

PERSPECTIVE

Defining excellence: next steps for practicing clinicians seeking to prevent diagnostic error

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The Institute of Medicine (IOM) released its report on diagnostic errors in September, 2015. The report highlights the urgency of reducing errors and calls for system-level intervention and changes in our basic clinical interactions. Using the report's controversial definition of diagnostic error as a starting point, we introduce the issues and the potential impact on practicing physicians. We report a case used to illustrate this in an academic conference. Finally, we turn to the challenge of integrating these ideas into the traditional peer-review process. We argue that the medical community must evolve from understanding diagnostic failures to redesigning the diagnostic process. We should see errors as steps toward diagnostic excellence and reliable processes that minimize the risk of mislabeling and harm.

Keywords: *diagnostic error; Institute of Medicine; patient safety; peer review; graduate medical education*

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Received: 19 April 2016; Revised: 30 July 2016; Accepted: 5 August 2016; Published: 7 September 2016

The Institute of Medicine (IOM) released its report on diagnostic error in September 2015 (1). The report captures current understanding of the importance, indeed the urgency, of addressing diagnostic error, which may be the 10th leading cause of death in the United States. Diagnostic error is likely to impact each of us as patients at least once in our lifetimes. The report and the accompanying *New England Journal of Medicine* editorial coalesce a diverse but immature literature (2). While calling for system-level intervention that right now may seem irrelevant to a clinically focused physician, the report underlines the need for fundamental changes in our basic clinical interactions. Even the IOM definition of diagnostic error disrupts assumptions many of us see as basic (3).

As an introduction to the issues and call to action for practicing physicians and educators, we share Foster's experience as an internal medicine program director observing reactions to the definition at the 2015 Diagnostic Error in Medicine (DEM) conference organized by the co-sponsor of the Institute of Medicine (IOM) report, the Society for the Improvement of Diagnosis in Medicine (SIDM). We then describe an educational case designed to explore these issues and the corresponding resident response. Finally, we turn to the challenge of integrating these concepts with our workhorse measure of physician quality – our traditional peer-review process. As with other aspects of the safety revolution, we will

need to transition from simply recognizing and understanding diagnostic failures to redesigning the system of diagnosis in order to prevent them. The IOM report assists with this process by establishing the technical literature in epidemiology, diagnostic algorithms, decision aid tools and technological assistance, cognitive processes, and framing issues. Adopting the IOM definition of error is a first step, but, to implement it effectively, clinicians will need to learn how to respond efficiently to the daily opportunities for improvement. Ultimately, the IOM definition of error prods us to develop a definition of diagnostic excellence as reliable processes that minimize the risk of mislabeling and harm. The IOM report calls on physicians to change our practice.

So, what is the controversy around the definition? The IOM defined 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 definition presumes the perspective of the patient bringing health concerns to a complex medical machine and asking for an explanation. The IOM wording is simple, providing an unambiguous goal that every patient can understand. The reactions observed among attendees can be categorized in terms of three basic groups: patient representatives, safety researchers, and clinicians. Their different responses are instructive.

The patients' perspective is heard through an impassioned group of loved-ones. At the meeting, Foster found

himself sitting among a group of such patient advocates. For clinicians, honest communication has focused on sharing information after events (4). Patient advocates see this as insufficient. In their eyes, until medicine can effectively share with patients the diagnostic choices being made on their behalf, there will be unnecessary, hidden risk in the process. Transparency, they believe, is necessary for progress. Several of the patient advocates argued that patients represent both the most reliable and most neglected indicator of potential error. In contrast to clinicians caught up in the work, a well-informed patient has few biases against reporting. As you might imagine, the patient advocates exulted in the IOM's definition.

In contrast, many cognitive psychologists and safety researchers trying to understand the diagnostic process did not hear the clarity they sought. The researchers echoed the IOM report's description of diagnosis as a process of complex interactions in need of careful dissection. Diagnoses are not singular events – they are evolving processes where time is an essential tool. A provider gathers information, develops hypotheses, and manages sequences of testing and treatment. Imprecision and incorrect data disrupt every stage of the process. Errors can occur in thinking or in systems for testing (5). Indeed, some diseases are simply undiagnosable. Some errors as seen from the patient's perspective cannot be prevented. Furthermore, the patient's view of a diagnosis adds a subjectivity to diagnostic accuracy and timeliness which muddies categorization. From the perspective of researchers, patient communication is an important but separate complicating variable. The researchers present wanted a definition for error that enables clear counting and categorizing of errors to help illuminate gaps between existing and best possible care.

