Measuring and Improving Diagnostic Safety in Primary Care: Addressing the "Twin" Pandemics of Diagnostic Error and Clinician Burnout

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Diagnostic errors are a source of unacceptable harm in health care. However, improvement efforts have been hampered by the lack of valid measures reflecting the quality of the diagnostic process. At the same time, it has become apparent that the healthcare work system, particularly in primary care, is chaotic and stressful, leading to clinician burnout and patient harm. We propose a new construct that health systems and researchers can use to measure the quality and safety of the diagnostic process that is sensitive to the context of the health care work system. This model focuses on three measurable practices: considering "don't miss" diagnoses, looking for red flags, and ensuring that clinicians avoid common diagnostic pitfalls. We believe that the performance of clinicians with respect to these factors is sensitive to the health care work system, allowing for context-dependent measurement and improvement of the diagnostic process. Such process measures will enable more rapid improvements rather than exclusively measuring outcomes related to "correct" or "incorrect" diagnoses.

J Gen Intern Med
DOI: 10.1007/s11606-021-06611-0

Safe, accurate, efficient, and timely diagnosis is the cornerstone of effective modern medical care. Since nearly all therapeutic and prognostic decisions are made on the basis of diagnostic decisions, an error at a given point in the diagnostic process may lead to multiple downstream consequences. Primary care encounters have long been especially vulnerable to diagnostic errors,[1,2] given time constraints and the nonspecific nature of undifferentiated symptoms patients bring to primary care. These challenges are now potentially compounded by "virtual visits," which are challenged by the lack of a face-to-face encounter and physical examination.[3]

There has been an increased focus on diagnosis in recent years as the striking and unacceptable burden of diagnostic error has become better understood. Approximately 15% of inpatient and 5% of outpatient diagnoses are in error and diagnostic errors tend to be more harmful than other types of medical errors.[2,4] However, much of the work (including ours) to date has addressed the incidence and causative factors leading to diagnostic error, with relatively few trials producing measures or evidence of pragmatic strategies that improve the safety of diagnostic processes.

Received June 16, 2020
Accepted January 7, 2021

WHAT SHOULD WE MEASURE?

Measuring diagnostic accuracy may be expensive, difficult, and fraught with potential for blaming clinicians when a diagnosis emerges that they may not have been able to make sooner.[5,6] Approaches and measures focusing attention upstream—examining the diagnostic *process*—may be better suited as targets for preventing diagnostic errors rather than focusing on imperfect outcome measures that may or may not reflect the process used. That is, diagnoses may be made by serendipity rather than high-quality diagnostic processes; these "good" outcomes (accurate diagnoses) should not be used to rate flawed processes upstream.

Identifying key process steps that lead to misdiagnosis would represent an important step toward measuring and improving diagnosis. These process measures must be meaningful and reliably measurable, allowing determination of the extent that performance on these process measures is linked to diagnostic outcomes. Furthermore, these measures must be actionable for improvement, allowing us to move forward in both measuring and improving the diagnostic process.

ACKNOWLEDGING, UNDERSTANDING, AND IMPROVING THE CONTEXT AND CONTENT OF CARE

A parallel emerging aspect of patient safety and quality is the growing evidence around work conditions and clinician burnout.[7–9] Multiple studies have shown that health care work systems often have deleterious effects on providers, and which thereby may negatively impact patient care. Many factors have been identified, including depersonalization and commoditization of health care, discontinuities

Published online: 11 February 2021

driven by insurance or geographic disruptions, lack of cohesion among teams, ineffective communication, and burdens and inefficiencies of electronic medical records and other factors, such as chaos in the health care system.[10] Prior studies demonstrate strong linkages between burnout and adverse work conditions.[9] The same studies linked the work environment to objectively defined errors, including missed preventive practices and errors in diabetes care, but did not show direct links between burnout and errors. More recent studies strongly link burnout with self-reported errors and care deficiencies. Studies are thus needed to assess the relationships between objectively defined diagnostic errors and system factors as well as clinician burnout.[7,8]

One commonly discussed factor leading to both diagnostic error and physician burnout is the perceived lack of adequate time for clinical encounters. Time pressure has repeatedly surfaced in studies examining provider satisfaction, burnout, and quality of care. Clinicians frequently note discordance between the time needed and time available for clinical encounters. Additionally, studies have also demonstrated that the context of care (e.g., chaos in the clinic) is associated with medical errors overall,[10] and find correlations between adverse work conditions and patient outcomes.

