

An Urgent Call for Leaders to Support More Accurate and Timely Diagnoses

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Research released in July 2019 adds to the mounting evidence that diagnostic errors are the most common, catastrophic, and costly of serious medical errors—those resulting in permanent disability and, in the worst cases, death. The issue, however, does not receive anywhere near the attention it deserves despite its prevalence and the serious toll it takes on patients' health—to say nothing of the financial cost to the U.S. healthcare system, estimated to exceed \$100 billion annually (Newman-Toker et al., 2018).

If healthcare executives are serious about mitigating risk, they must first understand the extent of misdiagnosis. Then they can lead efforts to resolve system failures and support improved clinical judgment and decision-making in their organizations.

NEW CLARITY IN UNDERSTANDING DIAGNOSTIC ERROR

Researchers at the Johns Hopkins University School of Medicine and CRICO Strategies (including Dana Siegal, coauthor of this column) analyzed more than 55,000 malpractice cases with closed claims from CRICO Strategies' National Comparative Benchmarking System database (2006–2015). They found that one in three cases (34%) resulting in serious harm (including death) was due to an inaccurate or a delayed diagnosis (Newman-Toker et al., 2019).

Funded by the Society to Improve Diagnosis in Medicine (SIDM) through a grant from the Gordon and Betty Moore Foundation, the study analyzed more than one quarter (28.7%) of all U.S. malpractice claims. Other key findings from the research included the following:

- Nearly three quarters (74.1%) of inaccurate or delayed diagnoses that result in permanent disability or death are attributable to just three disease categories: cancers (37.8%), vascular events (22.8%), and infections (13.5%).
- The two most prevalent conditions misdiagnosed in each category that result in serious harm are lung and breast cancers (cancers), stroke and myocardial infarction (vascular events), and sepsis and meningitis/encephalitis (infections).

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- These three categories alone accounted for roughly \$1.8 billion in diagnosis-related malpractice claim payouts over 10 years.

More than 46% of these malpractice claims were associated with inaccurate or delayed diagnoses made in emergency departments (EDs) and inpatient settings and disproportionately involved vascular events and infections. Those made in non-ED ambulatory care settings disproportionately involved cancers.

As part of the analysis, Newman-Toker et al. (2019) also looked into the causes of misdiagnoses. While most malpractice claims cited multiple causal factors, more than 85% of those involving serious harm from inaccurate or delayed diagnoses involved issues related to clinical reasoning or judgment. Clinical judgment factors contributing to a missed diagnosis included failure or delay in ordering a diagnostic test, failure to establish a differential diagnosis, misinterpretation of diagnostic studies, and failure or delay in obtaining a referral. System failures, found in about 22% of claims, included patients not receiving results, failure to follow up on a new finding, and failure or delay in completing recommended tests.

OBSTACLES TO AN ACCURATE, TIMELY DIAGNOSIS AND THE CORRESPONDING RISKS

More often than not, physicians and other clinicians make the right diagnosis at the right time. Yet the burden to patients from inaccurate or delayed diagnoses is still substantial. Improvement is possible—and it is a moral imperative (National Academy of Medicine, 2015).

Physicians and other clinicians face genuine obstacles in making an accurate diagnosis. The diagnostic process involves myriad systems and individuals working together, relying on each other and on patients to put the puzzle together. With more than 10,000 possible diseases and more than 5,000 available laboratory tests, yet only a couple hundred symptoms, the challenge is formidable. Understanding the human and system vulnerabilities in the diagnostic process is critical to improving diagnostic outcomes. Mistakes will happen, but we must reduce their frequency to mitigate the risk that inaccurate and delayed diagnoses pose.

NEXT STEPS TO IMPROVE DIAGNOSIS AND PATIENT SAFETY

The Johns Hopkins/CRICO research provides important insights into where opportunities for improvement exist. Applying those insights to the diagnoses of cancers, vascular events, and infections—given that they are the most common disease categories—may provide the best chance to substantially reduce the overall burden of serious patient harms.

A significant amount of research is necessary to fully understand the issue and develop interventions that improve diagnostic quality. These interventions should support clinicians as they strive to make the right diagnosis in a timely manner and communicate that diagnosis to the patient. Potential solutions include computer-based tools such as device-based decision support, simulation-based training, and diagnostic performance

feedback. Improving diagnostic quality also requires abandoning the view of diagnosticians as solitary figures and instead engaging the broader healthcare team, as well as healthcare systems and other provider organizations that develop and implement diagnostic quality measures.

In addition to clinicians and their employers, others have a role to play in reducing harms associated with inaccurate or delayed diagnoses. Improving diagnosis also depends on radiologists and laboratory scientists, patient safety and quality experts, and, of course, patients.

SIDM, under contract to the Health Research & Educational Trust (HRET), developed a change package to support healthcare organizations in reducing patient safety incidents caused by actions during the diagnostic process (HRET, 2018). The package was developed through clinical practice sharing, organizational input, and contributions from subject

matter experts, patients, and families. It helps healthcare organizations understand scenarios in which diagnostic errors can occur and engages all team members, especially patients and families, in strategies to improve diagnostic quality and safety.

The change package notes that patients and family members must be engaged partners in the diagnostic process as well as in diagnostic improvement efforts. To accomplish this, the package offers specific suggestions for healthcare organizations, including the following:

1. Provide patients and their families with opportunities to learn about the diagnostic process.
2. Create environments in which patients and their families are comfortable engaging in the diagnostic process and sharing feedback about diagnostic errors and near misses.
3. Ensure that patients and family members have access to electronic health records, including clinical notes and diagnostic testing results, to better engage them in their care and allow them to review their records for accuracy.
4. Identify opportunities to include patients and their families in efforts to improve the diagnostic process by learning from diagnostic errors and near misses.

CONCLUSION

All healthcare organizations want to deliver high-quality care while minimizing risk. In pursuit of these twin goals, healthcare executives and the larger delivery system must turn their attention to an often overlooked issue at the root of many preventable poor outcomes: inaccurate or delayed diagnoses, which result in harm for millions of patients and billions of dollars in aggregate costs every year (Singh, Meyer, & Thomas, 2014). Yet, as members of a healthcare community, we are just starting to understand the scope of the problem and ways to address it.

The fiscal year 2020 House appropriations bill proposes to increase funding for diagnostic quality and safety research to “not less than \$4 million,” up from \$2 million in

the fiscal year 2019 appropriations bill (Tucker, 2019). The federal Agency for Healthcare Research and Quality has called inaccurate and delayed diagnosis an urgent challenge and highlighted the need to apply “evidence-based patient safety strategies, predictive analytics, personalized and precision medicine, and new technologies at the point of care” to improve diagnostic quality and safety (Khanna, 2019).

Healthcare systems and other provider organizations must begin to measure diagnostic accuracy and timeliness within their walls. In so doing, they will be able to identify the disease categories and care settings where misdiagnoses are most likely to occur and appropriately target their practice improvement interventions. Ultimately, the entire healthcare community must work together to apply the risk management lessons learned in other areas of healthcare delivery to the pressing concern of inaccurate and delayed diagnoses.

NOTE

In addition to his roles as CEO and cofounder of the Society to Improve Diagnosis in Medicine (SIDM), Mr. Epner is chair of the Coalition to Improve Diagnosis, a collaborative of more than 50 leading healthcare societies, health systems, patient organizations, and organizations focused on improving quality, including the American College of Healthcare Executives. Ms. Siegal is the director of patient safety services at CRICO Strategies and serves on the SIDM board of directors.

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