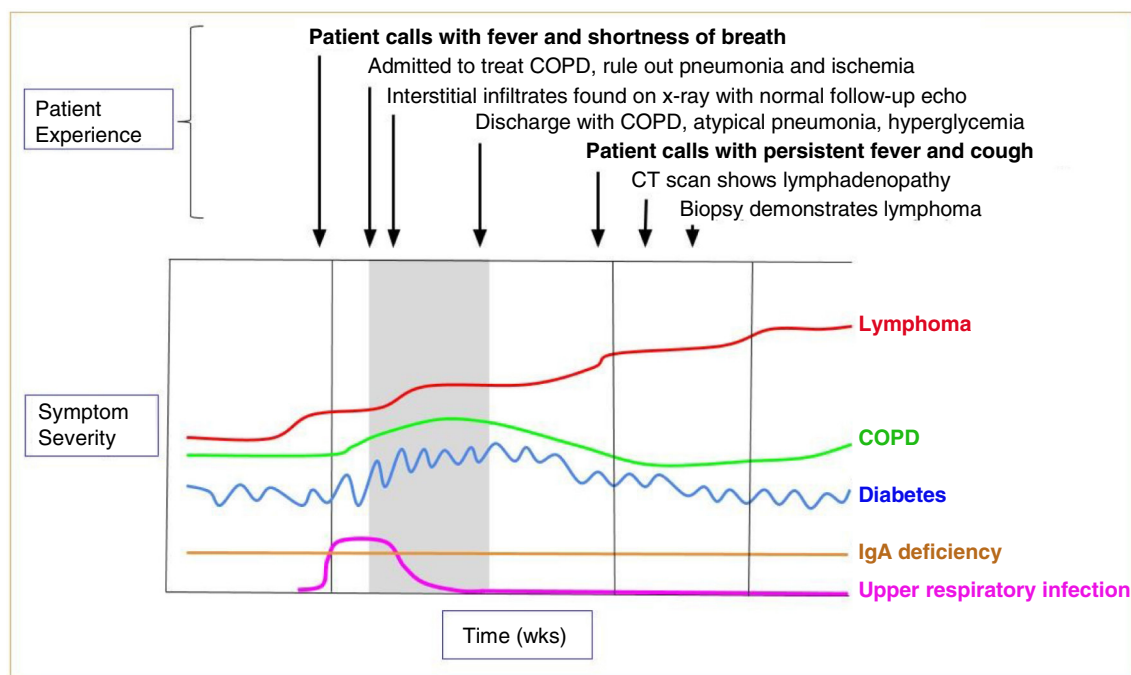
Conversations with practicing physicians raised different objections. Faced with simultaneous management of multiple patients, clinicians manage presentations algorithmically. They fully expect that patients with rare conditions or atypical presentations will require repeat cycles of analysis and take time to ripen fully for diagnosis. They wish to protect their patients from the depth of uncertainty, lest they trigger unnecessary anxiety. The clinicians want a definition that takes into account their process and distinguishes culpable from unavoidable error. From their perspective, a useful definition would target delays which harm patients and/or wasteful, risky sequences of testing. Culpability would follow failures to pursue a result or obtain appropriate consultation. In particular, practicing physicians may feel vulnerable to an avalanche of retrospective bias as the clarity of a final diagnosis seems to incriminate a tentative but necessary judgment call. Practicing physicians look, in short, for a definition that treats their efforts humanely.

The three groups' receptions of the IOM report underline the complexity of weaving consensus from

such diverse perspectives. Additionally, physicians may feel particular unease at the magnitude of change under discussion and disorientation as longstanding clinical traditions come under critique. Nevertheless, by positioning the patient's experience as the central test of a diagnostic error, the IOM report actually orients us to a solid and traditional foundation. Every participant starts with the ethical imperative to protect our patients from harm. We accept in principle data showing an increase in treatment efficacy when we engage the patient in shared decision making (6). Regularly screening our patients for perceived surprise diagnoses will be a starting point. We will then need to re-imagine the patient-clinician relationship to allow efficient and non-harmful engagement.

