

PPIC® Closed Claim Case Review

Test Tracking Errors: Where Does the Responsibility Fall?

by Patricia A. Bliujus RN, BSN, MHA, CHPN, CCM, PPIC® Claims Analyst/Risk Consultant

Abstract

Evidence-based practice in medicine means that clinical decisions are formally supported by data that are derived from prospectively designed, randomized, and controlled clinical trials. It has become an important part of everyday care and has led to the publication of a number of practice guidelines. Still, no matter what the clinical situation, it is the responsibility of the physician to use therapeutic measures wisely because most patients possess only limited medical knowledge and must rely on their physicians for advice. This article will demonstrate how a delay in breast cancer diagnosis can occur if there is a break in communicating the patient's biopsy results.

Overview

A 38-year-old female claimant who had not been to a doctor in five years was seen by an internal medicine physician in the fall of 2001. She presented with what she described as a mole on her breast with a hard lump under the skin. The internist ordered a mammogram, which was benign, then referred her to a surgeon (the insured). In deposition, the internist alleged that she told the claimant to return to her for follow-up after she saw the surgeon. The plaintiff alleged that she was referred to the surgeon but not instructed to return to the internist.

The claimant initially saw the insured surgeon in November 2001, at which time the insured described a discrete 1.5 to 2 cm mass in the right breast. He performed a needle aspiration biopsy and sent it to pathology for lab analysis. When deposed, the insured alleged that he instructed the claimant to obtain an ultrasound and gave orders accordingly. He also stated that he told the claimant to return for follow-up after the ultrasound was performed, and that even after a negative biopsy he would have needed to see the patient again. The claimant alleged that the insured told her that if she didn't hear from him, her biopsy was negative and she would not need additional tests.

The pathologist indicated that the differential diagnosis was between atypical cells and ductal carcinoma. A follow-up tissue biopsy was recommended for definitive diagnosis. In his report, the pathologist stated that the diagnosis was called to the surgeon that day. While this information was communicated to the insured, he never informed the claimant or the primary care doctor. Furthermore, the claimant did not follow-up after the ultrasound, nor did she return to her primary care physician.

The claimant testified that she did not seek any medical care and treatment from winter 2001 until spring 2004, when she returned to have the "mole" re-examined. At that time, its color had changed on the skin, but its size was relatively unchanged. Further testing indicated metastatic breast cancer, prompting a diagnosis of grade II infiltrating ductal carcinoma.

In July 2004, the plaintiff began a series of 26 radiation treatments, and in October 2004 underwent a right total mastectomy. Her breast cancer was confirmed by the pathologist with 6 out of 12 positive nodes. She had been receiving hormonal therapy since the surgery, and was in remission. When deposed, the plaintiff alleged that the insured had a duty to inform her of the positive biopsy and his failure to do so resulted in her advanced cancer.

The insured testified that his usual practice is to notify patients of positive biopsies and that he was unsure why he did not do so in this case. The pathologist who performed the biopsy testified that he called the insured with the biopsy results and also sent him a written report. The insured did not deny this conversation or receipt of the biopsy report.

Expert Opinion

Plaintiff experts testified that the physician bore the sole responsibility for failing to relate the abnormal laboratory and/or pathologic information to the patient, even though they agreed that it was permissible for the physician to inform the patient to call for the results. They stated that the ultimate responsibility lies with the doctor to make sure that these results are communicated to the patient, even when patients do not follow the physician's instructions.



One of the two plaintiff experts testified about prognosis, stating that in 2001 the tumor probably represented carcinoma in situ or stage I invasive carcinoma; also that in the case of carcinoma in situ, the claimant's five-year survival rate would have been 100%. With stage I carcinoma, she had a five-year survival rate of 95%-98% with appropriate treatment. If the clinical condition of the tumor was accurately reported in the insured's note and the tumor was fixed to the skin, the expert testified that this claimant would probably be categorized as having a stage III cancer with an approximately 50% survival rate for five years. This expert was clearly uncomfortable with the small change in the size of this tumor from November of 2001 until March of 2004, when the plaintiff returned to the health care system. He also could not adequately explain why the tumor had such minimal growth and reluctantly acknowledged that he would have expected it to be much larger in 2004 if it was an aggressive disease.

Defense experts' opinions regarding this case were mixed. They expressed concerns about the casual documentation contained in the insured's records. They also felt, however, that because the insured told the claimant to call for biopsy results and to make her own ultrasound appointment as well as a follow-up appointment with the surgeon, there was no deviation from the standard of care.

One expert felt that her five-year survival rate was less than 50%, even though she was presently cancer free. Multiple experts noted that the tumor was a very slow-growing cancer based on the fact that it only went from 1.5 cm x 2 cm in 2001 to 2 cm x 2 cm in 2004. They believed that the diagnosis in 2001 would likely have been the same, and have required the same treatment, only with less nodal involvement. This belief was due to the lack of significant tumor growth in two years and the subsequent lack of relapse. Also, the claimant's ER/PR positivity was likely a marker for slow growth.

This case settled for \$900,000.

Discussion

The 1999 Institute of Medicine (IOM) report on medical error estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. In that report, *safety* was defined as freedom from accidental injury and *error* was defined as the failure of a planned action to be completed as intended, or as the use of a wrong plan to achieve an aim. A number of universal factors found in the healthcare system can increase the likelihood of errors, including fatigue, stress, delays, complications, and hand-offs. Some errors are due to negligence, but most are due to accident, miscommunication, or procedural malfunction. Some errors cause serious harm, others do not.

One of the goals of medical intervention is to avoid harm to the patient in the course of care. Others include promoting health, preventing disease, curing disease, preventing untimely death, and educating the patient of their compromised status (Jonsen, 2009). These goals of medicine employ some of the basic responsibilities of physicians. Most of these goals can be met simultaneously; however, there can still be conflict between them. One example is when curing disease is impossible and the new goal becomes achieving comfort only due to a patient's advanced condition. In this case, the quote "cure sometimes, support frequently, comfort always" (anonymous) is apt.

Risk Prevention Strategies

Organizations should:

1. Institute strong systems to prevent errors that might be due to system faults.
2. Link computerized physician order entry (CPOE) with clinical decision support systems, which produces a better diagnosis and gives the physician added insight into appropriate steps on positive lab and radiology reports.
3. Ensure that care information, especially changes in orders and ordered diagnostic tests, is referred in a timely and clearly understandable form to the patient and all of the patient's current health care providers.

4. Ask each patient to repeat what he or she has been told during the visit.
5. Employ a verification process to ensure that all relevant documentation and studies are available and have been reviewed, with completion of missing information or resolution of any discrepancies within a given time period of study.
6. Use simple standardized algorithms or checklists for routine procedures and care processes.

Summary

This case had a difficult twist. The insured admitted that he told the claimant to follow-up on her test results, yet he also admitted that he usually contacts his patients and the referring doctors in cases of positive biopsies. Although experts opined that he met the standard of care, they also stated that in their practices they contact the patient when there is a positive test result. As this appears to be the common experience of most patients, we believed the standard of care argument would be hard to sustain.

If a violation of standard of care was found, the question of whether a delay in diagnosis had caused damage to the claimant, would arise. Experts were very favorable in terms of whether there was a significant change in her prognosis during the delay. They were also favorable in terms of the curability of her type of cancer. Nevertheless, she did have metastatic cancer, which required chemotherapy and lessened her chance of survival.

It is interesting to note that the plaintiff stated that she had not had any follow-up treatment, including a mammogram, since her initial diagnosis and treatment. Her treating breast surgeon indicated that she was past due for those procedures. At a trial of this matter a jury might hold this fact against her.

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