

Early Diagnosis of Breast Abnormalities

Delays in the diagnosis of breast abnormalities is a growing cause of concern. These materials, developed by the Task Force on Early Diagnosis of Breast Cancer, were developed for three reasons:

1. To improve the quality of care of women with breast abnormalities
2. To promote a consistent approach among various specialties, and
3. To reduce malpractice lawsuits for failure-to-diagnose.

Based on reviews of malpractice claims, we estimate that use of this protocol will prevent three out of four lawsuits for failure-to-diagnose breast cancer.

This packet, developed for use by primary care physicians, includes the following materials:

- Diagnostic Protocol: Early Diagnosis of Breast Abnormalities
- Notes
- Patient Handout: Understanding Breast Lumps and Other Breast Changes
- Breast Care Progress Note
- Improving Follow-Up of Patients with Breast Abnormalities
- Avoiding Breast Cancer Lawsuits: Six Reasons Why Doctors Get Sued

This protocol is intended to be a guideline and should not be considered a standard of care. We encourage you to adapt the protocol and accompanying materials according to your clinical judgment and organizational policies. When you do adapt the protocol, document your reasoning in the chart. These materials are not proprietary, and may be reproduced and used by any individual or organization, provided proper credit is given.

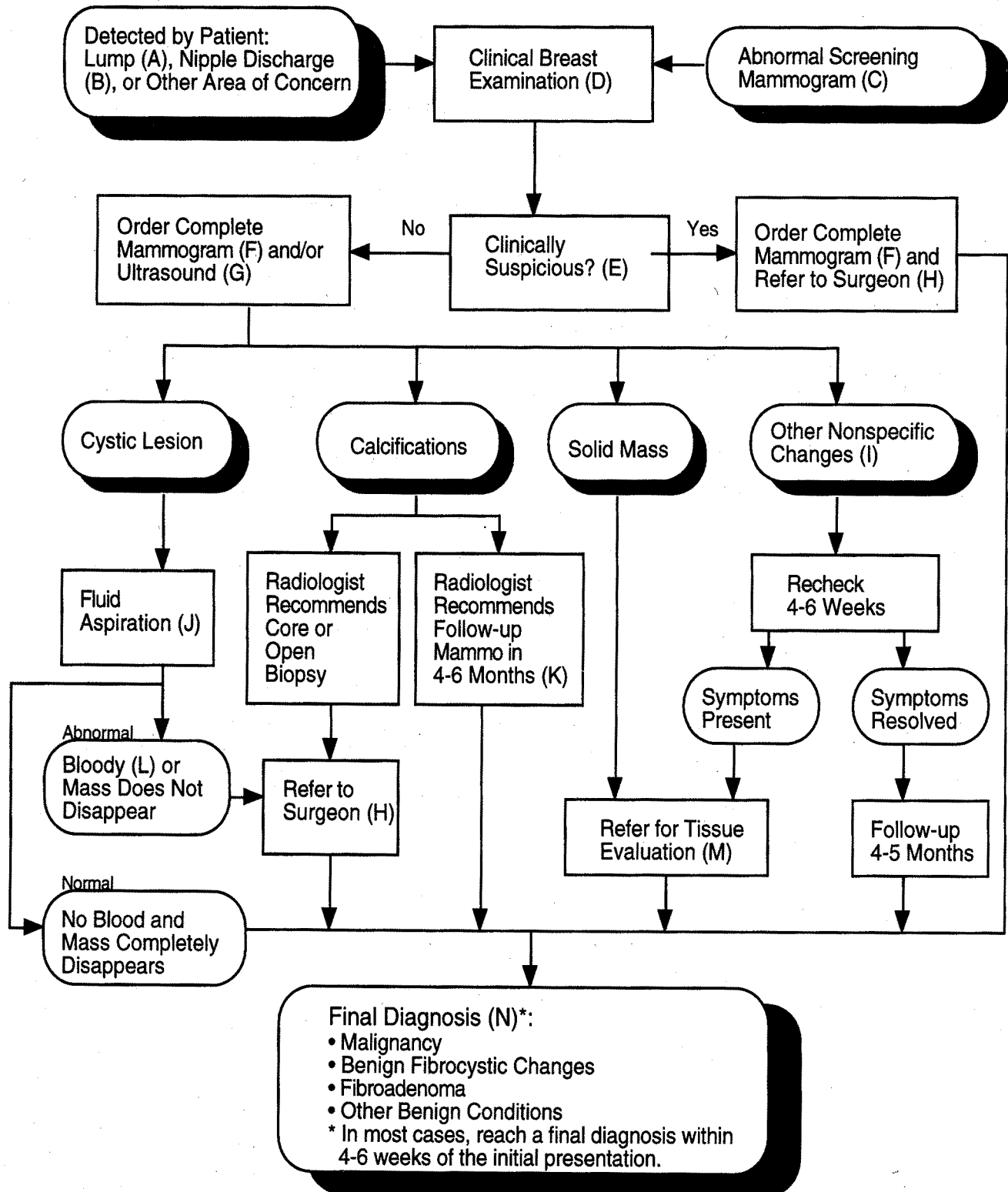
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This project is supported by educational grants from Frontier Healthcare, Bedford Hills, NY, and FPIC, Jacksonville, FL. If you have further questions, please contact Edward E. Bartlett, PhD, Coordinator, Early Diagnosis Steering Committee, P.O. Box 1404, Rockville, MD 20849. Telephone 301-670-1964, Internet eba@intr.net.



