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Sued for misdiagnosis? It could happen to you

Plaintiffs' attorneys and patient safety advocates alike are increasingly focusing their attention on diagnostic errors. Here are the key pitfalls and ways to avoid them.

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Made a medical error? What to say to the patient
John Davenport, MD, JD

PRACTICE RECOMMENDATIONS

- *Create a problem list for each patient, including chronic and acute conditions, unexplained signs and symptoms, medications, and allergies.* (C)
- *Avoid attributing every new symptom to the patient's documented medical conditions.* (C)
- *Develop and adhere to "don't-miss" lists of signs and symptoms that warrant rapid action.* (C)
- *Establish a fail-safe system to ensure that you receive notification whenever a final imaging or lab report differs from the preliminary report and document your response to each abnormal result.* (C)

Strength of recommendation (SOR)

- (A) Good-quality patient-oriented evidence
- (B) Inconsistent or limited-quality patient-oriented evidence
- (C) Consensus, usual practice, opinion, disease-oriented evidence, case series

Misdiagnosis accounts for more malpractice claims than medication errors—indeed, for more lawsuits than any other medical misstep.[1-5] Yet until recently, diagnostic errors garnered little attention from patient safety advocates.

That's no longer the case. In 2007, the Agency for Healthcare Research and Quality (AHRQ) identified diagnostic errors (a catchall category encompassing delayed, incorrect, and missed diagnoses) as a problem that warranted closer study.[6] The inaugural conference on Diagnostic Error in Medicine, cosponsored by AHRQ and the American Medical Informatics Association, took place in 2008. The third annual Diagnostic Error in Medicine conference will be held in Canada in October, reflecting the expanding focus on uncovering root causes of diagnostic error and developing preventive measures aimed at safeguarding patients and avoiding lawsuits.

Because diagnostic errors have long been underemphasized and understudied—and remain difficult to track—it is hard to know just how often they occur. Estimates of their frequency fluctuate widely from 1 study to another, but are generally in the range of 10% to 15%.[7] Fatal illnesses appear to be misdiagnosed more frequently than less severe conditions: A review of more than 50 autopsy studies found that, on average, about 1 in 4 (23.5%) major diagnoses were missed.[1]

Whatever the numbers, diagnostic missteps are clearly common enough to be on patients' radar screen. In a recent survey of US adults, 55% of respondents cited misdiagnosis as their greatest concern when they see a doctor in an outpatient setting.[8] In a Harris Poll commissioned by the National Patient Safety Foundation[9] several years earlier, 1 in 6 adults reported having had a condition that was misdiagnosed.

Evidence suggests that while years of experience and strong diagnostic skills help prevent diagnostic errors, they do not afford full protection against the cascade of events that can result in a serious diagnostic error. In fact, overconfi-

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Diagnostic errors rarely had a single cause. More than 4 in 10 cases involved more than 1 clinician.

dence may contribute to the problem.[10,11]

The take-away message: No physician is immune to misdiagnosis or to a subsequent lawsuit. There are, however, steps you can take to safeguard your patients and yourself, but first you need to know where the pitfalls lie.

Misdiagnosis in primary care: What malpractice claims reveal

Diagnostic errors that result in malpractice claims undergo extensive legal review. Thus, they provide an excellent opportunity for analysis, as the authors of a study of 181 "closed," or completed, claims from 4 malpractice insurers found.[12] The errors all occurred in ambulatory settings, with primary care physicians most frequently involved.

Nearly 6 in 10 of the lawsuits were for missed or delayed cancer diagnoses, followed by misdiagnosis of infection, fracture, and myocardial infarction. Overall, 24% of the cases involved breast cancer. No other disorder came close.

The most common problems, or "breakdowns," in the diagnostic process were:

- failure to order the appropriate diagnostic test (which occurred in 55% of the cases)
- failure to create a proper follow-up plan (45%)
- failure to obtain a thorough medical history or to perform a thorough physical examination (42%).[12]

Notably, however, diagnostic errors rarely had a single cause. A median of 3 breakdowns per case was identified, and more than 4 in 10 cases involved more than 1 clinician.

Additional sources of breakdowns ran the gamut from patient factors (eg, noncompliance, atypical presentation, or a delay in seeking care) to system errors (eg, delay in seeing a test result, referral delay, or a mishandled handoff). Rarely was misdiagnosis attributed to a physician's cognitive error alone. Most diagnostic errors, the authors reported, involved "a potent combination of individual and system factors."[12]

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Lessons from court

Check out the 3 legal cases in the pages that follow from the files of John Davenport, MD, JD. Dr. Davenport, a medical malpractice attorney, provided legal representation in each of these cases.

