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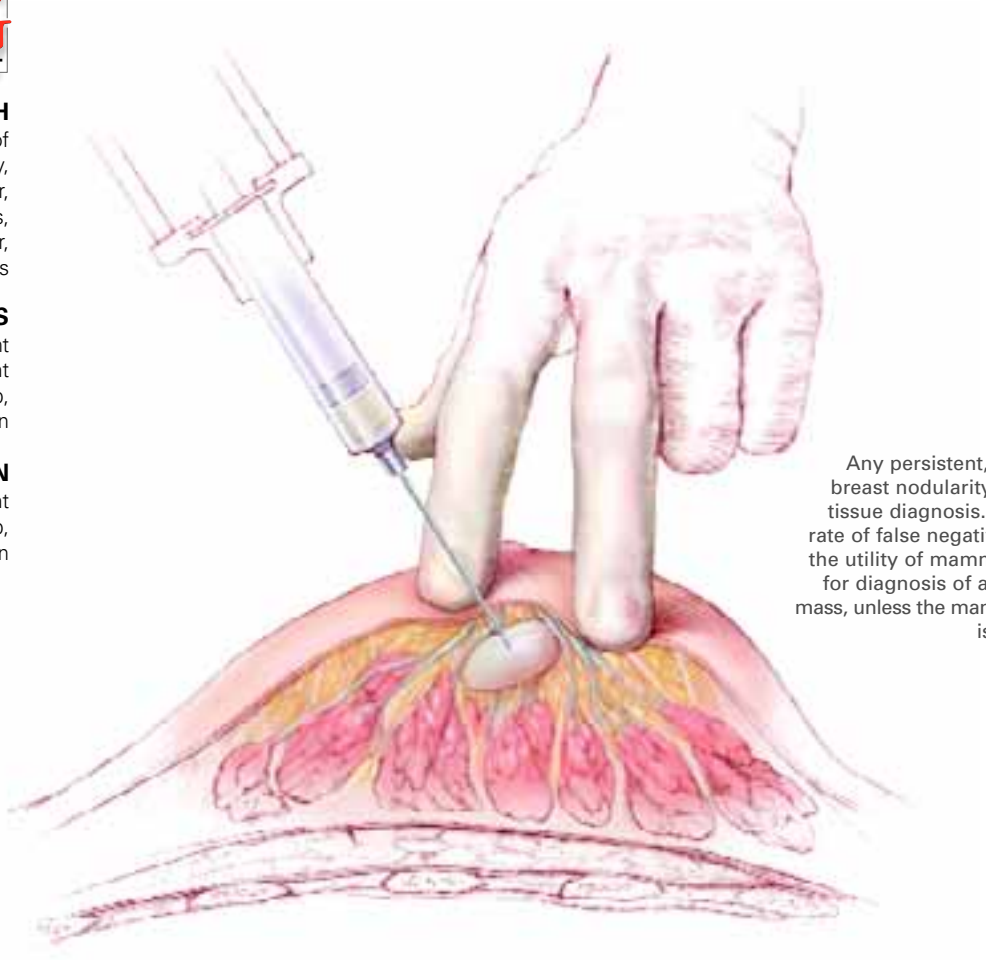


Any persistent, palpable breast nodularity requires tissue diagnosis. The high rate of false negatives limits the utility of mammography for diagnosis of a palpable mass, unless the mammogram is positive.

IMAGE: KIMBERLY MARTENS

IN THIS ARTICLE

4 CASES OF FAULTY FOLLOW-UP

Cutting the legal risk of breast cancer screening

Inadequate follow-up is usually at the root of lawsuits that allege missed or late diagnosis

Breast cancer is the number 1 most frequently misdiagnosed condition in malpractice claims, and failure to perform adequate and timely follow-up is often at the root of these cases.

This article considers lessons to be learned from 4 malpractice cases involving allegations of inadequate follow-up and misdiagnosis of breast cancer. We focus on specific red flags, and a "systems approach" to adequate follow-up of breast screening findings and patient complaints. We focus on these questions:

- Which are the most important factors in risk management related to breast cancer?
- What can you do to reduce your risk?