Early Diagnosis of Breast Abnormalities

Letters in parentheses refer to Notes



Notes

A. Lump or Other Areas of Concern

70% of breast masses are discovered by the patient. Other areas of concern include nodularity, thickening, pain, asymmetry, or changes in skin or breast contour. It is important that the physician acknowledge the emotional content of the lump.

A lump or other changes discovered by the woman should be considered an *urgent* medical problem, even with a negative clinical exam, with prompt referral for radiologic evaluation.

B. Nipple Discharge

If the patient presents with a nipple discharge and no mass, perform a Hemocult test on the discharge (if discharge is non-bloody). If heme positive, obtain comprehensive mammography and consultation. If heme negative, order prolactin levels and consider for consultation.

C. Screening Mammogram

A screening mammogram consists of two views, cranial caudal (CC) and medial-lateral oblique (MLO). Frequency of screening mammography is recommended, consistent with the ACS guidelines: 40+ years--every year.

D. Clinical Breast Exam

Use a Health Maintenance Flowsheet to assure a clinical breast exam is performed annually. Exam should be done after menses. Twenty percent of breast masses are discovered by the physician.

E. Clinically Suspicious

Clinically suspicious changes include skin changes; fixed, firm, irregular, and/or palpable nodes.

F. Complete Mammography

Complete mammography is useful to detect breast lesions but usually cannot establish a diagnosis. Complete mammography (sometimes misleadingly referred to as "diagnostic" mammography) includes spot views and other views as needed.

Mammography has a 10-15% false negative rate, especially in a dense breast. When a palpable mass is present, its value is to visualize the mass and to exclude occult disease, especially in the opposite breast.

G. Ultrasound

Ultrasound is indicated when the woman is under 30 years of age.

H. Surgical Referral

At this point, responsibility for evaluating and treating the breast abnormality transfers to the surgeon, who should keep the referring physician informed of the patient's progress.

The surgeon should arrange for follow-up mammograms and assure the patient is advised of study results.

The primary care physician should maintain periodic contact with the patient, and may continue to treat the patient's other medical problems. The nature of these responsibilities should be clarified with all parties involved.

I. Other Nonspecific Changes

These include persistent thickening, tenderness, and other changes.

J. Fluid Aspiration

Aspiration is accomplished with a regular syringe. The fluid should be analyzed for occult blood. If no blood, the fluid can be discarded. If bloody, cytological analysis is indicated. Non-symptomatic cysts do not need to be aspirated.

K. Follow-up Mammography

If unchanged at 4-6 months, follow radiologist's recommendations for follow-up.

L. Blood in Fluid

The presence of blood in aspirated fluid or the persistence of a mass after aspiration raise the small possibility of malignancy. Bloody fluid should be examined cytologically.

