

clinical
series

a risk management distance learning cme course

Failure to Diagnose Breast Cancer

clinical & risk management perspectives

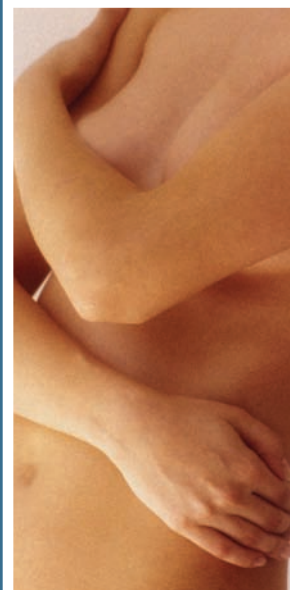


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Introduction/CME Information

Needs Assessment

Activity needs were assessed through a review of the following:

- National claims data from the Physician Insurers Association of America (PIAA)
- NORCAL claims experience
- Current medical literature

Why a Risk Management CME Course on Failure to Diagnose Breast Cancer?

NORCAL Mutual Insurance Company is proud to publish the 3rd edition of our CME course on failure to diagnose breast cancer. Breast cancer remains the most common form of cancer in women, and 1 in 7 women will get the disease in her lifetime. Next to lung cancer, breast cancer is the most common form of cancer-related death in women, and is expected to claim nearly 41,000 lives in 2005.¹

In addition to high morbidity and mortality, breast cancer continues to be a leading professional liability concern. According to the PIAA, the most prevalent and second most expensive condition resulting in malpractice claims against physicians continues to be breast cancer. Over 41 percent of all claims involving breast cancer result in an indemnity payment to the claimant. The average of these payments was more than \$215,000 in the period ranging from 1985 to 2001, with recent payments averaging over \$290,000.²

Using NORCAL data, national data and case studies, this course examines the most common reasons that physicians miss a diagnosis of breast cancer, including delays in ordering tests, misinterpreting tests and failure to refer patients for appropriate care. We offer risk management strategies that can help reduce patient death due to physician negligence and, as a result, reduce malpractice risk.

What Are the Common Threads in Breast Cancer Claims?

The PIAA Breast Cancer Study (2002) illuminates several themes in breast cancer litigation (extrapolated from 450 malpractice cases that were resolved in the period between 1995 and 2001):²

- Approximately 74 percent of breast cancer claims involve pre- and perimenopausal women who are considered to be less likely candidates for the disease.
- More than 68 percent of women claimants are under age 50. Claims initiated by women under 50 account for 78 percent of total indemnity, and the average indemnity payments for women in this group is 63 percent higher than for patients older than 50.
- Almost one-third of claimants are under age 40. This group accounts for 43 percent of total indemnity, and 47.5 percent of deaths.
- Radiologists are the most frequently targeted physicians in breast cancer litigation. More than one-third of paid claims are against radiologists. The most prevalent associated issue for radiologists is “mammogram misread,” representing more than 75 percent of radiology claims. The average delay in diagnosis for radiologists is 18 months.

* Keep in mind the information from the PIAA is limited to cases that resulted in professional liability claims. The actual incidence of medical errors related to breast cancer may be greater than that which is presented in this course.

INTRODUCTION

- Obstetricians/gynecologists are the second most frequently targeted physicians in breast cancer claims. The most prevalent associated issues for OB/GYNs are “physical findings failed to impress” and “failure to refer to specialist for biopsy.” The average delay in diagnosis for OB/GYNs is 15.4 months.
- Approximately 80 percent of breast cancer cases reported to the PIAA contained documentation of a first mammogram, which was reported as negative or equivocal. Patients who underwent a second mammogram received negative or equivocal results in 61 percent of cases.

The top five medical specialties associated with breast cancer claims are:

- Radiology
- OB/GYN
- Corporation (e.g., medical group)
- Surgical specialties
- Family practice/general practice

How Was This Course Developed?

All of NORCAL's CME courses are rooted in an analysis of NORCAL and industry-wide claims experience. When we develop a course, we examine claims data and analyze the financial loss by condition/procedure and outcome. Then we look at closed cases in which there was a significant dollar amount awarded. These cases are used to write clinical vignettes which explore the outcome from both clinical and risk management perspectives. The review process is the same for each case study:

- 1) Identify instances during a patient's treatment that compromise a good outcome;
- 2) Suggest methods and strategies that may have improved the outcome of the case; and
- 3) Prevent similar outcomes from occurring in the future.

Because failure to diagnose breast cancer can result in such serious consequences, it is important to examine the causes from both clinical and risk management points of view. While it is neither our intention nor our scope of practice to set the standard of care, this course does contain summarized national guidelines and specific risk management recommendations. In NORCAL's extensive claims experience, these are the areas in which physicians continue to leave themselves vulnerable to allegations of malpractice.

What Forms the Basis for the Standard of Care?

In order for a physician to be sued and found liable for a breast-related claim, four elements must be established: duty, negligence, damages and causation. First, there must be an established doctor-patient relationship that creates a **duty** to care for the patient. If the physician's involvement in the patient's diagnosis and/or treatment is not consistent with the standard of care in the community where he or she practices, that care is deemed **negligent**. Finally, the patient must have sustained verifiable **damages** that were caused by the physician's **negligence**.

Whether or not the standard of care was met is determined through the testimony of medical experts. Clinical practice guidelines are playing an increasing role in expert assessment of physician negligence, especially since their publication on the Internet makes them widely available regardless of the physician's location. These guidelines are produced by panels of specialists in the medical field after an exhaustive review of the latest research.

The acknowledged primary sources of clinical information about the detection, diagnosis and treatment of breast cancer are the material produced by the American Cancer Society, the American College of Radiology,

INTRODUCTION/CME INFORMATION

Sponsored by NORCAL Mutual Insurance Company

Original release date: July 2005

Expiration date: July 2008

Estimated time to complete this activity: 2 hours

This enduring material is a monograph.

The method of physician participation in this educational activity is to read the monograph and complete the Evaluation and CME Attestation Form.

the American College of Obstetricians and Gynecologists, the American College of Surgeons and the American Society of Clinical Oncology. The guidelines set by these organizations are based on evidence gleaned from clinical experience and published, peer-reviewed articles. These evidence-based guidelines and NORCAL's decades of claims and risk management experience form the backbone of the recommendations made in this course.

How Is the Course Organized?

This course contains three closed cases that illustrate adverse outcomes related to failure to diagnose breast cancer cases. Each case comprises the following:

- **Learning objectives**
- **A chronological narrative** that outlines the patient's care
- **A case analysis** that explores errors made on the part of the physician and lessons that can be learned from those mistakes

In addition to the closed cases, there is a more in-depth discussion of various clinical and risk management topics.

Learning Objectives

Given the high morbidity and mortality associated with breast cancer, implement the guidelines for screening asymptomatic individuals that are recommended by the American Cancer Society.

To minimize the number of women whose cancers are missed because they fall outside the "normal" profile of a woman with breast cancer, demonstrate a higher index of suspicion in young and premenopausal women by following all breast complaints to a complete and final resolution.

To reduce the number of failure-to-follow-up allegations made against physicians, develop and strengthen communication and tracking systems and demonstrate your efforts with appropriate and thorough medical records documentation.

Target Audience

This course is intended for all healthcare providers involved in the diagnosis and treatment of breast cancer including: general/family practice physicians, general surgeons, internal medicine physicians, obstetricians/gynecologists, pathologists, radiologists, plastic surgeons, geriatricians, oncologists and allied healthcare practitioners.

INTRODUCTION/CME INFORMATION

Credit Designation Statement

NORCAL Mutual Insurance Company designates this educational activity for a maximum of 2 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

ACCME Accreditation Statement

NORCAL Mutual Insurance Company is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Instructions for Completing the Course and Receiving CME Credit

After reading through the closed cases and discussion, complete the Evaluation and CME Attestation Form.

Important: You must attest to the number of hours you spent in this educational activity on the form. CME certificates will be issued approximately seven to ten business days after the form has been received.

Mail your Evaluation and CME Attestation Form to:

NORCAL Mutual Insurance Company
Attn: Risk Management
560 Davis Street, 2nd Floor
San Francisco, CA 94111

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INTRODUCTION/CME INFORMATION

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Disclosures

There are no commercial supporters for this activity. The NORCAL Planning Committee and expert reviewers have nothing to disclose. This activity does not include a discussion of unapproved drugs or devices.

Disclaimer

The information in this course has been obtained from sources generally considered to be reliable; however, accuracy and completeness are not guaranteed. The information is intended as risk management advice. It does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about topics covered in this course should be directed to your attorney.