Is it cancer? Failure to test or follow up

Cancer may not be the most frequently misdiagnosed condition, but because of the dire consequences often associated with a delay in detection, cancer is No. 1 in frequency of diagnostic error lawsuits[13]—with breast cancer typically at or near the top of the list. Evidence suggests that clinician preconception plays a role.

Most women who develop breast cancer are over the age of 50, but plaintiffs in breast cancer suits tend to be younger.[14,15] This may be partly because of overreliance on age as a predictive factor, causing some physicians to offer a younger woman what may be unwarranted reassurance that a breast lump is due to fibrocystic tissue rather than malignancy (**CASE 1**).

Ordering a test is not enough. Even when physicians order the correct test, follow-up may fall short. In the closed claims study, physicians incorrectly interpreted test results in 37% of the cases.[12] Other evidence suggests that about a third of women with abnormal mammograms do not receive follow-up care that's consistent with established guidelines.[16]

What's more, physicians sometimes overlook the fact that diagnostic tests are rarely 100% accurate. Mammography misses approximately 20% of breast cancer cases,[17] for example, and a woman with a palpable lump should be closely watched, not dismissed on the basis of a negative mammogram result.[1,15]

What happens to test results? In other cases, the problem is not that a test result

Rarely was misdiagnosis attributed to a physician's cognitive error alone.

CASE 1 A 32-year-old woman sought care for "sore breasts" 4 months postpartum. Her primary care physician found "bilateral lumpy and tender breasts," diagnosed fibrocystic breast disease, and prescribed a nonsteroidal anti-inflammatory drug. There was no follow-up plan documented.

She returned in 4 months, stating her symptoms were better but she still had soreness in her left breast. The physician did not examine her, but changed her medication to a different anti-inflammatory. Follow-up was to "return to clinic PRN."

On her next visit she complained of a lump in the left breast. The physician found a "spongy irregular 2 cm lump" in the upper outer quadrant of the breast, diagnosed a fibrocystic lesion, and reassured the patient. Follow-up again was to return PRN.

Several months later, the patient saw another physician, for back pain and a painful and enlarging breast lump. The physician suspected fibrocystic disease but was unable to obtain fluid by fine needle aspiration. The patient was referred to a surgeon, who obtained a nondiagnostic needle biopsy and an excisional biopsy, which revealed breast cancer. The patient's back pain turned out to be from metastatic breast cancer. She sued for failure to diagnose breast cancer. The case was settled for an undisclosed large sum.

Commentary: Failure to diagnose breast cancer is a leading cause of malpractice lawsuits, many of them in younger women. Plaintiff recoveries correlate with the length of the delay in diagnosis.

In this case, experts identified a series of missteps in the care of this patient which, when combined with a young, very sick, and sympathetic plaintiff, led to a large recovery. Although it may have been reasonable to diagnose fibrocystic disease on the first visit, experts cited the failure to take a family history (the patient's aunt and maternal grandmother had had breast cancer) and the failure to document a follow-up plan as damaging to the doctor's case. They also faulted the physician for failing to examine the breast on the second visit and failing to do fine needle aspiration or refer on the third visit, and for the nonspecific follow-up plans.

Diagnostic lesson: Although breast cancer is less common in women younger than 40, it does occur, and the same diligence in examination, charting, and follow up is required regardless of the patient's age.

doesn't match the clinical findings, but that the result is not reviewed by the physician or conveyed to the patient in a timely manner. Indeed, the title of a published report of a survey of internists starts with the quote, "I wish I had seen this test result earlier!" [18] Of the 262 internists surveyed, only 41% expressed satisfaction with their method of handling test results.

What would satisfy these physicians? Respondents said what they wanted in a test result management system were tools that would help them generate letters to patients detailing the results, prioritize their workflow, and track orders for tests to completion.

By the way, doc …

Harried physician, hurried response

What physician isn't familiar with the patient who comes in for care of 1, or several, chronic conditions, but mentions another problem as he or she is getting ready to walk out the door (**CASE 2**)? If that problem appears to be a transient and treatable condition, the temptation is to make a hasty diagnosis and write a prescription, without the usual degree of history taking, patient examination, contemplation, or documentation. Doing so, however, poses considerable risk, to both patient and physician.

If the condition or symptom is serious enough to address in the course of the visit, it requires the same level of attention as any other presenting problem. When time constraints prevent you from addressing the complaint with the proper diligence, it would be appropriate—assuming the symptom in question is nonurgent—to ask the patient to make another appointment. But be sure to document that you did so.

How sure are you of the diagnosis?

