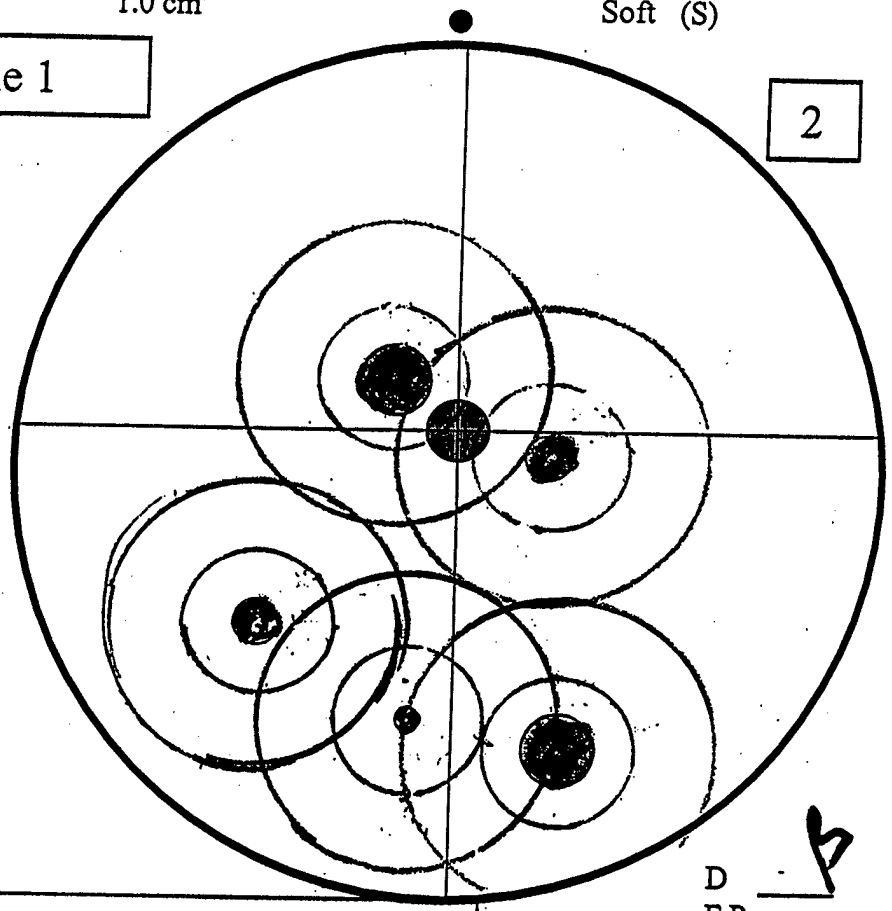
1



D ____
F.P. ____

A

2



D ____
F.P. ____

B

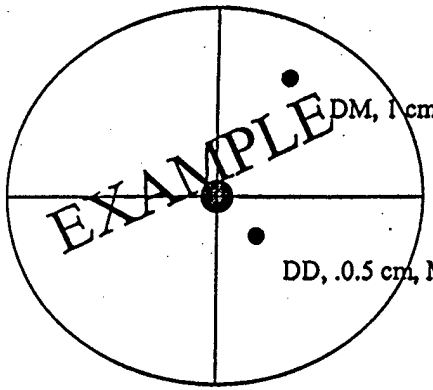
Total D ____ Total F.P. ____ Sensitivity ____% Specificity ____%

# *Essentials of Breast Care*

## *Clinical Breast Examination Form*

July 15, 1999

## *Post-test Silicone Breast Models*




These breasts simulate the breast tissue of a 50 year old woman.

