

PART 1: INTRODUCTION

Breast Cancer in US & Maine

Breast cancer is the second major cause of cancer death among women in the nation and in Maine, after lung cancer. An estimated 41,200 women died from breast cancer in the United States in 2000 and 200 women died in Maine, according to the ACS. For many decades, breast cancer incidence gradually increased, while mortality rates remained stable. We are now seeing a true decline in deaths from this cancer, a decline that in large part can be attributed to early detection from mammography. Smaller cancers are associated with better survival rates and mammograms can detect smaller tumors at a time when they can be treated more successfully.

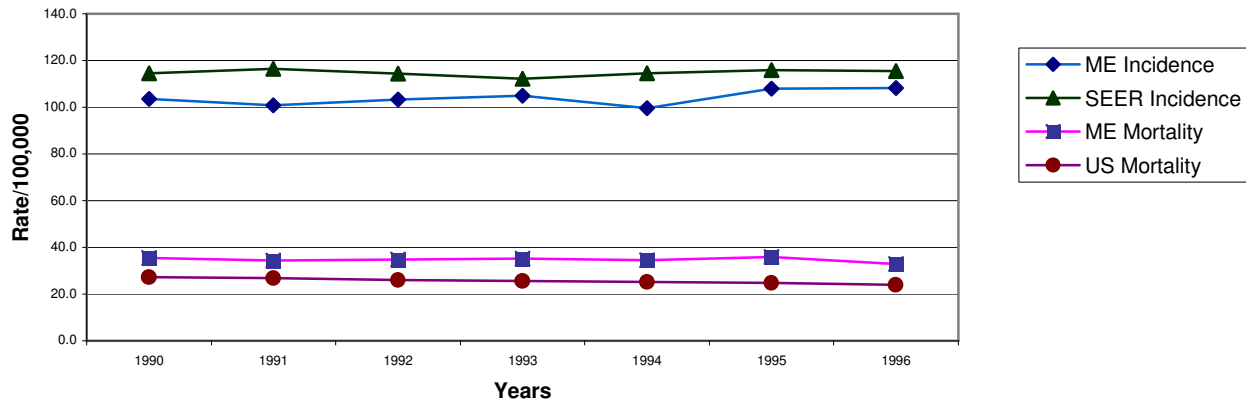
Excluding cancers of the skin, breast cancer is the most frequently diagnosed cancer and the second leading cause of cancer death among women in Maine and nationally. The American Cancer Society estimated that 182,000 new cases of breast cancer occurred in women in the United States and 900 in Maine during 2000.

Incidence

National data from the Surveillance, Epidemiology and End Results Program (SEER) show that between 1988 and 1996, incidence rates of breast cancer have been nearly constant. (The SEER Program at the National Cancer Institute collects and publishes cancer incidence and survival data from 11 population-based cancer registries and three supplemental registries covering approximately 14 percent of the U.S. population.) During the 1980s, there was a rapid increase in incidence (4% per year) largely due to the greater use of mammography screening and resulting in the detection of more cancers at earlier stages of development. In the US and in Maine, a stabilization in the rate of new breast cancer cases occurred between 1990 and 1996, following a generally increasing trend during the 80's. (In 1995 and 1996 the Maine Cancer Registry began using a different method of case finding that includes death clearance and use of pathology records which may have had an undetermined, but minor, effect on incidence rates.)

The general public's impression that breast cancer has become an epidemic is not supported by these data. One reason for this impression is the increase in the actual numbers of women being diagnosed with the disease, a trend which largely reflects the aging of the US population, particularly the large cohort of women in the "Baby Boom" generation. As noted above, the incidence **rate** has actually stabilized in recent years, although the number of cases continues to increase.

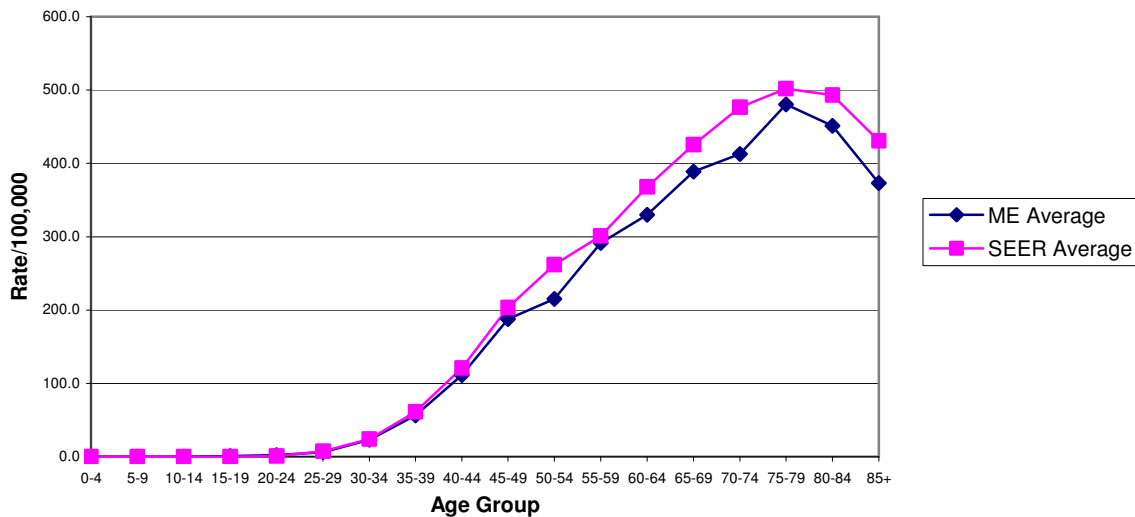
**Invasive Breast Cancer Incidence and Mortality,
Maine vs. SEER/US White Females, 1990-96**



Mortality

There has been a notable reduction in breast cancer death rates since 1989 nationally and since 1990 in Maine. This decline in breast cancer mortality has been attributed both to increased use of chemotherapy in breast cancer treatment and earlier detection of cancers at earlier and more treatable stages through increased mammography screening. Nationally, during the 1990s, death rate declines have been most notable in white women (-2.2% for women under 50 and -1.6% for women over 50). As more breast cancers are diagnosed while *in situ* or at earlier stages of invasive disease, death rates should continue to decline.

**Invasive Breast Cancer, Age-Specific Incidence Rates,
Maine vs. SEER White Females, 1990-96**

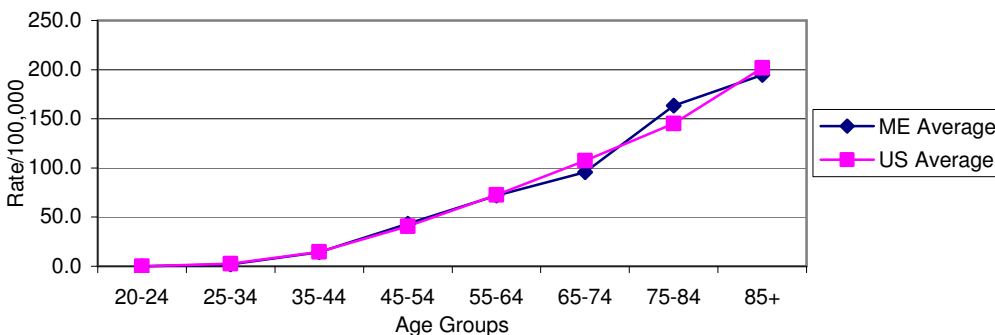


Interpretation

Maine's incidence rate for breast cancer has been consistently lower than the SEER rate since 1990, but the mortality rate has been slightly higher than the US rate. Therefore, the possibility exists that Maine experiences an excess of breast cancer mortality than that which would be expected from incidence or we have been underreporting new cases.

