

# .....BREAST CANCER.....



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Victoria Kennedy, R.N. and Carol A. Austin - Editors

## BREAST CANCER UNTIL PROVEN OTHERWISE



by Catherine S. Andrews, M.D.

Delay in diagnosis of breast cancer is the most common clinical scenario resulting in malpractice in the United States.<sup>1</sup> It is also the leading source of indemnity payments issued.<sup>2</sup> Breast cancer is the most frequently litigated condition and proportionately has twice as many lawsuits as its incidence in the general population.<sup>3</sup> In a recent study of cases tried, obstetricians and gynecologists were involved in the greatest number, followed by family practitioners, internists, general surgeons and radiologists.<sup>4</sup>

There are a number of terms to describe findings on a clinical breast examination. When any of these terms are present in the medical record, the physician must recognize that they all have an equal opportunity of being **CANCER**. If any of these terms appear in the medical record, they are assumed to be associated with **CANCER UNTIL PROVEN OTHERWISE**. These terms include but are not limited to:

- Lump
- Bump
- Mass
- Cyst
- Nodule
- Tumor
- Lesion
- Growth
- Knot
- Thickening
- Swelling
- Distortion
- Spontaneous discharge
- Erosion
- Nipple retraction or pain
- Tenderness
- Skin irritation
- Dimpling
- Asymmetry of breast contour
- Asymmetric thickening

As a physician who assumes the primary responsibility for a patient's breast care, **it is imperative that the diagnosis of breast cancer is assumed until it is either RULED IN OR RULED OUT.**

### How did we get here?

#### Public Expectation

In an effort to urge women to participate in screening programs for breast cancer detection, the media, in collaboration with professional organizations, has simplified and distilled results of research studies to the point where the public expects that "early" detection will result in almost a universal cure of the disease.<sup>5</sup> Relatively few people realize that even if all women received yearly mammograms and physical examinations, 70 percent of breast cancer deaths would be unaffected.<sup>6</sup>

#### Clinical Presentation

Your goal is to ensure that your patient does not have breast cancer or, if she does, that the diagnosis is made **PROMPTLY AND WITHOUT DELAY**. Classic symptoms are:

- Clinically occult mammography abnormality
- Breast mass (lump, etc.)
- Asymmetrical breast thickening
- Spontaneous nipple discharge
- Skin dimpling
- Nipple scaling
- Skin erythema and/or thickening
- Focal breast pain<sup>7</sup>



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The most common presentation of breast cancer is a palpable abnormality, most often discovered by the woman herself. Some women are able to sense that something is wrong in a particular location of the breast, a perception that cannot always be confirmed by the examiner.<sup>8</sup> **Do not ignore or minimize a woman’s concerns that something is wrong just because your examination has negative findings. You should continue your efforts to rule out cancer until you and your patient are satisfied that cancer is not present.** Breast cancer detection is a team effort.

### The Disease

The detection of breast cancer, even at its earliest presentation, is not usually possible, on average, until eight years after the first cancer cell appears in the breast. The survival outcome in women diagnosed with breast cancer is directly related to the biology of the tumor. Groups of

women do survive longer if diagnosed at an early stage, but this is partially a reflection of lead-time bias; that is, although the length of time between diagnosis and death is longer for earlier stages of the disease, life is not actually lengthened.<sup>9</sup>

### Mammography

Performed on a patient younger than 30, mammograms are extremely inaccurate. In one study, mammograms failed to image 74 percent of the masses in women younger than 30. There is a 10 to 22 percent false-negative rate overall.<sup>10</sup> Mammography alone is not synonymous with breast cancer screening. As recommended by the American Cancer Society (ACS), good breast screening includes mammography, examination by the physician on a regular basis and monthly self-exam by the patient. One frequently published author believes that diagnostic mammograms ordered to evaluate a palpable mass may be misleading to clinicians when they fail to image the lesion, thus giving them the impression that it is benign.<sup>11</sup> Notwithstanding any reported finding or lack of finding on mammography, it is imperative that the family physician correlate the mammographic findings with his/her physical findings when ordering a diagnostic mammogram. **Be sure that the area discussed on the mammographic report is the area in question on the physical exam.**