We analyzed 132 breast cancer cases closed by ProMutual Group of Boston, the total number of breast cancer cases closed by the company between January 1999 and December 2004. These cases closed with an aggregate indemnity payment of over $47 million, including 12 cases with payments of $1 million or more.

Defendant lineup

The 132 cases involved 279 defendants, including:

- 129 radiologists (46%),
- 78 women's health professionals (ObGyns, internists, and family physicians; 28%),
- 43 surgeons (15%),
- 2 pathologists (1%), and
- 1 physician each from several different specialties.

Although the number of defendants included in this 6-year study differs only slightly from the number identified in an earlier 12-year study,[1] the percentages of cases attributable to women's health practitioners (28%) and radiologists (46%) have reversed. In the older study, women's health care providers were cited as defendants in 45% of cases and radiologists in 24%. The other percentages have remained constant.

Red flag high-risk patients, screen early and in-depth

Diagnosing breast cancer in its earliest stages is the most effective way to reduce risk of litigation, as well as morbidity and mortality. The first step is to identify the patients at high risk and take care to perform earlier, and perhaps more in-depth, screening for these women.

Kern's triad of errors portends litigation

Kern[2] identified a "triad of errors" to beware:

- young age
- self-discovered breast mass
- negative mammogram.

When all 3 of these factors are present, litigation is especially likely.

Analyses of these breast cancer cases[1,3] reveals that patients with an eventual breast cancer diagnosis of stage II or higher are more likely to file claims (though claims are not limited to this group).

LUCY'S CLAIM

35 office visits and no screening

Lucy, age 66, was seen 35 times by her physician and other health care providers over an 8-year period. Although she had a positive family history of breast cancer, no clinical breast examination was conducted at any of the visits. Ultimately, a mammogram was performed and found to be suspicious for cancer. A biopsy was positive. One year later, she had widespread metastases and filed a malpractice claim. Defense experts faulted the physician for "failing to undertake any preventive care."

The case closed with an indemnity payment in the $500,000 range.

Completely omitting breast cancer screening invites a lawsuit, but avoiding litigation is not as simple as performing regular screening.

You must be prepared to question negative test results when the clinical examination is positive, to listen to the patient, and to follow through *to diagnosis* each positive clinical finding and every complaint that the patient brings up.

Inadequate follow-up: Many and varied

FIONA'S CLAIM

Negative aspirate and palpable mass

Fiona, 33, presented to her ObGyn with a painful breast mass of 3 months' duration. The ObGyn referred her to a surgeon, who performed a fine-needle aspiration. Cytology revealed neither cells nor fluid, and the surgeon diagnosed "residual fibrocystic changes." Eighteen months later Fiona was diagnosed with metastases to the liver. Defense experts faulted the ObGyn for not following up on the negative fine-needle aspiration: "When a needle aspirate is negative or does not reveal fluid and a mass is palpated, the mass is cancer until proven otherwise."

This case closed with an indemnity payment of roughly $500,000.

FAST TRACK

3 red flags

- young woman
- self-discovered mass
- negative mammogram

FAST TRACK

#1 reason for claims of misdiagnosis: "Physical findings failed to impress the physician"

Failure to perform adequate and timely follow-up lies at the root of many breast cancer cases, according to successive studies by the risk management department of ProMutual Group. In some instances, a missed screening or diagnostic test was not rescheduled; in others, a mammogram or slide was misread or the wrong breast mass was excised.

In some lawsuits, the issue was the physician's assumption of benign disease before cancer was ruled out.

Reality: Patients do detect malignancies by self-exam

Breast cancer can be difficult to diagnose in its earliest stages. Correct diagnosis may be preceded by multiple complementary examinations, the first of which is likely to be the patient's breast self-examination. Although self-examination has been derided in some professional circles of late, many physicians are alerted to the presence of a breast mass only after a patient reports finding a "lump."