Further examination of age-specific **incidence** clearly shows that Maine's rates for the period 1990-1996 are *lower* than the SEER white female population for women age 35 years of age and older. However, age-specific mortality for the same time period shows that Maine's age-specific mortality rates are either approximately equal to or only slightly different than the SEER rates.

Invasive Breast Cancer, Age-Specific Mortality Rates,
Maine vs. US White Females, 1990-96



PART 2: SCREENING FOR BREAST CANCER

A. Screening Guidelines

Routine mammography screening is generally not recommended for women under the age of 40. Women over the age of 40 should be screened every year with mammography. Screening should not be terminated or performed less frequently solely on the basis of advanced age. However, at all ages, screening may not be appropriate in the presence of severe health problems and limited expected survival.

All women over 40 should receive an annual clinical breast exam (CBE) and should be encouraged and taught to do monthly breast self-examination. The American Cancer Society recommends CBE every three years for women ages 20 to 40.

RISK FACTORS

- Previous history of breast cancer in one breast (risk increased 2-4 times).
- Family history of breast cancer: any first-degree relative (risk increased 2-4 times, depending on age at diagnosis); one first-degree relative, premenopausal, bilateral (risk increased 4-6 times); two or more first-degree relatives (risk increased substantially depending on age at diagnosis, 4-14 times). *
- Age at first full-term pregnancy: ≥ 30 (risk increased 1.4 times); ≥ 35 (risk increased 1.4-1.6 times).
- Nulliparity (risk is increased 1.2-1.7 times for women over the age of 40-45).
- Benign breast diseases: no evidence of proliferative disease (risk increased 0.9-1.6 times), proliferative disease without atypia (risk increased 1.6-2.2 times), benign proliferative disease with atypical hyperplasia (risk increased 2.5-5.3 times).

*A woman with a first degree relative with premenopausal breast cancer may be a candidate for earlier mammography and/or annual CBE. A woman with a *significant family history* of breast and/or ovarian cancer has an increased risk of getting these cancers. Physicians may wish to discuss the pros and cons of genetic testing with women who have two or more close family members who have had breast and/or ovarian cancer and the breast cancer in the family member was found before the age of 50.

NOTE: Throughout this document, the terms “primary care provider” and “breast specialist” are used. These terms are defined as follows: “breast specialist” is a physician with breast surgical experience (e.g., FNA, open biopsy); a “primary care provider” is a physician or mid-level practitioner specializing in family practice, ob/gyn/family planning, or general internal medicine.

B. Patient Education

In addition to performing clinical breast exams and referring for mammography, the primary care provider should discuss the topics below. Women must have the opportunity to ask questions and express concerns, and responses must be conveyed to them as clearly as possible, with a sensitivity to cultural and ethnic diversity and language.

Written materials should be provided to the patient on Breast Self Examination (BSE), Clinical Breast Examination (CBE), and mammography to reinforce recommendations.

1. BSE: Techniques and normal findings.

- The performance of monthly breast self-exams should be assessed and skills updated, if necessary.

2. Indications for calling provider about signs or symptoms of breast cancer.

- mass
- nipple discharge
- ***persistent*** pain
- skin changes

3. Importance of age-appropriate screening.

- The two main risk factors for breast cancer are being a **woman** and getting **older**. (Only about 10% of breast cancer cases are hereditary.)
- Explain that about 70% of all breast cancers occur in women without any known risk factors. Describe the leading risk factors and signs of breast cancer.
- Normal results never rule out the later development of disease, which is why ongoing regular screening is so strongly recommended.

4. Radiation Risk.

- The amount of radiation produced by mammography is extremely low. Federal mammography guidelines limit the radiation for two views of one breast to one (1) rad. In practice, most mammograms deliver just a small fraction of this amount. Although a linear dose-response relationship has been documented (the greater the dose, the greater the risk), no data exists for estimating the risk associated with such low levels of exposure. However, it is clear that the risk of exposure to even much higher doses of radiation

decreases sharply with age and diminishes significantly beginning at around age 40.

5. Explanation of procedures: CBE, mammogram, followup.

- If possible, women should be scheduled for screening mammography when they are not experiencing cyclic breast tenderness or conditions that increase breast density. Discomfort during the examination is among the reasons cited by women for not adhering to recommended guidelines for screening mammography.
- Advise women not to wear any deodorant, perfume, powders or ointments of any sort in the underarm area or on the breast on the day of the exam. These products may cause shadows to appear on the mammogram. Wearing a two-piece outfit will allow the woman to easily undress above the waist for the exam.
- It is helpful to mention to the previously unscreened woman that two pictures are taken of each breast – one from the top and one from the side. The breasts are placed between plastic plates and flattened somewhat to get a clear picture.
- Women are more likely to have pain during a mammogram if they expect it. Reassure women that adequate compression can usually be accomplished without pain. However, breast compression is necessary for good quality mammography and lowers the x-ray dose needed. Compression may be uncomfortable and women should be encouraged to tell the radiologic technologist if it becomes painful.
- Prior to referring the woman to specialists, the primary care provider should discuss with the patient what to expect from specialists in terms of tests and procedures and what her responsibilities are for keeping appointments, providing films and reports, and adhering to recommendations.

6. Limitations of screening mammography.

- No screening test is 100% accurate: therefore, up to 15% of cases of the disease may be unavoidably missed.
- The detection of an abnormality does not mean the abnormality is cancerous. Only about 20% of the women with abnormal screening results will, after further evaluation, be diagnosed with breast cancer.
- A negative mammogram does not rule out malignancy in the presence of a palpable mass or other breast abnormality.

- Although mammography should be performed for women with implants, it may be less effective in detecting cancers.

7. Cost of screening mammography:

- In Maine, the cost of screening mammography ranges from approximately \$80 to \$200. This includes both the interpretation by the radiologist and the procedure. ***In Maine, all individual and group coverage policies must reimburse for screening mammograms performed at least once a year for women 40 years of age and older.*** (Providers should be aware that self-insured employers are not subject to this requirement.) Medicaid also covers mammography and Medicare pays 80% toward mammography every year for its beneficiaries.

C. Screening Programs

Definition of Screening and Diagnostic Mammography:

Screening mammography is an x-ray examination to detect unsuspected breast cancer at an early stage in asymptomatic women; it usually consists of two views of each breast.

Diagnostic mammography is an x-ray examination used to evaluate a patient with a breast mass or masses, other breast signs or symptoms (spontaneous discharge from the nipple, skin changes, etc.), an abnormal or questionable screening mammogram, a history of breast cancer with breast conservation, or special characteristics such as augmented breasts. Diagnostic mammography includes additional views including “spot compression” and “magnification” which are intended to better define a possible mammographic abnormality.

To reduce mortality from breast cancer in the population, a screening program must be able to provide mammography procedures of sufficient sensitivity to detect the disease at early stages, and it must have effective strategies to ensure acceptance and utilization of its services by the target population. A quality screening program must also attempt to avoid any adverse effects. These include: poor participation of the target population, a false sense of security for some, unnecessary anxiety and suffering for others, unnecessary biopsies, unnecessary radiation exposure, and missed breast cancers.

D. Referral for Mammography

Primary care providers should tell women whether they are being referred for screening or diagnostic mammography and how they will be informed of results. If the referral is for a diagnostic mammogram, tell the patient why it is needed, what to expect at the examination, and the necessity of follow-up.

