

Placing Diagnosis Errors on the Policy Agenda

Timely Analysis of Immediate Health Policy Issues

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Robert A. Berenson, Divvy K. Upadhyay, Deborah R. Kaye

Introduction

“A goodly number of ‘classic’ time-honored mistakes in diagnosis are familiar to all experienced physicians because we make them again and again. Some of these we can avoid; others are almost inevitable, but all should be borne in mind and marked on medical maps by a danger-signal of some kind: ‘In this vicinity look out for hidden rocks,’ or ‘Dangerous turn here, run slow.’” — Richard C. Cabot, 1912¹

Diagnosis errors¹ are common, produce avoidable disability and death, and are often costly; yet they are rarely recognized in public policy as a serious quality and safety problem deserving attention and action. Virtually wherever one looks in the health care system, a broad array of research demonstrates that wrong, missed, and delayed diagnoses occur in the range of 5 and 15 percent of health care encounters.²

While one might hope that diagnosis errors occur when physicians are confronted with rare conditions and uncommon presentations of common diseases, they actually occur most often in relatively common diseases that are misdiagnosed or missed entirely.³ They are found across the entire spectrum of clinical areas and virtually throughout all specialties. They occur in primary care physicians’ offices, clinical labs, emergency rooms, intensive care units, and the general floors in hospitals. With some variation, high rates of diagnosis errors are found in autopsies, patient and clinician surveys, malpractice claims, second reviews, and case reviews.

Diagnosis errors are the leading cause of paid claims

¹ Although most of the literature refers to the problem as one of “diagnostic errors,” we have chosen to use the term “diagnosis errors,” as a few others have done, based on our view that “diagnostic error” should reference the diagnostic process involved in arriving at a diagnosis, whereas “diagnosis error” is the final multifactorial outcome of interest, of which diagnostic process is one factor.

for malpractice,⁴ with such errors accounting for twice as many suits than any other type of medical error.⁵ The public’s concern about correct diagnosis can be found in the many articles on the subject routinely found in mainstream media and online forums, such as a column titled “Diagnosis” in the *New York Times Magazine* or the *Wall Street Journal* health section front page story about diagnosis errors being “[t]he biggest mistake doctors make.”⁶ From surveys, it is clear that worries about not obtaining an accurate and timely diagnosis are at the top of the public’s concerns about health care quality and safety.⁷

Despite diagnosis errors emerging as a pervasive quality and safety problem, and garnering public interest, the issue has largely been ignored by policy-makers and institutions dedicated to improving quality and protecting patient safety. Across the rapidly growing number of initiatives attempting to improve patient safety and value-based purchasing promoted by Congress, the Centers for Medicare & Medicaid Services (CMS), large health care purchasers and health plans, virtually none relate to accuracy and timeliness of diagnosis.

This lack of attention is not new. A major opportunity to bring diagnosis errors into the national limelight was lost when the landmark 1999 Institute of Medicine report, “To Err is Human,”⁸ focused on medication errors and adverse events, virtually ignoring diagnosis errors. Simply, at that time there was a dearth of research pointing to the extent of the problem; the report cited only three relevant studies.

Among the relatively few clinical researchers and practicing clinicians currently studying the diagnosis error problem, there is agreement that the issue, to quote Robert Wachter, “gets no respect.”⁹ The medical profession did not pay organized or focused attention to diagnosis errors until recently, with the formation of the Society to Improve Diagnosis in Medicine. Perhaps the lack of serious attention thus far is based on the perception that diagnosis errors either represent a

simple lack of clinical knowledge, or reflect individual cognitive biases in processing information.¹⁰ They seem to be considered inevitable and certainly difficult to demonstrate. In contrast to medication errors where fixes such as physician order entry systems had been tested and proved successful, there have not been ready approaches to address the much more complex problem of diagnosis errors.¹¹

Only in recent years have patient safety researchers focused seriously on the possibility of reducing diagnosis errors by substantially improving clinicians' diagnostic thought processes.¹² Similarly, the belief that diagnosis errors reflect hard-to-change cognitive biases has obscured the view that diagnosis errors represent remediable systems problems, as strongly promulgated in "To Err is Human."¹³

At the same time, the field of quality performance measurement has gained considerable momentum through health care purchaser and consumer interest in promoting accountability, quality improvement activities, and provider choice. Unfortunately, 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. The challenges of measuring diagnosis errors, especially in real time, are daunting. Many individuals go to their graves 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 performance measures. Other approaches are available and can be fostered if we have the will to push them forward.