Each such mass requires clinical investigation, starting with a breast exam to evaluate symmetry, contour, texture, nodularity, the mass itself, tenderness, and any nipple discharge.

Mammography is imperfect

Although mammography is the most widely used screening tool, its reliability is limited, particularly in young women, whose dense, fibroglandular tissue can obscure the diagnosis. The number of false-negative reports may make mammography a questionable diagnostic tool for symptomatic women—unless the results are positive.

No "best" technology

Ultrasound yields information about variations in tissue sound transmission, while cytology reveals the microscopic appearance of the cells and other tissue components.

Each assessment tool has its place and limitations, and these vary from patient to patient.

Lawsuit is likely if screening ends too soon

OLIVIA'S CLAIM

Negative mammogram, palpable mass

Olivia was 31 when she reported finding a mass in her breast. Her ObGyn examined her and noted "dense fibroglandular breast tissue with specific nodularity." A diagnostic mammogram followed and was negative. When the physician observed no changes at a visit 2 months later, Olivia was told she need not return until her next annual examination. When she did, she was diagnosed with infiltrating ductal carcinoma.

After reviewing the case, defense experts noted, "It is common to find negative mammograms and yet have palpable masses that require either ultrasound or core biopsy for diagnosis. This patient had specific complaints at numerous intervals in the course of her clinical history. The physician's inaction may have [been responsible for the] change in her clinical course."

Olivia's case closed with an indemnity payment of just under $1 million.

In the absence of comprehensive follow-up, a malpractice suit alleging "failure to diagnose breast cancer" is likely, as in Olivia's case.

Misdiagnosis is another common cause of litigation. According to surveys conducted by the Physician Insurers Association of America (PIAA) in 1990 and 1995,[4,5] breast cancer is the number 1 most frequently misdiagnosed condition in malpractice claims. The most common reason given by expert reviewers in the PIAA study: "Physical findings failed to impress the physician." Consider this example:

JACQUELINE'S CLAIM

Cancer or galactocele?

Jacqueline, 33, was told by her ObGyn that a breast mass discovered while she was in labor was a "clogged milk duct." The medical record was not annotated. When the same mass was palpated postpartum, Jacqueline was told it was

a sebaceous cyst. Again, the medical record failed to reflect the findings. One year later, Jacqueline changed physicians and underwent fine-needle aspiration, which confirmed malignancy.

Defense experts faulted the physician for his poor recordkeeping and failure to order a mammogram, ultrasound, or any follow-up despite the continued concerns of the patient.

This case closed with an indemnity payment in the $1 million range.

"Systems approach" to cutting risk of lawsuits

The cases of Lucy, Fiona, Olivia, and Jacqueline represent only some of the issues that give rise to malpractice claims. Since breast care is fragmented across medical specialties, a systematic approach is encouraged.

Systems form the basis of good risk management. The ProMutual Group advocates that every medical practice—whether office- or hospital-based—have a comprehensive risk management program that incorporates some or all of the following suggestions.

Annual exam not always enough

Even more frequent screening may be necessary if the patient has a specific breast complaint.

Every practice should have guidelines for these exams, including instructions on identifying women at risk because of personal or family history (**ALGORITHM, PAGE 58**).

Ultrasound, MRI for young women

Younger, otherwise healthy women with unimpressive findings such as nodularities, nipple discharge, or tenderness deserve extra attention. The physician may want to consider additional diagnostic tests such as ultrasound or MRI for this group.