Screening

- Primary care providers should ensure that women have routine mammography as well as CBE according to recommended guidelines.
- If necessary, request films from last mammogram to be forwarded to current facility.
- Primary care providers should be aware of current quality assurance standards for mammography facilities enforced by the FDA. The positive predictive value of mammography can vary significantly from one facility to another.

Diagnostic

- Referring providers should clearly specify to the mammography facility whether diagnostic or screening mammography is being requested. They should also communicate information about special patient needs or disabilities at the time of referral.
- A negative mammogram should not delay continued clinical evaluation, including a possible biopsy of a breast lump or other suspicious clinical finding.
- Patients should understand that ultrasound is not a screening test; it is an adjunct to other diagnostic tests. A negative ultrasound does not assure the absence of malignancy.
- At the time of referral, the results of an abnormal clinical breast exam should be communicated to the mammography facility in writing. (The information may be sent with the patient, faxed, or mailed, whichever is most reliable and expedient.) Specify the location of any palpable abnormalities as to breast (left or right) and quadrant (upper outer, upper inner, lower outer, and lower inner). Also, provide information about whether any previous breast surgeries or recent needle aspirations have been performed and, if so, their exact location. (A sample Breast Evaluation Form appears on page 13.)
- Women may have substantial anxiety when they have to return for additional views. These views should be done as soon as possible to reduce anxiety.
- Referring providers should directly contact the interpreting physician when scheduling mammography for women under 35.
- To facilitate the referral and communication process, the primary care physician may wish to make the appointment for the woman and schedule a follow-up primary care visit following consultation.

- Aspiration of a palpable abnormality can cause a hematoma in breast tissue, which can decrease the accuracy of subsequent mammography for at least a week. The referring provider should inform the mammography facility if aspiration is attempted.
- Referring providers may wish to consider sending women with breast implants, recent breast surgery or radiation therapy to a facility with personnel experienced in performing mammography on these patients.

Part 3: THE CLINICAL BREAST EXAM

A. Clinical Breast Exam

Any investigation of a woman with a breast lump or suspicious change in breast texture starts with a history, physical examination, and usually mammography. The goal of breast evaluation is to classify findings as normal physiologic variations, clearly benign, or possibly malignant. Most lumps detected are not malignant. However, once a lump or suspicious change in breast tissue is discovered, it is necessary to establish whether or not it is malignant.

The efficacy of the clinical examination in distinguishing malignant from benign breast lumps depends on the expertise and experience of the examiner.

An article in the October 6, 1999 issue of the Journal of the American Medical Association (JAMA) entitled “Does this Patient Have Breast Cancer? The Screening CBE: Should it be done? How?”, concluded that indirect evidence supports the effectiveness of CBE in screening for breast cancer. Although the screening clinical breast examination by itself does not rule out disease, the high specificity of certain abnormal findings greatly increases the probability of breast cancer. A well-conducted CBE can detect at least 50% of asymptomatic cancers and may contribute to reduction in the mortality rate in women screened. The JAMA article reviewed all literature on all controlled trials and case-control studies in which CBE was at least part of the screening modality.

Clinical evaluation should include a thorough history and a thorough examination of the breast, axilla, and supraclavicular areas. The technique of breast exam is learned and improved with training and practice. An exam must take more than 3 minutes to be considered a thorough evaluation and training can improve sensitivity by an average of 13 percentage points.

THE MAMMACARE METHOD OF BREAST EXAM: A BRIEF EXPLANATION

- Palpation should be performed in the upright and supine positions
- Use the pads (not tips) of your three middle fingers
- Apply three levels of touch: very light touch, mid-level, and deep chest wall assessment
- Use dime size circles as you use the three levels of touch
- Move one inch at a time, fingers should never leave the breast tissue
- Follow a vertical strip pattern that extends from under the armpit, down the side of the chest wall to the bra line, across the bra line to the sternum, up the sternum to the clavicle, and across the clavicle and back down the armpit.

Primary care providers should use the following categories to document the results of the CBE:

- Normal exam
- Benign finding such as probable fibrocystic changes (i.e., diffuse lumpiness or nodularity)
- Discrete palpable mass (this includes both dominant and nondominant masses).

B. Breast Health History

Conducting a breast health history is an essential part of the clinical breast exam (CBE) and evaluation of a breast complaint. While primary care providers frequently complete medical histories as a routine, they may not include extensive questioning related to breast health. A comprehensive breast health evaluation-whether for the investigation of a patient's breast lump, a change in breast texture, or other symptoms-begins with a thorough risk assessment coupled with a thorough physical exam and usually includes mammography. The history should include age, personal breast health history, family history, reproductive history, and symptom assessment.

Clinical Findings in Malpractice Cases

- Patient discovered the lesion in 60% of cases
- Physician discovered the lesion in 20% of cases
- Mammogram discovered the lesion in 18% of cases
- Most common presenting symptom was a painless mass
- Mammogram was most commonly performed study (83%) results were negative or equivocal in 80% of patients who had mammograms.

The history-taking process will vary to some degree depending on whether the patient presents with a self-identified lump and particularly if the patient has not been seen before by the provider. In-depth information about the lump should be gathered and the patient and provider should collaborate on locating the lump. When a patient is new the provider may want to determine the patient's breast self exam skills and whether she has previously discovered any lumps.

Suspicion for everyone should be the same -- high. For any individual patient, risk factors alone should not cause increased or decreased suspicion.

In addition to the clinical history (see Breast Health History Form on page #13) be sure to ask the following:

- When did she first notice the lump?
- Is it new?
- Has she followed it through a cycle if pre-menopausal?
- Has it changed?
- Where is it?
- Does it hurt?
- Is she worried?

C. Findings

Smooth, well-demarcated lumps are usually benign and are either cysts or fibroadenomas. Lesions that are less smooth and less mobile, with poorly defined margins, should increase suspicion of carcinoma. Rubbery-type plaques that blend into the surrounding breast tissue are not true masses but are usually benign zones of fibroglandular change.

A mass presenting a **high level of concern** has some of the following qualities:

Texture:	firm to hard
Borders:	irregular
Mobility:	fixed (to skin or underlying tissue)
Skin changes:	redness, dimpling
Lymph Nodes:	unilateral hard nodes
Appearance:	visible
Prior history:	diagnosed with hyperplasia with or without atypia (information usually not available)
Family history:	first-degree relatives or multiple second-degree relatives
Other:	new, different finding

Lumps/masses presenting a **low level of concern** are characterized as follows:

Texture:	soft to firm
Borders:	regular and smooth
Mobility:	mobile
Skin changes:	none or not associated with the breast
Nodes:	symmetric and/or soft
Other	lump not part of breast tissue (e.g., sebaceous cyst or lipoma); related to cyclic changes; lump has history of long-term presence and is known to be benign

