

BREAST CANCER LITIGATION

When Is the Physician Liable?

by Sharon S. Lutz

[Close Window](#)

Family practitioners, obstetrician-gynecologists, and internists are gatekeeper physicians with the first professional opportunity to detect breast cancer. When they fail, the results can be fatal.

The women most affected by delay in diagnosis tend to be young (under 40). They typically have relatively high socioeconomic status and are covered by private health insurance.

The typical scenario is as follows. The woman presents with a self-discovered mass that is painless. The doctor performs a physical exam and feels a mass but believes it to be benign because of the patient's age. The doctor orders a mammogram, and the results are negative for abnormalities or malignancy, despite the palpable mass. The patient is diagnosed with fibrocystic disease, which is hormonally induced, and told she does not have cancer. Of course, she is tremendously relieved. The doctor does not recommend a biopsy or refer the patient for further consultation.

A delay of an average of 13 to 15 months precedes the ultimate diagnosis of breast cancer. When the diagnosis is eventually made, the cancer will be at a more advanced stage.¹

In three studies of women with breast cancer diagnostic errors, over 80 percent of the women discovered their breast mass and then went to see a doctor.² The failure of the physician to be concerned about the mass accounts for most of these errors. Many errors are attributed to the physician's disbelief that cancer occurs in young women.³

Many women are well educated about this horrible disease. They are aware of breast self-examination and diagnostic tools like mammograms. They recognize that early diagnosis and treatment mean a greater likelihood of survival. Yet, when they discover their own breast mass, and their physician tells them not to worry because it is fibrocystic disease, which later turns out to be cancer, they become justifiably angry.

Breast Examination

A woman's yearly gynecological exam, by either her gynecologist or primary care physician, is primarily for a Pap smear, which detects cervical cancer. But women expect—and should expect—more. Most physicians perform breast exams, although some do not. Those who do not must inform the woman that the procedure will not be done and should recommend that she have it done elsewhere. Otherwise, the patient may assume the doctor believes everything is fine and that breast examination isn't necessary. The notification to the patient should be documented.

If a patient is seeing a physician for a number of reasons, she may not be certain when a breast exam should be performed. If the physician does not read the chart before seeing the patient, or if the physician's record keeping is sloppy or imprecise, the breast exam may be overlooked.

The onus is on the physician to identify when a patient requires a breast exam and any factors that put her at higher risk for breast cancer. The doctor must also make sure the patient is aware of those risk factors. Any discussions of this nature should be documented.

Risk factors that should send up warning flags include

- age over 50;
- family history of breast cancer or other cancer, especially if it occurs in a mother or sister;
- no children or late birth of first child;
- start of menopause past age 50;
- obesity;
- high-fat, low-fiber diet;
- history of use of birth control pills or estrogen therapy; and
- early onset of menses (before the age of 12).

4

Even when physicians perform breast exams, it is not a given that they have been adequately trained or have the experience to distinguish between normal and abnormal masses in the breast tissue. In many instances, the physician cannot feel a mass that the woman has already found and erroneously determines that there is no mass.

The breast exam needs to be thorough. The physician should note skin

changes, bulges, or any difference in the size of the breasts. The doctor should gently squeeze the nipple looking for discharge. The presence of discharge does not necessarily mean cancer, but it can be a warning sign. The physician should also look for any nipple irregularities or peculiar skin appearance.

The doctor can palpate the breast using the circle method, the up-and-down line method, or the wedge method. The physician should always use the same method to become proficient at it. The physician should also palpate under the arm because this is where breast cancer cells often collect and where cancer frequently spreads. An armpit lump can be one of the first signs of cancer, even in cases where there is no irregularity in the breast tissue.

It is crucial for doctors to educate patients about breast self-examination. In doing so, they should take into account limitations a woman may have that might make it difficult for her to do the exam. For example, arthritis in an upper extremity can limit movement and placement of the hand. In a case like this, the physician should recommend that the woman have a close friend or relative perform a monthly breast exam for her, or have the woman come in to the office more frequently so a nurse can perform the exam.

One problem some women face is the physician who fails to pay attention to the woman's insistence that she has a lump, especially if she examines her breasts regularly. If the physician cannot feel the lump, he or she should send the patient for a mammogram and have her come back for further examination after her next menstrual period.