"...one of the unanticipated outcomes of the growing reliance on performance measurement is that quality and safety problems not easily amenable to measurement are often ignored, certainly in public policy."

This paper explores the challenge of measuring diagnosis errors and why it is difficult to estimate the extent of the problem. We present the different reasons such errors are common, briefly exploring the growing science of cognitive bias leading to error and what might be done to reduce their effects. We review the potential of electronic health records (EHR) and artificial intelligence, which offer promise—and pitfalls. We conclude by observing that there is a

paucity of serious policy recommendations to reduce diagnosis errors, but offer a number of suggestions for placing the issue on the policy agenda.

The Nature and Extent of the Diagnosis Error Problem

"Mistakes in diagnosis may be due to various causes—to inherent obscurity of signs and symptoms of disease, to misleading statements by patients or malingerers, or to our imperfect physiological knowledge; but in addition to these inherent causes of error, mistakes too frequently arise from the carelessness or the ignorance of the surgeon. We may, perhaps, divide medical men into two classes, those who are overcautious and those who are overconfident."—William Cadge, 1891 (Excerpt from a speech read at East Anglian Branch meeting of the British Medical Society.)¹⁴

Because making correct diagnoses is a core element of the practice of medicine, it is not surprising that the challenge of incorrect or missed diagnoses has been observed going far back into the history of medicine. While the problem has been acknowledged, it has been hard to quantify. Part of the challenge relates to the broad definition of what is considered a diagnosis error. Most clinical researchers, addressing the subject, consider "diagnosis error" to be a wrong, missed, or delayed diagnosis.¹⁵ Complicating the matter is that some diagnosis errors lead to harm, while most do not. Measurement ideally would sort between both presence of error and degree of harm, and could tell us whether the harm could have been prevented or lessened by accurate and timely diagnosis.

A further challenge in estimating the extent of the problem is that some would also expand the definition of diagnosis error to include the growing recognition of the problem of overdiagnosis, which includes providing a new, diagnostic label to common, relatively minor symptoms as well as finding real diagnoses that are unlikely to cause harm.¹⁶ These forms of overdiagnosis can lead to increased health care utilization and costs, clinical labeling with possible insurance and employment repercussions, and deleterious "downstream" consequences caused by unnecessary testing and treatments increasing anxiety and decreasing the quality of life. An increasingly recognized clinical area where overdiagnosis is viewed by many clinicians and researchers as a problem is in the diagnosis of some usually indolent forms of cancer (e.g., prostate, thyroid, breast, and lung)¹⁷ as suggested by the recent Canadian randomized trial casting doubt

on the benefits of mammography screening.¹⁸

One of the first attempts to quantify the extent of diagnosis errors came nearly three decades ago in the landmark Harvard Medical Practice study, in which clinicians reviewed 30,195 randomly selected medical records in 51 New York state hospitals in 1984. Adverse events were found in 3.7 percent of the hospitalizations, 14.0 percent of which were attributable to diagnosis errors—the third most common reason for an adverse event, preceded by errors found during procedures, and in failures to take necessary preventive measures.¹⁹

At about the same time, autopsy studies were advanced as a gold standard for measuring diagnosis errors. In a paper reviewing 53 autopsy series performed from 1966 to 2002, researchers estimated that of the annual deaths occurring in U.S. hospitals (850,000), at least 8.4 percent of deaths occurred without a major clinical diagnosis (71,400), and half of these (34,850) could have been prevented if misdiagnosis had not occurred.²⁰

Consistent with the recent discovery of diagnosis errors, Mark Graber, one of the leading clinical researchers in the field, reviewed several approaches that might be used to measure the nature and extent of diagnosis errors (see “Research Approaches to Measure the Nature and Extent of Diagnosis Errors” on page 4).