BREAST EVALUATION FORM

Name _____ DOB _____ AGE _____

Self-referral

Routine Exam

Other physician/provider referral _____

Complained of: lump L R **Family History** _____

 pain L R _____

 nipple discharge L R **LMP** _____

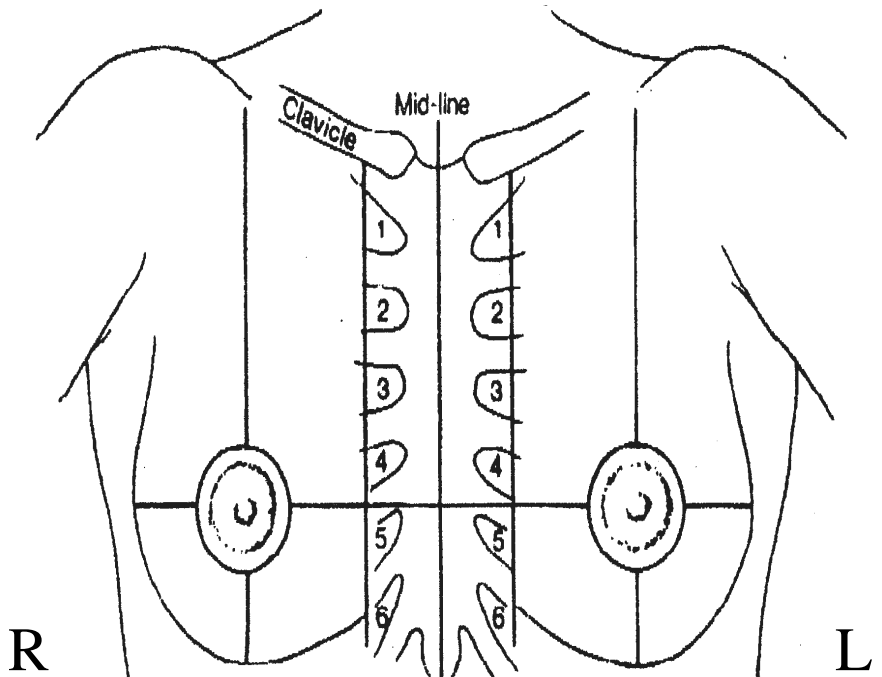
 skin/nipple changes L R **ERT** Yes/No

Ultrasound: Date _____ **Mammogram:** Screening Diagnostic
 Date _____ Facility _____

- | | |
|---------------------------------------|--|
| <input type="checkbox"/> inconclusive | <input type="checkbox"/> assessment incomplete |
| <input type="checkbox"/> cystic | <input type="checkbox"/> negative |
| <input type="checkbox"/> solid | <input type="checkbox"/> benign finding - negative |
| | <input type="checkbox"/> probably benign - short interval follow-up |
| | <input type="checkbox"/> suspicious abnormality, biopsy should be considered |
| | <input type="checkbox"/> highly suspicious of malignancy |

Breast Findings:

- _____ location
- _____ mobility
- _____ approximate size
- _____ consistency and tenderness
- _____ type of nipple discharge
- _____ nipple or areola abnormalities
- _____ skin abnormalities






PART 4: FOLLOW-UP GUIDELINES AND TIMELINE

This section contains several tools intended to assist primary care providers to systematically ensure and document the follow-up of all abnormal breast findings. These tools provide general guidelines; not all circumstances presented by individual patients can be included. These tools are not intended to replace a clinician's judgment.

Algorithms indicate what is considered timely follow-up, when to refer to a specialist, and what are the areas of controversy, thus allowing better assessment and plans for patient care and risk management. Although providers are often faced with breast problems beyond the scope of these algorithms, those included here provide guidance for common breast problems. You are encouraged to adapt the algorithms as necessary for individual clinical decision-making. Algorithms must be kept updated and current to be considered as an acceptable standard.

The tools found in this section include:

-  Algorithm/Practice Guidelines for Breast Cancer Screening and Follow-up
-  Definitions for Algorithm/Practice Guidelines
-  Follow-up Schedule

“Definitions for Practice Guidelines”

1. Mass and Mass Characteristics – Dominant masses are three-dimensional, distinct from surrounding tissues, and generally asymmetrical in relation to the other breast. Masses suggestive of cancer are: 1) firm, with irregular borders, or have attachments to the skin or deep fascia; 2) lack of tenderness is characteristic but NOT a dependable sign. On the other hand non-dominant masses are not suggestive of cancer and are: discrete, regular, with mobile margins.

Structures sometimes mistaken for a mass: 1) prominent rib or costochondral junction, 2) a firm margin at the edge of the breast or at the edge of a defect due to a biopsy, 3) a furrow in the tissue, 4) lobulated circular terminus of firm breast tissue at the border of the areola 5) inframammary ridge.

Cysts cannot be distinguished reliably from solid masses through physical exam.

2. History of Persistent pain/tenderness: Persistence of noncyclic localized pain not responsive to conservative measures.

3. Nipple discharge: Spontaneous, unilateral, or bloody discharge.

4. Skin/nipple change: Skin breakdown on the nipple-areola complex; dimpling; retraction; erythema, scaling.

Equivocal Clinical Findings

A discrete mass clinically felt to be negative for cancer. Slightly lobulated breast tissue, particularly premenstrual, an area of diffuse, poorly defined thickening that may or may not be matched in the opposite breast, or an area of irregularity or prominence such as irregular or nodular normal breast tissue.

Mammography/Ultrasound (BI-RADS Categories used for Mammography)

Negative Mammogram: Category 1: Negative – There is nothing to add. No masses, architectural disturbances or suspicious calcifications present OR Category 2: Benign finding--negative: there is nothing to suggest cancer, but there are findings that although benign may warrant reporting. Included in this category are benign inflammatory lymph nodes; involution, calcifying fibroadenomas; fat-containing lesions such as oil cysts, etc.

Positive Mammogram: Category 4: Suspicious abnormality - - biopsy should be considered: these are lesions that have moderate probability of malignancy although statistically they are likely to be benign OR Category 5: Highly suggestive of malignancy - - appropriate action should be taken: these lesions have a high probability of being cancer.

Equivocal Mammogram: Category 3: Probably benign - - short interval follow-up suggested: these are lesions that have benign radiographic characteristics. The radiologist anticipates no change, but close follow-up evaluation is suggested because there is a very low probability of malignancy.

Negative Ultrasound: Ultrasonography can confirm a simple cyst if 1) round or oval shape, 2) sharply defined margins, 3) anechogenicity, and 4) posterior acoustic enhancement.

Positive Ultrasound: Solid mass or complex cyst confirmed by ultrasound.

Action/Follow-up Plans

Repeat CBE: Return visits for a repeat CBE should be limited to one and should occur **5-10 days after menstruation starts.** (Additionally CBE may be necessary to monitor a nondominant mass felt to be mammographically and clinically negative for malignancy.)

Definitive Diagnosis: For the follow-up of any abnormal findings, definitive diagnosis should either be based on a surgical opinion that there is no evidence of cancer or pathological evidence that there is or is not evidence of cancer.

Diagnostic Evaluation and Appropriate Procedures: The procedures listed below (alone or in combination) should be used to reach a definitive diagnosis. It is assumed that all biopsy procedures, with the possible exception of FNA, would be performed by a breast specialist or surgeon.)

- **Surgical Consult**
- **Diagnostic Mammogram**
- **Fine Needle Aspiration (when appropriate)**
- **Needle Core Biopsy**
- **Excisional Biopsy**

Ultrasound may be used to guide any of these procedures and stereotactic mammography may be used to guide needle core biopsies and fine needle aspirations.

Annual Follow-Up: Refer to accepted age-appropriate national screening guidelines for CBE, mammography, and BSE.

Short-Term Follow-up Mammogram: This recommendation is made by the radiologist when a mammogram report is “probably benign.” The standard interval is six months, however, the interval and type of mammogram should be determined by the radiologist.

Follow-up Schedule for Abnormal CBE and Mammographic Findings

No more than **six weeks** should elapse between the identification of a palpable abnormality, particularly a dominant mass, and the final diagnosis. **Regardless of mammographic findings palpable abnormalities should be handled clinically within this timeframe.** Abnormal mammograms should be followed quickly by additional views and other diagnostic procedures completed within six weeks. Thus, within six weeks of either a palpable abnormality or abnormal mammogram the resolution of a mass will be confirmed, a simple cyst identified, or a definitive diagnosis by adequate tissue sample made.