M. Tissue Evaluation

Tissue evaluation includes fine needle aspiration or biopsy.

N. Final Diagnosis

A diagnosis is confirmed when the clinical evaluation, mammographic studies, and pathological studies all agree. The diagnostic process is completed when:

- 1) FNA cytology or biopsy has established the diagnosis of fibroadenoma, fibrocystic changes, or other benign condition, or
- 2) FNA cytology or biopsy has established the presence of malignancy, or
- 3) Both patient and physician agree the lump has completely disappeared.

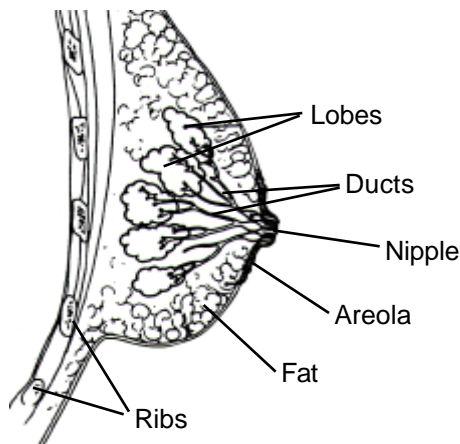
If the diagnosis is initially indeterminate, the coordinating physician should see the patient for up to two additional visits at 2-3 month intervals, and order repeat studies as needed. *In most cases, though, a definitive diagnosis should be reached within 4-6 weeks of the initial presentation.*

Understanding Breast Lumps and Other Breast Changes

Breast changes are a common event. They include those that normally occur during the menstrual cycle and pregnancy, as well as with aging. Most breast lumps—8 out of 10—are NOT cancer, but only a doctor can tell whether or not a condition is malignant (cancer) or benign (not cancer). This handout explains how your doctor will evaluate your breast lump or other breast changes.

A look inside the breast

The breast consists of glandular tissue, fatty tissue, and fibrous tissue. Each breast has 15-20 sections, called lobes, each with many smaller lobules. The lobules end in dozens of tiny bulbs that can produce milk. The drawing shows how the lobes are linked together by a series of thin tubes called ducts:



What could be causing the lump or other changes?

Occasionally the breast feels lumpy, but this is normal. Many women experience swelling, tenderness, and pain before and sometimes during their periods. Every woman should become familiar with how her breast feels by doing breast self-examination (BSE).

The following are some of the conditions the doctor will be considering:

- Fibrocystic Changes—General breast lumpiness, which is benign.
- Cysts—Fluid-filled sacs. They occur most often in women 35-50 years of age. The cysts often enlarge and become tender just before a woman's menstrual period. Cysts are usually handled by observation or by withdrawing fluid with a small needle.
- Fibroadenomas—Benign masses of tissue that do not contain fluid.
- Cancer—When cells grow without control or order.

Breast pain—Is it serious?

Breast pain is very common in premenopausal women. The pain can be shooting to the nipple, burning, itching, or aching. One breast may hurt more than the other. Usually it starts two weeks after menstruation and gets worse until the beginning of your period. It gets better for two weeks, then the cycle starts over. Breast pain is more common in women in their 30's and 40's, and gets better after menopause. If you have pain or soreness with a lump or redness, you should call your doctor immediately.

How does the doctor evaluate the lump or other breast changes?

Your physician will evaluate your breast changes using a combination of a breast examination, mammography, ultrasound, and/or biopsy. Although no one of these procedures is 100% accurate, when combined they will usually diagnose your condition correctly. Therefore you, your personal doctor, radiologist, and surgeon need to work together as a team.

What is mammography?

A mammogram uses a weak X-ray to take pictures of the breast. The breast is compressed between two plastic plates and two X-ray pictures are made of each breast. The mammogram is read by a radiologist, who will give you and your physician the results. A mammogram is 85-90 percent accurate. Therefore, 10-15 percent of cancers cannot be seen by mammogram.

There are two types of mammograms:

- 1) Screening for women without a breast problem—every woman over the age of 40 should have a screening mammogram on a regular basis.
- 2) A diagnostic or complete mammogram for women with a lump or other breast concern.