To illustrate how a patient-centered approach may change physicians' perspective, consider the following case constructed for our residents as an educational exercise (see Figs. 1 and 2). In our view, the residents' reactions reflect a culture that shapes senior physicians as well. A 52-year-old light smoker calls his primary care provider with acute respiratory symptoms including fever, coryza, wheezing, and shortness of breath. The thoughtful physician evaluates him and refers him to the hospital out of concern for his chest tightness and respiratory symptoms. The hospital physicians correctly recognize an upper respiratory infection complicated by a chronic obstructive pulmonary disease (COPD) exacerbation. They assess for and rule out myocardial ischemia. They attribute an abnormal chest x-ray to a mild scarring or possibly an atypical pneumonia. They connect the patient's undiagnosed diabetes to an effect of corticosteroids. The physicians explore a number of academic possibilities to explain the symptoms but ultimately efficiently assess only their leading diagnoses. The differential diagnosis forms a fraction of conceivable contributing diagnoses. They leave out the undiagnosed IgA deficiency which has contributed to his chronic bronchitis. Importantly, their rapid fire and standard review of systems misses 6 months of intermittent fever and night sweats. Three weeks later, the patient calls to report persistent fevers after completing his course of antibiotics, leading to his ultimate diagnosis.

In walking through a morning report style presentation of the case, a group of interns gave their opinion on whether this case of delayed diagnosis contained an error. They responded that the clinicians provided exemplary care. The physician cared for the patient's urgent issues, and then responded quickly to the patient's persistent fever. No harm came to the patient. In contrast, an aggressive evaluation in the hospital could have been harmful and wasteful if applied in general to patients with this presentation. Statistically, even with undiagnosed chronic illnesses, the patient most likely had a viral process with atypical pneumonia and a COPD exacerbation.



This timeline shows a conceptual model of a 52-year-old light smoker calling his primary care physician with acute respiratory symptoms including fever, coryza, wheezing, and shortness of breath. His symptoms of diabetes had not been previously identified. His increasing chronic respiratory symptoms, night sweats, fever, and weight loss from his lymphoma were missed by the team's review of systems. His underlying IgA deficiency was never identified as a cause for his early COPD. The x-ray showing interstitial changes was not followed up until after the patient called back several weeks later.

Was this a typical complex medical patient visit carefully followed up? Or was this a delayed diagnosis of a life-threatening condition? Is the delay significant? Should we blame the primary physician for missing the diabetes or chronic lymphoma symptoms? Would it seem more like an error if his delayed diagnosis was active pulmonary tuberculosis instead? Is it important that the patient felt the physician erred in his diagnosis of fever and shortness of breath?