Guidelines presented should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtain the same results. The ultimate judgment regarding the propriety of any specific procedure must be made by the physician in light of the individual circumstances presented by the patient.

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Case One

LEARNING OBJECTIVES

After reading this case and the associated discussion, consider implementing the following risk reduction measures:

- Develop policies and procedures to ensure that the evaluation of a breast mass is followed to its conclusion.
- Always distinguish between a diagnostic and a routine mammogram. Diagnostic mammograms should have the clinical problem including the size and location of any masses on the order form.
- Use a tracking or “tickler” system to ensure that the evaluation of a breast mass is completed in a timely fashion.
- In a clinic setting, develop systems to ensure that an individual physician is responsible for completion of the evaluation of a breast mass. Another member of the staff should also take responsibility for the evaluation in order to add redundancy and decrease the risk of medical errors.
- Radiologists should specify additional imaging tests to evaluate mammographic abnormalities.

Allegation:

Delayed diagnosis of breast cancer resulting in decreased prognosis in a 61-year-old female.

The Event

A 59-year-old patient arrived at a clinic for her annual well woman visit. On her intake form, she reported low energy, frequent urination and overweight. She also wrote “lump in right breast, suspect cyst (breasts always lumpy) but to check out.”

Her primary care physician (Physician #1) conducted a complete physical examination without discussing the breast lump with the patient and without documenting a discussion in the chart. When the time came for breast and pelvic examinations, the patient said she would prefer a female physician. Physician #1 obliged the patient by deferring her breast, pelvic and Pap examinations to a later date when a female physician would be available at the clinic.

Two weeks later, the patient came to the clinic for her visit with a female physician (Physician #2). A medical assistant wrote in the medical record that the patient was present for a Pap and “breast exam—feels lump.” Physician #2 deferred the pelvic and Pap for one month so that it would occur exactly one year from the last Pap smear. In concen-

trating on the breast, Physician #2 wrote as to the present problem, “patient with right breast lump for one month. Last mammogram two years ago.”

Physician #2 examined the patient and drew pictures of her findings. A palpable mass in the left breast was at the one o'clock position and was 2 cm in diameter, soft and mobile. In her opinion, it was consistent with a benign cyst. Neither the patient nor the physician was concerned about this mass. (Ironically, this turned out to be the area where cancer was later discovered.)

In contrast, a mass in the right breast at 12 o'clock was new and concerning to both the physician and the patient. Physician #2 documented that the new right mass was different from the one on the left and more worrisome. For this breast mass, she communicated and documented that the patient should have a mammogram as soon as possible. The physician additionally felt that the mass was sufficiently worrisome and that the patient would likely end up with a biopsy; for that reason, she referred her to a general surgeon at the same time.

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Physician #2 then verbally warned the patient that one out of every eight women develops breast cancer and that she could be at risk.

The physician accompanied the patient out of the exam room and told the office manager that the patient needed a mammogram appointment and a general surgeon consultation. The physician then told the patient to schedule a follow-up once the mammogram and the general surgery referral were accomplished. The patient left the office.

A “Referral Request” form for the mammogram was completed by the office manager the next day. The office manager both prepared the form and signed Physician #2’s name on it, a procedure authorized by the medical group. Under “Diagnosis” the office manager wrote: “Well Woman” and under “Services Requested” she wrote “Well Woman Mammogram.” The referral was not reviewed or signed by any physician at the clinic before it was sent to the radiology group.

When the office manager attempted the biopsy referral, she was told that the general surgeon wanted the mammogram films in hand at the time he saw the patient. It was agreed that the office manager would recontact the general surgeon’s office once the mammogram was completed, set the appointment then, and complete the paperwork at that time. No referral form was generated for the biopsy; the office manager instead called the patient and told her to call the medical clinic once the mammogram was completed.

Six weeks later the patient had her mammogram. The radiologist made the following comments on the mammography report: “Bilateral smooth masses increased in size since [date of previous mammogram two years prior] consistent with cyst. Left breast cyst upper outer quadrant and lower inner quadrant. Assessment: Benign. Recommendation: Routine screening in 1 year.”

After the mammogram results were returned to the medical clinic, the office manager contacted the patient by telephone and reminded her that the general surgery appointment needed to be made. The patient, however, told the office manager that the mammogram results were benign and

she did not want to see the surgeon citing that she had been through all this before. The office manager took this information to one of the physicians at the medical clinic (“Unknown Physician”) who chose to do nothing more under the circumstances. There was no entry made in the patient’s medical record and the referral to the general surgeon never occurred.

About five months later the patient was seen by a third physician (Physician #3) at the medical clinic for her deferred pelvic examination. Physician #3 inquired about her mammogram of five months prior and recorded that it was within normal limits, but he did not examine the patient’s breasts and did not re-refer her to a general surgeon to follow-up on Physician #2’s concerns.

Approximately seven months later, the patient returned to the medical clinic and saw Physician #3 again with a complaint of a new *left* breast mass. (Recall that Physician #2 had been concerned about a mass on the *right* breast.) After his examination, Physician #3 referred the patient for a mammogram and ultrasound, bilateral breasts. He also referred her to a general surgeon for consideration of an excisional biopsy.

The mammogram of the left breast showed a “new” spiculated mass at 12 o’clock, precisely where Physician #2 described the probable “cyst” on the left breast one year prior. A general surgeon conducted an excisional biopsy of the mass and the pathological exam showed a 2.5 cm poorly differentiated carcinoma with extensive carcinoma in situ.

A month later the patient underwent a left partial mastectomy, sentinel node dissection and a left axillary dissection. Pathological examination of the specimens revealed that the cancer involved two out of nine lymph nodes but had not spread to any other locations.

The following year the patient saw Physician #2 again. Physician #2 asked the patient “Why didn’t you go to the surgical referral that I recommended on [date two years prior]?” The patient said “Because the mammogram was benign. I didn’t feel the need to follow-up with the surgeon.” Physician

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#2 told the patient she was upset with her for not following her orders to go to the surgeon. The patient apologized to the physician and said, “you were the only one who told me this could happen.” One month later, the patient filed suit against the medical clinic, naming all three of the primary care physicians involved in her care.

Case Analysis

This case is an example of how ineffective communication and follow-up can lead to a delayed diagnosis and an expensive malpractice settlement. Each of the physicians in this patient’s care has some responsibility in the outcome of this case, as does the clinic as a whole.

Physician #1

This physician arguably met the standard of care when the patient presented to the clinic for her routine examination. He performed the exam and, at the patient’s request, deferred breast, pelvic and Pap examinations to a time when a female physician was available.

From a risk management perspective, however, not at all mentioning the “lump in breast” that the patient noted on her intake form is an area for further analysis. At face value, this physician could argue that because the patient’s breasts were to be examined at a later date by a colleague, it was not necessary to discuss the breast problem at this visit. But when Physician #1’s role is scrutinized subsequent to the filing of a negligence lawsuit against the medical clinic, the question becomes whether his lack of verbal acknowledgement of the patient’s presenting problem may have contributed to the patient’s overall feeling that the physicians at this clinic were not appropriately concerned for her.

Patients who sue their doctors explicitly link communication problems with their dissatisfaction.[†] While it may not have impacted the ultimate outcome of this case, it would have been more proactive for Physician #1 to at least question the patient about the lump, discuss her concerns, clarify the role of clinical breast examination and

diagnostic testing, and document the discussion in the patient’s medical record. Then a separate visit could be scheduled for the patient to be examined by a female physician. This level of interaction between physician and patient may have provided a vital patient education component (regarding the detection of breast cancer and the importance of follow-up) and may have created a sense of continuity for this patient who was seen by at least three primary care physicians at this practice.

Physician #2 and the Office Manager

The problems in Physician #2’s care of this patient are inseparable from the problems seen in the medical practice as a whole. Even though, by patient account, this was the only physician who told the patient directly that breast cancer was a concern and took resolute action to achieve a diagnosis, there were some serious gaps in her follow-up care.

Physician #2 ordered two referrals, a mammogram and a general surgery consult. The trouble with the mammography referral was that the office manager wrote “Well Woman” under “Diagnosis” and “Well Woman Mammogram” under “Services Requested.” This is equivalent to requesting a general “screening” mammogram rather than a “diagnostic” mammogram, which is certainly not what Physician #2 intended. However, because this physician did not directly communicate the purpose of this mammogram to the office manager, and because the medical clinic did not require physician oversight of referral requests, the radiologist was ignorant of the specific area of concern to this physician.

