Risk Factors That Contribute to Diagnostic Errors

Looking Beyond Clinical Judgment and Communication

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Diagnostic errors are a major patient safety and liability issue. Studies suggest that 12 million patients are misdiagnosed annually, and serious misdiagnoses — such as failure to diagnose cancer — occur in 80,000–160,000 of these patients.[1] The National Academies of Sciences, Engineering, and Medicine's influential report *Improving Diagnosis in Health Care* further elaborates on the burden of diagnostic errors by noting that they represent "the leading type of paid medical malpractice claims and are almost twice as likely to have resulted in the patient's death compared to other claims."[2]

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Various factors can contribute to diagnostic errors. Two of the most common risk factors are clinical judgment and communication.[3] These risk factors, and strategies to address them, are covered in MedPro's articles *Clinical Judgment in Diagnostic Errors: Let's Think About Thinking* and *Communication in the Diagnostic Process: Preventing Breakdowns and Missed Opportunities*.

Beyond clinical judgment and communication, other risk factors play a role in diagnostic errors, such as patient behavior, clinical system failures/administrative issues, and documentation. This article (a) uses MedPro case data to examine how these factors contribute to diagnosis-related allegations, and (b) offers strategies for addressing these risks in healthcare settings.
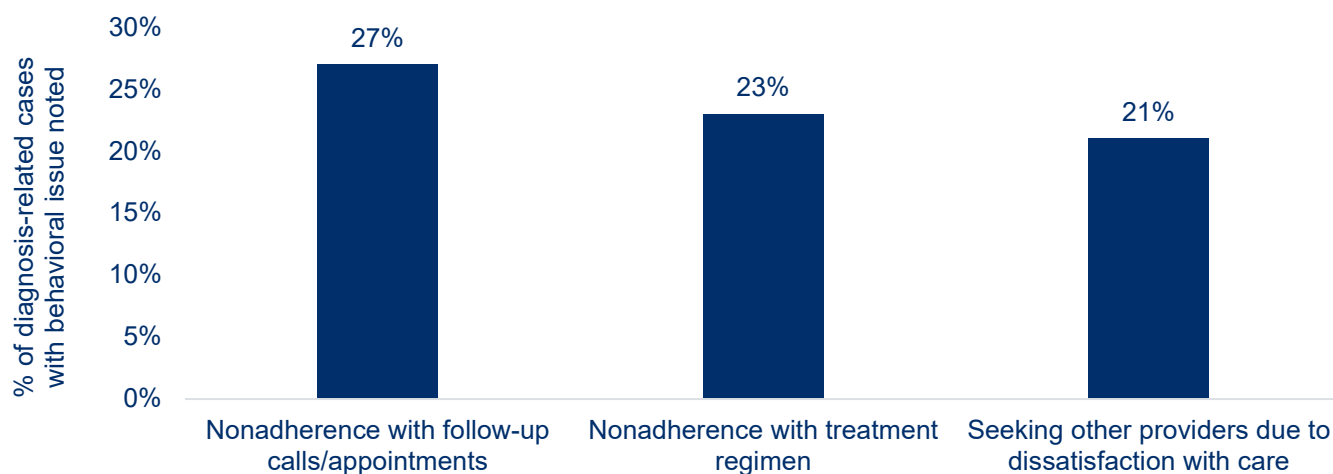
Patient Behavior

Patient and provider/staff behavior can influence the dynamic of healthcare encounters and contribute to diagnostic errors and malpractice allegations. Generally, behavioral issues can

occur with patients or with members of the healthcare team. However, analysis of diagnosis-related cases reveals that the vast majority of behavioral issues are associated with patients.

Problematic patient behavior can erode the provider–patient relationship and increase liability risks. Within diagnosis-related claims, three categories related to patient behavior rise to the top, as shown in Figure 1.

Figure 1. Top Patient Behavioral Issues in Diagnosis-Related Claims

Source: MedPro Group diagnosis-related cases, opened 2013–2022.

Patient nonadherence with follow-up calls/appointments is the most prevalent behavioral issue, and it can contribute to poor outcomes. Consider the following scenario.

Case Study 1: Patient Behavioral Issues

Overview: A 72-year-old female with a history of Type 1 diabetes mellitus presented to her healthcare provider with complaints of swelling in her right groin area. Five days earlier, the patient had self-inserted a needle into the area to drain it. The area was red and warm, with a tender, grape-sized abscess.