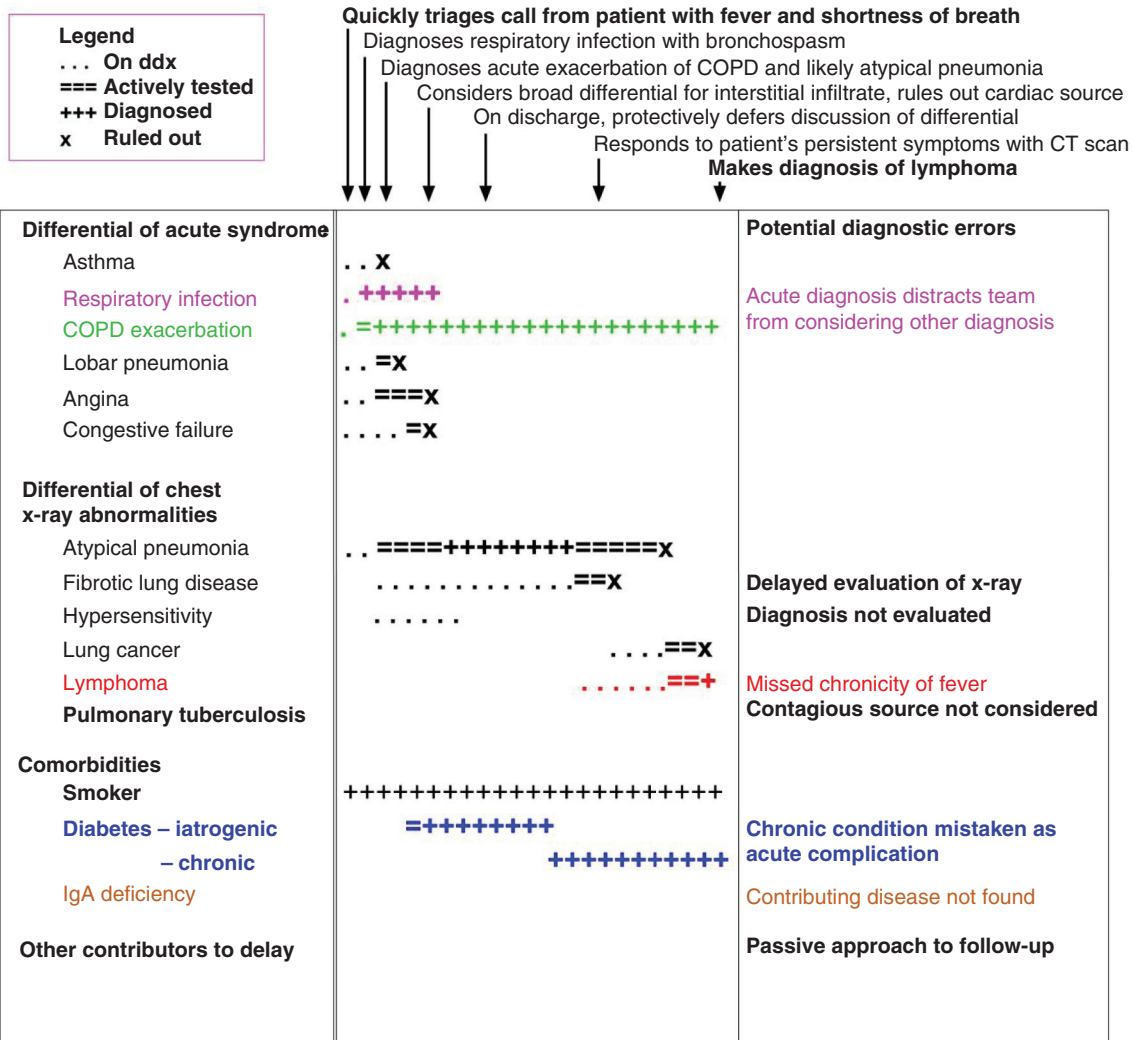
The IOM report defines diagnostic error as a system failure where multiple participants, including the patient, contribute to the failure. The question of "who made the error?" needs redefinition as "how can we improve this system?" Improvements that might have prevented this case include reinforcing our technique for a review of systems, ensuring early follow-up regarding resolution of symptoms, and systematically extending the differential diagnosis.

Fig. 1. Is there a diagnostic error? A residency thought experiment.

After re-framing the case from the patient's perspective, the interns recognized other problems. The patient hears the reassurance about ruling out ischemic disease as false. He imagines what might have happened if he had not spoken up. Could things have become worse? The interns recognized the team's failure to prepare the patient for complications or the potential for other diagnoses. They agreed that a transition call 2 days after the hospitalization could have caught the persistent fever. Such a call would also have clearly communicated a caring attitude toward the patient. They understood that early closure on a seemingly obvious upper respiratory infection interfered with an adequate review of systems that could have captured 6 months of intermittent fever, chills, and weight loss. Nevertheless, the interns struggled to decide whether to accept blame for other care gaps, such as the delayed outpatient diagnosis of diabetes, the undiagnosed IgA

deficiency, and an incomplete differential for the abnormal chest x-ray. They questioned whether the IOM would define this case as an error or a near-miss, and whether failure to follow the patient closely represented a diagnostic failure. Yet when re-evaluating the scenario with a different outcome such as active pulmonary tuberculosis, they acknowledged greater culpability for missing a morbid and contagious disease. Revealing our inherent outcome bias, they decided that there would be a clear diagnostic error in that case.

Blame, legal risk, and retrospective bias weigh heavily on clinicians' discussion of diagnostic error and how we teach it. What senior physician can listen to a diagnostic error case without imagining the discussion within their hospital peer-review committee or a court of law? What is the community standard for evaluating a particular decision? Did the practitioner document correctly?