Controversy exists about whether immediate workup is warranted in every case of a mass or whether the clinician can wait and reevaluate the woman within six weeks. The latter may be an option in cases where the clinician or the radiologist is confident that the lesion is benign. The clinician making this decision should be experienced and confident of his/her ability to make such a determination.

A referral to a surgeon is warranted if the clinician **or the patient** has any uncertainty. To ensure that patients are not "lost to follow-up", a callback system must be in place so that the subsequent appointment is made and the patient reevaluated.

If the primary care physician chooses to reevaluate a premenopausal woman patient with such a mass, the followup exam should occur in five to six weeks and 5-10 days after the start of menstruation. Experts agree that if a non-dominant mass **persists** for 3 months, a breast biopsy is warranted. Further delay in workup is not prudent. Any patient with an irregularity that persists after three months and is distinguished from remaining normal breast tissue (asymmetric from the other breast) should be referred to a surgeon.

Surgeons experienced in evaluation of breast masses may closely observe the patient until the presenting mass resolves or is excised. Close and vigilant surveillance is critical because of the consequences of a delay in diagnosis.

In the workup of a physical finding --such as:

- a breast lump,
- skin change,
- or spontaneous nipple discharge

A provider should never delay further evaluation, (e.g., FNA or biopsy) after a negative or probably benign mammogram. **Around 15 percent of mammograms that appear negative or benign in the presence of a palpable mass are later determined to be cancer.**

Excerpt from JAMA...

"Normal breasts are often lumpy; the clinician's job is to distinguish normal from abnormal (cancerous) lumps. Cancers classically are characterized as hard, fixed, and irregular, while benign breast lumps are the opposite: soft or cystic, movable, and regular. However, many cancers do not conform to the classic picture and benign masses can mimic cancers. Because the characteristics of cancerous lumps overlap with those of noncancerous lumps, clinicians rarely diagnose breast cancer with CBE. Careful CBE can locate abnormalities. Further evaluation with other tests is then required."

The authors also noted that clinicians who do not perform careful screening CBE may have heightened liability.

JAMA, October 6, 1999

Additional mammography **alone** after an abnormal clinical breast finding is not adequate.

A patient with a self-identified lump not confirmed by the provider should come back within five to six weeks (5 to 10 days after onset of menses) for reexamination. If resolved from both patient and provider perspective, the patient can return to routine screening. If the mass persists from the patient perspective but is still not confirmed on CBE, the patient should be referred for surgical evaluation. Definitive diagnosis, whether the results are benign or suggestive of malignancy, is necessary within six weeks.

Follow-up Schedule	
Abnormal CBE to date of Mammogram	≤ 2 weeks
Date of mammogram to mammogram results	≤ 2 weeks **
Abnormal CBE to follow-up procedures	≤ 2 weeks
Abnormal mammogram to Dx procedure	≤ 2 weeks
Date of Dx procedure to Final diagnosis	≤ 1 week
From initial presentation to diagnostic work-up completed	≤ 6 weeks
* Highly suspicious palpable masses should be expedited through the diagnostic work-up process. ** In cases where prior films must be obtained from out-of-state, additional time may be needed.	

PART 5: MANAGEMENT OF ABNORMAL FINDINGS

A. Dominant Unilateral & Distinct Palpable Mass: Suspicious and Non-suspicious

A dominant mass is palpable and discrete, clearly differentiated from the surrounding parenchyma and usually asymmetric. A discrete palpable mass is three dimensional, different from surrounding tissues and usually asymmetric. Clinical signs that are suggestive of benignity, but not diagnostic, include a mass that is soft or rubbery and mobile. Features suggestive of malignancy include a mass that feels firm or hard, has an irregular shape, is solitary, and feels different from surrounding breast tissue. Occasionally, breast cancers are fixed and associated with other signs such as skin retraction. Dominant palpable masses may be considered suspicious or non-suspicious clinically. Clinicians must use careful judgment and level of concern (both their own and patient concerns) when classifying a dominant lump as suspicious or non-suspicious.

Open excisional surgical or core needle biopsy is required for any suspicious solid, dominant, persistent mass. Alternately, FNA may be performed if experienced cytology evaluation is available but is most reliable only in limited situations i.e., when a mass is strongly felt to be a simple cyst and confirmation is desired, or when a mass is strongly felt to be malignant and tumor type is needed to plan definitive surgery. A definitive diagnosis of a palpable mass, determined not to be a cyst, can only be established by examination of a tissue sample under a microscope. Therefore, a negative FNA in a patient with a suspicious mass requires follow up with a definitive biopsy.

The purpose of mammography for a patient with a palpable breast lump is to further define the lump and to rule out the presence of nonpalpable breast cancer in the ipsilateral or contralateral breast. Mammography, although a valuable tool for screening and identifying breast abnormalities, is not perfect. Thus, although a suspicious mammogram may increase the probability of the presence of a malignancy, a normal mammogram should not exclude a cancer that is suspected on clinical grounds. A negative or benign mammogram should never delay further evaluation or prevent care for a physical finding such as a breast lump, skin change, or spontaneous nipple discharge. Mammography has a false negative rate of at least 15 percent, depending on the patient's age. (Mammography is less effective in younger women, in part due to the density of their breasts.) Therefore, among all women diagnosed with breast cancer, about 15 percent will have had a negative or benign mammogram.

Common Pitfalls

- Failure to describe physical findings clearly and accurately in the medical record
- Failure to review written mammogram report, including filing a report without review, or relying on a verbal report
- Failure to evaluate and follow-up on all palpable breast abnormalities
- Undue reliance on negative mammogram when a palpable lump or other complaint is noted
- Failure to initiate follow-up contact with a patient who misses an appointment
- Failure to followup on referral or consultation

In **premenopausal** women, fine-needle aspiration (FNA) or core needle biopsy is often a prudent step either at the time of initial breast exam or with ultrasound (for guidance). If a mammogram is indicated, radiologists prefer that FNA be performed after the mammogram. Whenever referring a woman for a mammogram or other care, make sure she knows the location of the lump and indicate this clearly in any accompanying paperwork. Also, it may be appropriate to request that the radiologist place a radiopaque marker on the skin over a palpable lesion to ensure that the additional view is accurate.

In **postmenopausal** women, the risk that a mass is carcinoma increases; therefore, the provider needs to be particularly suspicious of a discrete mass or asymmetric thickening of the breast tissue. Patients with discrete solid masses should be referred to a surgeon or a physician with expertise in breast evaluation. It is appropriate to order a diagnostic mammogram concurrently with referral to a surgeon in a woman over 35 years of age with a solid mass to define characteristics of the mass and, primarily, to look for synchronous lesions in either breast that are non-palpable.

Fine needle aspiration (**FNA**) or core biopsy is frequently an appropriate extension of evaluation of a palpable mass. FNA should not be used unless the examiner is familiar with it and an experienced cytopathologist is available. The validity of FNA depends on the training and experience of the operator. The provider who does FNA must (1) be trained in the procedure (2) have experience in FNA, and (3) perform FNA often enough to maintain expertise. If the primary care physician does not routinely perform aspirations, referral to a surgeon is appropriate. The false positive rate is only in the range of 1%-2% but the false negative rate may be as high as 15%-20%. A cyst that recurs more than once, displays bloody fluids, or leaves a residual palpable mass postaspiration warrants cytological examination and further evaluation.