Patients should never be led to believe there is no urgency in diagnosing a breast mass. They can safely (without additional risk) be followed through one or even two menstrual cycles if there is no change in the mass. But if the lump remains after two menstrual cycles or if it has changed, cancer must be ruled out.

Mammography

Screening mammography screens women for breast cancer in the absence of signs or symptoms of the disease. Diagnostic mammography is performed on women with physical breast abnormalities and abnormal screening mammograms. Abnormal physical findings might include spontaneous nipple discharge, nipple retraction, or skin changes, as well as lumps.

There is currently a substantial dispute between the American Cancer Society (ACS) and the National Cancer Institute (NCI) as to the value of

screening mammography for women between 40 and 50 years. In 1994, the NCI revised its guidelines and stopped recommending the procedure for women age 40 to 49 because its effectiveness for women in this age group and younger is in dispute.⁵ Because younger women's breasts are denser, screening accuracy ranges from 60 percent to 84 percent compared with 86 percent to 95 percent in older women.⁶

The ACS agrees that screening mammograms may not be as effective in younger women. But the organization says the studies conducted on this group have not been large enough to arrive at any definite conclusions. Thus, the ACS, along with the American Medical Association, continues to advise that women get a baseline mammogram at 35. After that, these organizations recommend that women get mammograms every one to two years from age 40 to 49 and an annual mammogram from age 50 on.

As of October 1, 1994, the Mammography Quality Standards Act (MQSA) requires that all mammography facilities (except Department of Veterans' Affairs facilities) be certified by an FDA-approved accreditation body. This requires on-site inspections by a qualified MQSA inspector.⁷

Screening mammography should consist of two different views of each breast: the mediolateral oblique (MLO) and craniocaudal (CC). The MLO is taken from the side, and the CC from above. Both views should include all breast tissue. For women with breast implants, four views should be taken of each breast. Diagnostic mammography evaluates specific breast masses or symptoms and can use a variety of views, depending on the problem. In every case, the technical quality of the films must be determined to be adequate before the patient leaves so she does not have to return to the facility.

Depending on the facility, either a radiologist or mammographer interprets the films. It is obviously the interpreting physician's responsibility to interpret the mammogram correctly. Misdiagnosis cases often involve a woman who has had regular mammograms, all of which have been reported negative. Later, she or her physician discovers a lump that turns out to be cancerous and, in any many cases, metastatic. The mammograms are re-interpreted at a different facility and found to have signs of malignancy that had been overlooked. If the cancer was there to be found, the interpreting physician should have found it.

The radiologist or mammographer should review the medical history of the patient, correlate any clinical findings with the mammogram, and correlate the findings in the current mammogram with prior ones. Comparison of current and prior films improves diagnostic capability, reduces the number of unnecessary procedures, and assists in following a benign finding. Changes that occur between mammograms may suggest that a malignant tumor is growing.

Although the referring physician is responsible for following up, monitoring, and tracking women who have abnormal mammograms, the mammography facility is responsible for correctly reporting the results of the procedure to the referring physician. The report should include an overall assessment of the findings and recommendations for further action, if warranted.

The American College of Radiology has developed a Breast Imaging Reporting and Data System using the following standard terminology and treatment recommendations:

- A: Needs additional evaluation.
- N: Negative. Nothing to comment on. Routine follow-up. A negative mammogram shows nothing unusual in the tissue, benign or malignant.
- B: Benign finding. Negative for cancer, but the interpreting physician may wish to describe a typically benign finding, such as calcified fibroadenoma.
- P: Probably benign finding. Short-interval follow-up suggested. A finding with a high probability of being benign that is not expected to change over the follow-up interval.
- S: Suspicious finding. Biopsy should be considered. A finding without the characteristic form and structure of breast cancer but having a definite probability of being malignant.
- M: Highly suggestive of malignancy. Appropriate action should be taken. These findings have a high probability of being cancer.

8

Abnormal results must be reported promptly and in a manner designed to get the referring physician's attention. If a woman goes to a facility without a referral, the interpreting physician must communicate the results to her and explain their significance, as well as advise her about the next steps she should take. This information should be given in writing as well as orally and should not be left on an answering machine or given to another person. These communications should be noted in the medical record.