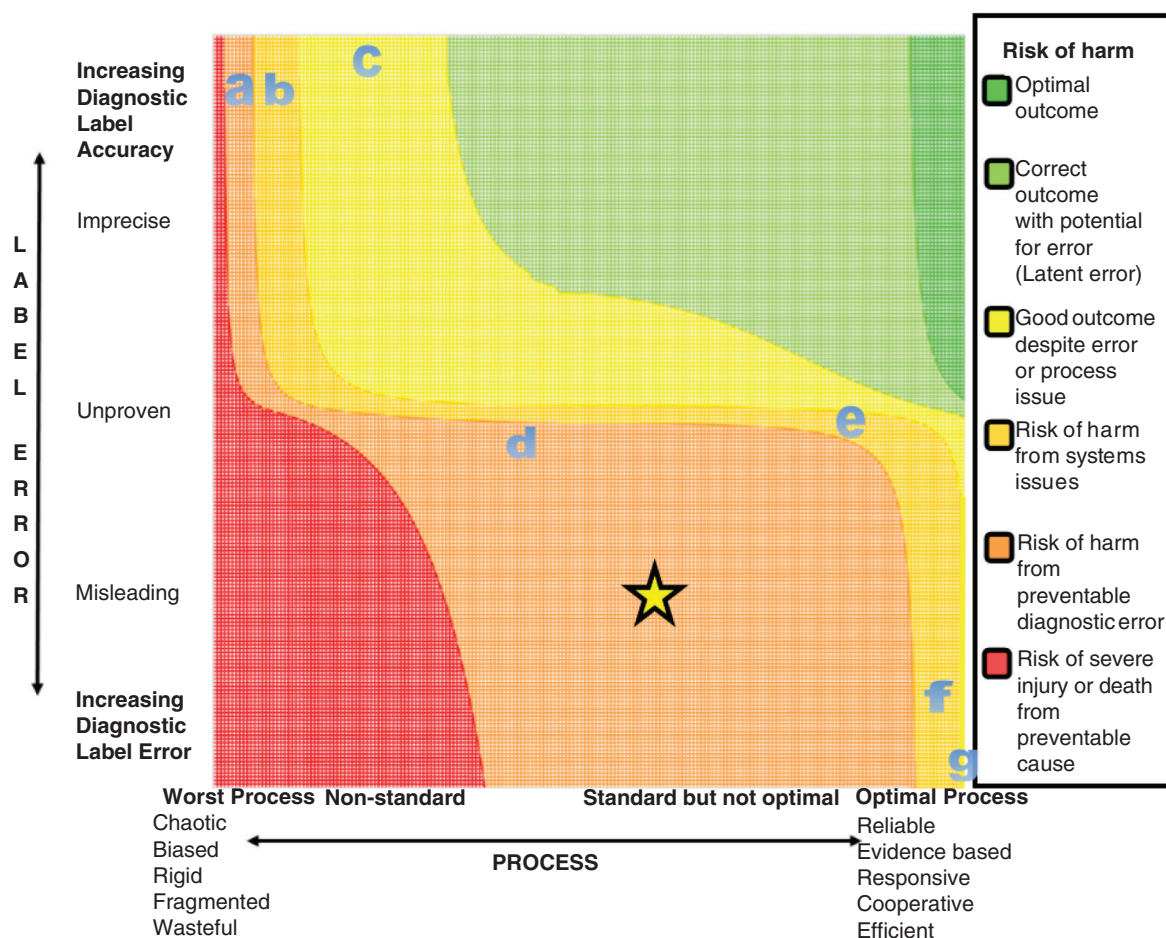


The patient believes there was a diagnostic error, but the medical team may disagree. Figure 2 imagines a timeline of the patient's differential diagnosis in relation to the workup. With exhaustive evaluation, at least eight factors contributed to the patients diagnostic delay, with varying degrees of omission or commission. Arguably these had little impact on the patient's ultimate course, and likely most diagnostic evaluations could retrospectively identify such errors. However, these latent errors contribute to inefficiency and unnecessary emotional distress. If not improved, they will likely eventually contribute to morbidity. The IOM approach emphasizes that the patient's surprise at a diagnosis or perception of delay is an underappreciated trigger to assess communication and diagnostic process. Clinicians may find realizing these opportunities uncomfortably personal and truly challenging.

Fig. 2. Evolution of diagnostic possibilities in the physician's mind.

These concerns illustrate many of the problems connecting diagnostic error with our current peer-review process and how far we have to go in becoming comfortable with transparent, real-time collegial feedback. However we allocate individual culpability, we must explore diagnostic error in a manner that controls for these powerful fears. The IOM report touches on the problem of fear by emphasizing the need to see diagnostic errors as system problems rather than individual errors. In the eyes of our hospital safety committee, the safety movement has unpacked personal errors as system errors for many aspects of medical care. We now see a nurse

accidentally administering insulin instead of heparin as a manifestation of medication storage problems, look-alike labeling, nursing fatigue, and multitasking (7). In a similar way, we need to unpack physician errors and make them less personal. Where our physician peer-review process has focused on individual culpability, we need to expand our analysis from individual judgments to shared learning opportunities. As with other safety events, we should be hunting for learning opportunities and analyzing them as quickly as possible. We designed Fig. 3 to illustrate how opportunities exist in almost every case, particularly the innocuous ones.



