



Risk-management implications of a missed, incorrect, or delayed diagnosis

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The National Academies of Sciences, Engineering, and Medicine defines diagnostic error as “the failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient.” The National Academies also state that a diagnosis is considered wrong when “the original diagnosis is found to be incorrect because the true cause is discovered later”.¹

Diagnostic errors make up significant numbers of patient safety issues in healthcare, and they do the most harm to patients. Patients surveyed revealed that as many as one patient out of three may experience diagnostic errors.

Diagnostic errors made up the largest portion of 350,706 paid medical malpractice claims studied over 25 years by Johns Hopkins researchers (28.6 percent), with the highest total amounts paid out (35.2 percent) for same. The number of diagnostic error claims in outpatient settings (68.8 percent) was almost double those that had occurred in inpatient care (31.2 percent).²

Inpatient diagnostic mishaps have resulted in a higher rate of mortality. Most of these errors have been related to missed diagnoses versus delayed or incorrect ones. There are no one-size-fits-all or magic bullet solutions to these issues, as these types of errors are more varied and complex than other patient safety errors. One estimate suggested that for patients seeing a physician for a new condition, the average diagnostic error rate could be as high as 15 percent.³ Johns Hopkins’ researchers estimated that between 80,000 to 160,000 patients suffer potentially preventable diagnosis-related serious injury or death each year in the United States. In their review of 25 years of malpractice claim payouts between 1986 and 2010, approximately \$38.8 billion was paid out for diagnosis-related malpractice claims in the U.S.⁴

Diagnostic errors are one of the most significant patient safety problems in healthcare, resulting in death or disability nearly twice as often as with other types of clinical errors. This includes missed, delayed, and incorrect diagnoses.

A “**missed diagnosis**” may include a patient’s complaints or symptoms not being formulated into an accurate diagnosis that can be treated or explained.

A “**wrong diagnosis**” is when a diagnosis is made and later recognized to be in error, after the correct diagnosis is made.

A “**delayed diagnosis**” is when the diagnosis should have been made earlier.

1 What is Diagnostic Error?, Society to Improve Diagnosis in Medicine, <https://www.improvediagnosis.org/what-is-diagnostic-error/>, p.1

2 Diagnostic Errors More Common, Costly and Harmful Than Treatment Mistakes, COVID-19 Update, Johns Hopkins Medicine, April 23, 2013, p.2 https://www.hopkinsmedicine.org/news/media/releases/diagnostic_errors_more_common,_costly_and_harmful_than_treatment_mistakes

3 Diagnostic Errors More Common, Costly and Harmful Than Treatment Mistakes, COVID-19 Update, Johns Hopkins Medicine, April 23, 2013, p.2 https://www.hopkinsmedicine.org/news/media/releases/diagnostic_errors_more_common,_costly_and_harmful_than_treatment_mistakes

4 Diagnostic Errors More Common, Costly and Harmful Than Treatment Mistakes, COVID-19 Update, Johns Hopkins Medicine, April 23, 2013, p.1 https://www.hopkinsmedicine.org/news/media/releases/diagnostic_errors_more_common,_costly_and_harmful_than_treatment_mistakes

Obviously, every effort needs to be made to minimize these types of patient safety events due to the significant impact they can have on those evaluated and treated each and every day.

Primary care considerations

Delayed diagnoses in primary care have not been adequately monitored or measured, in spite of the fact that they are common, harmful, and expensive. In one study described in "BMC Family Practice", more than 500 primary care providers were invited to participate, with 22 percent responding. Top issues were thought to be mostly system- and patient-related, and contributing factors identified were:

- Poor communication between primary and secondary care providers
- The lack of access to medical care and/or social support mechanisms
- Having numerous symptoms expressed, along with multiple underlying conditions including psychiatric disorders, which could make diagnosis more difficult
- A lower level of the patients' educational status and/or understanding of health-related matters
- Deficiencies in the continuity of care and follow-up
- Providers' time constraints, including limited time for patient visits

It was noted that most of the problems identified and proposed recommendations centered around the actual care visit between the provider and the patient. The most common solutions proposed related to:

- Developing better mechanisms to communicate abnormal test results to patients and to discuss their future plan of care
- Better communication between caregivers during patient handoffs
- "Hotlines" or other streamlined mechanisms to reach specialists, so that significant patient matters could be discussed promptly
- Specific referral guidelines and protocols for management of the most common significant patient conditions
- More economical continuing medical educational opportunities, with a focus on identifying the most common conditions that can be easily missed
- Examining each case where diagnosis was delayed to assess why and how it may be prevented in the future