Never disregard a complaint

If a woman complains of discomfort or a self-detected mass, immediate evaluation is

4 essentials of good breast care

1. CLINICAL BREAST EXAM

- Perform annually, at minimum
- Develop and follow guidelines
- Obtain medical history and identify high-risk patients
- Ask the patient if she has any breast complaints
- Pay special attention to any patient-detected abnormality
- Ask patient if another clinician is currently providing breast care
- Follow up previous complaints in both routine and episodic visits
- Immediately evaluate gravidas with breast complaints
- Follow to resolution any patient with a breast complaint

2. SCREENING MAMMOGRAM

- Develop and follow screening guidelines
- Consider screening at-risk women earlier than others
- Compare current mammogram with previous films
- Beware of false negatives

3. DIAGNOSTIC MAMMOGRAM (when abnormalities are present)

- Have patient identify any lump or abnormality
- Assume cancer until it is ruled out
- Perform ultrasound if mammogram is inconclusive
- If ultrasound is inconclusive, proceed to tissue diagnosis

4. TISSUE DIAGNOSIS

- Perform tissue diagnosis or refer if abnormality does not resolve by follow-up breast exam or imaging studies
- Correlate results of fine-needle aspiration or biopsy with clinical findings and mammography

OTHER IMPERATIVES

Communication

- Identify which physician is coordinating care
- Explain the benefits and limits of mammography to the patient
- Develop and implement a system for tracking results and follow-up that includes all providers
- Develop and implement a system for notifying patients of findings