A NEW FRAMEWORK FOR ENSURING AND ASSESSING DIAGNOSTIC PROCESS SAFETY

If reliable measures of the diagnostic process that are essential for good diagnosis and sensitive to work conditions could be developed, what framework should be employed? While many different aspects of diagnosis could be considered, one logical starting point for diagnostic safety would be a clinical framework that builds on ways "good" clinicians approach diagnosis to ensure that important diagnoses are not harmfully missed or delayed. We propose a framework conceptualized by three intersecting paradigms (Fig. 1): do not miss diagnoses, red flags, and diagnostic pitfalls. Most encounters evaluating patients' symptoms or signs lead to a clinician formulating a differential diagnosis that emphasizes "most likely" as well as less-likely but nonetheless important "do not miss" diagnostic considerations. Clues to ensure consideration of such critical diagnoses are often referred to as "red flags" and, if overlooked, can lead to suboptimal diagnostic assessment. Studies suggest "failure to consider" such conditions is the leading factor in diagnostic error,[11] and strategies to proactively guard against such failures, including simple measures such as reaching out to colleagues, should be incorporated into clinician workflow and documentation. Additionally, a retrospective review of diagnostic error cases demonstrates recurring patterns or "traps"; identifying these pitfalls could help improve situational awareness and avoid errors. Thus, giving clinicians specific and measurable factors on which to focus during an encounter may help equip them to improve their context-specific diagnostic performance.

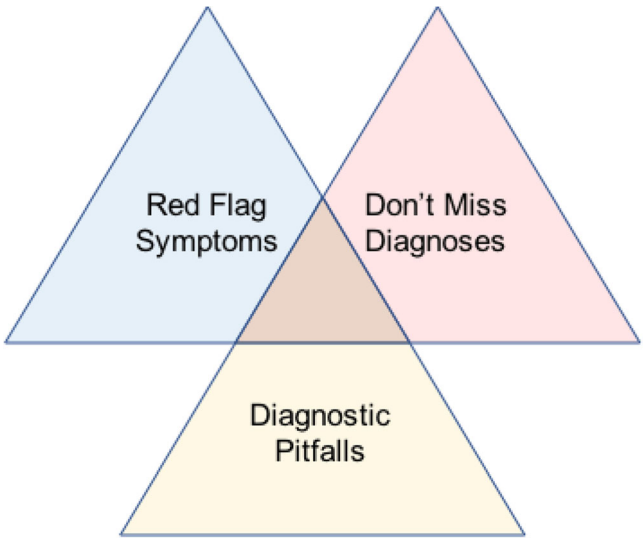

Figure 1 Tripartite framework of diagnostic process safety. Diagnostic safety critically depends on not missing or harmfully delaying key worst-case scenario diagnoses. This construct of "don't miss diagnoses" overlaps with needed situational awareness and practices that are designed to recognize important red flags (symptoms, signs, labs) that operationalize avoiding what can go wrong (pitfalls related to diagnostic mimics, atypical presentations, or misleading (false-negative or false-positive) tests/imaging results, etc.). Contextual factors (particularly time pressures, interruptions, electronic medical record design, or other workflow design factors) can either enhance or impair clinicians' ability and likelihood to strategically address these 3 constructs.