The survey feedback from physicians indicated that they underestimated the likelihood of diagnostic errors and patient factors. Also, they didn't seem to recognize the impact of cognitive factors, which are thought to be most significant in contributing to diagnostic errors. Cognitive errors (i.e., related to knowledge and judgment) were made more often when seeing a patient for the first time and having unusual or complex presentations. Additional resources and improved training were believed to be the most likely way to improve in these areas. However, resource constraints in the current economic environment could hinder the implementation of these suggestions.⁵

Issues identified in ambulatory care

A retrospective review of 307 closed malpractice claims related to missed or delayed diagnoses found that most resulted from a number of breakdowns and included both individual and system

factors. Once again, these kinds of errors have not been studied well due to the difficulty in identifying omissions. There is no mechanism for standardized reporting, and documentation in patient health records is often not detailed enough to allow an in-depth analysis. However, general observations of the issue seem to be related to a provider's failure to be vigilant or clinically current in the provision of care. Over a 10-year period, the most common type of claim in the U.S. was the allegation of negligent misdiagnosis. The second most common allegation made was related to breakdowns in making diagnoses, leading to severe adverse outcomes.⁶

The study referenced above found that 59 percent of the claims involved diagnostic errors that resulted in serious patient harm, and 30 percent resulted in death. Of those seriously harmed, the most common diagnosis was cancer, and more than half of those had breast or colorectal cancer. The most prevalent causal factors identified were:

- Failure to order the appropriate diagnostic test (55 percent)
- Lack of an adequate follow-up plan (45 percent)
- Inadequate history or physical exam (42 percent)
- Inaccurate diagnostic test interpretation (37 percent)
- Failure to initiate a referral (in 26 out of 47 cases)
- Patient not complying with the follow-up plan (22 percent)

In addition, according to this same study, the top contributing factors to diagnostic errors (usually between two and four factors per claim) were:

- Judgment failures (79 percent)
- Memory failure or lack of vigilance (59 percent)
- Clinical knowledge (48 percent)
- Factors related to patients (46 percent)
- Handoffs (inadequate communication of patients' conditions) (20 percent)

Other common factors included inadequate supervision, heavy workloads, unusual presentations, unclear lines of responsibility, poor documentation, communication problems among providers, and complex patient histories.⁷

Recommendations for improvement may include:

- Considering systems that may support decision making and reduce reliance on memory (i.e., electronic decision support in the computerized health record)
- Developing protocols or checklists that can enhance adherence to approved diagnostic measures and treatments for conditions commonly seen
- Encouraging second opinions in complex cases
- Providing a structured communication process for handoffs to other groups of caregivers
- Requiring prompt over-reads for providers reading and acting on film(s) or tests outside of their normal areas of expertise
- Improving scheduling of providers to minimize heavy workloads
- Developing a method to track and ensure tests results are reviewed and communicated to providers and patients
- Ensuring scheduled follow-up is achieved or that additional measures are implemented for "no shows"

5 Car, Lorraine Tudor, et al. *Clinician-identified problems and solutions for delayed diagnosis in primary care: a PRIORITIZE study*, BMC Family Pract. 2016; 17(1):131.

6 Gandhi, Tejal K, MD, MPH, et al. *Missed and Delayed Diagnoses in the Ambulatory Care Setting: A Study of Closed Malpractice Claims*, Annals of Internal Medicine, American College of Physicians, Volume 145, Number 7, October 3, 2006. Abstract

7 Gandhi, Tejal K, MD, MPH, et al. *Missed and Delayed Diagnoses in the Ambulatory Care Setting: A Study of Closed Malpractice Claims*, Annals of Internal Medicine, American College of Physicians, Volume 145, Number 7, October 3, 2006. Abstract

Emergency department concerns

Diagnostic-related matters of concern in the emergency department (ED) are similar to those in other ambulatory care settings. The primary difference is in the often unrelenting intensity of care required, with multiple disciplines involved, all working at a stressful pace. Of course, the onset of COVID-19 only added to this in untold ways, in all care settings, but especially in dramatically increased volumes in EDs.

As with the other settings, little is known about the cause of diagnostic errors in the ED. Physicians and others from the Division of Medicine and Department of Emergency Medicine at Brigham and Women's Hospital, along with the Harvard School of Public Health and the University of Texas Health Science Center, presented a study of 122 closed malpractice claims in which patients had an alleged missed or delayed diagnosis in the ED. It was found that 79 claims had missed diagnoses in the ED that resulted in harm to patients. Of those, 48 percent resulted in serious harm, and 39 percent resulted in death.⁸

The study referenced above found that the top diagnostic process issues related to:

- Failure to order the appropriate diagnostic test (58 percent)
- Inadequate medical history or physical exam (42 percent)
- Inaccurate reading of a diagnostic test (37 percent)
- Lack of order for needed consultation (33 percent)

Factors that contributed to this study's findings included:

- Cognitive issues (96 percent)
- Patient-related factors (34 percent)
- Inadequate supervision (30 percent)
- Incomplete handoffs (24 percent)
- Very heavy workload (23 percent)