The referring physician must have a system to make sure he or she receives information back from the radiologist. Once the results arrive, the physician must keep in mind that mammograms have a false negative rate of 10 percent to 15 percent. So if a patient has a breast mass and a mammogram report comes back "normal," that is no assurance the mass is not cancerous. In one study, 38 percent of mammograms were misinterpreted as normal or showing fibrocystic disease. This researcher believes there is a lack of awareness among physicians of how often mammography is falsely negative in the presence of a palpable mass.⁹

Mammography cannot diagnose what a breast mass is, so the physician must find a satisfactory explanation for the mass, no matter what the mammogram says.

Definitive Diagnostic Measures

Physicians who take a wait-and-see attitude beyond one or two menstrual cycles after a breast lump is discovered—or those who mistakenly assume that a breast lump in a young woman is hormonally induced—are playing with fire. Breast cancer is becoming more prevalent and is often more severe in younger women.¹⁰ It is impossible to rule out breast cancer by palpation or mammography. Other steps such as aspiration, biopsy, or ultrasound are required. The definitive method to rule out cancer is biopsy.

A breast mass that is a suspected cyst must be aspirated. Aspiration involves inserting a needle in the mass and withdrawing any fluid that is present. If the lump is a cyst, the fluid should be clear or straw-colored, and the mass should go away immediately.

If the mass remains after the aspiration, a breast biopsy must be performed. This is usually done by a surgeon. In an open biopsy, the physician removes the mass and sends it to a pathology lab for evaluation.

For women with suspicious areas on mammograms that are not palpable masses, a newer diagnostic procedure is ultrasound breast biopsy. Doctors use an ultrasound machine to find the suspicious area, and then take five tissue samples with a spring-loaded biopsy gun. The material is then examined by a pathologist. The procedure is very difficult and should only be performed by first-rate ultrasonographers.

The defendant's refrain is "you can't biopsy every lump." However, when prompt diagnosis can make the difference between life and death, the physician had better.

Referrals

If a patient needs a referral to have a mammogram or other diagnostic procedure done, the physician cannot simply tell her she needs to undergo the procedure and expect her to do it. The physician should have a staff person set up the appointment and make sure the patient goes.

If the patient does not attend the appointment, the referring physician must call or send a letter reminding her of the pressing need for the procedure. A patient may think it's all right to wait until her next checkup or get the impression that the problem is "nothing to worry about." It is important that the physician convey a sense of urgency to the patient.

Documentation

Maintaining good medical records is crucial to the proper care of patients. If a patient has a breast mass, its location and characteristics must be documented. Any recommendations, including when the patient should act on them, must be written down.

An inappropriate filing system can be disastrous. For instance, if a mammogram report is filed in the patient's chart without the physician's seeing it, a cause of action may lie. The physician should have a system for noting that he or she has seen the report.

Some physicians file diagnostic reports in a location different from the patient's chart, so that when the patient returns for a follow-up visit, the report may not be readily available. The physician should have a system to indicate when a patient is returning for a breast mass follow-up so that the doctor does not assume she is there for a routine check-up.

Case Histories

Failure to conduct the appropriate tests or to follow careful testing and administrative procedures can have devastating—even fatal—consequences for the patient. The following cases provide examples.

- A middle-aged woman visited a clinic for low-income patients for monitoring of a chronic health problem. Physicians at the clinic were scheduled to spend only a few minutes with these patients. At one visit, the physician noted that the patient had never had a mammogram or complete physical so she recommended that the woman schedule a

longer exam at a later date. (Clinic policy did not allow the physician to do the exam at that time).

The patient never scheduled the longer visit, and after three more short visits, she reported a lump in her breast. The physician arranged for the woman to be seen at a hospital, and metastatic breast cancer was diagnosed.

In the resulting litigation, the physician escaped liability, but a jury returned a verdict against the hospital and clinic. The jury found that the physician was thwarted by the policy requiring the patient to schedule a longer visit and that the health clinic needed a better scheduling system.¹¹

- A 32 year old woman went to her gynecologist complaining of a lump in her left breast. She was sent for a mammogram, and the radiologist interpreted the film as showing "moderately severe mammary dysplasia with no distinct clusters of microcalcifications."