After appropriate diagnostic procedures, most solid, dominant, persisting masses are removed by surgical biopsy. Even if a lesion is benign on mammogram and biopsy, a woman, in consultation with her physician, may decide to have the mass removed. Others may choose to monitor a benign appearing mass or seek a second opinion. For some women, if a mass is not removed, it may cause continued concern and anxiety.

Unfortunately, a large category of “palpable masses” are perceived by the patient, but not considered a palpable mass by the physician or surgeon. The range of

Palpable masses

Biopsy options for palpable masses include fine needle aspiration biopsy (FNA), large gauge needle core biopsy and excisional biopsy:

- FNA extracts cells rather than tissue
- Core Biopsies use a 14-18 gauge needle, usually in a spring-load instrument, to extract several cores of tissue (3-5mm incision). This technique is relatively simple, minimally invasive, and can be performed in a variety of outpatient settings.
- Excisional biopsy surgically removes an entire mass and zone of tissue surrounding the mass leaving small scar (2-cym) scar. The procedure requires a sterile operating room setting.

abnormalities that patients feel and call a “mass” is wide. The health provider may feel this area only as slightly lobulated breast tissue, particularly premenstrually, an area of diffuse poorly defined thickening that may or may not be matched in the opposite breast, or an area of irregularity or prominence such as nodular breast tissue. If there is any sense of concern or anxiety on the patient’s part, it is good medical practice to advise the patient to return within five to six weeks for re-examination (or seek an opinion from a surgeon) until she is convinced of the benign or functional nature of the changes. In menstruating women, re-examination ideally should occur 5-10 days after menstruation starts.

When the patient returns, if the nodularity has resolved from the patient and provider perspective, the patient can return to routine follow-up. If the mass persists from the patient’s perspective but is still not confirmed on CBE, the patient should be referred for surgical evaluation.

The presence of discomfort and pain is not a reason to assume that the lesion is benign. While, by-and-large, painful or tender areas in the breast are functional in nature, caution should be exercised not to over-interpret the benign implication of this symptom.

Cysts

A palpable mass strongly suspected to be a cyst, should be evaluated by a physician and by aspiration (Post menopausal women should have had a mammogram within the past six months.) The decision to attempt aspiration of a suspected breast cyst will probably be based on several factors, including the size of the mass and ease of access, the strength of the clinician’s suspicion that a mass is a cyst, and the availability of mammography and ultrasonography. The decision not to aspirate a simple palpable cyst can be made only by an experienced referral physician in consultation with the patient. A decision not to aspirate may be appropriate in a patient with previous similar findings.

If the mass does not completely disappear, one may try to re-aspirate immediately. If a residual mass remains or if the aspirate contains bloody fluid, send it for cytologic exam and evaluate further with imaging and adequate tissue biopsy. If a cyst is successfully aspirated, the patient should be re-examined for cyst recurrence at approximately four to six weeks. Rapid recurrence of a cyst after aspiration should lead to surgical referral. There is no indication for routine ultrasonography in such patients. (An ultrasound is not useful for screening; it is most useful if an abnormality is found on a mammogram.)

Simple Cysts: fulfill the following four criteria: round or oval shape, sharply defined margins, lack of internal echoes, and posterior acoustic enhancement;

Complex Cysts: lesions that do not fulfill the ultrasound criteria for a simple cyst;

Gross Cysts: collections of fluid (in the breast) which are felt as lumps and that usually can be emptied by aspiration.

Success in obtaining satisfactory samples for cytologic exam is operator-dependent and accuracy of interpretation depends on the availability of a pathologist experienced in cytology. If the mass does not disappear completely with aspiration or if the aspirated fluid is grossly bloody, the fluid should be sent for cytologic analysis and the patient should be referred to a surgeon. Clear or grey-green cyst fluid does not otherwise need to be analyzed.

Ultrasound is most useful when a nonpalpable abnormality is detected on a mammogram or when a palpable mass is only partially or poorly seen. The ultrasound can then determine if the lesion is cystic or if it is solid and needs to be biopsied. Ultrasonography can be relied upon for the diagnosis of a simple cyst if four criteria are fulfilled: 1) round or oval shape; 2) sharply defined margins; 3) anechogenicity; and 4) posterior acoustic enhancement. Significant experience with ultrasound is necessary to make this diagnosis confidently.

Ultrasound should be used to resolve specific breast abnormalities, especially to differentiate cystic from solid masses, and in certain circumstances, to detect clinically palpable masses not visible mammographically. In some cases, ultrasonography should be used in guiding needle breast biopsies. Ultrasound is not useful for screening asymptomatic women of any age.

Upon palpation, fibroadenomas feel very similar to cysts. They are round, circumscribed, firm and very moveable. They tend to occur in young women from the teens onward, whereas cysts tend to occur somewhat later in life, beginning in the third or fourth decade.

B. Non Dominant Palpable Mass: Vague Thickening or Nodularity

During palpation of the breast, the provider will usually feel nodularity in most patients' breasts. A patient without some nodularity is actually unusual. If the nodularity is not symmetrical, or there is an area of irregularity, then further evaluation is necessary. The next issue is to determine whether there is a mass, density, lump, or other area that stands out or is discrete from the surrounding tissue. If the answer is yes, then further evaluation is necessary for you to know whether that discrete area is cystic or solid.

Any mass detected in a **post-menopausal** woman must be considered suggestive of cancer until proven otherwise, even if the woman is taking hormone replacement therapy. Questionable areas in **post-menopausal** woman, including those post-

Workup of a Palpable Cyst

- If you do not **routinely** perform cyst aspiration, refer patients to a surgeon or breast specialist for this procedure.
- If a lump in a patient's breast is aspirated and there is no residual mass after the fluid is removed, then it can be concluded that the abnormality was a simple cyst.
- If the mass does not disappear completely when aspirated, or if the fluid is grossly bloody, the fluid should be sent for cytological analysis and the patient referred immediately for radiological and surgical consult.
- Aspiration will relieve a painful cyst.
- A patient with an aspirated cyst should be reexamined for recurrence. If a cyst does recur, the patient should be referred for surgical consultation.

menopausal women on estrogen replacement, should be referred to a surgeon for consideration of fine needle aspiration or biopsy. The role of fine needle aspiration in this situation has not been completely established and referral to a surgeon is preferred. For **premenopausal** women, re-examine after four to five weeks, (5-10 days after menstruation starts). If a localized area remains abnormal after 6 weeks and repeated examinations, refer to a surgeon.

It is appropriate to order a diagnostic mammogram for women over age 35 with a palpable mass, if one has not been performed within six months in order to look for synchronous lesions.

C. Non-Palpable Masses Found on Mammography

As the use of mammographic screening increases, more radiographic abnormalities are being detected in apparently healthy women. Although most of these abnormalities turn out not to be due to cancer, all of them cause anxiety. Therefore, each time an abnormality is detected on a screening mammogram it is important that a diagnosis be made as soon as possible with the minimum of anxiety, pain, and inconvenience to the patient. The overall lack of followup of abnormal mammograms in the US is 18 percent. In a large nationwide CDC-funded screening program, incomplete follow-up was 17% for Breast Imaging Reporting and Data Systems (BI-RADS)TM categories 4 & 5 which always require followup. Approximately, 6.5 to 12% of all screening mammograms are reported as abnormal. However, of these, approximately 5% to 10% are caused by cancer.

The objective of the radiologic work-up of a nonpalpable mammographic abnormality is to produce an accurate description of the abnormality and an estimate of the level of suspicion of cancer, based on high-quality diagnostic mammograms. With this information, the decision can then be made whether to follow it up with periodic clinical and mammographic examinations or to carry out a biopsy.