The most common missed or delayed diagnoses related to fractures (19 percent) and infections (15 percent). Others included myocardial infarctions (10 percent) and cancer (9 percent). Generally, missed diagnoses involved acute as opposed to chronic conditions. These four types of patients made up more than half of the missed diagnoses. While ED providers are quite skilled in treating these disorders, prompt over-reads of X-rays by a radiologist (or a second provider's opinion) and consultations with timely referrals to cardiology, infectious disease, or oncology could be helpful, to the extent they are readily accessible.⁸

Half (52 percent) of those who missed diagnoses were ED physicians. General internists missed 28 percent, and surgeons missed 20 percent of diagnoses. Physicians in training were also involved in 56 percent of these cases. It was also noted that trainees were the highest number of personnel who contributed to missed-diagnosis type of events.⁹

The top three contributing factors in missed diagnoses were mistakes in judgment (87 percent), inadequate technical knowledge or skill (58 percent), and vigilance or memory issues (41 percent). In 96 percent of the cases cited in the aforementioned study, cognitive factors contributed to the missed diagnosis.¹⁰

As with the other settings discussed, multiple diagnostic process issues and contributing factors typically were involved in these

errors. The ED is frequently a challenging workplace, with numerous high-acuity patients moving through many workflow processes, including triage, clinical evaluations, testing, and consultations with other providers. There may also be shift changes in the midst of the patient's stay in the ED, which can also add to the opportunity for error. Sometimes students or other trainees are involved, who require supervision in their care processes. In addition, a wide variety of patient types and ages typically flow through the ED. Patients may be critically ill or injured, or they may present to the ED for a common ailment, especially if they don't have a primary care provider. Unfortunately, little is known about system-related factors in the ED that can contribute to diagnostic mishaps. There are certainly myriad opportunities for system, as well as process, failures.

Decisions often have to be made quickly to move patients to observation beds, admit to an inpatient unit, send directly to the operating suite, transfer to another facility, or discharge. There are a lot of moving parts that make up a patient's ED visit, and they often overlap each other. Also, providers seldom have ongoing relationships with patients during these very stressful clinical encounters.

Suggestions for minimizing the number of missed, delayed, or inaccurate diagnoses in the ED may include:

- Develop protocols for diagnoses with high potential for being overlooked.
- Assess workloads to ensure generally adequate staffing, including enough time for supervision of any trainees that may work in the ED; enhance staffing as needed and available.
- Ensure clinical competency of all trainees and providers; consider double checking interpretations of certain test results.
- Evaluate handoff processes utilized for adequacy in clinical communications.
- Review the specifics of the patient population presenting to the ED; utilize data that may be available from internal quality improvement/peer review and/or root-cause analysis processes to assess where additional education or process and systems improvements may be needed.
- Consider special studies to determine if there are any opportunities for improvement in conducting histories and physicals, ordering or evaluating test results, use of consultations and referrals, and adequacy of patient education and planned/unplanned returns to the ED (if not already being tracked).
- Evaluate claims data that may include any diagnostic-related issues.
- Assess the process for reporting of critical test results to see if there are any actual or potential lapses; consider direct communication of results to ED providers.
- Utilize comments received from patient satisfaction surveys that may indicate displeasure with the diagnosis made.
- Consider any decision support systems that may be available, if practical, given what the budget and technological support allows.

Missed diagnoses in the ED are a significant patient safety concern and may result in severe adverse patient outcomes, including death. An added emphasis on quality/performance improvement, peer review, and risk-management activities may be well worth the extra effort required to improve in this area.

⁸ Kachalla, Allen MD, JD, et al. *Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims From 4 Liability Insurers*, Annals of Emergency Medicine, American College of Emergency Physicians, Volume 49, No. 2: February 2007, pp. 196.

⁹ Kachalla, Allen MD, JD, et al. *Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims From 4 Liability Insurers*, Annals of Emergency Medicine, American College of Emergency Physicians, Volume 49, No. 2: February 2007, pp. 199-200.

¹⁰ *Ibid*, pp. 200.

Summary

Circumstances that result in missed, delayed, or incorrect diagnostic errors that can harm patients are very complex, regardless of the setting where care is provided. Too often, the alignment of contributing factors and multiple process breakdowns occur in these cases, similar to the Swiss cheese theory related to adverse clinical events. Time and resource constraints often contribute to these errors, which only reinforces the need for entities to use quality improvement and peer review methodologies to streamline and improve in certain areas.

Efficiency, quality, and safety typically go together to achieve positive patient care outcomes. In meeting those objectives, an organization's reputation may be protected, and financial losses, including potential increases in professional liability insurance premiums, may be minimized.

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What is Diagnostic Error? - Society to Improve Diagnosis in Medicine

