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Diagnostic Errors—The Next Frontier for Patient Safety

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DURING THE PAST DECADE, AWARENESS AND UNDERSTANDING of medical errors have expanded rapidly, with an energetic patient safety movement promoting safer health care through “systems” solutions. Efforts have focused on translating evidence into practice, mitigating hazards from therapies, and improving culture and communication. Diagnostic errors have received relatively little attention. Although the science of error measurement is underdeveloped, diagnostic errors are an important source of preventable harm.¹⁻³ In this Commentary, we offer definitions for diagnostic error and misdiagnosis-related harm, present an overview of the magnitude of diagnostic errors, and give suggestions for how research can mature.

Distinguishing Errors From Harms

In considering diagnostic errors, it is important to distinguish between the error (a process) and the resulting harm (an outcome). *Diagnostic error* can be defined as a diagnosis that is missed, wrong, or delayed, as detected by some subsequent definitive test or finding.¹ However, not all misdiagnoses result in harm, and harm may be due to either disease or intervention. *Misdiagnosis-related harm* can be defined as preventable harm that results from the delay or failure to treat a condition actually present (when the working diagnosis was wrong or unknown) or from treatment provided for a condition not actually present.

An estimated 40 000 to 80 000 US hospital deaths result from misdiagnosis annually.⁴ Roughly 5% of autopsies reveal lethal diagnostic errors for which a correct diagnosis coupled with treatment could have averted death.⁵ In the Harvard Medical Practice Study, physician errors resulting in adverse events were more likely to be diagnostic than drug-related (14% vs 9%), and misdiagnoses were more likely to be considered negligent (75% vs 53%) and to result in serious disability (47% vs 14%).⁶ Not surprisingly, tort claims for diagnostic errors are nearly twice as common as claims for medication errors and result in the largest payouts.⁷ As with all types of medical error, the human toll of misdiagnosis on an individual or family can be tremendous, particularly when a healthy patient experiences an adverse event.

Diagnostic errors often are unrecognized or unreported, and the science of measuring these errors (and their effects) is underdeveloped.^{1,2} Available statistics consider neither deaths due to misdiagnosis in outpatients nor misdiagnosis-related morbidity and associated costs. For example, stroke, the leading cause of serious, long-term disability in the United States, affects 780 000 Americans annually.⁸ Opportunities to prevent disabling stroke are missed when patients experiencing mild or transient warning symptoms receive misdiagnoses. According to a recent systematic review, 9% of all cerebrovascular events are missed initially, and the odds of misdiagnosis increase at least 5-fold when symptoms are mild or transient.⁹

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Table. Suggestions for Context-Based Approach to Classifying Diagnostic Errors to Facilitate Systems Solutions

Clinical Scenario	Typical Problem	Potential Systems Solutions	
		Low Technology	High Technology
Visual diagnosis (eg, pathology, radiology)	Failed visual pattern recognition	Independent second reads	Computer-assisted feature matching
Complex hospitalized patient (eg, critical illness, major trauma)	Information overload amid multiple physiologic derangements	Structured diagnostic protocols/algorithms	Data visualization tools
Routine ambulatory patient (eg, headache, fatigue)	Complacency regarding uncommon dangerous causes	"Don't-miss-diagnosis" checklists at sick visits	Symptom-oriented diagnostic decision support
Patient with rare symptoms (eg, hearing their eyes move) or unusual constellations of symptoms	Lack of specialized knowledge of rare symptoms/diseases	Streamline triage to diagnostic experts	Using Internet search engines for information on possible diagnoses ¹³
Asymptomatic patient (eg, routine cancer screening)	Forgot to trigger screening protocol	Screening checklists at well visits	Automated reminders in electronic health records

Thus, misdiagnoses probably represent an enormous unmeasured source of preventable mortality, morbidity, and costs.

Despite their major public health implications, diagnostic errors have received relatively little public or scientific attention, including from the patient safety community.^{1,3} Misdiagnosis has not featured prominently in patient safety campaigns. In the Institute of Medicine's report *To Err Is Human*, diagnostic errors were mentioned only twice, compared with 70 mentions for medication errors.³ The Joint Commission, National Quality Forum, and Leapfrog Group have all emphasized treatment errors over diagnostic errors.¹ None of the 20 evidence-based Patient Safety Indicators established by the Agency for Healthcare Research and Quality (AHRQ) or the 30 safe practices recommended by the National Quality Forum specifically measures failure to diagnose.^{1,2}

There has been little systematic study of diagnostic errors.^{1,2} A 2003 report of 93 AHRQ-funded patient safety projects found only 1 focused on misdiagnosis.² Scientific work in diagnostic errors has emphasized developing error classifications, assessing cognitive pitfalls in diagnostic reasoning, or measuring the effect of education or decision support tools on diagnostic accuracy in written case scenarios. A few studies have tried to measure the frequency or causes of misdiagnosis in patients using autopsy data or narrowly defined disease, consultative, or medicolegal cohorts, but such efforts have often been limited by patient selection, inadequate reference standards for diagnosis, or concerns about hindsight bias.^{2,10}