Unfortunately, there are many limitations to reliance on these potential research approaches. Unlike most health care quality performance measures in use, these are not based on submitted claims, and therefore raise major data collection challenges. The high cost of data collection for many of these approaches, for example, makes them prohibitive for routine use. And although tools are being developed to more efficiently search for relevant information in EHRs, the record itself may not reveal a delayed or missed diagnosis, as it does a clinical indication for ordering a guideline-based test or procedure. A number of the approaches are also subject to selection or response bias. In short, for the most part, these approaches currently would seem most useful for further clarifying the epidemiology of diagnosis errors and for use in quality improvement projects by organizations working on specific diagnosis error problems, but not routine public reporting.

Although the increasing publication of studies using a broad range of research methods have helped establish the pervasive nature of the diagnosis error problem, we still lack firm estimates of the incidence of such errors

and the extent of harm resulting. Academic experts have attempted somewhat heroic, “ball park” estimates of the extent of the diagnosis error problem, extrapolating from, admittedly, limited data. A 2002 estimate by Leape, Berwick, and Bates attributed 40,000 to 80,000 preventable deaths per year in the U.S. to missed diagnoses alone.²¹ A recent analysis by Singh and colleagues using detection methods based on EHRs yielded a rate of 5 percent of outpatient diagnosis errors and suggested that one in 20 or roughly 12 million U.S. adults are affected by diagnosis errors every year.²² In short, while these estimates are probably conservative, we do not currently have reliable estimates on the incidence or harm caused by diagnosis errors. It is safe to say such errors represent a pervasive quality and safety problem, seriously affecting hundreds of thousands of patients at any time.

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.²³ These categories frequently overlap to cause an error,²⁴ with the share of contribution somewhat dependent on the type of diagnosis error that occurs.²⁵ Research shows that cognitive mistakes and biases are most commonly responsible for wrong diagnoses, whereas systems-based errors are more prevalent in delayed diagnoses.²⁶ Improved systems can play a protective role in assuring that cognitive errors are prevented or found and corrected before actual harm occurs.²⁷

Cognitive biases

A breakdown in cognitive functioning can occur at any point in the clinical encounter. It is highly likely that most people intuitively assume that lack of knowledge is a primary contributor to diagnosis errors although a study on internists in academic medical centers shows that mistakes caused by lack of knowledge may be relatively uncommon.²⁸ Mistakes generally occur for a host of reasons: poor data gathering, faulty context application, inaccurate diagnostic synthesis, faulty context application, inaccurate diagnostic synthesis, faulty interpretation of diagnostic findings, premature closure, bias, and inadequate knowledge.²⁹ 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.³⁰ These are failings in processing perceptions, i.e., the way the

Research Approaches to Measure the Nature and Extent of Diagnosis Errors

Autopsies. A review of 31 studies that included autopsies of 5,863 adult ICU patients found that one in 12 ICU patients die from something other than what they were being treated for. Twenty-eight percent of patients had at least one missed diagnosis at death. In 8 percent of patients, the diagnosis error was serious enough to have caused or contributed to the individual's death and, if known, would have changed treatment.³¹

Patient and provider surveys. In a survey of 2,000 patients, 55 percent listed fear of misdiagnosis as their chief concern when seeing a physician in an outpatient setting.³² In a survey of 6,400 clinicians, half saw diagnosis errors at a monthly rate and most believed these errors were partly preventable;³³ in another survey, half of the pediatricians reported making a diagnosis error at least once or twice a month.³⁴

Standardized patients. In a study, internists misdiagnosed 13 percent of patients presenting with common conditions to clinic.³⁵ In these studies, real or simulated patients with classical presentations of common diseases, like rheumatoid arthritis, asthma, or chronic obstructive pulmonary disease are sent anonymously into real practice settings.

