

Claim Review

# Follow-up System Failure Leads to Missed Diagnosis

A patient and her primary care physician do not receive communication about an abnormal mammogram, and a failure to timely diagnose breast cancer results.

SPECIALTY	ALLEGATION	PATIENT SAFETY & RISK MANAGEMENT FOCUS
<ul style="list-style-type: none"> <li>✓ Radiology</li> <li>✓ Family practice</li> </ul>	<ul style="list-style-type: none"> <li>✓ Failure to timely diagnose breast cancer</li> </ul>	<ul style="list-style-type: none"> <li>✓ Follow-up system failures</li> </ul>

**Facts of case**

A primary care physician (PCP) saw a 45-year-old woman for a routine exam and ordered a screening mammogram. The radiologist interpreted the mammogram as showing a region of potential distortion within the upper-outer quadrant of the left breast and recommended additional imaging. The radiologist initiated an electronic process to generate and send a letter to the woman and a report to her PCP indicating that the mammogram showed findings that required additional imaging studies to rule out disease.

One year later, the woman saw her PCP, complaining of a palpable lump in her left breast. The PCP ordered a mammogram that revealed a solid lesion in the upper-outer quadrant of the left breast that was highly suspicious for cancer. The radiologist recommended a biopsy of the lesion. Following the biopsy, she was diagnosed with breast cancer and underwent pre-operative chemotherapy

followed by a mastectomy with sentinel node biopsy. She then underwent radiation to the left breast.

The woman filed a malpractice claim against the PCP, the radiologist and the radiology center alleging failure to timely diagnose breast cancer and lost chance of survival.

**Disposition of case**

The malpractice case was settled against the radiologist and the radiology center.

**Patient safety and risk management perspective**

The investigation of this case revealed that the radiologist correctly interpreted the mammogram but a system-generated letter to the patient and report to the ordering clinician were not sent due to a failure in the reporting technology. Neither the patient nor the PCP received the communications about the initial abnormal mammogram. A root cause analysis

of this adverse event included a health information technology (HIT) investigation that found a recent software update triggered a failure in the reporting system and that many patients could have been affected.

The experts who reviewed the case were critical of the radiology center because they had no quality assurance process to test whether system-generated letters and reports were received by patients and ordering clinicians. The PCP's clinic was also criticized for not having a follow-up system in place to ensure that test result reports were received, reviewed and communicated for all ordered tests. The patient testified that she assumed "no news was good news" when she didn't receive communication about the mammogram results.

### Preventing follow-up system failures

The Mammography Quality Standards Act (MQSA) requires a radiology practice that performs mammograms to prepare a written report of the results of any mammography examination signed by the interpreting physician, provide the written report to the patient's physician(s) and provide a written letter to the patient in terms easily understood by a lay person. Most radiology practices use an electronic system to generate patient letters and reports to ordering clinicians, as well as track biopsies and follow-up exams. Most primary care clinic EHRs have the capability to track computer-ordered tests for receipt, review and patient notification. Safety audits of these systems can indicate whether they are working correctly and identify gaps in follow-up processes before a patient is injured.

Radiology and primary care practices can perform a failure modes and effects analysis (FMEA), a prospective process, on test management and reporting processes to identify where and how the process might fail, the likelihood the failure will be detected, the effect of the failure on the patient, and what can be

## Support during an adverse outcome and malpractice claim

For many clinicians, clinics, hospitals and senior living organizations, facing an adverse event and malpractice claim is a real possibility. A claim can have a significant impact on clinicians, care team members and the organization.

The aforementioned radiologist was deeply affected by the filing of this malpractice claim. While she had correctly read the mammogram, she felt guilt over the failure of the communication system and the possibility that many more patients could be affected. Our claim team was able to connect her with our Clinician Peer Support program staff, who helped her to manage those emotions and use that energy toward performance improvement. Our risk and patient safety consultants were able to help both the radiology and primary care practice analyze their follow-up systems, re-engineer safer systems and implement safety audits to ensure the systems continued to work.

Constellation provides resources and support for clinicians and care team members to

keep them focused and productive after an unexpected outcome and malpractice claim, including:

- ✓ Information about what to expect in the claim and litigation process
- ✓ Clinician Peer Support program: counseling and support to address the emotional impact of adverse events, including burnout and second victim syndrome
- ✓ Resources to understand the relationship between burnout and the potential for future adverse events and claims
- ✓ Help to create internal peer support teams
- ✓ Resources and coaching on apology and communication processes that support clinicians, team members, patients and their families
- ✓ Education and resources to recognize the risks to patient safety/malpractice claims
- ✓ Education and resources to create a learning culture so that the experience of an adverse event can be used to improve performance

done to prevent the failure. Using the results of the FMEA, processes can be re-engineered to be more reliable and safe. A root cause analysis (RCA) can also be performed after a failure to diagnose event like this to determine the causes and contributing factors of the event to make processes safe and reliable.

HIT team members or consultants can assist radiology practices with the integration of imaging systems with a closed-loop follow-up workflow that includes patient letters, ordering clinician reports and summaries, biopsy results,

and recommendations and tracking reminders. HIT team members can also assist primary care practices in fully implementing the tracking features of their EHRs.

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