In her defense, at deposition the office manager explained that the medical clinic considers the “Referral Request” to be a standard billing form. The staff does not feel obligated to be meticulously accurate on the form and it is routine to write “Well Woman Mammogram” for billing purposes. The systematic failure to adequately document the precise reason for a referral for a mammogram and distinguish between a diagnostic and routine mammogram reflects a major deficiency in the clinic’s referral system. In addition, it is unacceptable for

[†] For more information on the relationship between communication problems and professional liability, refer to NORCAL’s CME enduring material entitled *Communication & Follow Up*. Available at: www.norcalmutual.com/cme.

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an office manager to sign a physician's name to any documentation, even a referral request. Without direct oversight by a physician, this practice could never be justified in a court of law.

Furthermore, the responsibility for the never-accomplished general surgery referral falls partly on Physician #2. The office manager testified that she placed Physician #2's chart note on her desk with other charts needing expedited referrals. When she got to the referral two days later and was informed by the surgeon's office that the biopsy wouldn't take place until the surgeon was able to view the mammographic images, she put the chart note aside on her desk. It would have been more appropriate for the office manager to process and send the referral anyway to the surgeon's office, and advise the patient to bring the mammogram films to the general surgery appointment. This would have helped to generate documentation that could facilitate better follow-up care of this patient *and* aid the defense of a future malpractice allegation. Again, if there had been physician oversight of the referral process, this error may not have been made.

The "Unknown Physician"

A question is raised to whether the standard of care was met by the unknown clinic physician who received the news from the office manager that the patient refused the surgery referral after the benign mammogram and who instructed the office manager to drop pursuit of this referral. In the interest of patient safety, continuity of care and risk management, it would have been more proactive if this physician had contacted the patient to discuss the issue or, better yet, brought the patient's refusal to Physician #2 who may have been in the position to make a better clinical judgment about how to proceed with this particular patient. At the very least, this physician should have used the patient's medical record to document the rationale behind his or her decision.

Physician #3

When Physician #3 saw this patient for her deferred pelvic examination, he asked about her mammogram seven months prior, but did not examine the patient's breasts, and did not re-refer

her to a surgeon to followup on Physician #2's concerns. By doing so this physician missed an opportunity to correct the follow-up problems generated by the last visit and, as a result, made this case indefensible.

The Radiologist

The first mammogram was reported as "[b]ilateral smooth masses increased in size since [date of previous mammogram two years prior] consistent with cyst." It is accepted that masses that are enlarging require further diagnostic imaging and an ultrasound (not a mammogram) is preferable in determining whether a mass is cystic or solid. Regardless of whether or not the referral was marked "screening" or "diagnostic," the growing mass should have alerted him to take additional views and recommend further imaging.

The American College of Radiology Practice Guideline for Diagnostic Mammography states that "[t]he request for diagnostic mammography should be regarded as a request for diagnostic breast imaging consultation, which may also include additional separate studies (e.g., ultrasound, magnetic resonance imaging [MRI] as indicated)." The guideline further says that "[t]he goal of diagnostic mammography is to obtain information that leads to specific interpretive conclusions and/or further diagnostic and management recommendations or courses of action."

The Clinic

This case illustrates a common problem in clinics where multiple treating physicians see individual patients. Every time a clinical problem is passed from one provider to another, an opportunity is created for miscommunication and inadequate follow-up of the problem. A single error by one provider in this chain of visits can derail the process required to adequately evaluate the patient's breast mass. This is particularly problematic with the complete evaluation of a breast mass which often involves the participation over a period of time of at least three physicians: a primary care physician, a radiologist and a general surgeon.

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The primary care physicians involved in this case were primarily concerned with the care at the time of the patient's visit. No one physician "owned" the responsibility to complete the evaluation of this breast mass. As the care was passed from one physician to the next, errors were propagated. One approach to this problem would be to assign responsibility for follow-up and completion of the breast mass evaluation to a single physician. In this case, Physician #2 would be the obvious choice. When the patient resisted a visit with the general surgeon, this information would have been directed specifically to Physician #2 who presumably would have intervened and encouraged the patient to see the general surgeon.

The most conscientious physicians will make errors in the course of patient care. An error in the evaluation of a breast mass leading to a delay

in the diagnosis of breast cancer has the potential to cause great harm to the patient. To reduce such errors, the concept of highly reliable systems is being introduced in the medical arena. In this approach, the clinic could require that both an individual physician and a member of the medical staff take responsibility for completing the evaluation of a suspicious breast mass. The office manager would ensure that the patient had completed the mammogram and seen the general surgeon by a certain date, using a calendar or "tickler" file or electronic medical records system to remind her. As an additional safeguard in this high-risk circumstance, the physician could use a reminder system to ensure the evaluation had been completed. Medical clinics have a duty to ensure that appropriate systems are in place to minimize the risk of patient injury from medical errors.

Case Two

LEARNING OBJECTIVES

After reading this case and the associated discussion, consider implementing the following risk reduction measures:

- Develop clear policies and procedures for review of test results by the ordering physician and ensure that all staff members comply with these procedures.
- Clarify the roles and responsibilities of the various care providers that the patient sees and document this information in the chart.
- Maintain a master problem list and continue any problem on the list until resolution.
- Periodically review the patient charts in order to ensure that ongoing problems have been completely evaluated and important screening tests such as mammograms and Pap smears have been evaluated.
- When a mammographic finding is ambiguous, radiologists should ask patients to return for additional imaging studies. If patients do not respond, a certified letter should be returned to the patient requesting them to return for additional studies. The documentation of that certified letter should be kept on file in case the patient does not return.

Allegation:

27-month delay in diagnosis of breast cancer resulting in mastectomy and metastasis.

The Event

A primary care physician saw a then 49-year-old female patient when she transferred her care from another medical group. The visit consisted of a discussion of her chief complaints, and she returned one month later for a complete physical. The physician performed a breast exam, which was noted to be within normal limits. The patient was given a referral for a mammogram, which she had approximately two weeks later.

On the day of the mammogram, the primary care physician received a “wet reading” via facsimile from the radiologist which stated the “left breast negative, right breast has one area of increased tissue density, but not a true mass. Should be followed.”

Upon receipt of the faxed report, the physician set it aside with the intention of waiting for the final-

ized report before informing the patient; however, the report was removed from his desk without his knowledge (presumably by an office staff member) and filed in the patient record. When the final report arrived from the radiologist, it too was filed away without the physician seeing it.

Over the next two years, the patient was seen by this physician a total of nine times for various health problems unrelated to the breast. Rather than reviewing the patient’s chart before each visit, the physician’s custom was to review a fact sheet which records illnesses, procedures and diagnostic examinations. Upon medical records review, it was discovered that this sheet did not indicate the patient’s mammogram of two years prior.

With regard to a screening mammogram that should have occurred one year after the original mammogram, the physician testified that after

CASE TWO

one of her visits he had referred the patient to an OB-GYN for hirsutism and knew that she was being followed thereafter by the OB-GYN for gynecological care. He assumed that the other physician would address the need for mammography and did not inquire of the patient whether her annual breast, pelvic and Pap examination (including mammography) were being performed by the OB-GYN.

Approximately two years and two months after her first visit, the patient returned to the primary care physician with a chief complaint of a red spot on her right breast for three to four weeks. On examination the patient had a vague pink area in the medial right breast which exhibited slight warmth and tenderness. The left breast was noted to be normal. It was at that time that the physician looked back in the chart at the patient's prior mammography results and realized this was the first time he had seen the mammogram report of more than two years prior.

The patient was referred immediately for a mammogram and stereotactic core biopsy. The biopsy revealed moderate to poorly differentiated infiltrating ductal carcinoma. The patient underwent a right modified radical mastectomy. Pathological reports described an ill-defined tumor measuring approximately 2x1 cm located 8 cm laterally from the nipple. The diagnosis was poorly differentiated infiltrating and in-situ ductal carcinoma with extensive lymphatic invasion. Metastatic tumor was observed in 5 out of 17 lymph nodes.

Case Analysis

The Primary Care Physician

The following bullets summarize the ways in which the physician in this case was vulnerable to allegations of malpractice. Each problem is discussed in detail below.

- Failure to properly track mammography results (i.e., the report was filed without physician knowledge)

- Failure to immediately and directly communicate results indicative of a life-threatening condition to a patient
- Failure to ensure that a female was having annual gynecologic examinations, including mammography

At deposition, the physician explained that his custom was to wait for the final mammogram report prior to discussing the results with the patient. Upon receipt of a faxed report containing abnormal results, he stated that he customarily placed the report on his desk until the finalized report arrived, at which time he would initiate the appropriate action.