The provider incised the abscess, placed a small rubber drain, and obtained a culture (which was negative). He prescribed an oral antibiotic and recommended additional surgery to fully open and drain the abscess. However, the provider did not document this discussion in the patient's health record, and he did not initiate a formal consultation with a surgeon.

Case Study 1: Patient Behavioral Issues (continued)

The patient decided to forego the additional surgery, but returned to the provider's office 4 days later. At that time, the provider readjusted the drain. He noted that the area was still red and swollen; a second culture was negative (although it was later alleged that the culture was not deep enough). The provider again recommended further surgical drainage, but he again failed to document the advice.

Two days after the patient's second appointment, she was admitted to the hospital and diagnosed with right leg necrotizing fasciitis. She required an amputation of the right leg at the hip, and she underwent debridement multiple times and suffered extensive tissue loss.

Discussion: Although the provider in this case made numerous missteps — such as inadequate patient assessment, failure to obtain a consult, and insufficient documentation — the patient's nonadherence to the provider's recommendation for additional surgery very likely contributed to her poor outcome. Further, as this case and Case Study 3 illustrate, behavioral issues are closely related to other areas of risk, and these issues can compound to produce more serious outcomes.

Nonadherence and other problematic patient behaviors — such as unrealistic demands and expectations, hostility, incivility, disruptive actions, etc. — might not always be obvious from the outset; however, some red flags for behavioral issues may include patients who:

- Have undiagnosed or untreated psychiatric disorders

- Have substance use/abuse issues

- Are "frequent flyers" within the health system

- Exhibit rude, unpleasant, threatening, or aggressive behaviors that might potentially escalate over time into violence

- Display needy or manipulative tendencies (e.g., threats of complaints or lawsuits)

- Have repetitive and/or varying complaints without clear clinical significance

- Make frequent requests for refunds or waivers of fees

Although behavioral issues can be difficult to address due to their sensitive nature, healthcare providers and staff members can work to effectively manage patient behavior by setting clear expectations and boundaries, establishing limitations, and thoroughly documenting patient nonadherence and disruptive incidents.

Behavior-Related Risk Tips

The following strategies can help healthcare providers address behavioral issues that could potentially contribute to diagnostic errors:

- Establish a policy defining the basic rights and responsibilities of each patient. This policy provides a foundation on which to build an effective provider–patient relationship. Display this information and make it available to all patients online and in print.

- During each patient encounter, emphasize the importance of following the prescribed treatment regimen, even if symptoms subside. Explain the possible consequences of not following the agreed-upon treatment plan.

- Consider patients' lifestyles and medication costs when prescribing. Social determinants of health — such as economic stability, healthcare access, education level, environment, and social issues — can contribute to issues of nonadherence.

- If a patient has financial, physical, or emotional limitations that lead to nonadherence, determine whether any community services are available to assist the patient and potentially improve adherence.

- With the patients' permission, include family members/significant others in education about the importance of following treatment plans. These individuals might help reinforce the importance of sticking with the treatment regimen.

- Address cultural and health literacy issues that might manifest as inappropriate behaviors because patients are confused, frustrated, or feel disrespected. Patients from all backgrounds might have limited health literacy, which can lead to nonadherence.

- Use a technique, such as teach-back, to ensure that patients fully understand the information and instructions provided.

- Provide patients with education about their treatment plans both verbally and in writing, especially if the patient has serious health problems. Make sure written materials adhere to the principles of plain language.

- If a patient is missing appointments, try to determine the reason. Consider transportation, family care, or financial issues that may prevent the patient from keeping appointments, and determine if solutions are available.

- After several missed appointments, consider sending the patient a letter stressing the importance of keeping the appointments and adhering to the treatment plan.

- Document missed or canceled appointments by noting either "patient no-show" or "canceled" in the patient's record. If possible, note the reason for a cancellation — e.g., "no transportation" or "child care issues."

- Do not delete original appointment entries, as the appointment log may become a valuable tool if you have to demonstrate a patient's continued nonadherence with appointments.

- Document a description of all clinical nonadherence, as well any education provided to the patient/family regarding the consequences of not following the treatment regimen. When documenting nonadherence, use subjective statements from the patient/family and objective information obtained through patient encounters.

- Avoid disparaging remarks or editorializing when documenting information related to patients' nonadherent behaviors.

- Consider using patient agreements to address problematic patient behaviors in an effort to preserve the provider–patient relationship (or to support the process of terminating the relationship).

For more information related to behavioral issues, see MedPro's *Managing Nonadherent Patients* guideline.