Second reviews. A study suggested second reviews could detect 2 to 5 percent of critical abnormalities.³⁶ These reviews are performed in visual subspecialties (e.g., radiology, pathology, dermatology) by a second physician in the same specialty who reviews the initial interpretation. In studies, 10 to 30 percent of breast cancers were missed on mammography;³⁷ 1 to 2 percent of cancers were misread on biopsy samples.³⁸

Diagnostic testing audits. An analysis found laboratory results are misleadingly wrong in 2 to 4 percent of cases, and that such misleading results are some of the most common reasons for diagnosis errors.³⁹ The processes of ordering, performing, interpreting, communicating, and acting upon diagnostic test results remains vulnerable to errors. Most laboratory-related errors originate while the physician orders and interprets the test result.⁴⁰

Malpractice claims. Problems relating to diagnosis errors are the leading cause for paid malpractice suits. Recent analysis of a 25-year period identified 100,249 cases of diagnosis error. Diagnosis error was the most common reason for a claim (29 percent) and the most costly, averaging \$386,849 per claim. Between 1986 and 2010, the total diagnosis-related payments were close to \$38.8 billion.⁴¹

Retrospective case reviews. A review of 198,919 stroke admissions found that at least 23,809 (12.7 percent) cases were potentially "missed strokes" (i.e., discharged from their initial emergency department visit with a non-cerebrovascular diagnosis).⁴² Review of more than 8,000 emergency room patients found a delayed diagnosis of stroke in 9 percent.⁴³

Voluntary reports. In a 2009 survey, 583 cases of diagnosis errors were reported by 310 physicians. Of these, 162 errors (28 percent) were rated as major (resulting in near life-threatening event, disability, or death). Among common missed or delayed diagnoses were pulmonary embolism, medication errors, and lung cancer. These occurred frequently in the testing phase (failure to order, report, and follow-up lab results) or were clinician assessment errors (failure to consider competing diagnosis).⁴⁴

EHR-based triggers. Symptoms and presenting complaints can be tracked through EHRs. A set of "triggers" could be developed to alert physicians to potential diagnosis errors. A study found 1,047 cases of missed or delayed diagnosis of prostate or colorectal cancer analyzing EHRs of 300,000 patients.⁴⁵ Another study focused on triggers based on patterns of patients' unexpected return visits after an initial primary care visit and found 190 instances of diagnosis errors. Common missed diagnosis included pneumonia and congestive heart failure. Most errors occurred in the patient-provider interaction because of inadequate history-taking and examination.⁴⁶

This information has been adapted from Mark Graber's paper, "The Incidence of Diagnostic Error."⁴⁷ We have added "EHR-based triggers" to Graber's summary due to recent developments in its research potential. As discussed later, these might be adapted for quality improvement.

brain works when making decisions.

Cognitive functioning occurs via two processes: intuitive (Type 1) and analytical (Type 2).⁴⁸ Intuitive processing occurs about 95 percent of the time.⁴⁹ It frequently involves quick decision-making based on previous experiences and heuristics, or mental shortcuts, and often results in accurate decision-making.⁵⁰ Type 2, or analytical processing, is a more thought-based and conscious approach to decision-making.

Overconfidence, where diagnoses are based primarily on intuitions, is a Type 1 processing bias and may lead to misdiagnosis. However, diagnosis errors are not necessarily correlated with Type 1 processing, so slowing down the analytic process does not necessarily prevent diagnosis errors.⁵¹ Some studies suggest that analytic reasoning can decrease diagnosis errors for complex scenarios.⁵² System factors, such as fatigue, distractions, sleep-deprivation, cognitive overload, resource limitations, and team and patient factors play a critical role in decision-making and the likelihood of Type 1 cognitive biases.⁵³