As the chronology of this case shows, however, this method of follow-up did not work. Both the initial faxed report and the final report were filed away without action on the part of the physician, in this case severely compromising a patient's care. Physicians are liable for acts and omissions on the part of office staff, and should have written procedures that specifically outline the process for managing lab results and filing reports in the medical record *after* physician review.[†]

Another problem in this case was the physician's failure to inquire as to the mammography results in his *nine* subsequent visits with the patient. Although he testified that the medical record contained a summary sheet that he reviewed before each visit, the sheet did not indicate any mention of the mammography referral, the results or the follow-up plan. While such sheets can be an important risk management and patient safety tool, if they are not used consistently, a physician's care is not defensible.

Though it is unreasonable and inefficient to expect a physician to review the entire chart on every patient visit, it is important to review the patient's chart on a periodic basis. One method would be to review the prior office note on every visit. Ongoing problems would be documented in the current note in order to facilitate appropriate follow-up at subsequent visits. Briefly review the prior

[†] For more information on policies and procedures and their role in malpractice litigation, refer to NORCAL's October 2004 Claims Rx entitled "Key Areas for Policy and Procedure Development in Clinical Practice." Available at: www.norcalmutual.com.

CASE TWO

year's notes at the time of every annual examination. Summary sheets should be updated at the onset of a new medical problem and at the time of annual exams.

Finally, by not ensuring that the patient was having annual gynecologic examinations (including mammography) by her OB-GYN, this physician failed to meet the standard of care as the patient's primary care physician. From a litigation standpoint, his assumption that the other doctor would address the need for mammography demonstrates that he was not sufficiently concerned for the welfare of his patient and, had this case gone to trial, may have seriously compromised his credibility in front of a jury.

Errors may be made when a patient is seen multiple times for different problems and when the patient has two providers who share primary care responsibilities. Primary care providers should develop systems to ensure that patients are obtaining their annual mammograms and Pap smears. At the end of a visit, primary care providers should determine the time of the next annual examination and emphasize that annual examinations are important, even for patients who are seen frequently throughout the year.

The annual visit is a good time to clarify the roles and responsibilities of the various care providers

that the patient sees and document this information in the chart. When a woman sees both an internist or family practitioner and a gynecologist for regular care, it is important for the respective physicians to know which physician is managing which aspects of the patient's care. For example, an internist may document in the chart that the gynecologist orders annual mammograms, while the internist orders periodic blood tests. It is advisable that all tests ordered on a female patient be copied to both providers.

The Radiologist

The radiologist bears some responsibility in this case as well. His report was ambiguous and incomplete: "area of increased tissue density, but not a true mass." If the patient did have an area of increased tissue density, it should have been worked up with further imaging, typically in the form of magnified spot compression views and ultrasound (see Case One). Another option may have been short-term follow-up (i.e., six months). In this scenario, the radiologist would have been responsible for using reminders to guide the patient through the imaging work-up until complete. The ordering physician, too, would need to be directly informed of the further imaging studies.

Case Three

LEARNING OBJECTIVES

After reading this case and the associated discussion, consider implementing the following risk reduction measures:

- Recognize that breast cancer can occur in young, breastfeeding and pregnant women.
- Utilize the “WIT-D” approach to rule out the worst possible diagnosis, even if you suspect a more benign condition.
- Obtain a tissue diagnosis with fine needle aspiration or biopsy on every persistent dominant mass.

Allegation:

Failure to diagnose metastatic breast cancer resulting in a five-month delay in diagnosis for a married mother in her 30s.

The Event

A 38-year-old woman, postpartum and breast-feeding, presented to her primary care physician (Physician #1) with complaints of pain and a golf ball-sized lump in the outer lower quadrant of her left breast. Assuming it was a breast infection, the physician prescribed a 10-day course of antibiotics.

About two weeks later, the patient sought care from her gynecologist (Physician #2) reporting a nontender mass in her left breast. Physician #2 placed the patient on a one-week trial of Keflex®. The patient followed with Physician #2's partner (Physician #3) for continued left breast pain. Despite the antibiotics, the breast was noted to be red and indurated. Physician #3 felt the patient possibly had an abscess and put her on an additional 14-day course of Keflex® and referred her to a radiologist for an ultrasound, which showed a 2 cm hypoechoic area at the 4 o'clock position. Physician #3 referred the patient to a surgeon for a needle-guided aspiration.

Ten days later, the surgeon (Physician #4) met with the patient to attempt aspiration; however, he could find no fluid to aspirate. He switched her antibiotics and indicated that he wanted to perform a “punch biopsy” to rule out inflammatory breast cancer. A week after this visit, the surgeon performed an incision and drainage of the lump on the lateral aspect of the left breast. A large pocket of fluid was cultured and loculations within the pocket were broken up. The surgeon's operative report described cutting a “small piece of skin ellipse” for biopsy to rule out inflammatory cancer.

The pathologist (Physician #5) read the sample as benign skin with mild perivascular chronic inflammation and no evidence of breast cancer. In her report, however, she clearly stated that the sample contained no breast tissue, only skin. The surgeon's records indicated that he received the pathologist's report and initialed it.

Over the ensuing weeks, the patient continued to see the surgeon. The surgeon noted that although the induration never completely cleared up, the patient seemed to be getting better. When four months had passed, the surgeon felt that the infection was persistent enough that he referred her to an infectious disease specialist (Physician #6) for evaluation of left-sided mastitis.

Physician #6's impression was “progressive, dramatic left sided mastitis with failure to respond to long-term IV and oral antibiotics.” He stated there was not an ongoing infectious process and believed the patient had an inflammatory process, possibly breast cancer or lymphoma. He ordered lab tests and stated she should follow up with Physician #4 (the surgeon).

Ultimately a breast biopsy (involving two sites on the breast) was performed five months after the punch biopsy in which only a skin sample was obtained. The report from this biopsy showed poorly differentiated infiltrating ductal carcinoma of 1.8 cm in size and elements of high grade ductal carcinoma in situ on the lateral portion of the breast (the area of the skin biopsy five months prior). In the medial breast sample, the report

CASE THREE

showed a 3.8 cm of poorly differentiated invasive ductal carcinoma with a minor component of high grade ductal carcinoma in situ and extensive lymphatic invasion.

A CT of the chest and abdomen showed extensive liver and bone metastases and the patient was diagnosed with stage T4, N1, M1 cancer. Before she died, the patient and her husband filed suit against all the practitioners involved in her care.

Case Analysis

This is a complicated case with questionable liability as to many of the physicians involved in the patient's care. In malpractice law, even when there is a clear case of delay in diagnosis (in this case five months), the burden is on the plaintiffs' attorneys to prove what, if any, effect on prognosis would have occurred as a result of the alleged delay in diagnosis. In the discovery phase of this trial, it was determined that the cancer was actually detectable on the original biopsy slide that contained only a skin sample. This made the pathologist the main target of the lawsuit and the case ultimately settled.

While it is beyond the scope of this course to analyze the pathology slide in question, there are some other problematic aspects (on the part of all involved physicians) that contributed to the patient's delay in diagnosis. The patient's sense of betrayal by her healthcare providers in the end may have contributed to her decision to sue.

Did the physicians in this case have a low index of suspicion regarding this patient?

The physicians in this case made a clinical diagnosis of mastitis in a young breastfeeding woman with a painful red indurated breast mass. Mastitis is common in breastfeeding women and the clinical presentation certainly was typical for this diagnosis. However, inflammatory breast cancer should always be a part of the differential diagnosis of an inflammatory breast lesion, even if it is not the first diagnosis to be considered. Initial treatment with antibiotics was appropriate, but when the condition had not improved with antibiotics, the physicians halfheartedly considered breast cancer, and did not complete the appropriate evaluation to

rule out the disease in a timely fashion.

Ruling out the worst possible diagnosis is a proven axiom of healthcare risk management. One of the simplest but most helpful formulations of this advice is the "witty" or "WIT-D" approach to patient safety proposed by Carolyn Buppert:³

W = *Worst thing (identify it, rule it out)*

What is the worst thing the patient could have with this presentation? This guides the physician in establishing a prioritized differential diagnosis.

I = *Information (needed to rule out the worst thing)*

What information is needed to rule the worst case scenario in or out? Knowing what information to seek will guide the physician in performing the history and physical, ordering studies and asking for consultations.

T = *Tell someone (about the worst thing)*

What information must the physician share—with the patient and other involved healthcare providers—to ensure that he or she is notified of all signs and symptoms that could help establish the diagnosis and determine the treatment plan?