Suggestions for Reducing Diagnostic Errors

Practical solutions to reduce diagnostic errors have lagged behind those in other areas of patient safety. Computer-based diagnostic decision support systems, often touted as the optimal strategy to reduce misdiagnosis, have not been validated against patient outcomes, and none is in widespread clinical use.¹¹ Diagnosis is still largely viewed as an individual art rather than evidence-based science. The complexity of diagnostic problems and relative infancy of methods to study misdiagnosis, combined with limited funding for research in diagnostic safety, have further slowed progress.²

Improved diagnostic accuracy will likely require a multifaceted approach that includes renewed emphasis on traditional clinical skills teaching, exploration of new methods for diagnostic education (eg, simulation or gaming), major improvements in health information technology systems, and a substantial investment in the basic science of clinical diagnosis. To move forward, studies should focus on diagnosis, leveraging both symptom-oriented and disease-oriented designs. Evidence-based knowledge repositories should be developed for diagnostic decision making. Research capacity should be expanded by training clinical investigators focused on diagnostic safety, perhaps even explicitly creating multidisciplinary training paths for clinical experts who specialize in diagnosis.

These major changes will likely require cultural shifts, organizational restructuring, and political action. While awaiting such change, reformulating the approach using a systems-oriented lens might allow some progress. Below are 5 suggestions to help safety researchers work toward reducing misdiagnosis-related harm.

Develop Systems Solutions to Cognitive Problems. Diagnostic errors are often seen as cognitive errors rather than systems errors, and this perspective has perpetuated the view that individual physicians are to blame and systems-oriented solutions do not apply. This false notion has hindered development of error-reduction interventions. Parallels in medication safety offer an alternative view. If the problem is illegible physician handwriting in medical prescriptions, the most efficient solution is probably not handwriting retraining but computer-based prescription writing. Likewise, if the problem is a cognitive bias such as a tendency to overestimate the probability of a rare diagnosis recently encountered, the most efficient solution might not be cognitive debiasing training for all physicians but computer-based decision support systems that provide accurate estimates of disease probability.

Create Actionable Categories of Errors Based on Context Rather Than Cause. Historically, diagnostic errors have been grouped by presumed cause, emphasizing cognitive traps (eg, premature closure, confirmation bias).¹² However, if systems solutions ultimately sidestep cognitive psy-

chology, grouping errors based on clinical context rather than the cognitive defect may prove more productive. A context-based approach that focuses on the nature of the clinical problem helps identify potential systems solutions and possible pathways for research (TABLE). For example, in a clinical scenario in which a patient describes rare symptoms, such as noting, "I hear my eyes move," the clinician may assume a mental illness, whereas an Internet search might identify a rare but treatable disorder such as superior canal dehiscence syndrome.

Emphasize Misdiagnosis-Related Harm Rather Than Diagnostic Error. Researchers who study diagnostic safety have often focused efforts on identifying diagnostic errors. Compared with diagnostic errors, however, misdiagnosis-related harm is easier to measure and monitor. For example, if ways to reliably identify harm due to diagnostic errors in specific clinical scenarios could be developed (eg, outpatients with headache who die of aneurysmal subarachnoid hemorrhage), researchers could link these outcomes to what symptoms and signs the patient had, what tests were ordered, and how test results were interpreted. Based on these associations, interventions to mitigate harm could be developed without adjudicating the harder-to-assess intermediate of "diagnostic errors" per se. Systematically recording key clinical inputs (symptoms/signs/tests) and outputs (morbidity/mortality/costs) would also offer a platform for continuous quality improvement through structured feedback (crucial to improved diagnostic performance when overconfidence is a fundamental part of the problem¹²).

Build Workflow-Sensitive Solutions. There is a rich history of failure in pursuit of solutions to reduce diagnostic error, particularly with computer-based tools.¹¹ These tools are often introduced to a clinical setting by fiat with limited pilot testing and little understanding of how they affect workflow.¹¹ Investigators should design and pilot solutions that are practical as well as effective. Research conducted in actual clinical settings (and with input from clinicians) is more likely to yield implementable solutions that benefit patients.

Focus on Comparative and Cost-effectiveness. New diagnostic tools or decision aids have sometimes been held to an expectation of perfect accuracy or "vetted" using unconfirmed physician diagnoses as the reference comparison. As a result, apparent performance of these diagnostic aids often falls short, limiting the use of potentially helpful interventions. As an alternative, researchers could identify solutions that outperform current practice at an acceptable cost. If the benefits, potential harms, and costs of these tools are robustly evaluated, physicians may have greater confidence that using them will benefit patients and reduce risk of litigation.

Conclusion

Because it is impossible to eliminate all diagnostic errors, open dialogue is necessary about how much diagnostic safety

medicine can afford. Tort reform is needed to reduce excessive testing associated with the practice of "defensive medicine,"¹¹ and defining acceptable error rates should be a policy imperative. These complexities notwithstanding, with nearly 10 years having passed since publication of *To Err Is Human*, there is cause for optimism that the next decade will see diagnostic errors "get the respect"³ they deserve. A scientific community is starting to form. In 2007, AHRQ announced a special emphasis on funding diagnostic errors research,¹⁴ and in 2008, the inaugural Diagnostic Error in Medicine conference was convened for investigators to share their work on misdiagnosis.¹⁵ With funding and collaboration, researchers are poised to increase the visibility of diagnostic errors and to advance the science of how to identify and prevent them. As with most scientific advances, this will likely be a long and arduous journey, but the next frontier for patient safety is in plain view.

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