Dysplasia is poorly structured but nonmalignant breast tissue, and microcalcifications are small white specks of calcium salts that can, in clusters, represent early cancer, or they may be benign breast changes. The gynecologist instructed the patient to return after her next menstrual period for a follow-up exam.

The patient did not return for that visit. Two years later she was diagnosed with breast cancer by another gynecologist. She died a year and a half later.

Her family sued the original gynecologist and radiologist. The allegation was that the radiologist had improperly read the mammogram and that the gynecologist should have referred the woman to a surgeon for biopsy of the lump rather than simply ordering a mammogram. The gynecologist contended that he might have referred her for a biopsy if she had kept the second appointment. The family settled with the gynecologist, but a jury returned a substantial verdict against the radiologist. The jury found the patient 25 percent negligent for not seeking follow-up care sooner.¹²

- A 43 year old woman had a mammogram because of a lump. The results were reported to her primary care physician rather than the gynecologist who referred her for the mammogram. A nurse in the primary care physician's office reported to the woman and her husband, in separate telephone calls, that the mammogram showed fibrocystic disease and not to worry. She also told them that it was not necessary for the woman to see the physician again.

Seven months later, another physician performed a biopsy and mastectomy. Four of eleven lymph nodes were positive for cancer. The

woman died soon after.

The primary care physician claimed he did not know the nurse was making diagnoses and giving medical advice to patients over the phone. He could not remember if he had seen the results, but stated he would have followed up with further testing and treatment if he had.

The radiologist, primary care physician and nurse were sued. The radiologist and primary care physician settled the case, and a jury returned a verdict against the nurse. The radiologist should have reported the findings to the gynecologist rather than the primary care physician, and the nurse overstepped her authority in reporting the mammogram results to the patient.

Causation

Defendants in these cases argue that they did not create the disease. They also say that the overwhelming odds are that the cancer had spread before it could be diagnosed by known methods and that the opinion that a delay resulted in a loss of a chance of recovery or extended survival is speculation.

A study by Dr. John Spratt, a favorite of defense attorneys, describes the promotion of mammography as "overpromotion that skirts on scientific fraud."¹³ Spratt believes mammography gives women a false expectation that breast cancer can be detected early enough to cure it, leading to liability claims. According to Spratt, a cancer big enough to produce symptoms (palpable mass or positive mammogram) is not an early cancer, and its lethality has already been determined. Thus, if prognosis is measured from the onset of symptoms, then physician or patient delay does not alter the prognosis—it has been predetermined, good or bad.

These arguments are contrary to what physicians call "lead-time bias." This is the concept that periodic screening detects many hidden cancers at an early stage. The patients may not be cured, but they may live longer after diagnosis.

Breast cancer patients and their families—as well as jurors—tend to believe that those with a palpable breast mass are less likely to survive when there is a delay in diagnosis. Although the American Cancer Society's promotion of mammograms to achieve early diagnosis and favorably affect outcome may be an oversimplification, early diagnosis is clearly associated with improved prognosis.

One study found a direct correlation between tumor size and survival. Eighty six percent of patients who had a tumor 1 centimeter in diameter or smaller survived 20 years. In this study, tumor size, with or without lymph

node metastases, was crucial.¹⁴

Other studies have shown that the presence of metastases at the time of diagnosis of even very small tumors is more important than the size of the tumor. Tumor characteristics are often more significant than duration of symptoms.¹⁵ Characteristics like tumor grade, lymph node involvement, and response to estrogen testing are not known until a biopsy is performed and the tissue analyzed by a pathologist. This underscores the need for early removal of the malignancy.

Slower-growing tumors are most likely to be discovered during yearly screening exams, whereas more rapidly growing ones are likely to arise in the interval between exams. Therefore, patients whose tumors are discovered during screening exams will have a better chance of survival because the tumors are probably growing relatively slowly.

Causation issues are the prime battleground in breast cancer cases. Although researchers like Spratt suggest there is no hope no matter how early the diagnosis, this argument fails. Why should we have mammograms, chemotherapy, and cancer specialists if they cannot detect the disease and save lives, or at least extend life spans?