D = *Document*

Documenting your decision-making process is crucial for both continuity of care and defense of your actions should your care later be questioned.

Had the physicians in this case utilized the WIT-D approach, they first would have identified the worst diagnosis that the patient could have with this presentation: inflammatory breast cancer. They would then have taken the appropriate steps to rule out inflammatory breast cancer by obtaining a breast biopsy in a timely fashion. (The surgeon's decision in obtaining a skin biopsy was inadequate; a breast tissue sample was warranted.) All patients with a persistent dominant breast mass should be evaluated with a clinical breast exam, breast imaging studies (mammogram and/or ultrasound) and histologic sampling (FNA or breast biopsy). As discussed in the introduction to this course, the PIAA Breast Cancer Study (2002) found

CASE THREE

that one of the most prevalent issues for OB/GYNs is failure to refer to specialist for a biopsy.

There is a vital piece of patient education that goes with this approach. If breast cancer had been seriously considered as part of the differential diagnosis, it would follow that the physicians would

have taken extra steps to talk to the patient about cancer, and the importance of diagnostic testing. Communication such as this is constructive and proactive and demonstrates to the patient that her doctors want to rule out the worst possible diagnosis, even if they suspect a more benign condition.

About Breast Cancer

LEARNING OBJECTIVES

- Approximately 1 in 7 American women will develop breast cancer in her lifetime.
- Breast cancer is the second leading cause of cancer death in American women.
- Female gender, advanced age (50+), heredity, long menstrual history, nulliparity, obesity and alcohol use are all positive risk factors for breast cancer.
- Early diagnosis and treatment can significantly improve survival.

Breast Cancer Statistics

According to statistics from the American Cancer Society, with the exception of nonmelanoma skin cancers, breast cancer is the most common form of cancer among American women. A woman in the United States has a 1 in 7 (13.4 percent) chance of developing invasive breast cancer at some point in her lifetime. In 2005, an estimated 211,240 cases of invasive breast cancer will be diagnosed, and 40,110 will die from the disease. In addition to invasive breast cancer, 58,490 new cases of in situ breast cancer are expected to be reported.¹

Breast cancer death rates have been declining over the past decade, probably due to earlier detection and better treatment. Nevertheless, breast cancer is the second leading cause of cancer death in women (following lung cancer). An American woman has a 1 in 33 (3 percent) chance of dying from breast cancer, and in 2005, over 40,000 women will die from the disease (470 men).¹

Types of Breast Cancer¹

Infiltrating ductal carcinoma (IDC) is the most common type of breast cancer, accounting for approximately 80 percent of all invasive breast cancers. It starts in a breast duct and then passes into the fatty tissue of the breast where it can metastasize.

Infiltrating lobular carcinoma (ILC) is similar to IDC, but it originates in the milk-producing lobules of the breast. IDC may be more difficult to detect by mammography and accounts for 10 percent of all breast cancers.

Ductal carcinoma in situ (DCIS) and **lobular carcinoma in situ (LCIS)** are noninvasive breast cancers that are confined to the ducts or lobules where they originated. DCIS will account for approximately 20 percent of new breast cancer cases.

Inflammatory breast cancer (IBC) accounts for 1-3 percent of all breast cancers, and is associated with dimpling of the skin (“peau d’orange”), erythema and skin nodules—all of which advance quickly and are associated with aggressive metastases.

Risk Factors¹

Nonmodifiable Risk Factors

Female gender is the most obvious risk factor for breast cancer; the disease is 100 times more common in women than in men. Age is the second most important risk factor, with 77 percent of breast cancers diagnosed in women older than 50.

A personal history of breast cancer in one breast comes with a 3- to 4-fold risk of developing a new cancer in either breast. The inherited genetic mutations BRCA1 and BRCA2 account for approximately 5-10 percent of all cases, and women who carry these genes have up to an 80 percent chance of developing the disease in their lifetime. Other gene mutations associated with a high rate of breast cancer (e.g. ATM and CHECK-2) are currently being studied as well.

Beyond inherited genetic mutations, any family history of breast cancer is associated with a higher risk of developing the disease. The risk is increased

ABOUT BREAST CANCER

when a person has two or more relatives with breast or ovarian cancer and when the disease occurs before age 50 in a mother, sister, grandmother or aunt. A first-degree relative with breast cancer can double a woman's risk, while two first-degree relatives with the disease increase her risk by five times. Risk is also higher when a person has Ashkenazi Jewish heritage in addition to a family history of breast cancer. Li-Fraumeni and Crowdens Syndromes are other (rare) but familial links to breast cancer risk.

A woman with biopsy-confirmed atypical hyperplasia (ductal or lobular) has a 4- to 5-times higher risk of developing breast cancer. Previous abnormal biopsies that have detected fibroadenoma with complex features, hyperplasia with atypia, sclerosing adenosis or solitary papilloma are associated with a 1.5 to 2 times greater risk of developing breast cancer.

Some reports have shown that women who as children or young adults underwent previous breast radiation (as therapy for another cancer) have as much as a 12 times higher than normal risk for developing breast cancer. The age of the patient at the time of radiation appears to mitigate this risk (e.g., younger patients have a higher risk).

Women who started menstruating early (before age 12) or who stopped menstruating late (after age 55) have a somewhat higher risk of developing breast cancer.

Modifiable Risk Factors/Lifestyle-related Factors

A slightly increased risk of breast cancer has been associated with women who delay having children (after age 30) or who have never had children, obesity (especially after menopause) and alcohol use. The extents to which oral contraceptives, post-menopausal hormone therapy and high-fat diets are risk factors for breast cancer are also being studied and evaluated.

A decreased risk of developing breast cancer has been linked to modest to vigorous physical exercise and, to a lesser extent, breastfeeding (especially longer than 1.5-2 years); however, not all studies confirm this.

Tamoxifen has been proven to decrease the risk in women at increased risk, and preliminary data suggests that raloxifene may also decrease risk in these women.

Signs and Symptoms

The earliest sign of breast cancer is usually an abnormality detected on screening mammogram. Such abnormalities can be detected before a woman or her healthcare provider is able to detect anything through palpation, underscoring the value of regular screening. When physical signs and symptoms do exist (i.e., after a breast mass has grown to that point), they may include breast lump, swelling, thickening or distortion; skin dimpling or irritation; and nipple pain, scaliness, retraction, ulceration or spontaneous discharge.

Conclusion

With the exception of skin cancers, breast cancer is the most common form of cancer among American women. The disease is strongly associated with heredity, although the majority of breast cancers are detected in women who have no family history of the disease. In addition to heredity, common risk factors include previous atypical hyperplasia, nulliparity, a long menstrual history, obesity (especially after menopause) and alcohol consumption; however, it is important to note that most women with breast cancer have no apparent risk factors. These statistics provide support for routine screening mammography in women starting at age 40. Screening mammography creates an opportunity to detect preclinical breast cancer and, thus, significantly improve life expectancy for many women diagnosed with the disease.

Detection/Diagnosis

KEY POINTS

- Women of average risk should begin screening mammography at age 40.
- High-risk women may benefit from earlier screening, shorter intervals between screening and the use of modalities other than mammography.
- If an abnormality is detected, clinicians should work together until a definitive diagnosis has been achieved.
- CAD systems are extremely useful, but require additional documentation on the part of radiologists in order to mitigate professional liability risk.
- Skill, attention to detail and the correct application of additional imaging procedures are keys to minimizing malpractice risk for radiologists.

Breast Cancer Screening

Screening is a method by which asymptomatic individuals are tested for occult disease. Through screening, breast cancers can be detectable before they are at the palpable stage, which can improve prognosis and the efficacy of treatment. The value of breast cancer screening has been demonstrated in numerous studies; indeed the majority of recommendations endorse mammography as the gold standard in preventive care. However, there are also some limitations in screening. Breast cancer screening will not benefit all women who develop breast cancer (if their disease is particularly aggressive), and it may potentially lead to unnecessary biopsies.⁴

In 2003, the American Cancer Society issued new breast cancer guidelines to illustrate the benefits, as well as the limitations and potential harms of breast screening. The recommendations made in these guidelines are summarized in the table below.

American Cancer Society Guidelines for Early Breast Cancer Detection, 2003

Women at Average Risk

Begin mammography at age 40.

For women in their 20s and 30s, it is recommended that clinical breast examination be part of a periodic health examination, preferably at least every three years. Asymptomatic women aged 40 and over should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.

Beginning in their 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do a BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly.

Women should have an opportunity to become informed about the benefits, limitations and potential harms associated with regular screening.

