

Summary

Placing Diagnosis Errors on the Policy Agenda

Timely Analysis of Immediate Health Policy Issues

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Diagnosis errors are common, produce avoidable disability and death, and are often costly. But diagnosis errors are rarely recognized in public policy as a serious quality and safety problem amenable to corrective action. The lack of serious attention thus far is likely based on the perception that diagnosis errors either represent a simple lack of clinical knowledge, or reflect fixed, individual cognitive biases in processing information. In short, they seem inevitable and thus not readily reducible. Further, one of the unanticipated outcomes of the growing reliance on performance measurement is that quality and safety problems that are not easily amenable to measurement are often ignored, certainly in public policy.

Many individuals go to their grave with significant missed or incorrect diagnoses—some of these errors are discovered only at autopsy, now infrequently performed in the U.S. This means, that at least in the near term, the diagnosis error problem must likely be addressed without much reliance on publicly reported performance measures. Yet, other approaches to attacking this important quality and safety problem are available and can be fostered.

In this paper, we argue that diagnosis errors should no longer be viewed as inevitable and, therefore, an acceptable—if regrettable—by-product of even high-quality health care. Rather, it is likely these errors represent failures that can be reduced substantially. As evidenced by essays going back more than a century, physicians have long known that making correct and timely diagnoses is an essential part of their professional duties and responsibilities. Given the centrality of diagnosis in the tradition and culture of medicine and in medical education, it is quite possible that concrete action steps—and some early success stories—would appeal to health professionals' intrinsic motivation to support their patients' well-being.

The Nature and Extent of the Diagnosis Error Problem

Most clinical researchers consider a “diagnosis error” to be a wrong, missed, or delayed diagnosis. Some diagnosis errors lead to harm, while most, probably, do not. Some researchers also consider overdiagnosis—providing a new, diagnostic label to common, relatively minor symptoms, as well as real diagnoses unlikely to cause harm—as a diagnosis error.

Traditional research approaches used to measure the nature and extent of diagnosis errors include autopsies, malpractice claims, and retrospective case reviews, among other approaches. Recent analysis of malpractice claims over a 25-year period (1986-2010) identified diagnosis error as the most common and most costly reason for a claim. Autopsy studies indicate that anywhere between 10 to 20 percent of cases show major unexpected discrepancies that could have changed the line of management, and thus probably saved the life or reduced harm to the patient. A recent estimate based on electronic health records (EHRs) suggests that one in 20 U.S. outpatient adults could be affected by diagnosis errors.

How and Why Diagnosis Errors Happen

Medical diagnosis is a complex process involving clinician- and system-level factors. The etiologies of such errors are numerous and can be categorized as “cognitive,” “systems,” or “no-fault” errors in order to understand why they occur.

A “cognitive bias” is generally a result of breakdown in cognitive functioning that can occur at any point in the clinical encounter. Mistakes occur for a host of reasons, including poor data gathering, inaccurate diagnostic synthesis, faulty interpretations, or inadequate knowledge. Cognitive biases may lead clinicians to see correlation as causation, misinterpret because of

temporal relationships, be led astray by logical fallacies, and see meaningful patterns where none exist. “Systems errors” include inefficient processes; poorly standardized procedures; lack of teamwork; discontinuous care and handoffs; poor communication; pressures for productivity; fatigue; excessive workloads; excessive administrative requirements; inaccurate test results; and inadequate follow-up and notification of test results. Fewer than 10 percent of diagnosis errors can be labeled as “no fault” and they are most commonly seen when patients come in with uncommon symptoms or rare diseases.

The Potential of Electronic Health Records and Artificial Intelligence

Health information technology (HIT) has the potential to decrease errors in each stage of the diagnostic process, but requires improvements before its full potential is realized. Potential advantages of HIT include more post-encounter physician communication with patients, improved referral processes, and greater opportunity for patients to have access to their clinical records in order to correct erroneous items and provide additional information as their symptoms evolve. Computer support tools may assist clinicians in generating a differential diagnosis for the patient being assessed. This has the potential to decrease cognitive errors with somewhat promising, if mixed, results. A reason they have not had greater impact is that many clinicians do not use them. A new entrant on the scene is “big data.” Use of big data with traditional database tools, now combined with “artificial intelligence,” has the potential to assist clinicians in creating differential diagnoses and treatment algorithms that are less subject to cognitive bias.