Some women worry about the effects of radiation from a mammogram. Nowadays, the amount of radiation received is less for a mammogram than a chest X-ray. A mammogram can cause some discomfort, due to compression of the breasts. If a woman has tender breasts, it is best to have the mammogram done after menstruation, when the breasts are less tender.

What is ultrasound?

Ultrasound is used for women under 30 years old, or as a complement to mammography. It is used if a mammogram shows a change that needs to be diagnosed as a real mass or fibrosis. If it is a real mass, ultrasound can distinguish a benign cyst from a solid mass that may need to be biopsied. Also, ultrasound is used when the mammogram is normal but an abnormality is detected through a physical examination.

What is a biopsy?

Often the best way to find out the cause of your condition is to have a small piece of tissue removed from the breast and sent to the laboratory to be examined under a microscope. There are four types of biopsies:

1. Fine needle aspiration—A thin needle is inserted into the suspect tissue and some cells are removed.
2. Core biopsy—A larger needle removes a small piece of tissue.
3. Incisional biopsy—A surgeon removes only a slice or wedge of the suspicious area.
4. Excisional biopsy—The surgeon removes the entire lump and some of the surrounding tissue.

A final word...

Breast lumps and changes can be frightening. Remember that most lumps and changes are normal, and often disappear on their own. Every lump that does not go away on its own or is not filled with fluid needs to be evaluated further. Some lumps and changes are more difficult to diagnose, and require several tests. It may take several weeks to reach a final diagnosis. Waiting for the results causes anxiety, but is the best way to avoid unnecessary surgery.

Alert the doctor to changes you notice in your breasts, and be sure to follow the doctor's recommendations for follow-up procedures. You should be advised of all test results, and feel free to ask any questions you may have.

Breast Care Progress Note

Patient Name: _____

Initial Visit:

cc: _____

Date: _____

First detected by:

___ Patient

___ Physician

___ Mammogram

Date first detected: _____

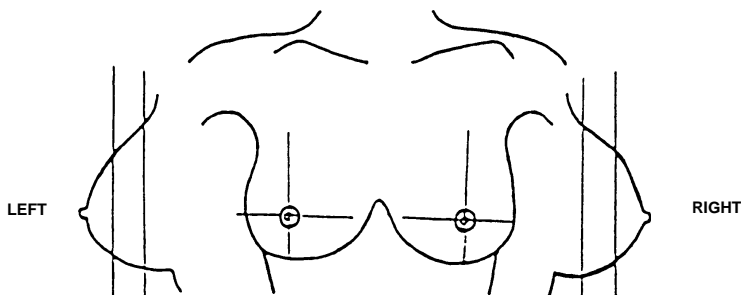
History:

Physical Examination:

Nodes: _____

Breast: _____

Nipples/Skin: _____



Clinically suspicious?

___ Yes ___ No

Impression: _____

Plan: ___ Mammography

___ Ultrasound

___ Refer to surgeon

___ Routine follow-up

___ Other: _____

MD Initials

Follow-Up (as indicated):

Ultrasound/Mammography: Date: _____

___ Normal ___ Abnormal ___ Questionable

___ Cystic ___ Solid ___ Calcifications _____

Additional diagnostic studies (if needed): Date: _____

___ Normal

___ Abnormal: _____

Referral to surgeon on (date): _____

Final Dx: _____ Date: _____

MD Initials

Improving Follow-Up of Patients with Breast Abnormalities

In many cases of diagnostic delays, the patient did not follow the doctor's advice for follow-up evaluations. These suggestions can help avoid losing the patient to follow-up:

- Explain to the patient about the concept of shared responsibility. You and the patient need to work together as a team.
- Always set an appointment for the next visit before the patient leaves the office. Even if the patient doesn't know her schedule, set a tentative date, then call later to confirm.
- When you send the patient for a consultation or diagnostic test, have your receptionist call to schedule the appointment. Then schedule your next visit with the patient to fall a few days later, when the results from the evaluation will be in hand.
- Are you tracking whether the patient is receiving periodic screening mammograms? If you don't use a flowsheet, you will forget to remind the patient.
- If the patient breaks an appointment, consider the "two phone calls and a letter" rule. Make two phone calls to reschedule, then a letter if necessary. Document patient non-compliance in the chart. If the patient is a chronic appointment-breaker, consider discharging the patient from your practice.