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DETECTION/DIAGNOSIS

Older Women	Screening decisions in older women should be individualized by considering the potential benefits and risks of mammography in the context of current health status and estimated life expectancy. As long as a woman is in reasonably good health and would be a candidate for treatment she should continue to be screened with mammography.
Women at Increased Risk	Women at increased risk of breast cancer might benefit from additional screening strategies beyond those offered to women of average risk, such as earlier initiation of screening, shorter screening intervals or the addition of screening modalities other than mammography and physical examination, such as ultrasound or magnetic resonance imaging. However, the evidence currently available is insufficient to justify recommendations for any of these screening approaches.
<small>Excerpted from Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP, et al. American Cancer Society Guidelines for Breast Cancer Screening: Update 2003. CA Cancer J Clin 2003;53:143.</small>	

Considerations for Hereditary Breast Cancer

There are numerous statistical models designed to calculate risk for women with known factors associated with breast cancer. Patients who are high-risk because of family history (including those with inherited BRCA1 or BRCA2 mutations) have different screening options than women of average risk. As noted in the table above, these screening options include earlier initiation of screening, shorter screening intervals and the addition of screening modalities other than mammography. The American Cancer Society emphasizes, however, that the current medical evidence does not justify a universal guideline for the screening of high-risk individuals. Options for surveillance and prevention should be discussed on an individual basis between high-risk women and their health-care providers.^{4,5}

From patient safety and risk management perspectives, it is important that physicians inquire about family history of cancer, and counsel their high-risk patients about the benefits, limitations and risks of various screening options, including genetic testing for the BRCA1/2 mutations. Such discussions, and the decisions that are made as a result, should be thoroughly documented in patient medical records.

Other Detection Procedures and Definitive Diagnosis

Once a breast mass has been discovered, usually by palpation or mammography, there are numerous procedures available to help physicians and patients achieve a definitive diagnosis. The accuracy of all detection procedures depends heavily on the ability of the clinician performing the procedure. It is important to refer only to radiologists, pathologists and surgeons with demonstrated skill and experience.

Ultrasound

The main application for ultrasound in breast imaging is to differentiate solid masses, which may be malignant, from cystic lesions, which are usually benign. Secondary uses of ultrasound are to guide core needle biopsies or breast localization procedures. Several recent studies have shown that ultrasound may be of benefit as a frontline diagnostic tool, with the diagnostic accuracy of ultrasound approaching or exceeding that of mammography, especially with regard to the detection of invasive breast cancer. (Mammography remains superior to ultrasound in the detection of in-situ disease.) Some experts predict that a combination of mammography and ultrasound could become the “gold standard” moving forward.⁶

DETECTION/DIAGNOSIS

Computer-aided Detection (CAD) and Diagnosis

Much has been written over the past decade about the usefulness of CAD systems to assist radiologists in the performance and interpretation of mammography. Recent studies suggest that CAD systems may substantially improve the detection of early-stage malignancies. CAD software designed to be used in concert with screen-film mammography has been likened to a “spell-checker” for mammograms.^{4,7}

Full-field Digital Mammography (FFDM)

FFDM systems use digital detectors to convert x-ray photons to digital signals. As a result, these systems can significantly improve the storage and retrieval of images, including the ability to transfer information to remote locations. One study demonstrated FFDM to reduce the number of unnecessary biopsies, but unfortunately showed the method to be inferior to film-screen mammography in terms of sensitivity. More research is required before the method is used for general screening.^{4,7}

Magnetic Resonance Imaging (MRI)

Contrast-enhanced MRI is a new modality for the detection of breast cancer. Controversy remains about whether this technique can be used for breast cancer screening, but it has exhibited effectiveness in defining tumor location and the extent (staging) of disease in patients with known breast cancer. MRI is currently considered a useful diagnostic adjunct to mammography and breast ultrasound, especially in high-risk women or women with extremely dense breast tissue. Some surgeons order MRIs before they operate so they can better plan their course of action.^{4,8}

Invasive Diagnostic Procedures

Breast imaging studies are not considered diagnostic. Only a biopsy will yield a tissue diagnosis on which treatment decisions can be based. There are several ways of obtaining a tissue sample. These include stereotactic or ultrasound guided core needle biopsy, breast needle localization of a lesion under mammographic or ultrasound guidance followed by surgical excision, and fine needle aspiration (FNA). The imaging guided biopsies (stereotactic or ultrasound) have the advantage of seeing definitively whether the area in question is being biopsied and they are, at the same time, minimally invasive.

Malpractice Risks Associated with Computer-aided Detection (CAD)

CAD helps radiologists identify suspicious lesions on mammograms. The technology is designed to offer a second review of the radiologist’s interpretation of the mammogram by highlighting areas of concern that might otherwise be overlooked. The radiologist then makes his or her final diagnosis based on all the information available.¹

CAD systems are obviously meant to augment (not replace or override) a radiologist’s interpretation; however, a professional liability exposure may exist if a radiologist dismisses a CAD-highlighted area that subsequently develops into a cancer.²

The following risk management recommendations for radiologists pertain to the use of CAD in conjunction with mammography:

- If you hold a different opinion from the CAD system with regard to a highlighted area, document the difference of opinion and the decision-making rationale that led you to your final opinion/recommendations.
- Keep CAD results in patient medical records.

1 Smith A, Hall P, Marcello D. Emerging Technologies in Breast Cancer Detection. *Radiol Manage* 2004 Jul-Aug;26(4):16-24.

2 Berlin L. Computer-aided detection in mammography: Perplexing medical/legal issues for new technology. *Applied Radiology*. August 2001.

DETECTION/DIAGNOSIS

Each of these methods has diagnostic value, depending on the skill level of the practitioner. From patient safety and risk management perspectives, before performing any surgical procedure, it is essential that a thorough informed consent process takes place. The radiologist or surgeon should discuss the procedure with the patient in a face-to-face manner, including its risks, benefits and limitations. Using educational materials solidifies the discussion and can help manage patient expectations from a risk management point of view. Finally, fully documenting the informed consent discussion and obtaining a signed consent form creates a record that the discussion took place.

Conclusion

The justification for early detection through the universal application of breast cancer screening is supported by numerous studies. However, as with any medical testing, breast cancer screening comes with certain risks and limitations, that should be discussed with patients as part of the informed consent process. The American Cancer Society Guidelines for the Early Detection of Breast Cancer emphasize annual mammographic screening for women of average risk beginning at age 40. Other imaging procedures should be used to confirm a suspicious mammographic finding, with the goal of definitive diagnosis and resolution. Higher-risk women can benefit from more aggressive screening and surveillance, and should be counseled on an individual basis regarding their options.

Risk Management

KEY POINTS

- Breast cancer is the 2nd most expensive condition generating professional liability claims nationwide.
- Patients should be counseled in a straightforward manner about breast cancer, their risk factors and the importance of regular screening mammography.
- Improved communication among providers can ensure that all positive, suspicious or incidental findings are followed up.
- Appropriate documentation practices can enhance the continuity of care with patients and help defend a malpractice allegation should one arise.

Professional Liability Data

As outlined in the introduction to this course, breast cancer is the second most expensive condition generating liability claims nationwide, following brain damaged infants.²

In the PIAA Breast Cancer Study that was conducted in 2002, radiology was the most frequently targeted specialty in breast cancer claims, accounting for 33 percent of all claims, and with an average indemnity of \$346,247. The prevalent error on the part of radiologists is “mammogram misread,” indicated in over 75 percent of all radiology claims.²

Second to radiologists were obstetrician/gynecologists, who accounted for nearly 23 percent of all breast cancer claims. The average indemnity for OB/GYNs was \$368,798, and the most frequent error for this group was “physical findings failed to impress,” followed closely by “failure to refer to specialist for biopsy.”²

Other groups/physician specialties associated with breast cancer claims included corporations (i.e., medical groups), surgical specialties, general and family practice physicians, internal medicine physicians, hospitals and pathologists.²

Tips for Avoiding Breast Cancer Claims

Anchored in evidence-based practice guidelines and malpractice claims experience, this course contains numerous tips and strategies for promoting patient safety and reducing your likelihood of being named in a professional liability lawsuit. The following bullet points were adapted from the PIAA Breast Cancer Study (2002) and summarize the risk management recommendations made in this course. These suggestions are by no means all-inclusive and are not to be interpreted as the standard of care.