At the same time, several major challenges accompany the use of HIT, and there is growing recognition that EHRs may themselves create errors. Templates and check boxes, commonly developed as a response to billing requirements, may actually distort the process of taking patient histories, performing physician examinations, and formulating an assessment of the patient’s situation, often requiring a differential diagnosis. Many clinicians complain that because of the demands of checklists, their own critical thinking—and the usefulness of the clinical record to permit exchange of such thinking—has declined. EHRs can also result in time inefficiencies and pose greater burdens for physicians. They can also contribute to diagnosis errors because of the growing use of copying and pasting information in the record without verifying its

accuracy.

The Policy Vacuum and How to Fill It

Diagnosis errors have not been featured prominently in patient safety campaigns. According to patient safety experts, organizations such as the Joint Commission, National Quality Forum, Leapfrog Group, and the Agency for Healthcare Research and Quality (AHRQ) have all emphasized treatment errors over diagnosis errors in their measurement and patient safety work. Efforts to produce useful measures of diagnosis errors should become a priority for those with a direct interest in the problem, especially organizations such as medical specialty societies; the Patient Centered Outcomes Research Institute (PCORI); the many physician specialty boards and other professional associations; the National Quality Forum; the National Committee for Quality Assurance; private payers and employers; professional liability risk managers; and, importantly, consumer advocacy groups.

The most active current initiatives are being led by the Society to Improve Diagnosis in Medicine and the Institute of Medicine. The Society was formed by a group of mostly academic physicians and other health care professionals who shared a common perception that it was time to get serious about the problem of diagnosis errors. The founders launched the first Diagnosis Errors in Medicine conference in 2008 and established the Society three years later. Having recently launched a new quarterly journal, *Diagnosis*, dedicated to research and practice improvement related to the issue, the Society has become a core intellectual hub for reducing diagnosis errors. The Institute of Medicine recently formed a committee on the problem as part of its ongoing Health Care Quality Initiative, with the first committee meeting scheduled for April 28, 2014. It is likely that work produced by these two institutions will make substantial contributions not only to a better understanding of the nature and extent of the problem and promising approaches to reducing the incidence of and harm caused by diagnosis errors, but also to policy approaches that offer promise. For now, public policy options for addressing diagnosis errors need to be developed under the assumption that important measures of the severity and frequency of quality errors will not be broadly available and publicly reported in the near future. Here we present some preliminary suggestions for other public policies that might be pursued to put the problem of diagnosis errors firmly on the policy agenda.

1. Enhanced research

There is need for additional research to help establish the extent of the problem, better define its often complex causation, and explore promising approaches to error reduction, at both the individual clinician and systems level. Organizations such as the National Institutes of Health, AHRQ, and PCORI could help develop the science of diagnosis error and its prevention within their current structures, putting out solicitations for research addressing particular causes of diagnosis errors, including reducing cognitive biases and improving systems for preventing error and harm. AHRQ and PCORI could also seek to fund research related to promoting patient-reported diagnosis errors.

2. Require enhanced conditions of participation in Medicare

In addition to emphasizing the obligation of Medicare participant facilities, including hospitals, to have systems in place to reduce diagnosis errors through Conditions of Participation, CMS' regulations for the Medicare Shared Savings Program for accountable care organizations (ACO) could also provide a new focus on the issue. Acceptance as an ACO in the Medicare Shared Savings Program requires organizations to indicate in detail how the ACO will assure that central quality and safety topics, for instance support of evidence-based medicine, are given explicit attention. Reducing the high prevalence of diagnosis errors could be included in the short list of topics the ACO must address with CMS, giving more weight and ongoing attention to the specific work plans that ACOs commit to, rather than relying just on performance measures to assess the ACO on quality and safety issues.