### Litigation

Most malpractice litigation involving patients with breast cancer involves relatively young women, usually younger than 50. The plaintiff most often discovered her own mass, which was incorrectly diagnosed by the physician as fibrocystic disease.<sup>12, 13</sup> The highest awards have been given to younger patients.<sup>14</sup>

In addition to allegations of misdiagnosis, litigation against physicians often stems from the allegation of a DELAY IN DIAGNOSIS even if the diagnosis of breast cancer is made eventually. Public education by healthcare organizations and advocates such as the ACS have done an excellent job in convincing the public that EARLY DETECTION is the essential element for a patient to have a chance for a favorable prognosis or cure and to attempt to argue against this position is imprudent. Additionally, the public upholds the theory that the longer the delay in diagnosing malignancy, the less likely a possible cure.

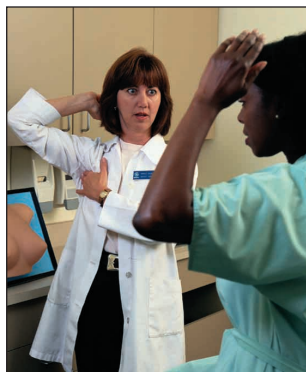
### What’s the solution?

#### Documentation Issues

It is important to record certain information in the medical record concerning the patient’s history, findings on clinical exam, follow-up instructions, notification of abnormal test results and communication. This is information that is often disputed in litigation. Without documentation, there is no evidence to substantiate the care provided by the physician.

Any patient who has breast problems should have documentation to reflect each step of the course of the disease management. The documentation should reflect discussions that transpired with the patient concerning the options they have for care and treatment, the possible serious consequences of not following up as discussed and the established time frames of tests and treatments. **It is extremely important to document patient non-compliance with follow-up care.**

When more than one physician or non-physician practitioner is involved in the patient’s breast care, it is important to coordinate the team and communicate, in writing, all information such as important clinical findings, test results, follow-up plans, scheduled checkpoints and your thought processes. There should be special efforts made to avoid miscommunication.



## Follow Up

When unresolved breast symptoms or nondiagnostic clinical breast examinations require serial examinations, follow-up must be clearly defined and well-documented. Treatment plans should be discussed with the patient so they understand what they can expect and what options they may have for further care and treatment. A specific follow-up visit should be scheduled at an appropriate interval. Instructing patients who have a suspicious

1 Zylstra Samuel, et al. A statistical model for predicting the outcome in breast cancer malpractice lawsuits. *Obstetrics and gynecology* 1994;84(3):392-398

2 Brenner R.J. Breast cancer evaluation. *Cancer Supplement* 1994;74(1):486-490

3 Kern Kenneth A. Medicolegal analysis of the delayed diagnosis of cancer in 338 cases in the United States. *Arch Surg* 1994;129:397-404

4 Kern Kenneth A. Causes of Breast Cancer Malpractice Litigation. 1992 *Arch Surg*;127:542-547

5 Osuch Janet R, Bonham Vence L. The timely diagnosis of breast cancer. *Cancer Supplement* 1994;74(1):271-278

6 See note 1 above

7 See note 5 above

lesion to return if not improved is ambiguous and may seem to have placed excessive medical decision-making responsibility on the patient.<sup>15</sup> Develop a “tickler file.” If a test or referral is ordered for a patient and you do not receive the result by a certain date, you are then alerted to contact the patient.

Finally and most importantly, do not fail to refer any unresolved or undiagnosed breast abnormality, despite a negative mammogram. ●

8 Ibid.

9 Ibid.

10 See note 4 above

11 Lannin Donald R, et al. Difficulties in diagnosis of carcinoma of the breast in patients less than fifty years of age. *Surgery* 1993;177:457-462

12 See note 1 above

13 Mitnick Julie S, et al. Malpractice litigation involving patients with carcinoma of the breast *Journal of the American College of Surgeons* 1995;181:315