All Practitioners Involved in the Diagnosis of Breast Cancer

- Document all patient complaints relative to the breast.
- Inquire and document all personal and family history of breast cancer.
- Inquire and request the results of any previous mammograms.
- Follow up with other physician consultants regarding test results.
- Pregnancy or breastfeeding status should not cause a delay in appropriate diagnostic studies.
- A palpable mass with a negative mammogram requires further workup with additional imaging, typically ultrasound, to determine if the mass is cystic or solid.
- Tissue diagnosis should be considered for solid lesions.

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RISK MANAGEMENT

- Palpable masses that are clinically suspicious should be biopsied even with negative imaging studies.

Primary Care Physicians and OB/GYNs

- Perform a thorough breast examination on each female patient as part of a complete physical exam, regardless of age or complaints.
- If a mass is palpated or suspected, additional studies must be done to rule out malignancy.
- Do not abandon further diagnostic studies because you are not impressed with the physical findings.
- Confirm and document that the patient understands the need for subsequent studies.
- Perform regular and timely follow-up examinations on patients who present with breast-related complaints.
- Utilize a "tickler" file or other reminder system to ensure that the patient obtains the recommended studies and/or sees the surgical consultant.

Radiologists

- If a mammogram results in a film of poor technical quality, repeat the study.
- If mammogram results are equivocal, recommend a repeat study using additional views and other imaging modalities as appropriate.
- Ensure that an adequate physical examination is performed and documented.
- Compare results of the present study to all previous studies performed.
- Promptly report your findings to the referring physician. If the patient was self-referred, the results of the study should be conveyed directly to her. The mammography center at which the study was performed is also required to send the results to the patient.
- If there is any suspicion of an abnormality, the patient should be advised to consult promptly with her primary care physician.
- If a screening mammogram is being performed on a self-referred patient, be sure to advise the patient of the importance of annual physical breast examinations by her physician.
- In cases of self-referral, ensure the patient receives proper follow-up.

Surgeons

- When a patient is referred, always perform an adequate examination and document your findings, especially when the referring physician's findings were unimpressive.
- When performing a biopsy, be sure a section of the lesion is being removed in both open and needle procedures. When performing an image-guided biopsy on a nonpalpable lesion, a mammographic image of the specimen should be obtained at the time of the biopsy. The radiologist should call the surgeon with confirmation that the correct area was successfully removed.
- Promptly report consultation and biopsy results to the referring physician and patient. ■

RISK MANAGEMENT

Physician-Patient Communication

The link between poor communication and malpractice litigation is well documented.^{9,10} Communication problems are often perceived by patients because of the time pressures that physicians face; that is, patients feel rushed in their communications with their physicians and that they may not be getting all the information they need to make informed decisions. Physicians may, in an attempt to save time, not provide sufficient information about all the aspects of a patient's medical treatment, including the reason for a particular test and the importance of complying with follow-up instructions.

Communicating with your patients about cancer is not an easy task. Cancer is an extremely frightening diagnosis for the patient. Most patients, however, want to learn more about their conditions, no matter how serious or poor the prognosis, even if they are reluctant to ask questions or do not know how to pose the right ones. Listening to the patient, understanding his or her needs, acknowledging that medical problems create anxiety and providing information are necessary aspects of quality patient care.

Reassurance

Many physicians want to reassure their patients about signs and symptoms or when referring patients for diagnostic tests. This reassurance can become problematic if a cancer is later diagnosed and there is a question about whether there was an act of negligence. Primary care physicians should focus on *educating* patients about their circumstances, the tests that are required and their treatment options. Providing reassurance can give patients false hopes and lead to professional liability allegations down the line.

Patient Education

Printed patient education materials can go a long way in educating patients about different aspects of cancer including prevention, screening, diagnosis and treatment. The American Cancer Society and National Cancer Institute are among those who have both printed and internet education resources for patients. These materials can be accessed at the following URLs:

American Cancer Society
www.cancer.org

National Cancer Institute
www.cancer.gov

Communicating About Tests

When you order a diagnostic test for a patient, explain the purpose using language that the patient can understand. Remember that patients may be too embarrassed to ask you to define words they do not understand or may not be able to read. Include the following information in your verbal and written explanations:

- The name of the test (e.g., mammogram, ultrasound, biopsy)
- What the test is meant to discover or rule out
- The urgency of the test or procedure
- The procedure the patient will undergo and any necessary preparations for it
- When the results are expected
- How you will contact the patient with the results
- What you or the patient can do to alleviate discomfort if the test is frightening, painful or uncomfortable.
- Posttest instructions
- The need for follow-up care and appointments

Physician-Physician Communication

Both referring and consulting physicians can improve the consultation process while helping to reduce liability exposure. Physicians on both sides of the consultation process should strive to clearly communicate all the necessary information to provide care.

Planning who will take primary responsibility for the patient or how care will be shared between two physicians is essential. Both specialists and primary care physicians should maintain clear and complete

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documentation of the consultation process in the patient medical records, including the following:

- Differential diagnoses
- Impressions
- Treatment plans
- Follow-up

Role of the Referring Physician

A study on the consultation and referral process found that the quality of consultant feedback to the referring physician was directly related to the quality of communication from the referring physician to the consulting physician.¹¹

The following suggestions for referring physicians can help improve communication with consulting physicians and improve the level of care that the patient receives.^{11,12,13}

- Communicate in writing the specific consultation request and include information about the patient's condition and expectations. Written communication should be clear and concise. A fact sheet containing relevant clinical information, any clinically suspicious findings and the physician's impression is an effective communication tool that can help ensure optimal test results.
- If a patient is referred following imaging or lab tests, relay results or information from those tests to the consultant. Document this communication in the patient's medical record.
- Call the consulting physician and document the call if the consultant's report is not received in a timely manner, something in the report is unclear, the clinical findings do not match the report or the consulting physician suggests follow-up that seems inappropriate.
- Take responsibility for coordinating additional referrals to other consultants.

Role of the Consulting Physician

A consultant's communication with the referring physician and the patient is essential in focusing priorities and expectations and reducing the potential for conflict. Consulting specialists must be aware that they have a responsibility to ensure that the referring, primary care physician is notified of the visit and of any significant findings.

Consultant physicians should consider the following suggestions:^{11,12,13}

- In the consultant report, address the referring physician's request and note any other issues related to the patient's condition. An effective written response can begin by:
 - re-stating the referring physician's question;
 - providing specific recommendations that are supplemented by patient history, physical examination and diagnostic test results; and
 - concluding with a discussion to clarify the recommendations.
- In a hospital setting, notify the patient's primary care physician of the patient's admission and provide that physician with discharge plans so that follow-up visits can be arranged.
- Let the patient's primary care physician coordinate additional referrals to other consultants. (Make sure that the primary care physician knows that he or she will be coordinating subsequent referrals.)
- Send a report to the primary care physician about subsequent follow-up visits.
- When the treatment is complete, refer the patient back to his or her primary care physician.
- Discuss any new issues that may arise with the referring physician, such as:
 - the need for additional consultations with other doctors;

RISK MANAGEMENT

- the need for further testing;
 - physician, patient, and family expectations; and
 - whether the patient's care will be co-managed by both physicians.
- Incidental findings not associated with the current problem or condition should also be included in the consultant report.

Follow Up

As was seen in the closed case examples, NORCAL's breast cancer claims are often caused by a delay in follow-up or a failure to follow up. Many claims involve patients who were never informed of a positive or suspicious result, and/or were not advised of the importance of follow-up. By the time the patient did receive the recommended diagnostic testing, he or she had much more serious symptoms and a much graver prognosis.

A thorough follow-up system encompasses not only tracking of test results, but also referral to specialists, appointments and telephone calls that require follow-up. The goal of the system is to manage clinical information, medical records and paperwork to ensure that all information is available to the physician when he or she makes clinical decisions.

While the ultimate responsibility for follow-up is the physician's, a secretary, medical assistant or nurse can maintain a sheet to check off test results or procedure reports as they are received. (See sample in the next column.)

Keep in mind the following "rules of thumb":

- Every patient with abnormal findings must be contacted, preferably by telephone.
- Do not allow reports to be filed until you have reviewed and signed them. Ensure understanding and use of this policy by all physicians and support staff in your medical office.
- Referring and consulting physicians should have a thorough follow-up system.

- A direct call to the referring physician reporting abnormal findings (and documentation of the same) will provide protection to all involved physicians, as well as to the patient.
- A few moments on the telephone may avoid patient injury or death and save years of litigation and untold dollar losses.