It's human nature to see things in terms of what you're familiar with. A doctor who has been treating a patient with migraine headaches for years, for example, is apt to assume that "the worst migraine I've ever had" is more of the same (**CASE 3**). Similarly, a clinician who has identified a disorder that matches several of a patient's symptoms may

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CASE 2 A 62-year-old man saw his family physician for routine care of hypertension, diabetes, and hyperlipidemia. During the visit, the patient mentioned that he had back pain, insomnia, and a sore tongue, which the physician diagnosed as aphthous stomatitis and for which a steroidal oral cream was prescribed.

The patient was scheduled to return for a routine visit in 4 months, but did not come in until 7 months had passed—at which time the physician noted a >1 cm nodular bleeding tongue lesion. Biopsy showed squamous cell cancer, and the patient required extensive surgery, chemotherapy, and radiation. He sued for misdiagnosis and delayed diagnosis.

The physician's defense was that given the symptoms and findings, aphthous stomatitis was a reasonable diagnosis and that he had instructed the patient to return to the office if he didn't feel better in a few weeks. The patient disputed this. His attorney noted that the patient had multiple risk factors for tongue cancer that were not in the medical record; nor was there documentation of a tongue examination or the claimed instructions for the return visit, indicating that the patient received substandard care. The case was settled at trial for $300,000.

Commentary: The contrast between the thorough documentation for the patient's chronic disease history and physical exam and the absence of documentation for the sore tongue suggests that this was an instance of a "by the way, doc" conversation—and a reminder of the risk that physicians assume when managing patients with multiple conditions.

Diagnostic lesson: The law does not give physicians a pass on the standard of care, regardless of how many conditions are treated in a single visit. To avoid a diagnostic error—and a potential lawsuit—a symptom-specific history, physical, and clear instructions with a follow-up plan are necessary for every condition that's addressed.

Lawsuits regarding failure to diagnose breast cancer frequently involve younger women, who are more likely to be thought to have fibrocystic disease.

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dismiss or overlook signs and symptoms that do not fit that explanation or diagnosis. Safety advocates refer to this phenomenon as "premature closure." It may also be a function of overconfidence.

One example of physician overconfidence comes from a study in which experienced dermatologists were asked to examine lesions and diagnose melanoma. Although the specialists confidently diagnosed melanoma in more than 50% of the test cases, 30% of their decisions were later found to be incorrect.[19]

Build a no-fault, fail-safe system

The purpose of analyzing diagnostic errors is not to assign blame or point a finger at physicians, but rather to find and fix flaws in the medical system.[20] That approach has been used by patient safety advocates to address other types of errors following the publication of the Institute of Medicine's landmark report on medical error 11 years ago.[21]

Physicians do not get a pass on the standard of care just because they weren't told about the condition until they were ready to move on to the next patient.

Since then, many physician leaders have looked to the airline industry—a field in which the consequences for not strictly adhering to a fail-safe system are likely to be fatal. That reality has led to the development of vital checklists, forcing functions (in which the user is prevented from moving to the next step until the current step is completed), and computerized reminders in an attempt to eliminate, to the extent possible, the chance of human error.

The same principle can be applied to misdiagnosis. Recommended steps—ordering diagnostic tests or referring to a specialist, for example—should be put into motion whenever a set of predetermined parameters are met, rather than relying on physician memory or choice.[20]

Similarly, checklists should specify questions to ask or criteria to be met under specified circumstances to prevent physicians from prematurely settling on a (possibly incorrect) diagnosis. To avoid a rush to judgment, some patient safety advocates[1] stress the importance of assessing the urgency of a patient's condition, rather than trying to arrive at a definitive diagnosis the first time he or she presents with a perplexing set of signs and symptoms. Other recommendations follow:

Mandate a second look. Develop and adhere to a set of criteria to determine when a referral to a specialist or a physician consultation is needed, rather than deciding on a case-by-case basis.

Plug the holes in your follow-up system. Develop a fail-safe system for reviewing diagnostic tests or laboratory findings and reporting them to patients without delay. This can be done with an electronic health record (EHR) system or by developing and adhering to parameters requiring, for instance, that no test result get filed until there are 2 signatures on it—that of the physician who ordered the test, indicating that he or she has seen it, and that of a staff member, indicating that the patient has been notified of the results. As an additional back-up, tell patients undergoing tests when to expect to get results, and stress the importance of calling the office if they do not receive such notification within a specified time frame.

Partner with patients. Engage patients in the pursuit of a definitive diagnosis. Discuss your preliminary findings, describe your treatment decision and what you expect to occur, and urge patients to contact you with evidence that confirms or refutes that expectation. Elicit additional feedback at each visit until either the symptoms have fully resolved or you have gathered enough information to arrive at a definitive diagnosis.