“Differential diagnoses,” or the systematic identification of plausible alternative diagnoses that should be considered, are important in the diagnostic process. Yet, in one study, a differential diagnosis was not present in 81 percent of missed diagnosis cases, suggesting that the correct diagnosis may never have been considered and that clinicians may arrive at diagnostic conclusions without adequately considering other possibilities.⁵⁴ Cognitive errors also occur because of interpretation in a false context. Each patient is unique and diagnostic clues must be ascertained and interpreted accordingly. Diagnosis errors surely do occur in patients with complex medical problems who display varied symptomatology, many unrelated to the missed diagnosis.⁵⁵

Different experts have arrived independently at about 100 distinct cognitive biases that may lead to cognitive error,⁵⁶ and physicians are no less susceptible to such biases than anyone else.⁵⁷ (See “Common Biases That Adversely Affect Clinical Decision-Making” on page 6 for examples of common biases that adversely affect clinical decision-making.)

System errors

System errors include inefficient processes; poorly standardized policies and procedures; lack of teamwork; discontinuous care and handoffs; poor communication; pressures for productivity; disruptions;

fatigue; excessive workloads; excessive administrative requirements; inaccurate test results; and inadequate follow-up and notification of test results.⁵⁸ In one large study, system errors were responsible for a larger share of diagnosis errors than clinician assessment or cognitive mistakes,⁵⁹ but not surprisingly, cognitive and system errors frequently overlap. For example, a clinician is responsible for following up on diagnostic tests, but there needs to be a back-up assurance that critical findings are also relayed to the responsible providers.

Some common systems errors (sometimes referred to as “process errors,”)^{60,ii} involve faulty patient-practitioner interactions, including inadequate history taking or physical examination; incomplete diagnostic work-up; failure to review previous clinic notes; failure to follow-up on diagnostic tests; and failure to make appropriate referrals.⁶¹ Delays in reviewing test results can lead to many types of errors. Results become available over a wide time period; testing sites may not know for what reasons the tests were ordered, therefore abnormal results may not be interpreted in the context of the patient. The volume of lab and other tests that need to be reviewed carefully can be daunting; an average primary care physician may review upwards of 800 laboratory results, 40 radiology reports, and 12 pathology reports per week.⁶² Patient actions or inactions can further result in systems errors.⁶³

No fault

Fewer than 10 percent of diagnosis errors can be labeled “no fault.”⁶⁴ Most commonly they are seen when patients come in with uncommon symptoms or rare diseases. Medical diagnoses are difficult because of many interacting and competing factors and processes and incomplete scientific understanding. Many diagnostic dilemmas or clinical puzzlers, the kind highlighted in the *New York Times Magazine* column “Diagnosis” or on famous long-running TV series such as the fictional “House, MD” and the nonfictional “Mystery Diagnosis,” occur in patients with nonspecific symptoms or atypical presentations.⁶⁵ Every test cannot be performed on every patient because the risks of the test outweigh the benefits in

ⁱⁱ Schiff et al. provided a fourth category of errors called “process errors” using the Diagnostic Error Evaluation and Research (DEER) project tool, distinguishing them from cognitive and systems errors. We follow the Graber et al. typology and assign common process errors to the other two categories, mostly systems errors, recognizing that process errors can be reduced through systems-based approaches to reduce their prevalence, and impact.

Common Biases That Adversely Affect Clinical Decision-Making

Availability. Physicians are predisposed to judge things as being more likely, or frequently occurring, if they readily come to mind. Thus, recent experience with a disease may inflate the likelihood of its being diagnosed. Conversely, if a disease has not been seen for a long time (is less available), it may be underdiagnosed.

Anchoring. Anchoring is the tendency to perceptually lock onto salient features in the patient's initial presentation too early in the diagnostic process, and failing to adjust this initial impression in the light of later information. This bias may be severely compounded by confirmation bias.

Ascertainment bias. Ascertainment bias occurs when a physician's thinking is shaped by prior expectation. Stereotyping and gender biases are both good examples. Sometimes this is seen when physicians could tend to be judgmental in their comments about patients during hand-offs to other colleagues.

Confirmation bias. In medical encounters, confirmation bias is the tendency to look for confirming evidence to support a diagnosis rather than look for disconfirming evidence to refute it, despite the latter often being more persuasive and definitive.