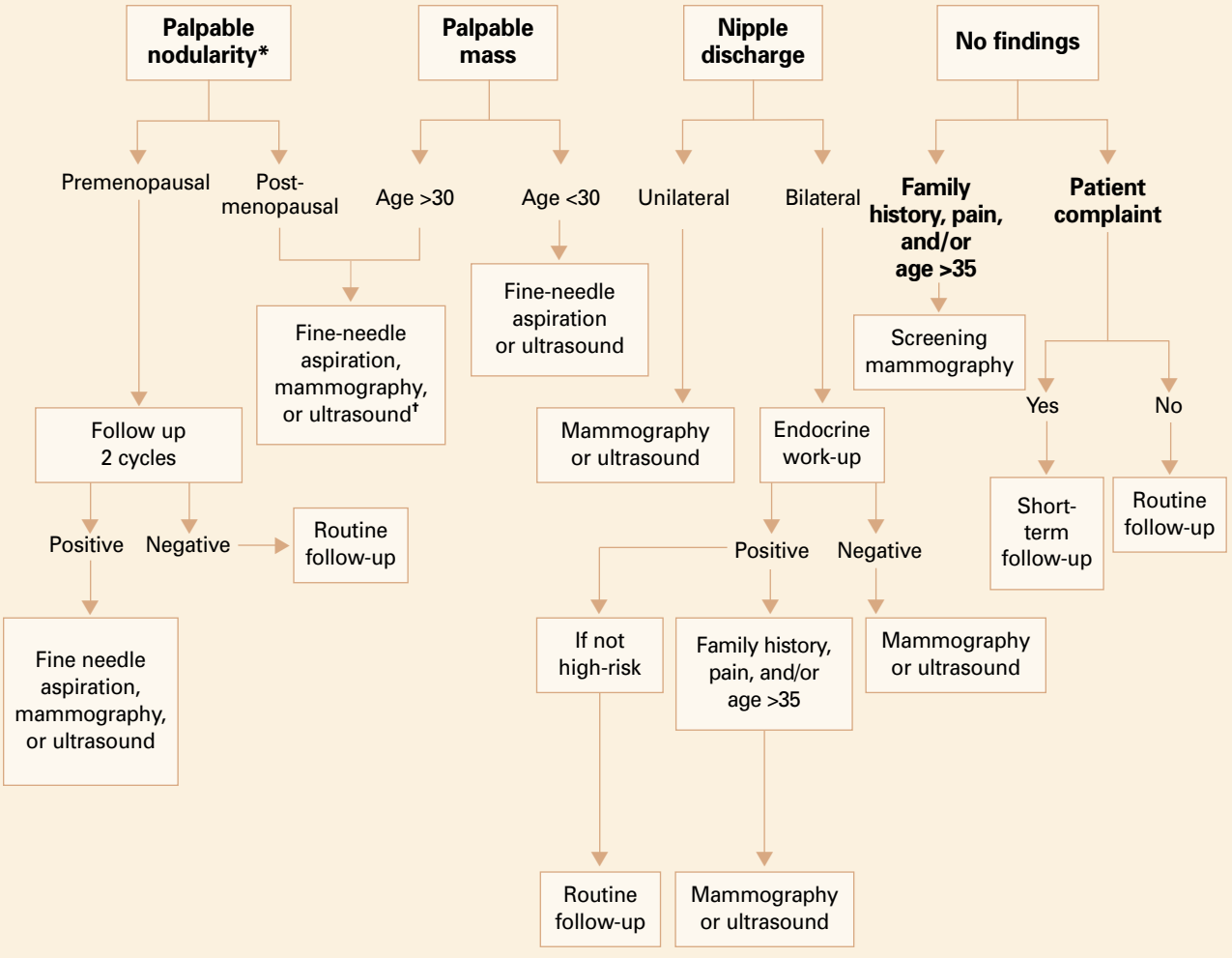
Documentation

- Record every step, including follow-up plan
- Use a breast diagram to record physical findings

Source: ProMutual Group. Managing risk in breast care. Cambridge, Mass.

ALGORITHM

How to follow up clinical breast exam findings



*Fibrocystic changes such as vague thickening, nodularity, fullness, cystic, lumpy, etc.
†Any persistent, palpable nodularity requires tissue diagnosis.

Source: ProMutual Group. Managing risk in breast care. Cambridge, Mass.

imperative. This includes pregnant patients; do not wait until after delivery to investigate an abnormality.

Use your own guidelines, but justify deviations from the norm

These may include earlier screening for women at risk, and need not match the recommendations of a nationally recognized group. However, in the event of a claim or suit, you will need to justify the reason for deviating from widely accepted guidelines.

Incorporate a systematic approach to diagnosis, treatment, referral (if required), and follow-up breast care.

Using an algorithm can help minimize error, confusion, and delays in care.

Assume cancer until it is ruled out

Consider diagnostic mammography and, when indicated, ultrasound imaging when the screening mammogram of a patient with a palpable mass is either negative or inconclusive.

A fine-needle aspiration or biopsy is a must to resolve indeterminate breast symptoms or inconclusive diagnostic breast imaging tests.

What not to say to patients

Do not assure the patient that a breast mass is benign until it is proven to be so.

Are you the "default PCP"? Screen for other cancers

When more than 1 physician is involved, someone needs to assume responsibility for the patient's ongoing breast care. In a malpractice case, a doctor cannot simply claim that a routine mammogram or diagnostic test was deferred because it was assumed another physician would handle it.

In most cases, the patient's primary care physician has the responsibility for her care.

ObGyn can be held to primary care physician standard. If the ObGyn is her only physician, the ObGyn may be held to a primary care standard—not only for breast and cervical cancer screening, but also for colorectal, skin, and other cancers.

Any physicians involved in a woman's care should decide between them, as early in the process as possible, who will assume responsibility for ongoing care. According to the Agency for Healthcare Research and Quality,[6–9] that physician oversees follow-up, monitoring, and tracking women with abnormal findings, including those for whom a biopsy is recommended.

The designation of responsibility and accountability should be documented in the medical record.

The radiology facility's responsibility. The facility that performs the patient's mammograms must share responsibility with the designated physician for follow-up, monitoring, and tracking abnormal test results. Each facility should have a system for tracking positive mammogram findings and, according to the Agency for Healthcare Research and Quality, "a process for correlating findings with biopsy results." It also has the duty to communicate urgent or significant findings to physicians and, under certain circumstances, to the patient directly.

If more than 1 physician is involved, everyone should know who is responsible for coordinating the patient's ongoing care. Good communication is especially critical when abnormal findings are involved and additional imaging or more invasive testing is needed.

Document, document, document

ProMutual Group's studies repeatedly show that inadequate records—whether paper or electronic—substantially reduce the chance for a successful defense. ■

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FAST TRACK

An ObGyn may be responsible as the "default PCP" for screening for colorectal, skin, and other cancers