Since 1999, all mammography reports sent by radiologists are required by the Mammography Quality Standards Act (MQSA) to use the BI-RADS lexicon created by the American College of Radiologists. The lexicon was developed because of concern that mammography reports were often ambiguous and the interpretation indecisive. In addition to the five BI-RADS categories, the mammographic report should include a precise description of the abnormal features and an estimate of the level of suspicion of cancer they imply. Description should include size, density, shape and margins. Other features that should be noted include micro-

There are six categories in the reporting lexicon required by the FDA for all mammography reports. Known as BI-RADS, the categories include:

- Category 0: Assessment Incomplete
- Category 1: Negative
- Category 2: Benign Findings, Negative
- Category 3: Probably Benign -- short-term follow-up suggested
- Category 4: Suspicious Abnormality-- biopsy should be considered
- Category 5: Highly Suggestive of Malignancy -- appropriate action (i.e., tissue biopsy) should be taken; these lesions have a high probability of being cancer

calcifications, architectural distortion, abnormal vasculature and asymmetry. The decision by the primary care provider to plan workup is based on the radiologist's recommendation and description in the report of mammographic appearance and the patient's family history, history of breast cancer, and other risk factors.

Once a screening mammogram indicates an abnormality, high-quality diagnostic mammograms are used to better show definition of the extent and location of abnormalities and may clarify the characteristics of poorly defined or indeterminate lesions. Magnification and spot compression views, in which local pressure is used to displace some of the surrounding breast tissue, frequently provide clearer definition of small densities and clarify the structure and extent of larger lesions. Micro-calcifications warrant further evaluation with magnification, which permits better evaluation of their size, density, shape, and number. Some abnormalities, such as clustered micro-calcifications, have a relatively high probability of cancer. However, at the other extreme, well circumscribed masses with smooth margins usually represent benign lesions.

Category 4 or 5: A mammography report with a Category 4 or 5 result should prompt an immediate referral to a surgeon. If additional mammographic evaluation is recommended, this should occur prior to the surgical referral. Referring physicians should be aware that women may have substantial anxiety when they have to return for additional or repeat views. These extra views should be done as soon as possible to reduce anxiety. Staff should be sensitive and supportive when answering any questions the woman may ask.

A decision as to what form of evaluation or biopsy is most appropriate for any given non-palpable lesion that is discovered by mammography or ultrasound should be made by the surgeon in consultation with the radiologist. Mammographic or ultrasound guided fine needle aspiration, stereotactic core needle aspiration or biopsy, large core biopsy or open surgical biopsy after needle localization are the options. The choice of biopsy technique must be guided by the local level of confidence established for each technique and by the need to arrive at a final diagnosis and treatment with a minimum of interventions.

Non-palpable lesions

Options for non-palpable lesions include needle-localization, ultrasound-guided localization and/or core biopsy, and stereotactic core biopsy:

- Needle localization involves inserting a guide wire through the lesion, which is verified through mammography, after which an excisional biopsy is performed. Following excision, specimen radiography is used to confirm lesion excision. Pathological analysis is performed to arrive at a diagnosis.
- Ultrasound can be used as the imaging method by which physicians can either place a guide wire for excisional biopsy or use a core needle to obtain tissue.

- Stereotactic core biopsy is performed using a special mammography apparatus. The breast is compressed between two mammographic plates and the suspicious area is located by an imaging system. A core biopsy needle in an automated spring-loaded biopsy instrument is inserted into the lesion. Multiple biopsies are obtained. A physician with special skills is required to perform this procedure.

Category 3: Probably Benign If the mammogram reading is “probably benign – short-term follow-up”, the patient may be followed with sequential imaging studies, the interval and type to be determined by the radiologist. This needs to be clearly communicated to the patient so that she understands the low but measurable risk for the delayed diagnosis of breast cancer. If she is unwilling to accept this, a referral to a surgeon or breast specialist is indicated.

Periodic follow-up is now a widely accepted strategy for women with low-risk abnormalities that are likely benign. The timing of follow-up is based on estimates of tumor doubling time. Most cancers will show a change within 1 year, although very rarely some may appear to remain stable for more than 2 years. Mammographic examination is **usually carried out at 6 month intervals for 2 years** and then the woman is returned to a normal screening schedule. Should a progressive change occur, however, intervention -- frequently in the form of a biopsy -- should be recommended.

The major limitation of periodic mammographic followup every six months for a two-year period is the inability to provide absolute assurance that the lesion in question is benign at the outset. This could be a missed opportunity to detect a small, nonpalpable breast cancer at a time when a successful clinical outcome is the most likely. Of course there is also the possibility the patient will not return for the appropriate follow-up. Concern also exists about the potential for litigation if there is delay in the diagnosis.

The ultimate decision regarding whether to follow up or to perform biopsy on a lesion that has low probability of being malignant must be made only after full discussion with the patient. Some patients may feel strongly that any risk is too high and will prefer to undergo a biopsy. If the follow-up option is chosen, the patient should be made fully aware that the lesion is being kept under observation because it may not be benign. When choosing any follow-up procedures, both the experience of the diagnostician and the availability of the technology in question must be considered.

Category 0: Assessment Incomplete: In a mammography screening facility, an indeterminate or incomplete assessment may be reported. Additional mammographic views (e.g., spot compression, magnification, ultrasound etc.) are then performed before a final opinion can be rendered. An incomplete assessment always requires attention by the primary care physician to ensure the recommended tests are completed. This followup should occur as soon as possible, preferably within one week -- both for patient’s peace of mind and to decrease loss to follow-up.

Non- Palpable Cysts

Non-palpable cysts detected by mammography and confirmed by ultrasound as simple cysts (i.e., without debris or ragged walls) need not be aspirated except for pain relief. A non-palpable presumed cyst found to have suspicious characteristics by ultrasound should be subjected to directed biopsy or aspirated with sonographic guidance. The primary role of ultrasound is to distinguish the nature of a non-palpable lesion (cystic vs. solid) found on the mammogram, differentiating simple cysts from complex cysts or solid masses. Whenever doubt exists, aspiration under ultrasonographic guidance (or in office) may both diagnose and treat the abnormality.

D. Other Physical Findings and Special Considerations

Nipple Discharge or Skin Changes/Nipple Retraction

Nipple discharge is an uncommon complaint constituting only about 3 – 7% of all referrals to breast clinics. In one clinic, only 14 of 259 referrals to the breast clinic proved to be cancer. The nature of the nipple discharge should be defined by a careful history. A patient with a spontaneous, unilateral clear, serous or bloody discharge should be referred to a surgeon. Cytologic analysis of nipple discharge is rarely useful and should not be performed.

Bilateral multiple duct discharge is almost always benign. Medical work-up of galactorrhea may be appropriate for profuse, persistent milky discharge, but pituitary adenomas are rare.

Unilateral breast skin changes or nipple retraction and patients with any skin breakdown on the nipple-areola complex should be referred to a surgeon. Biopsy of the nipple may be indicated to differentiate eczema of the nipple from Paget's disease (cancer) of the nipple. The external skin appearance of Paget's disease of the nipple will often heal with topical cortisone; therefore, steroids should be used only after biopsy is performed to rule out a diagnosis of Paget's disease. A patient with skin changes in or near the nipple area that has not been resolved with conservative treatment (e.g. antibiotics, observation) should be referred to a breast specialist.