Diagnosis momentum. Once diagnostic labels are attached to patients they tend to remain as such. Through intermediaries (e.g., patients, nurses, physicians), what might have started as a possibility gathers increasing momentum until it becomes definite, and all other possibilities are excluded.

Framing effect. Physicians should be aware of how patients, nurses, and other physicians frame potential outcomes and contingencies of the clinical problem to them. A doctor's diagnosis may be strongly influenced by the way in which the problem is framed (e.g., physicians' perceptions of risk to the patient may be strongly influenced by whether the outcome is expressed in terms of life and death).

Omission bias. In hindsight, events that have occurred through the natural progression of a disease are more acceptable than those that may be attributed directly to the action of the physician. The bias may be sustained by the reinforcement often associated with not doing anything, but it may prove disastrous. Omission biases typically outnumber commission biases, where as a result of overconfidence, there is tendency for action rather than inaction to prevent harm.

Outcome bias. Outcome bias is the tendency to opt for diagnostic decisions that will lead to good outcomes, rather than those associated with bad outcomes, thereby avoiding chagrin associated with the latter. It is a form of value bias in that physicians may express a stronger likelihood in their decision-making for what they hope will happen rather than for what they really believe might happen.

This information has been excerpted from Pat Croskerry's paper, "The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them."⁶⁶

many cases. But even here greater use of decision-support, information technology tools, and improved systems approaches might help address the tough diagnosis problem, as discussed below.

The Potential of Electronic Health Records and Artificial Intelligence

Health information technology (HIT) has the potential to decrease error frequency in each stage of the diagnostic process, but requires improvements before its full potential is realized. El-Kareh and colleagues recently outlined how HIT can affect each stage of the diagnostic process, including information gathering; improved data organization and visualization; assistance in differential diagnosis generation and weighting; more efficient ordering of diagnostic tests; improved accessibility to reference information; and tools for diagnostic collaboration.⁶⁷ Computer-based patient interviewing has been attempted in many clinical environments, and systems have been designed to help interpret diagnostic exam findings. One important study demonstrated that the physician and computer missed important—but different—clinical findings, suggesting that the computer might help, but cannot replace, clinical expertise.⁶⁸ Several other promising diagnostic tools and symptom trackers, including SymCAT and Symple, have been developed to empower patients in the diagnostic process.

EHRs have the potential to improve information organization and allow for aggregation, information trending, and easy visualization of data. EHRs also have the potential to improve clinical research.⁶⁹ Computer support tools may assist the clinician in generating a differential diagnosis, which has the potential to decrease cognitive errors. Several systems are currently in place or have been tested, including PEPID, DXplain, Diagnosis Pro, and Isabel, with mixed success. Isabel, for example, has been shown to assist development of differential diagnoses, therefore improving the diagnostic process and reducing errors.⁷⁰ In fact, a reason for lack of greater impact is not that the decision-support tools do not work, but rather that physicians do not use them.⁷¹ There remains concern that use of these decision-support technologies can lead to just as many clinician diagnoses being changed from correct to incorrect as the desired from incorrect to correct.⁷²

Clinical prediction tools have also been used to help weigh differential diagnoses. These diagnostic algorithms are embedded in the EHR to guide clinical

decision-making. While some initial results were promising, others found decision-making was not affected.⁷³

As noted, some physicians are unwilling to accept clinical decision support, and its use does not always result in improved diagnoses.⁷⁴ A 1987 review of computer-aided diagnostic systems found that except in extremely narrow clinical domains, using computer-based software to aid in diagnosis was of little to no practical value.⁷⁵ Nearly 30 years later, programs have yet to demonstrate broad, clinical impact.⁷⁶

A new entry on the scene is “big data,” the collection and analysis of numerous data sets that are too complex to be analyzed with traditional database tools. These tools, combined with machine learning and artificial intelligence, are being developed to assist clinicians in creating differential diagnoses and treatment algorithms which are less subject to cognitive bias.⁷⁷ Big data and EHRs, in general, may allow for improved evaluation of clinical outcomes from data standardization and free text data abstraction. Although progress has been made, data abstraction from EHRs and the use of artificial intelligence still face many challenges before their full potential is realized.⁷⁸

Currently, easily accessible reference materials and up-to-date, evidence-based clinical guidelines should help clinicians determine the appropriate work-up for particular clinical presentations. The use of “info buttons” in EHRs may allow for quick access to up-to-date information. Pop-up notifications to prompt clinicians to follow up on diagnostic tests may also decrease diagnosis errors.