**INSTRUCTIONS:** Draw each lump in the appropriate location and indicate in the following order:

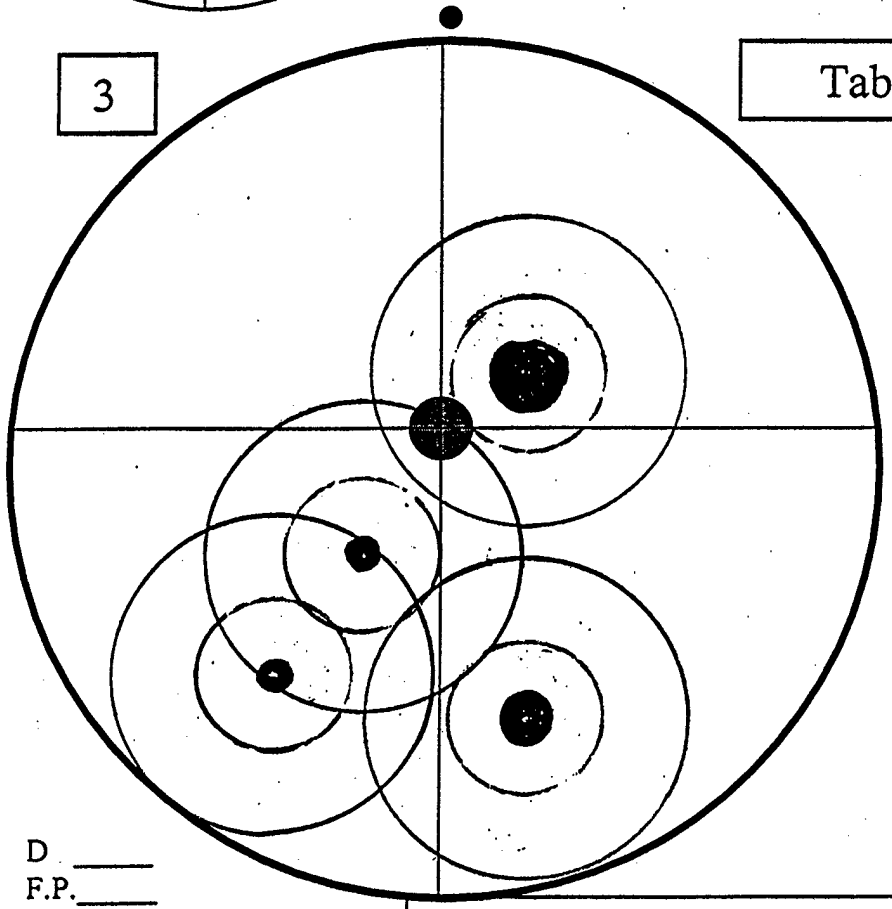
**1. Depth:** Medium (DM), Deep (DD)