Patient	Test Problem Procedure Consultation Referral	Date Ordered	Date of Results	Follow-up Needed and Initials	Completion Date and Initials
S A M P L E					

Documentation

Incomplete or nonexistent documentation can compromise patient care and the defensibility of a malpractice allegation. Documentation should be written in objective, nonjudgmental terms and include:

- Patient and family history of breast cancer and other cancers
- History of risk factors
- All breast symptoms
- Physical examination findings, clinical impressions and follow-up plans
- Location, size and physical description of the mass (e.g., a 1.5 cm smooth mobile soft nontender lump at 1 o'clock on the right breast, 4 cm from the nipple).
- Education given to the patient regarding breast cancer, including prevention, screening, diagnosis and treatment
- Screening and diagnostic methods used
- Diagnostic protocol if implemented
- Pertinent positive and negative findings
- Recommendations and areas of concern communicated to the patient

RISK MANAGEMENT

- Rationale for clinical decisions
- Informed consent or refusal given
- Signed and dated informed consent or refusal forms
- Referral information and consultation reports
- Follow-up procedure among providers and with the patient

Conclusion

Breast cancer is a clinical disease that mostly occurs in older women. It becomes a major professional liability concern, however, when the disease occurs in younger women and in patients for whom the index of suspicion is low. Low suspicion can cause physicians in all specialties to “drop the ball” on essential testing, follow-up and documentation procedures, making them vulnerable to allegations of negligence. It is important to never presume that a person does not have breast cancer just because they are low-risk.

Many of NORCAL's breast cancer claims are the result of misread or “false-negative” mammograms. Radiologists are encouraged to keep their interpretation skills current and obtain second opinions when in doubt. Radiologists are also encouraged to always call referring physicians with reports of positive findings suggesting malignancy and document the date and time of the call on their formal radiographic report.

When primary care physicians and obstetrician/gynecologists are the target of malpractice claims, the cause is often related to not following up on physical findings and failures or delays in referring patients for diagnostic testing. Primary care physicians are encouraged to make it a policy to pursue all breast complaints to final resolution, implementing whatever office procedures or forms that are necessary to facilitate this.

Often breast cancer cases involve negligence on the part of numerous physicians, often due to communication failures between providers or

breakdowns in office follow-up systems. All physician specialties are encouraged to evaluate their systems and forms on a regular basis. Are your procedures facilitating the most efficient and thorough evaluation of breast complaints? Where is there room for improvement?

Spend time with your patients to communicate the importance of certain tests and the need for follow-up. Document your discussions and follow-up plans in the medical record in a standardized, professional format. If you are a consulting physician (e.g., radiologist, surgeon or pathologist), remember that although you may not provide direct patient care, you still may have a physician-patient relationship and, therefore, a duty to the patient. You can decrease your liability risk by increasing contact and improving communication with the other physicians involved in a particular patient's care. Closing the gaps in communication and follow-up, and documenting your efforts, can make the difference between a missed or delayed diagnosis and a successful intervention or treatment.

Endnotes

- ¹ American Cancer Society. Cancer Facts and Figures 2005. Atlanta: American Cancer Society; 2005.
- ² Physician Insurers Association of America (PIAA). Breast Cancer Study. (3rd Edition). Spring 2002.
- ³ Buppert C. A Witty (WIT-D) Approach to Avoiding Mistakes. Gold Sheet 4(6), 2002. Available at: www.medscape.com/viewarticle/438381. Accessed: 7/16/2002. The Gold Sheet is published monthly by the Law Office of Carolyn Buppert.
- ⁴ Smith RA, Saslow D, Sawyer KA, Burke W, Costanza ME, Evans WP, et al. American Cancer Society Guidelines for Breast Cancer Screening: Update 2003. CA Cancer J Clin 2003;53:141-169.
- ⁵ Robson M. Clinical consideration in the management of individuals at risk for hereditary breast and ovarian cancer. Cancer Control 2002;9(6):457-465.
- ⁶ Benson SR, Blue J, Judd K, Harman JE. Ultrasound is now better than mammography for the detection of invasive breast cancer. Am J Surg. 2004 Oct;188(4):381-5.
- ⁷ Smith A, Hall P, Marcello D. Emerging Technologies in Breast Cancer Detection. Radiol Manage 2004 Jul-Aug;26(4):16-24.
- ⁸ Gundry KR. The application of breast MRI in staging and screening for breast cancer. Oncology (Huntingt). 2005 Feb;19(2):159-69; discussion 170, 173-4, 177.
- ⁹ Levinson W, Roter DL, Mullooly JP, Dull VT, Frankel RM. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. JAMA. 1997;277:553-9.
- ¹⁰ Huntington B and Kuhn N. Communication gaffes: a root cause of malpractice claims. BUMC Proceedings 2003;16:157-161.
- ¹¹ Bourget C, Gilchrist V, McCord G, et al. The consultation and referral process: a report from NEON (Northeastern Ohio Network Research Group). Fam Pract. 1998;46(1):47.
- ¹² Epstein RM. Communications between primary care physicians and consultants. Arch Fam Med 1995;4:403-9.
- ¹³ Stoekle JD, Toman LJ, Emanuel LL, Elrich CM. A manual on manners and courtesies for the shared care of patients. The Journal of Clinical Ethics. 1997;8(1)22-23.

Failure to Diagnose Breast Cancer

CME EVALUATION AND ATTESTATION FORM

NORCAL Mutual Insurance Company is committed to excellence in continuing education. Your opinions are critical to us in this effort. To assist us in evaluating the effectiveness of this activity and to make recommendations for future educational offerings, please reflect carefully and complete this evaluation form. **Please note: A CME certificate is issued only upon receipt of your completed evaluation form.**

Effectiveness in Meeting Identified Needs

Was the activity effective in meeting the identified needs (listed below)? Yes No

Breast cancer remains one of the most common forms of cancer in American women, and breast cancer is the most prevalent (and second most expensive) condition generating liability claims against physicians nationwide. Professional liability experience demonstrates that physicians need a higher index of suspicion for patients who fall outside the "normal" parameters of a breast cancer patient (i.e., younger women), and that strengthening of practice management systems can reduce malpractice exposure. The goal of this activity is to increase patient safety while reducing professional liability risk.

Learning Objectives and Learning Contract

Learning Objective	Teaching Effectiveness <i>Degree to which this presentation provided you with knowledge or skills to implement in your practice?</i>	Learning Contract <i>State a practice change you are committed to make based on these objectives.</i>	Degree of Certainty <i>How certain are you that you will make this change?</i>
Given the high morbidity and mortality associated with breast cancer, implement the guidelines for screening asymptomatic individuals that are recommended by the American Cancer Society.	<input type="checkbox"/> 5 (Superior) <input type="checkbox"/> 4 (Good) <input type="checkbox"/> 3 (Satisfactory) <input type="checkbox"/> 2 (Fair) <input type="checkbox"/> 1 (Poor)		<input type="checkbox"/> 100% <input type="checkbox"/> 80% <input type="checkbox"/> 60% <input type="checkbox"/> 40% <input type="checkbox"/> 20% <input type="checkbox"/> 0%
To minimize the number of women whose cancers are missed because they fall outside the "normal" profile of a woman with breast cancer, demonstrate a higher index of suspicion in young and pre-menopausal women.	<input type="checkbox"/> 5 (Superior) <input type="checkbox"/> 4 (Good) <input type="checkbox"/> 3 (Satisfactory) <input type="checkbox"/> 2 (Fair) <input type="checkbox"/> 1 (Poor)		<input type="checkbox"/> 100% <input type="checkbox"/> 80% <input type="checkbox"/> 60% <input type="checkbox"/> 40% <input type="checkbox"/> 20% <input type="checkbox"/> 0%
To reduce the number of failure to follow up allegations made against physicians, develop and strengthen communication and tracking systems, and demonstrate your efforts with appropriate and thorough medical records documentation.	<input type="checkbox"/> 5 (Superior) <input type="checkbox"/> 4 (Good) <input type="checkbox"/> 3 (Satisfactory) <input type="checkbox"/> 2 (Fair) <input type="checkbox"/> 1 (Poor)		<input type="checkbox"/> 100% <input type="checkbox"/> 80% <input type="checkbox"/> 60% <input type="checkbox"/> 40% <input type="checkbox"/> 20% <input type="checkbox"/> 0%

Continued on reverse....

Commercial Support and Disclosure

	True	False	Comments
Disclosure of faculty relationships with commercial organizations was made available to me.	<input type="checkbox"/>	<input type="checkbox"/>	
The activity was free of commercial bias.	<input type="checkbox"/>	<input type="checkbox"/>	
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If you answered "false" to any of the above questions, please provide details in the comments section below.

Future Educational Needs/Comments

Please list any other topics that would be of interest to you for future educational activities:

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