Clinical System Failures/Administrative Issues

Clinical system failures and administrative issues are closely aligned because they both relate to inconsistencies in, or problems associated with, organizational processes.

Clinical system failures involve breakdowns in office systems and procedures, namely tracking and follow-up systems. Problems with these systems can lead to errors and oversights that might ultimately contribute to diagnostic errors. Examples of possible clinical system problems include:

- Lack of, or inadequate, processes for tracking test results, consults/referrals, and patient follow-up (regarding test results, missed/canceled appointments, etc.)

- Insufficient maintenance of films from radiology studies

- Delays in receiving, or failure to receive, test results

- Lack of established timeframes for follow-up

- Failure to assign responsibility for follow-up

MedPro case analysis shows that the top clinical system issue in diagnosis-related claims is failure or delay in reporting findings. This issue is cited in about half of the claims involving a clinical system failure, calling attention to the need for healthcare organizations to assess their current tracking and follow-up systems to identify and address vulnerabilities.

Technical issues — such as problems with system interfaces, user errors, software or hardware glitches, and technology failures — also can play a role in clinical system failures.

Test Tracking Safeguards

Does your organization's test tracking system have safeguards to ensure that:

- Ordered tests are scheduled?

- Scheduled tests are completed?

- The organization receives test results?

- The ordering clinician reviews and signs all test results?

- A test reporting form and patient notification process are in place?

- The provider follows up on test results in a specified timeframe?

- Test results are filed in the correct patient record?

- Decisions about care are documented?

Like clinical system failures, administrative issues also are linked to process problems, and they might include lapses related to health records, adverse event reporting, staffing, and policies/procedures. Examples of administrative issues include:

- Failure of providers and staff to adhere to established protocols

- Lack of staff training and education on office systems and processes

- Inadequate supervision of clinical and nonclinical staff

- Failure to verify patient identifiers

- Failure of clinical staff (e.g., a nurse, advanced practice provider, or dental hygienist) to contact a doctor when warranted

Consider the following case, which demonstrates how clinical system failures and administrative issues can cause a delayed diagnosis and patient harm.

Case Study 2: Clinical System Failures/Administrative Issues

Overview: A 44-year-old female patient with a history of cervical dysplasia and breast masses/fibroadenomas was being monitored by her long-time OB/GYN doctor. Per her doctor's order, the patient had a breast ultrasound in the office. The images were sent to an imaging center for analysis.

The imaging center promptly reported the results as suspicious for malignancy and recommended a biopsy. Unfortunately, staff at the OB/GYN practice did not follow the appropriate protocol for notifying the doctor of the patient's results. Thus, the doctor did not review the report, and the report was not filed in the patient's health record.

The patient had an appointment for a mammogram approximately 2 weeks after the ultrasound, but she canceled the appointment. Subsequently, she made and canceled two more appointments within a 3-month timeframe. The patient finally returned to the office 10 months after the ultrasound. At that time, her left breast was red and very firm. A biopsy confirmed invasive ductal carcinoma with lymph node metastases. Although she underwent aggressive treatment, her prognosis was not promising.

Case Study 2: Clinical System Failures/Administrative Issues (continued)

Discussion: Several missteps occurred in this case, the first of which was administrative. The staff members at the OB/GYN clinic did not follow the appropriate protocol for managing the information they received from the imaging center. This set in motion a domino effect, in which the results were not appropriately reviewed or filed. Because of the improper protocol, the patient wasn't notified of the findings and wasn't aware of the severity of her situation.

Further complicating the matter was the practice's "no news is good news" approach to test results. The doctor had not actively engaged the patient in the diagnostic process by asking her to follow up if she didn't receive her results within a specified timeframe. Better patient engagement strategies might have triggered the patient to contact the practice when she didn't hear from any staff member, thus incorporating another safeguard into the process.

Finally, the practice did not have a well-established policy for following up with patients who missed or canceled appointments. Thus, when the patient scheduled and canceled three more appointments, she received no communication that stressed the importance of returning for additional care and testing.

Clinical System/Administrative Risk Tips

The following strategies can help healthcare providers address clinical system and administrative risk factors that could potentially contribute to diagnostic errors:

- Evaluate organizational processes for test tracking, patient follow-up, and referrals/consults. The identification of any gaps in these processes should prompt proactive measures to implement safeguards.

- Establish appropriate timeframes for following up with patients about test results, lab work, missed/canceled appointments, etc. Develop a mechanism that will trigger the immediate reporting and follow-up of critical test results.