**2. Size:** 0.3 cm, 0.5 cm, 1.0 cm

**3. Hardness:** Hard (H), Medium (M), Soft (S)

Table 2

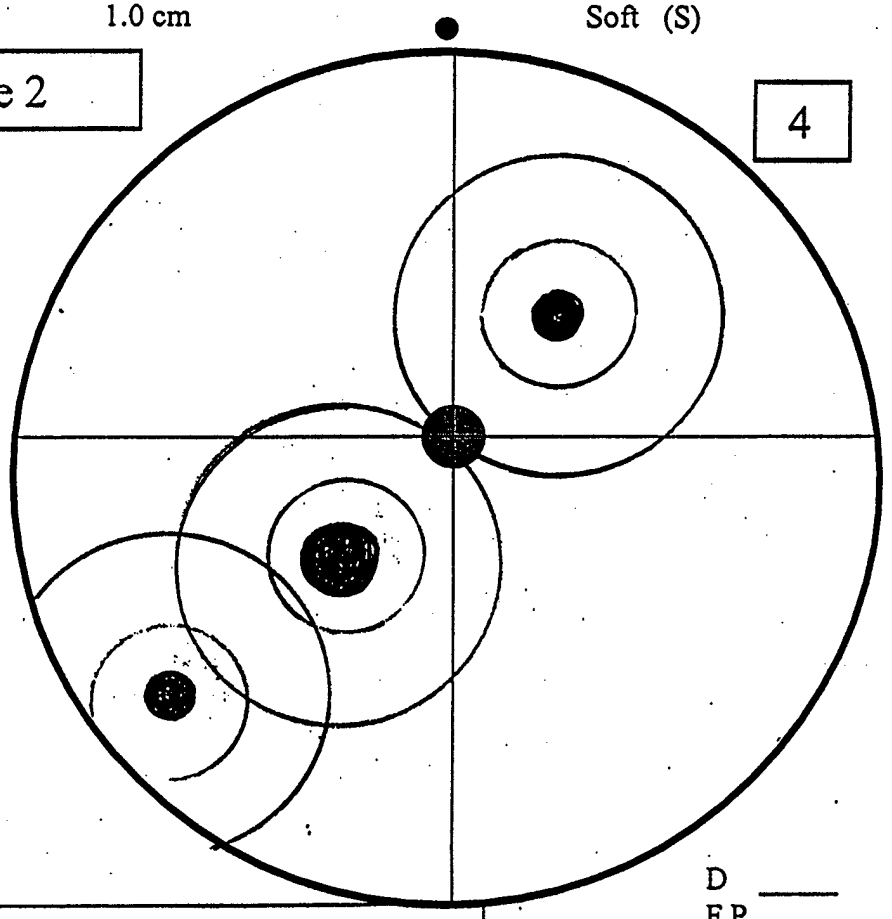
3



D ____
F.P.____

C

4



D ____
F.P. ____

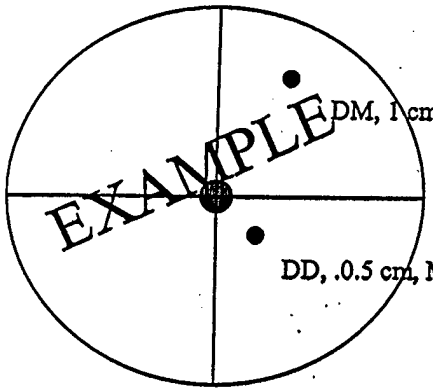
D

Total D ____ Total F.P. ____ Sensitivity ____% Specificity ____%

# *Essentials of Breast Care*
# *Clinical Breast Examination Form*

July 15, 1999

## *<u>Pre-test</u> Silicone Breast Models*

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**INSTRUCTIONS:** Draw each lump in the appropriate location and indicate in the following order:

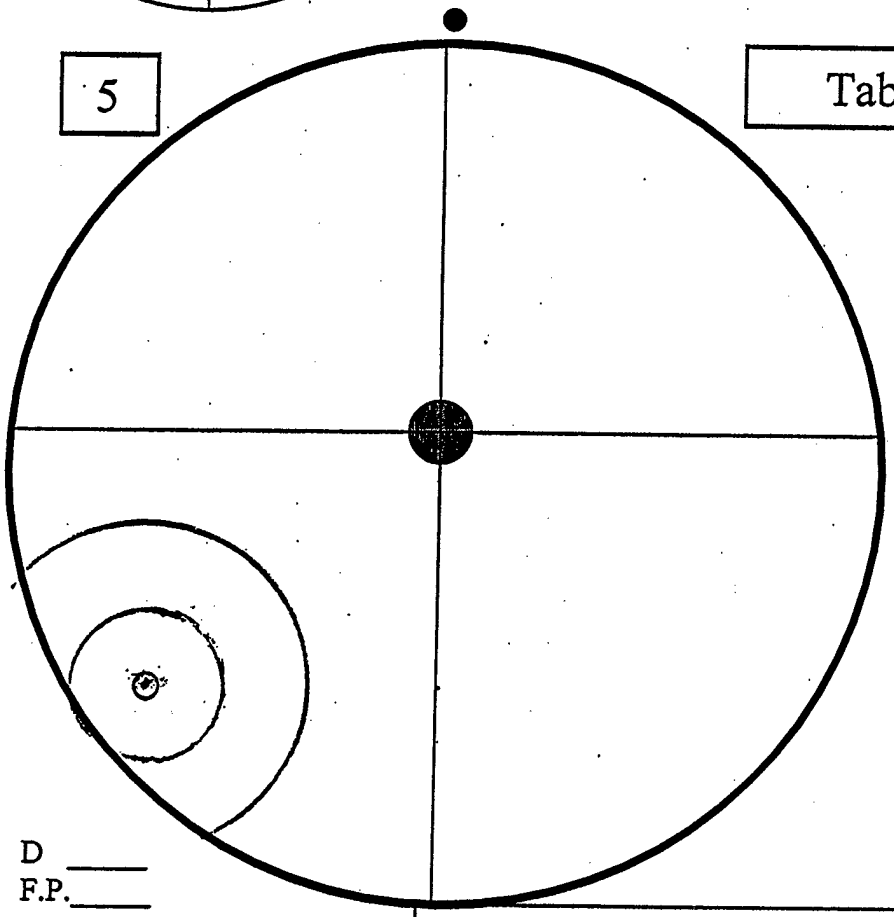
**1. Depth:** Medium (DM), Deep (DD)