14 See note 1 above

15 Dewar Marvin A., Love Neil. Legal issues in managing breast disease. *Postgraduate Medicine* 1992;92(5):137-151

## Delay in Diagnosis of Breast Cancer

# CLOSED CLAIM ABSTRACT - BREAST CANCER

by Victoria Kennedy, R.N., Senior Risk Management Consultant

### CLINICAL SEQUENCE

A 24-year-old, 5’7”, 220-lb. white female was seen at her obstetrician’s office by the certified nurse midwife. She was confirmed to be six weeks pregnant. During the visit, the patient also complained of a right breast lump. The nurse midwife documented that on physical exam she felt a two-centimeter mass on the right breast and that she instructed the patient to return for a recheck of the breast mass in four weeks. It was also noted that the patient should have a mammogram after the first trimester if the mass had not resolved. It is important to note that on this visit the patient completed a history and physical questionnaire that stated that her mother had a history of breast cancer in her 30s.

The patient returned to the office four weeks later and was seen again by the nurse midwife for a recheck of the right breast mass. The nurse midwife docu-

mented that she rechecked the right breast, and it was noted that no mass was felt on physical examination. There was no further documentation concerning the patient’s breast.

The patient continued to be followed by the nurse midwife and the physicians over the course of her pregnancy; however, the nurse midwife never informed the physicians of the breast mass although it was documented in the first two prenatal visits. The patient delivered a healthy baby.

The nurse midwife saw the patient in the office again six weeks postpartum. The physical examination reflected that her breasts were soft and without masses.

Two months later, the patient returned to the office with complaints of a slight leaking of the right breast and soreness. The nurse midwife saw her again and noted in the record that she felt a firm area in the

outer quadrant of the right breast and that milk was expressed.

Eight months later, the patient was diagnosed with metastatic Grade II moderately differentiated ductal carcinoma. This was 19 months from the date the patient initially complained of a lump in her right breast during her first prenatal visit.

### CLAIM SEQUENCE

The patient filed a lawsuit against the nurse midwife, the two physicians and the physician’s P.C. alleging that the nurse midwife had a duty to report the breast mass finding to the physicians on the first prenatal visit and also alleged that she was practicing beyond the scope of a certified nurse midwife. The main allegations concerning the physicians were delay in treatment and failure to diagnose breast cancer. Additionally, there was an allegation of failure to appropriately supervise the nurse midwife they employed.

## CASE DISPOSITION

The suit was settled for a large sum of money before trial.

## DISCUSSION POINTS

### MEDICAL/FAMILY HISTORY

Failure to consider the patient's medical and **family history**, even with clear documentation, compounded the problems associated with this case. The patient completed the History and Physical Assessment on her first prenatal visit and stated that her mother had a history of breast cancer at an early age.

### Risk Management Issues

**According to the American Cancer Society, the Centers for Disease Control and numerous other authoritative sources “Women with a family history of breast cancer, especially in a first-degree relative (mother, sister or daughter), have an increased risk of developing cancer themselves. The risk is even higher if more than one first-degree relative had breast cancer or if the relative developed breast cancer at an early age, or in both breasts.”<sup>1</sup>**

The patient evaluation should begin with a thorough risk assessment that includes a review of the patient's history. Physicians may “consider using a problem list in the medical record to flag patients at a higher risk for specific problems, i.e. first-degree relatives with family history of breast cancer.”<sup>2</sup>

## THE WHOLE PATIENT

This patient's primary reason for her initial visit to the obstetrician's office was to confirm her pregnancy and to begin her prenatal care. While the complaint of the “breast lump” was verbalized to the certified nurse midwife and followed through at the second office visit, the subsequent visits focused on the patient's pregnancy and there was no further documentation to reflect that her breasts were examined at all.

### Risk Management Issues

Too often, a breast lump may be identified by the patient or physician and may be dismissed as insignificant due to the patient's young age, history of fibrocystic disease, tenderness, where she is in her menstrual cycle, pregnancy or postpartum status. Reassurance may be given to the patient and later the

patient is diagnosed with breast cancer. There needs to be a reemphasis to avoid clinical “blindness” that shift the focus from the patient as a whole to tunnel vision of a specific body part or condition.