The chart emphasizes that diagnostic processes, labeling error, and risk of patient harm affect each other, but are independent of each other. We often only explore failed diagnosis when they near the bottom left corner, missing many opportunities. Potential for improvement is present in all but the dark green area. Many innocuous lucky diagnoses and near miss errors in particular provide opportunities.

The x-axis shows effectiveness of a diagnostic process, while the y-axis plots the impact on labeling when applied to a specific patient. Both are visualized as gradations of dysfunction rather than being simple binary descriptions (good versus bad). The colored contours represent increasing risk of patient harm similar to a topographical map. The area of the contours reflects the number of scenarios with a similar risk (not prevalence of a particular risk). Clinical decisions from a case resulting in a diagnostic error may be mapped on this chart to assist categorization and identify opportunities for improvement in an otherwise innocuous case.

For example, the patient in Fig. 1 at the time of his initial admission maps to the star, with standard but not optimal care by missing the chronicity of fever, a misleading diagnosis of COPD and viral URI, and little harm. Risk of harm could be substantial both in terms of potential delay in diagnosis and in the patient's confidence in the team. Other points of interest include: a – harm from a correct label that is delayed, miscommunicated, or mistreated; b – harm from a correct but unneeded label leading to diagnostic or therapeutic iatrogenesis (over diagnosis); c – incidentally correct label despite bad process {lucky diagnosis}; d – harm from an ineffective testing regimen that does not improve diagnosis (over testing); e – harm from unclear label despite good process; f – harm from unpreventable labeling error; g – negligible risk from an incorrect diagnosis because of excellent process. The chart suggests that small changes in process in these areas may have significant impact. Tracking processes' average label accuracy over many cases may also help target those most in need of change.

This chart shows a Cartesian adaptation of Newman-Toker's conceptual framework of diagnostic errors (8), which presented the same relationships as a Venn diagram. We derived the contours showing potential degree of risk by summing the potential impact from individual curves predicting risk based on degree of process failure and of mislabeling. We hypothesized that risk changes most rapidly at process good and bad extremes, whereas it might change more rapidly centrally on the gradient of good and bad labels.

Fig. 3. Diagnostic error: Relationship between process, label error, and risk of harm.

As we've learned in the safety literature, fixing seemingly innocuous errors can save us from major errors down the road. Instead of waiting for a pharmacy or nurse to flag a case, then, we should have physician huddles to audit for surprise diagnoses. Many hospitals have otherwise fairly robust safety reporting systems, but the confidentiality of prevailing medical-legal models of peer review makes it difficult to include physician mistakes, particularly mistakes involving cognitive or professional judgment errors. The confidentiality of our peer-review committees protects our reputations and allows us to make difficult but controversial decisions in safety. Ironically, however, that same protection undermines system ownership of diagnostic errors and facilitates repetition. In contrast, embedding daily review with system-wide analysis and tracking of minor cases should achieve the dramatic gains for accurate and efficient diagnosis that we have seen with other safety problems like central line infections and falls.

We require courage. Our vulnerability to opening our subjective experience to scrutiny may seem insurmountable. Yet small steps in this direction may build confidence that understanding and reducing diagnostic error leads not only to safer care but also to increased confidence and comfort. Viewing an error as common and shared may relieve us of a burden. This work does not have to be belabored or intellectually draining. In addition to patient surveys, simple audits might look for delays or unexpected outcomes. We can pull decision processes into our safety reporting systems, leaving the cloaked peer-review process for evaluation of true professionalism failures. We can actively cross-check each other's decisions within a culture of expected error.

We should embrace the IOM's decision to define diagnostic error around a patient's perspective. The epidemiological researchers will need to continue to find ways to systematically count an intrinsically subjective and fluid process. They will study ways to integrate informatics and

stimulate systematic cross-checking. Our diagnostic systems will need to embrace the power of standardization while increasing sensitivity for rare conditions to obtain both accuracy and value. For the clinicians, however, starting from the patient's perspective can be freeing. Each patient provides a test of our systems of evaluation, including our thinking. Rather than determining a level of error, we should rate our encounters for value in illuminating the flaws in our system. We may find the concept of error itself the wrong label for the vast majority of opportunities, and instead define them as steps toward clinical excellence.

Your comments are welcome.

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