- Delegate responsibility for follow-up activities to appropriate staff members.

- Verify patient identifiers (e.g., patient name, record number, and birth date) as part of information management processes.

- Verify that staff and provider training is consistent with roles and responsibilities, and ensure that appropriate training on new or upgraded systems is offered and completed.

- Reinforce the importance of adhering to test and referral/consult tracking processes.

- Evaluate staff and provider competency with clinical systems and ensure appropriate supervision.

- Include a review of clinical systems and administrative functions as part of your practice's quality improvement initiatives.

Documentation

Accurate, thorough documentation is an essential component of high-quality patient care, and it is crucial in the defense of malpractice cases. Yet, case analysis shows that documentation issues are consistently in the top five risk factors associated with diagnosis-related cases. These issues generally fall into three categories: insufficient/lack of documentation, content decisions, and mechanics (Figure 2).

Figure 2. Types of Documentation Issues in Diagnosis-Related Claims
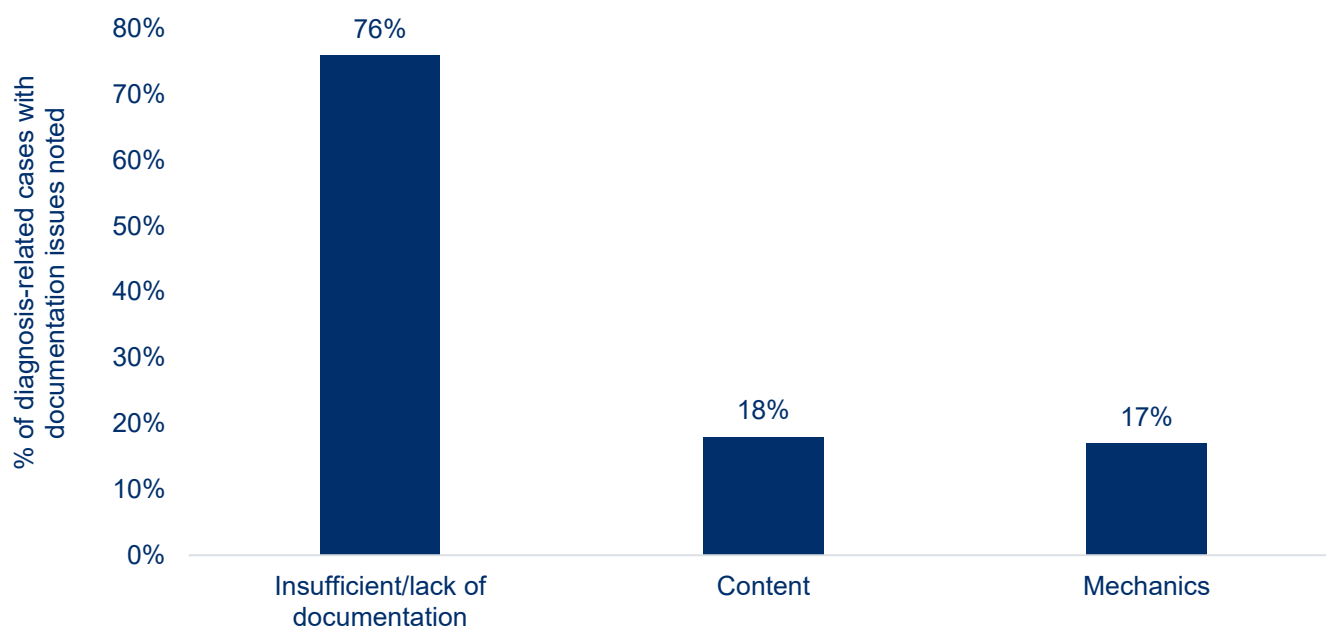
Source: MedPro Group diagnosis-related cases, opened 2013–2022. **Note:** Totals exceed 100 percent because generally more than one factor is associated with each case.

Insufficient Documentation

Among the categories represented in Figure 2, insufficient documentation dominates. Examples of situations that can lead to documentation deficits include:

- Failure to document attempts to follow up with a patient about care or test results.

- Failure of the healthcare provider to document involvement in a patient's care.

- Missing documentation in the patient's health record (e.g., patient problem list, test results, consultations, referrals, signatures indicating review, or medication lists).

- Failure to document adequate details about the patient encounter. This lack of details can be especially problematic in electronic health records (EHRs) because of reliance on form fields and check boxes.

Consider the following case in which insufficient documentation compounds issues associated with other contributing factors, such as clinical judgment and patient behavior.