Characteristics of pathologic nipple discharge

- Spontaneous
- Unilateral
- Single duct
- Intermittent
- Persistent

Breast Pain

A thorough medical history and physical exam are essential to determine the cause of breast pain. Noncyclic pain warrants further evaluation and is usually first investigated with a mammogram (except in the case of a woman younger than 30) unless she has a mass. In this case, a trial of nonnarcotic analgesics such as ibuprofen, acetaminophen, or aspirin and the use of a brassiere that provides good support are suggested. The elimination of caffeine, chocolate, or salt from the diet has no scientifically proven benefit, although some women may experience relief of pain with caffeine and sodium restriction. Refer the patient to a surgeon if there is persistent localized pain that is not responsive to conservative measures. If the physical examination and mammograms are negative, the most likely diagnosis is benign fibroglandular change, previously called fibrocystic disease. This pain is cyclic, usually beginning soon after ovulation and intensifying until menstruation begins, then disappearing rapidly. Refer to a breast specialist if there is persistence of localized pain or no response to conservative measures.

Lobular Carcinoma-in-Situ

While this document does not address treatment, a diagnosis of lobular Carcinoma-in-Situ (LCIS) falls into the mid-ground between diagnosis and treatment. The preferred management approach to LCIS is observation because the risk of developing invasive carcinoma is low (approximately 21% over 15 years). The risk of an invasive breast cancer following a diagnosis of LCIS in one breast is equal in both breasts.

Follow-up of patients with LCIS includes the performance of physical exams every 6 to 12 months for 5 years and then every year; also, in those being managed with observation, yearly mammography is recommended.

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PART 6: RISK MANAGEMENT

A. Principles of Risk Management

The most common reasons cited in the literature for delay in diagnosis due to physician error include:

1. Physical findings failed to impress the examiner;
2. Misinterpretation that a normal mammogram in the presence of a physical finding was an indication of no breast problem;
3. Failure to perform repeat exams when a mass was found that was not clinically suspicious; and
4. Failure to refer in a timely manner.

The following are some fundamental risk management principles:

- Pursue every breast complaint to resolution.
- Establish an office tracking system to trigger reminders about the need for breast cancer screening or short-term follow-up.
- Track results of all ordered mammograms and follow-up studies ordered. Ensure that reports of all studies are seen by a health care provider.
- Referring premenopausal women for any breast mass that persists through a menstrual cycle.
- Consider any asymmetrical breast finding, whether an overt mass or a subtle thickening, as a cause for concern.
- Refer every woman with a questionable breast finding on physical examination for consultation, regardless of the mammogram report.
- Carefully document patient history, physical exam findings, clinical impression, and follow-up plans.

Helpful Hints

- Develop or follow a specific algorithm (i.e., medical care path) for all patients who present with breast lumps. Specify when biopsy or aspiration is indicated.
- Describe all breast lesions clearly and accurately using a diagram or drawing in the medical record
- Reach a definitive diagnosis about all breast complaints within a timely period or refer to a specialist
- Establish an office system to assure that a referral visit was accomplished and recommendations followed.

- Avoid discounting patient concerns and giving misguided reassurances before reaching a definitive diagnosis.
- Ensure that the medical record contains documented evidence of dates and time sequence of events, as well as clinical findings and test results.
- Plan a follow-up evaluation of a breast lump with the same physician.
- Use extreme caution when continuing to treat persistent, unexplained symptoms.

B. Documentation and Communication

This section summarizes the responsibilities for documentation and communication for the primary care provider, mammography facility, and breast specialist. The Breast Health History Form and the Breast Evaluation & Follow-up Forms found in earlier sections of this protocol are intended to assist with documentation and communication.

Primary Care Provider

The referring provider is responsible for the follow-up, monitoring, and tracking of women whose results are abnormal, including those for whom a biopsy is recommended. The primary responsibility for communicating a recommendation for short-interval follow-up, diagnostic mammography, or adjunctive diagnostic procedures rests with the referring health care provider.

The referring health care provider should establish with the mammography facility protocols to ensure that the communication loop is closed and that the roles of the referring health care provider and the facility in communicating results and tracking compliance are understood by all parties.

Recommendations to Improve Documentation and Communication

This section summarizes the responsibilities for documentation and communication for the primary care provider. The Breast Health History Form and the Breast Evaluation Form found in this guide are intended to assist with documentation and communication.

- Utilize a medical record flow sheet to document referrals for mammography and performance of clinical breast exams and other preventive services. Keep the mammography report and related data, including all follow-up records and communications, clearly documented in the record.
- Establish an in-office system to ensure prompt reading of mammography reports when they arrive so that appropriate action is taken.
- As you may be identified as the primary care physician of a woman who self-refers for mammography (permitted in a number of Maine mammography facilities), you may receive mammogram reports for patients you have not seen

for a considerable period of time or that you did not order. **You are responsible for follow-up of abnormal results.**

- Results should be communicated to women in a sensitive, supportive, and appropriate manner.
- Communication delays and oversights can lead to unnecessary anxiety for women and could have significant consequences for individual patients. All reasonable steps should be taken to reduce delays. Timely communication is necessary whether results are normal or abnormal to avoid the possibility that patients “fall through the cracks.”
- Prompt response to requests from mammography facilities for outcome information will help facilities to correlate the results of the mammograms they perform and interpret with biopsy results. Mammography facilities should distribute to referring providers a summary of their cancer diagnoses and audit results at least annually.
- Establish an office protocol for contacting patients who do not adhere to follow-up recommendations. A minimum of two telephone contacts should be made followed by a registered letter outlining the possible diagnosis and recommended course of action.

Basic Communication Tips

- Explain why the patient may be referred to another site or provider
- Inform her how and when she should expect to receive her test results. Also, since many women think a positive mammogram means that they have breast cancer, assure them that a cancer diagnosis can be made only by biopsy and that not all positive mammograms turn out to be cancer. Whenever possible, try to schedule the biopsy promptly to reduce the period of anxiety.
- Discuss some of the benign reasons why a patient may be asked to have another mammogram (e.g., to magnify a particular area or “smooth out” a skin fold to rule out an abnormality).
- Identify a significant support person in the patient’s life and encourage her to bring that person to any follow-up visit.
- At the time of referral, the results of an abnormal clinical breast exam should be communicated to the mammography facility in writing. (The information may be sent with the patient; via a “secure” fax, or mailed, whichever is most reliable and expedient.) Specify the location of any palpable abnormalities as to breast (left or right) and quadrant (upper outer, upper inner, lower outer, and lower inner). Also, provide information about whether any previous breast surgeries or recent

needle aspirations have been performed and, if so, their exact location. (A sample Breast Evaluation Form appears on page #13)

- Make the referral appointment for the woman and schedule a follow-up primary care visit after the consultation.
- Assure that concerns about payment for services do not prevent adherence to recommendations.

IN YOUR PRACTICE

- *Do you have procedures to ensure good communications between doctors and nurses about follow-up care?*
- *Do you have written protocols for referrals and follow-up services?*
- *Do you send postcards or other reminders to patients when they are due for follow-up?*
- *Do you track whether the provider has received all test results?*
- *Are all tests reports reviewed by the provider and a determination made for follow-up?*
- *Are normal and abnormal results communicated appropriately to the patient and any responsible clinician?*
- *Do you track whether all screening test results have been received by the provider?*
- *Do you have a special process for handling abnormal results?*
- *How are outside referrals handled to assure that followup occurs and information is received and handled appropriately?*
- *Do you have a procedure to track the keeping of referral appointments?*
- *Do you have a system to ensure that all tests reports and referral communications are signed prior to filing in patient record?*

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