**2. Size:** 0.3 cm, 0.5 cm, 1.0 cm

**3. Hardness:** Hard (H), Medium (M), Soft (S)

Table 3

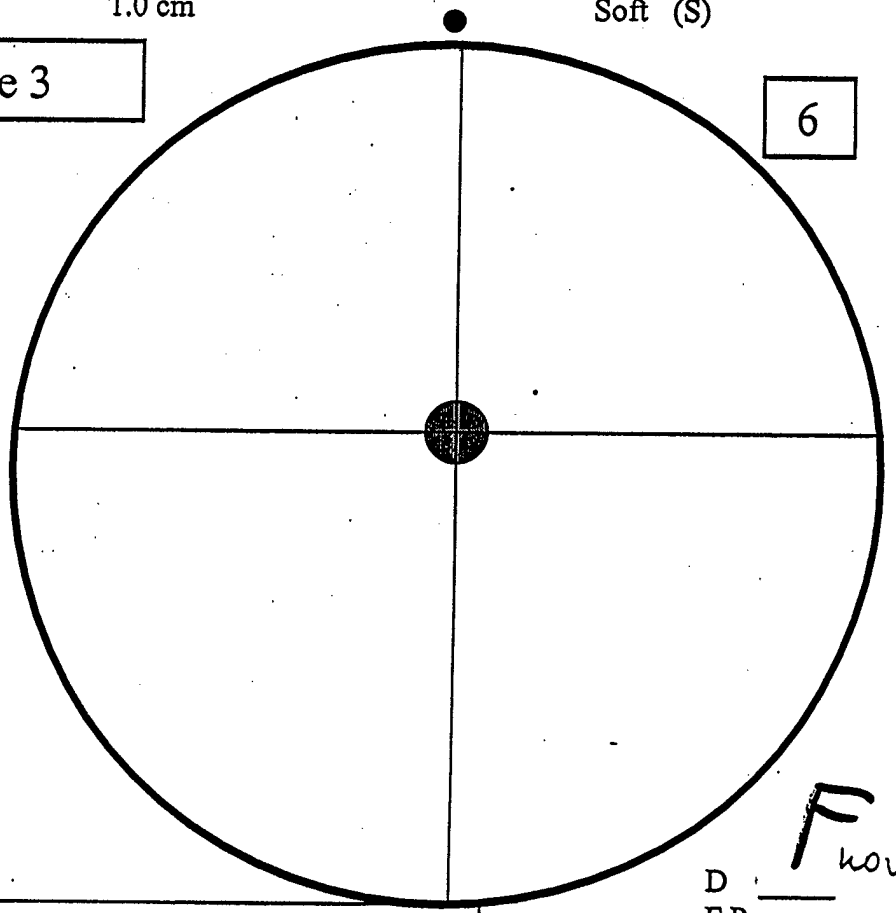
5



D ____
F.P.____

E (1)

6



D ____
F.P.____

Phone.