Case Study 3: Insufficient Documentation

Overview: The patient was a 65-year-old female who had been seeing her dentist for 20 years. She had an extreme build-up of plaque and calculus, deteriorating teeth, and bleeding gums. The patient was consistently nonadherent to her home oral hygiene instructions. She also would go for long periods (e.g., years) between dental appointments.

The dentist advised the patient that she had bone loss and tooth mobility, and he recommended that she consult with a periodontist. The dentist also advised the patient to come in for dental visits every 3 months. The patient insisted on only having yearly visits, and she did not follow through on seeing the periodontist.

Eventually, the patient required a full mouth extraction and extensive specialized care. She then filed a lawsuit against the dentist alleging delay in diagnosis and failure to treat.

Discussion: Although the patient's nonadherence to her treatment plan and dental appointments played a significant role in her poor dental health, insufficient documentation complicated matters in this case. Despite the fact that the patient had been seeing the dentist for two decades, documentation in her health record was very sparse.

Case Study 3: Insufficient Documentation (continued)

The dentist did not document the patient's general nonadherence to her oral hygiene plan, her inconsistency in presenting for routine care, or any attempts to contact her for follow-up appointments. Additionally, he failed to document his recommendation that the patient consult with a periodontist. As a result of the incomplete patient record and insufficient documentation, this case presented significant challenges for the defense and resulted in a settlement.

Content Decisions and Mechanics

The other two categories under documentation — content decisions and mechanics — refer to a range of issues. Content-related concerns include problems such as:

- Altered documentation (which might suggest an attempt to cover up mistakes)

- Opinions stated as medical facts

- Inappropriate comments or speculation (e.g., subjective vs. objective information)

- The proliferation of inaccurate information as a result of the copy/paste function in EHRs

- General inconsistencies in documentation patterns across records

The mechanics category refers to inaccurate documentation within a factual setting. Examples include:

- Inaccuracies in transcribing or writing orders

- Illegibility (including the use of nonstandard abbreviations, shorthand, or "text talk")

- Delays in documenting

- Failure to use an appropriate method for correcting documentation errors and making amendments

Documentation Risk Tips

The following strategies can help healthcare providers address documentation risk factors that could potentially contribute to diagnostic errors:

- Ensure your organization's documentation policies require providers to document:

    - Sufficient details related to the patient's history and physical exam. This documentation will help support continuity of care and comparison of findings from previous visits.

    - Patient adherence, including missed and canceled appointments and attempts to follow up with the patient. Providers should be careful to remain objective in their documentation and avoid editorializing.

    - Treatment plan changes, such as receipt of diagnostic results, follow-up with the patient, patient response, and phone conversations (including after-hours calls).

    - Consultations and referrals, including conversations with the consulting provider, agreed-upon consulting arrangements, and receipt and review of consultative reports.

    - Patient education, including written and verbal advice, recommendations, and educational materials — as well as tactics to gauge patient understanding of the information (e.g., using the teach-back method).

- Establish appropriate timeframes for completion of documentation following patient encounters, and monitor to ensure compliance.

- Consider whether documentation supports clinical judgment and decision-making, and whether it clearly identifies how a particular diagnosis was determined.

- Do not include incident reports or criticism of other providers in patient records. Root cause analysis of errors and near-misses should be documented as part of the practice's risk management and quality improvement efforts.

- Understand and educate staff about the appropriate methods for correcting or amending documentation.

- Ensure that documentation policies address issues unique to electronic documentation, such as the use of copy/paste, form fields, check boxes, etc.

For additional documentation strategies, see MedPro's *Documentation Essentials* and *Electronic Documentation* checklists.

In Summary

Various risk factors, occurring alone or in combination, can contribute to diagnostic errors. Patient behavior, clinical system failures/administrative issues, and documentation issues all represent persistent areas of risk in diagnosis-related malpractice allegations. Although eliminating risk entirely is unrealistic, proactive measures to establish safeguards, reinforce policies and procedures, and evaluate areas of weakness can help healthcare providers strengthen patient safety initiatives and potentially limit liability exposure.

Endnotes

[1] Page, L. (2016, March 28). Is misdiagnosis inevitable? *Medscape News & Perspective*. Retrieved from www.medscape.com/viewarticle/860747

[2] National Academies of Sciences, Engineering, and Medicine. (2015). *Report in brief: Improving diagnosis in health care*. Washington, DC: The National Academies Press.

[3] MedPro Group diagnosis-related cases, opened 2013–2022.