3. Quality improvement and collaboration

The CMS-led Partnership for Patients initiative seeks to create and sustain a broad collaboration among health professionals; employers; patients and their advocates; and private and government payers to reduce preventable readmissions. This model should be extended to addressing particular problems found under the broad rubric of diagnosis errors. Further, Patient Safety Organizations (PSOs) were created by legislation a decade ago to promote reporting of safety-related errors to facilitate analysis and suggest areas for improvement in a nonpunitive manner. Currently AHRQ lists only 79 PSOs operating in just 30 states. Little is known about what they actually do, much less whether they are effective in improving patient safety. There needs to be a policy-based review of whether a

revitalized PSO program could address diagnosis errors among other safety issues.

4. Follow-up and feedback

There is substantial evidence that patients are quite aware of the diagnosis error problem. Patients are able, willing, and motivated to participate in error-reporting systems. Even if not measurable, diagnosis errors often are memorable, leading physicians to learn from their mistakes as well. A good first step would be collegial feedback. However, rather than relying on fortuitous feedback, what is preferable is affirmatively promoting systematic feedback, from patients and peer physicians with an infrastructure that is hard wired to capture and learn from patient outcomes, and in a safe environment in which clinicians are encouraged to learn from mistakes rather than face punitive action.

5. Fundamental medical malpractice reform

Instead of trying to wall off the malpractice system from physicians' and hospitals' important disclosures about errors, it is time to change the legal system so that candid disclosure of errors is routinely provided, not just permitted under particular circumstances. A core element of such reform would be to replace a determination of "negligence" by a judge or jury with a determination of "avoidability" using administrative mechanisms, such as a dedicated health court. This would help bring errors out into the open for study and improvement rather than protecting against their disclosure, a result of the current adversarial system.

6. Improved technology and EHRs

There is one immediate action CMS could take to improve the potential of EHRs to improve diagnostic accuracy. The Medicare documentation guidelines for evaluation and management services, established in the mid-1990s to address "up-coding" on payment claims related to patient visits, have proved counter-productive. With the advent of EHRs, physicians are better able to cut-and-paste information from other parts of the clinical record to support the claimed level of code, while at the same time compromising the medical record as a source of useful clinical information by overloading it with redundant, often irrelevant and inaccurate information provided to justify up-coding. If CMS could bring in necessary changes, EHR vendors would be in a better position to design their software to focus more on decision support, including tools related to supporting useful differential diagnoses, rather than emphasizing

documentation of services provided, the current focus of EHRs.

7. Payment reform

Diagnosis errors cannot be measured reliably to be included in pay-for-performance schemes, however, overdue improvements in activity-based payment systems would help. A substantial body of evidence supports the critique that the relative values that underpin the Medicare physician fee schedule and that of most other third party payers are distorted, in relation to the underlying costs to produce the services, to favor procedures and tests, while squeezing payment for visits. This payment skew in turn contributes to productivity pressures and the kind of cognitive biases that lead to diagnosis errors. In addition, a particular problem with payments based on diagnosis-related groups for inpatient hospital care is that the system requires a determination of a principal diagnosis that was responsible for the hospitalization, not allowing symptoms to qualify as the reason for hospitalization. This requirement likely forces premature diagnosis in some cases, which then may be uncritically carried forward, just as cut-and-paste may memorialize

incorrect information in the medical record.

8. Medical education reform

Given the central role that a strong knowledge base, ability to find relevant information when needed, and having to manage cognitive biases play in avoiding diagnosis errors, education reform must be an important strategy. For the most part, medical education reform efforts have been outside the public policy arena. However, given the substantial financial support Medicare provides to hospitals that have residency programs, reducing diagnosis errors could be included as part of the package of educational reforms that would be fostered with a restructuring of indirect medical education payments to academic health centers.

To read the full paper, visit

<http://www.rwjf.org/en/research-publications/find-rwjf-research/2014/04/placing-diagnosis-errors-on-the-policy-agenda.html>.

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