We believe such a framework resonates with clinicians who generally are either explicitly or implicitly considering these three factors when evaluating patient concerns. It also provides a structured approach for designing and testing specific measures of diagnostic process safety. Thus, the critical aspect of diagnostic evaluation documentation—the clinician's written assessment—itself needs to have its quality assessed and assured. To evaluate diagnostic processes, we need to "assess the assessment" to evaluate whether the chief complaint was addressed and at least a basic differential diagnosis documented; frequent failures in these areas are often found during the review of malpractice cases. Second, we should see whether red flags (or their absence) are noted, do not miss diagnoses (worst-case scenarios) are considered, and known pitfalls are contemplated and commented upon. Finally, we should evaluate whether contingency plans were developed and documented. Such a tripartite evaluation of the diagnostic process would optimally examine not only written notes but also the discussions that clinicians and patients have in the context of an encounter. Review of these factors could potentially be automated via natural language processing of the note, more traditionally by manual chart review, or even by direct observation methods.

It must be noted, however, that clinical documentation in its present form may be limited in capturing the richness of the clinical encounter as well as a clinicians' thought processes. As busy clinicians ourselves we acknowledge that the aforementioned process metrics may hinge on adequate documentation. We recognize that documentation may be limited in

capturing the richness of the clinical encounter as well as clinicians' thought process. New methods of representing the clinical encounter as well as clinicians' cognitive processes may very well be needed. New developments in automated voice recognition point to one potential way the full richness of the diagnostic process could be more fully captured—an approach our team is beginning to explore. Efficient methods to record and process the information contained in a clinical encounter into a valid representation without increasing the burden of clinician data entry could be groundbreaking.

If this framework could be leveraged to design practical clinical quality behaviors and standards, the science of measuring diagnostic quality in the clinical encounter could be substantially advanced. The ultimate aim is obviously not just to measure or rate clinicians' diagnostic notes or behaviors, but to improve diagnostic safety. Thus, we need to ensure diagnosticians are equipped with the necessary factors—time, tools, teams, training, and technologies-to make high-quality, safe diagnostic decisions. If we can better define these factors, health systems, educators, and others can then support clinicians to carry out and document the activities required to fulfill diagnostic process quality and safety, which could then be measured and correlated with the time and supports clinicians realistically have.

NEXT STEPS IN THE CHAIN OF EVIDENCE

We have recently written of mechanisms to improve diagnostic accuracy and means of improving the culture of diagnostic safety.[6,12] As a next step in this evolving science, we propose testing key measures of diagnostic process safety grounded in the context in which care is delivered (often referred to as situated cognition, that is, one's thinking depends upon the environment in which one is contemplating a diagnosis).[13] Developing such metrics of the diagnostic process and of the work conditions that enable or hinder performance on these metrics will allow for the development of *standard systems for assessment of diagnostic processes and supportive contexts of care; linking these to diagnostic quality and errors could provide healthcare systems the means to measure diagnostic accuracy and revise workflows and support systems to improve diagnosis.* The ultimate result will be a step forward in our ability to design systems of care that will allow us to get the diagnoses right, even when time is short. Furthermore, it might encourage clinicians to identify cases in which they should reach out to colleagues for assistance or even obtain a second opinion. Given the increasing recognition of the need to urgently address the twin epidemics of clinician burnout and diagnostic errors, now made even more imperative by the COVID-19 pandemic, strategic leveraging of such models for safer diagnosis could help protect patients as well as empower clinicians to practice safer, more worry-free (and even joyful) diagnosis. By creating the culture and infrastructure to support this framework, we would be doing a service to clinicians and patients alike.

Acknowledgements: *Dr. Olson is supported by the Alliance for Academic Internal Medicine, CRICO (Harvard Risk Management Foundation), and the Gordon and Betty Moore Foundation for work focused on improving diagnostic safety. Dr. Schiff acknowledges the support of the Gordon and Betty Moore Foundation and CRICO (Harvard Risk Management Foundation) for diagnostic safety work. Dr. Linzer is supported by CRICO (Harvard Risk Management Foundation) for diagnostic safety work, and also by the American Medical Association, American College of Physicians, the Institute for Healthcare Improvement, and the American Board of Internal Medicine Foundation for burnout prevention research and training.*

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Declarations:

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

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