**Any patient with a mass in their breast should be managed as high**

**risk, regardless of their age or other low risk factors.** Low risk does not mean **NO** risk. The physician should address the patient's anxieties by offering to work together to solve the problem, as opposed to diagnostic reassurance that has no data or support to it. **Breast lumps are frightening and every woman who finds a lump is thrilled to**



**hear that it is benign. If they receive that reassurance from a physician, then they trust your knowledge as a physician.**

Data from interviews taken from jury pools on breast cancer cases clearly indicates that the public opines that physicians are supposed to know what to do and when to do it. They rely on the physician's education and knowledge to guide them with care and treatment.

While there may be evidence presented that the patient's long-term outcome may not be any different, even if the diagnosis had been made earlier, juries still feel the physician was negligent if there was a diagnosis delay.

**According to the Screening Guidelines set forth by the American Cancer Society (ACS), “Confirm complete resolution of the mass, confirm a simple cyst (using ultrasound or simple aspiration) or obtain a definitive diagnosis by adequate tissue sample within six weeks (a negative Fine Needle Aspiration (FNA) is not adequate).”<sup>3</sup>**

Additionally, Dr. Robert Smith, Ph.D., director of screening for the American Cancer Society, opined the following. **“It is important to understand that a negative mammogram in a woman with a palpable mass detected on Clinical Breast Exam (CBE) does not rule out breast cancer.”<sup>4</sup>** He believes that in cases where there is a palpable mass and a negative mammogram that **ultrasound and other diagnostic tests need to be pursued** to determine definitively whether the mass ultimately is benign or cancerous.

It is also important to recognize that mammography is accurate, but like most medical tests, it is not perfect. On average, mammography will detect about

90 percent of breast cancers in women without symptoms, and it is somewhat more accurate in postmenopausal women compared with premenopausal women. Breast cancers that are not identified by mammography may be missed for any one of the following circumstances:

- breast density
- faster growth rate and/or
- failing to recognize the small early signs of an abnormality.

According to the ACS, one to 10 percent of women will have an abnormal or inconclusive result that requires further imaging tests or a biopsy in order to make a definitive diagnosis.

### COMMUNICATION/ FOLLOW-UP AND DOCUMENTATION

In our closed claim abstract, after the second office visit, there was no further follow-up or documentation with this patient concerning the right breast mass. There was never any communication between the physicians and the nurse midwife with regard to the right breast mass, and there was nothing documented to reflect that the physicians had made note of the mass via the notes from the nurse midwife. **The nurse midwife may have forgotten about it since her main focus was to follow the patient’s pregnancy, and the patient may have gotten accustomed to denying it.**

#### Risk Management Issues

Communication errors can lead to a delay in diagnosis. The use of a team approach with the patient and direct communication with all the other providers involved will serve to clarify any confusion or discrepancies. Documentation of this communication is extremely important to provide clarification of the sequence of events if a dispute

arises later, in addition to the provision of quality care.

Often, a few words that restate the last office visit may help to prevent a communication gap. For example: “On your last visit to the office you were concerned about a breast lump; we need to make certain that this concern is resolved.” This serves as a reminder and a way of being sure follow-up is being handled appropriately until there is a definitive resolution of the problem.

Any of the following terms (but not limited to these when written in the medical record) associated with the patient’s breast, have an equal chance of being cancer:

- Lump
- Bump
- Mass
- Cyst
- Nodule
- Tumor
- Lesion
- Growth
- Knot
- Thickening
- Swelling
- Distortion
- Spontaneous discharge
- Erosion
- Nipple retraction or pain
- Tenderness
- Skin irritation
- Dimpling
- Asymmetry of breast contour
- Asymmetric thickening

**If these words or any equivalent terms, including descriptive terms such as palpable, discreet or dominant, are in the medical record, CARCINOMA SHOULD BE SUSPECTED UNTIL PROVEN OTHERWISE. Any patient who has this terminology in their medical record, regardless of whether it was the patient’s “complaint” or it was something determined by the examination, needs to**

**have their diagnostic status changed from a routine evaluation to an AGGRESSIVE DIAGNOSTIC EVALUATION. The aggressive diagnostic evaluation should include an appropriate and complete work-up to include an aggressive follow-up plan.**

A tickler system for the physician and/or physician extender and a recall system for the patient must be in place for every step of the breast management process. **The system should include a tickler that works as a reminder about this potential “high-risk” problem to the physician and/or the staff, if the patient has contact with the office later for any unrelated problem. The follow-up plan should be a structured system to ensure that every test gets followed-up, especially those that have been identified as potential “high-risk” problems.**

### CONCLUSION

Delay or failure to diagnose and treat breast cancer continues to be a leading cause of medical malpractice claims.