These three forms were developed by an Ohio physician to improve follow-up on patients with breast abnormalities. Consider adapting these forms to your practice:

R_x FOR _____ ACCT # _____
Diagnosis: Cystic Mastitis
DONE BY:
Jan. July 1995 <input type="checkbox"/> MAMMOGRAM: <input type="checkbox"/>
Feb. Aug. 1996 Screening Complete
Mar. Sept. 1997
April Oct. 1998 <input type="checkbox"/> COMPLETE MAMMOGRAM:
May Nov. 1999 <input type="checkbox"/> Additional Views Requested
June Dec. 2000 <input type="checkbox"/> Breast Ultrasound, if Cystic Attempt, Aspiration
Please bathe with Ivory soap. Do not use deodorant, talcum powder or perfume

Form No. 1: Mammography Request Form

Dear _____
Please call our office regarding your recent: ____ Lab Work ____ Mammogram ____ Pap Test
I tried to contact you by telephone, but was unable to reach you. Thank you for your prompt attention to this important matter.
Sincerely,

Form No. 2: If unable to reach patient by phone

Dear _____
<input type="checkbox"/> I have NOT received your mammogram report.
<input type="checkbox"/> I have not received your additional views of ultrasound mammogram report. Please have it scheduled.
<input type="checkbox"/> Please schedule your mammogram review appointment with my office TODAY! (Appt. to be within 30 days.)

Form No. 3: If patient misses appointment

Avoiding Breast Cancer Lawsuits: Six Reasons Why Doctors Get Sued

Failure-to-diagnose breast cancer is the number one cause of lawsuits against primary care physicians. Follow these pointers to avoid becoming a statistic:

Reason #1: Patient Complaints are Discounted

Many delays arise from discounting the patient's concerns. The patient may complain frequently of breast symptoms or may be histrionic in describing her problems. In many cases, the woman is under 50 years of age and does not fit the classical presentation of breast cancer. Recommendation: *Take any new breast symptom seriously, regard it as an urgent medical problem, and aggressively evaluate the complaint.*

Reason #2: Unremarkable Physical Examination

One of the most common reasons for diagnostic delays is an unremarkable physical examination, leading the physician to prematurely call off the diagnostic investigation. Recommendation: *Clinical breast examination has a high rate of false negatives. Further diagnostic evaluation--usually a mammogram--is in order.*

Reason #3: Negative or Ambiguous Mammogram

Mammography has come to be viewed as the "gold standard." Unfortunately, mammography carries a false negative rate of 10-15%. Recommendation: *Refer patients with persistent, unexplained breast changes for tissue evaluation sooner and more frequently, even if the mammogram is "normal."*

Reason #4: Denial Induced by False Reassurance

The patient presents with non-specific thickening or tenderness. The physical exam and mammogram are negative, so a diagnosis of "fibrocystic breast disease" is reached. The physician counsels: "I'm sure it's nothing. But if it gets worse, give me a call." As the cancer spreads, the patient remains in denial, induced by the physician's well-intentioned but misguided reassurance. Recommendation: *Do not offer premature, false reassurance.*

Reason #5: No Tracking System to Assure Follow-Up

The diagnostic evaluation often requires a coordinated effort among the patient, primary care physician, radiologist, and surgeon. In many cases, the patient misses an appointment or "falls through the cracks." Recommendation: Institute "tickler" or tracking procedures that assure effective follow-up.

Reason #6: Neglecting Breast Screening Procedures

With the growing time pressures of managed care, physicians often focus their attention on the patient's chief complaint. If the patient's chief complaint doesn't relate to the breasts, preventive screening measures, such as breast exam and mammography, are put off--until it's too late. Recommendation: Use a health maintenance flowsheet to record and track breast screening activities.

The Bottom Line:

1. If an unexplained breast symptom persists for more than four weeks, refer the woman for a tissue evaluation.
2. A definitive diagnosis generally should be reached within 4-6 weeks of the initial presentation.