Different states recognize different types of harm potentially caused by a delay in diagnosis and treatment. Some jurisdictions allow plaintiffs to prove damages by showing that the woman's chance for long-term survival has been reduced by some percentage. Damages may then be assessed in proportion to the lost chance. Other jurisdictions do not recognize loss of chance and require the plaintiff to prove that the woman's life expectancy has actually been reduced by the doctor's negligence.

In states that do recognize loss of chance, standards vary for determining whether a physician's negligence resulted in a loss of chance. Some jurisdictions use the "probability" standard, which requires the plaintiff to prove the woman had a greater than 50 percent chance of survival before the negligent act.¹⁶

Other jurisdictions have adopted the more liberal "substantial possibility" standard. For example, in a 1989 Maryland case, the court held that a plaintiff must prove with reasonable certainty that a substantial chance of survival was lost. It defined "substantial chance" to be more than minimal but less than 50 percent.¹⁷ Several other courts have used the phrase "loss of an opportunity for a more favorable outcome."¹⁸

Expert Witnesses

The nature of the medical negligence will determine which experts the attorney needs to prove the case. If the family practitioner or gynecologist failed to appropriately follow a breast mass, specialists in those fields would be needed. On the other hand, if the pathologist failed to identify or report a suspected malignancy, the attorney would need a pathology expert, and there would be no need for a family practitioner or gynecology expert unless, of course, those physicians were negligent as well. An oncologist is always needed to determine causation unless your expert is a surgeon who has extensive experience with breast disease.

A note about proving damages: There is almost nothing more poignant or sad than a young wife and mother dying of metastatic breast cancer. As macabre as it seems, the woman's pain and suffering and that of her family must be captured on videotape for the jury if there is any chance the woman will not live until trial.

In the future, it is clear that health care will be economically driven. As more medical decisions are influenced by the bottom line, we will see more failures to diagnose breast cancer and, as a result, more breast cancer litigation.

Notes

1. KENNETH A. KERN, SURGICAL ONCOLOGY CLINICS OF N. AM. MEDICO-LEGAL CONTROVERSIES IN BREAST CANCER 119 (1994).
2. *Id.* at 120.
3. *Id.*
4. PAUL KUEHN, BREAST CARE OPTIONS FOR THE 1990s 7 (1991).
5. Nancy Volkers, NCI Replaces Guidelines with Statement of Evidence, 86 J. NAT'L CANCER INST. 14-15 (1994).
6. Laurie Jones, Mammography Muddle: Consensus Elusive on Value of Screening in Younger Women, AM. MED. NEWS, Dec. 13, 1993, at 2-3.
7. 12 U.S.C.A. §263(b) (1992).
8. LAWRENCE W. BASSETT ET AL., QUALITY DETERMINANTS OF MAMMOGRAPHY 55 (Agency for Health Care Policy & Research Pub. No. 95-0632) (Oct. 1994).
9. Julie S. Mitnick, et al., Breast Cancer Malpractice Litigation in New York State, 189 RADIOLOGY 673-76 (1993).
10. Cheryl Weinstock, Breast Cancer and Young Women, AM. HEALTH, July/Aug. 1993, at 10-11.
11. *Tard Mix v. St. Louis Regional Hosp.*, No. 892-00634 (Mo., St. Louis City Cir. Ct. May 7, 1993).
12. *Darnell v Ulrich Co.* CV92-06-2245 (Ohio, Summit County Ct. Common Pleas Mar. 23, 1993).
13. John S. Spratt et al., Geometry, Growth Rates, and Duration of Cancer and Carcinoma in Situ of the Breast Before Detection by Screening, 46 CANCER RES. 970-74 (1986).
14. Paul Peter Rosen et al., A Long-term Follow-up Study of Survival in Stage I (T, NO, MO) and Stage II (T, N, MO) Breast Carcinoma, 7 J. CLINICAL ONCOLOGY 355-66 (1989).
15. Edwin R. Fisher et al., A Perspective Concerning the Relation of Duration of Symptoms to Treatment Failure in Patients with Breast Cancer, 40 CANCER 3160-67 (1977).
16. See, e.g., *Kilpatrick v. Bryant*, 868 S.W.2d 594 (Tenn. 1993).
17. *Kroll v. United States*, 708 F. Supp. 177 (D. Md. 1989).
18. See, e.g., *Falcon v. Memorial Hosp.*,