The ACS states that Early detection of breast cancer greatly improves the treatment options, the chances for successful treatment and survival. Data has been published by the Breast Cancer Detection Demonstration Project that outlined a 20-year follow-up of the first studies to explore the results from the concept of large-scale breast cancer screening. This study used screening protocol of the recommendations to obtain an annual two-view mammography and clinical breast examination. **“In large part due to this project, breast cancer screening has become widespread, and the rate of in situ and small, invasive cancers has increased dramatically while the rate of advanced**

**cancers has decreased. Breast cancer mortality in the United States has decreased by 6.3 percent in the past 20 years.**<sup>75</sup>

The key is for physicians to recognize that the public's perception, based on the education they have received from health-care organizations and advocates, is that early detection does correlate with a more favorable survival rate and therefore places physicians in a difficult situation. **The public believes that early diagnosis equates to, at least, a possible cure for their problem and that the longer the delay in diagnosing cancer, the less likely it is to increase the chance of survival.**

Breast cancer screening includes patient self-examination, clinical breast examination and mammography, but may be different or more detailed for high-risk patients. Once the screening process is complete, the management process proceeds until there is a definitive decision ruling cancer in or out. The management process requires the physician to follow the patient aggressively and perform additional tests promptly. Appropriate documentation in the medical record should reflect the treatment and follow-up care rendered.

As a physician who assumes the primary responsibility for patients with regard to their breast screening and breast management, it is important to have a system in place. The system should clearly reflect consistencies with recommended screening guidelines by the American Cancer Society and the Centers for Disease Control, and recommended practice guidelines by your Specialty Medical Society [i.e. American College of Ob/Gyn (ACOG), American College of Radiology (ACR)].

**THOSE GUIDELINES SHOULD INCLUDE:**

- Identify the breast problem
- Develop a clear and effective plan with outlined time-frames as to which tests will be done first, how much time will pass between each test and a follow-up plan until there is a definitive diagnosis and resolution of the problem
- Complete documentation that reflects the patient's breast-related history, risk factors, findings on physical examination, the recommended plan and follow-up instructions to the patient, including the outlined timeframes
- Clear documentation to reflect the conversations that have transpired with the patient concerning the

options and the management plan that includes patient education materials

- Communication between all providers and documentation to reflect that communication
- Documentation to reflect interpretation of test results and the plan for inconclusive or negative test results
- A tickler system that has a regimented plan of follow-up with time increments outlined and reminders in place for each patient
- A plan for scheduled check-points until there is a definitive diagnosis or confirmed referral with the responsibilities of the primary breast care clearly shifting from one physician to another
- Documentation of patient non-compliance with plan follow-up
- A system and protocol for how the practice will handle repeat, non-compliant patients that are in the high-risk category for breast cancer ●

- 1 American Cancer Society Statistics, *Breast Cancer Facts & Figures* 1999/2000
- 2 [www.rm.f.harvard.edu/ Forum Risk Management and Breast Cancer](http://www.rm.f.harvard.edu/ForumRiskManagementandBreastCancer)
- 3 [www3.cancer.org/](http://www3.cancer.org/)
- 4 [www2.cancer.org/](http://www2.cancer.org/)
- 5 CA Cancer J Clin 1997;47(3):134-49

MAG Mutual does not presume to establish any standard of care or establish rules for the practice of medicine. The particular patient-care strategies or range of patient-care strategies mentioned in this newsletter should be tempered by the physician's judgment.

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MAG Mutual Insurance Co.  
P.O. Box 52979  
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