Total D ____ Total F.P. ____ Sensitivity ____% Specificity ____%

# APPENDIX 17

## Abstract Submitted for Era of Hope Meetings to be held in Atlanta June 8-12, 2000 "Teaching Clinical Breast Examination: Pre-Post Training Evaluation"

DO NOT FOLD

ABSTRACT

# TEACHING CLINICAL BREAST EXAMINATION: PRE-POST TRAINING EVALUATION

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Introduction: Training in Clinical Breast Examination (CBE) is inconsistent among graduates of medical schools and residencies. To address this inconsistency, we developed a standard-based approach to breast cancer screening and management of abnormal findings. This paper presents the immediate effect of the initial phase of the intervention on knowledge, CBE technique and CBE sensitivity and specificity of breast lump detection.

Methods: We randomized eight family practice residencies into control and intervention groups. The intervention was a one-day training session composed of didactic, interactive and skills workshops. Comprehensive manual on breast care was provided. Before, and immediately after the training, we assessed: 1) knowledge, attitudes, and beliefs about breast cancer screening, risk factors for breast cancer, and follow-up for abnormalities; 2) CBE technique; 3) CBE sensitivity and specificity for lump detection. The skill workshops used patient instructors for technique evaluation and silicone models for lump detection.

Results: One hundred twenty two physicians, five physician assistants and two nurse practitioners participated in one-day workshops in July 1999. The proportion of correct answers to the 19 knowledge questions changed from a mean of 53% (range 12% to 86%) before to 80% (range 50% to 98%) after the training ($p<0.001$). The proportion of physicians correctly using all five components of palpation technique rose from 36% to 71% after the training ($p<0.001$). The mean percent of the total area missed during CBE decreased from 11.4% (range 0% to 72%) before to 1.1% (range 0% to 41%) after the training ($p<0.001$). The sensitivity for location of the breast lump, defined as the proportion of 18 lumps correctly detected (within 2 cm radius), increased from 67% at baseline to 71% after the training ($p<0.05$). The specificity, defined as percent of models without a false-positive, rose from 28% before to 42% after the training.

Discussion: CBE is an important and often poorly performed component of a comprehensive approach to breast cancer detection. This study shows that a comprehensive approach to training was effective in improving short-term knowledge, technique, sensitivity and specificity of CBE, which should translate to improved detection of breast cancer. We will re-test participants after 12 months to determine their retention of knowledge and CBE skills gained during the training.

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# APPENDIX 18

# Kappa Results

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

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

Note: "*" = 100% Kappa Result

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

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

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

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

| | *Mammogram Findings* | | | | | | | | | | | | *Fine Needle Aspiration Findings* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Abs ID | Cat[1] I Right | Cat II Right | Cat III Right | Cat IV Right | Cat V Right | Cat VI Right | Cat I Left | Cat II Left | Cat III Left | Cat IV Left | Cat V Left | Cat VI Left | Resolved/ Not bloody | Bloody Fluid | Residual Mass |
| 11 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 12 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 21 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 22 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 31 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 32 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 41 | * | * | * | * | * | * | 0 (80)% | * | * | * | * | * | * | * | * |
| 42 | 0 (75)% | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 51 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 52 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 61 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 62 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 71 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 81 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 82 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 91 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |
| 92 | * | * | * | * | * | * | * | * | * | * | * | * | * | * | * |

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

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

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

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

**Table 5: Kappa Results from Form-IV (Followup Form) -Surgeon's Letter**

| Abstractor ID | Surgeon's Letter | | | |
|---|---|---|---|---|
| | Further Tests | Evidence of Malignancy | Followup in Primary care office | Followup in Surgeon's office |
| 11 | * | * | * | * |
| 12 | * | * | * | * |
| 21 | * | * | * | * |
| 22 | * | * | * | * |
| 31 | * | * | * | * |
| 32 | * | * | * | * |
| 41 | * | * | 0 (93)% | * |
| 42 | * | * | * | * |
| 51 | * | * | * | * |
| 52 | * | * | * | * |
| 61 | * | * | * | * |
| 62 | * | * | * | * |
| 71 | * | * | * | * |
| 81 | * | * | * | * |
| 82 | * | * | * | * |
| 91 | * | * | * | * |
| 92 | * | * | * | * |

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