Develop "don't-miss" checklists. One list should cover diagnostic red flags to be considered anytime you see a symptomatic patient to ensure that you don't overlook important signs and symptoms, and include findings that warrant hospital admission, specified diagnostic tests, and immediate referral. (A patient who comes in with a "common pink eye," but has consensual photophobia, is at risk for iritis and needs an urgent ophthalmology evaluation, for instance.) Another list you should develop is a "must-do" list for well visits, featuring clinical scenarios to address and screening tests to remember, such as an eye exam for patients with diabetes.

Question your initial diagnosis. Beware of "premature closure"—the tendency to stop looking for other signs and symptoms once you find a presumptive diagnosis—and "diagnostic inertia"—evaluating new signs

and symptoms almost exclusively on the basis of past medical history. If aspects of a patient presentation do not fit your presumed diagnosis, use a decision support system, if available, to review other possibilities.

Head off hand-off errors. Develop a problem list for each patient to reduce the likelihood that crucial information will be overlooked when more than 1 clinician is involved in his or her care. Include chronic and acute conditions, unexplained signs and symptoms, medications, and allergies. Create a fail-safe system for other potential hand-off problems, as well—requiring confirmation that the findings in a preliminary radiology report are the same as those in the final report before you take action based on the preliminary report, for example, and ensuring that you receive prompt notification whenever that is not the case.

EHRs and decision support: Isn't it time?

In 2009, 44% of office-based physicians had EHRs, according to a Centers for Disease Control and Prevention preliminary report.[22] Federal funding to promote the adoption of EHRs is expected to accelerate their use. Among the benefits of EHRs are clinical reminders, system alerts, and documentation tools that can help reduce the risk of diagnostic missteps and avert misdiagnosis lawsuits.

The Department of Veterans Affairs uses a notification system called View Alert, for example, that tracks acknowledgement of abnormal radiology test results and flags those that remain unacknowledged.[23] EHR systems can also be programmed to issue automated appointment reminders that make it easier to track patients who do not show up for critical follow-up visits.

Diagnostic decision support software adds another critical element. When a clinician inputs a set of symptoms and patient-specific data, such systems produce lists of possible diagnoses, often divided by bodily system.

While many safety advocates believe that the use of such systems will increase the likelihood of accurate diagnosis, critics point out that the software is only as good as the clinician using it. One concern is that computerized systems typically come with a

Recommended steps—ordering diagnostic tests or referring a patient to a specialist, for example—should be based on predetermined parameters, not decided on a case-by-case basis.

CASE 3 A 47-year-old man with a history of migraines walked into his physician's clinic with a complaint of a severe headache. His physician was fully booked but he was given an appointment with a per diem physician. According to the patient and a friend who accompanied him, the patient told the doctor, "This is the worst migraine of my life." The physician simply documented, "flare of migraine." The chart indicated that the physical revealed normal vital signs and noted that the patient was "photophobic," but that his neurological exam was "intact."

Over the next several hours, the patient received sumatriptan and several doses of opioid analgesics. He stated that he still had a headache but felt better and was sent home with instructions to call or come in if the headache returned.

The next morning a neighbor, unable to reach the patient on the phone, went to his house and found him in a stupor, with slurred speech. The patient was taken by ambulance to a local hospital and found to have a subarachnoid hemorrhage. After weeks in the hospital and a rehabilitation center, he was left with significant cognitive and neurological impairments. He sued for failure to diagnose and won a multimillion dollar award at trial.

Commentary: Expert testimony clearly pointed to the history and physical as being substandard. Specifically, the physical should have included, among other things, a test for nuchal rigidity. Had the patient not had a history of migraines, he might have undergone a more complete medical history and physical evaluation and his symptoms would likely have been evaluated more thoroughly.

Diagnostic lesson: Be wary of "diagnostic inertia"—the tendency to depend too much on a past diagnosis when symptoms arise. Don't be trapped into attributing all new symptoms to an old disease.

"macro" ability—that is, the ability to enter large amounts of information with the click of a key. This raises the possibility that an overload of patient data, some of which may be incorrect, will be added to the medical record—or that the system will generate so many possibilities that clinicians will cease to pay attention. Both can lead to inferences of inattention or raise doubts about a physician's credibility in a legal setting.

Electronic prescribing software systems that flag potential drug interactions are a case in point. Forty-five percent of family physicians responding to a *Journal of Family Practice* Instant Poll about their use of such systems reported that they override them frequently. The problem, according to 1 respondent: The system gives "so many red flags that I routinely ignore them all—like the little boy who cried wolf." JFP

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Don't be trapped into attributing all new symptoms to an old disease.

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