Other 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. Specialist referrals can be easily completed and physicians may be able to use telemedicine for immediate remote access to specialists. HIT also has the potential to improve feedback to clinicians, especially by facilitating follow-up on long-term patient outcomes. Lastly, electronic records may aid in clinician education and improvement in diagnostic reasoning skills, though the outcomes of this data are conflicting.

Challenges that accompany HIT

There is growing recognition that EHRs may themselves create errors.⁷⁹ Templates and checkboxes, 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.⁸⁰ Increasing reliance on EHR templates and checklists may compromise the traditional reliance on free text findings and qualitative assessments, which are found to be more effective communication tools when dealing with complex tasks.⁸¹ 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 cause time inefficiencies and pose greater burdens for physicians. They can be poorly designed, resulting in juxtaposition errors caused by users clicking incorrectly on closely-spaced boxes.⁸² EHRs can contribute to diagnosis errors because of the growing tendency to copy and paste information in the record without verifying its accuracy. One study found that of the 7 percent of notes in which copying and pasting was performed, it contributed to 36 percent of diagnosis errors.⁸³ Further, the EHR can be so intrusive that it distracts the clinician from hearing the patient's history and conducting the physical exam. It can also distract the patient from providing a complete history. Relied upon diagnostic flags provided by HIT systems may not occur when they should, leading to a false sense of security and missed diagnoses. In contrast, sometimes there are too many flags. Physicians report feeling overwhelmed with the number of alerts and often respond by simply turning them off.⁸⁴

In summary, there are operational problems that interfere with the potential of HIT generally and EHRs specifically to improve diagnosis accuracy and timeliness. But, the potential for dramatically reducing errors in diagnosis are substantial and are being realized in some situations. It is neither likely nor advisable to go back to a time before broad adoption to EHRs and other HIT advances. The challenge is to learn from the problems, make long-overdue corrections to policies that contribute to these adverse results, and create a stronger clinical and business case for improving EHR functionality.

The Policy Vacuum and How to Fill It

As noted, diagnosis errors have not featured prominently in patient safety campaigns. According to patient safety experts, organizations such as the Joint Commission; National Quality Forum (NQF); Leapfrog Group; and Agency for Healthcare Research and Quality (AHRQ), have all emphasized treatment errors over diagnosis errors in their measurement and patient safety work.⁸⁵ For example, none of AHRQ's 20 evidence-based, Patient Safety Indicators nor NQF's 30 safe practices specifically address failure to diagnose accurately.⁸⁶ The National Strategy for Quality Improvement in Healthcare (NQS), led by AHRQ and the U.S. Department of Health and Human Services and launched in 2011 in response to requirements in the Affordable Care Act, is silent on the issue. The NQS identifies "improving patient safety and reducing harm" as one of its six priorities, but the efforts focus on reducing hospital readmissions and hospital-acquired infections, with reducing harm from inappropriate or unnecessary care listed as a long-term goal.⁸⁷ None address inaccurate diagnosis.

As previously noted, this failure in measuring diagnosis errors is understandable, perhaps given the measurement difficulties in this area.⁸⁸ However, this lack of attention also extends to other quality and safety improvement efforts that do not rely on measurement. For example, Wachter notes that virtually none of the broad policy initiatives that have created a business for safety, at least in hospitals, have focused on diagnosis errors.⁸⁹ He includes residency duty hour limits, central line-associated bloodstream infections and surgery checklist initiatives, NQF's "Never Events," and CMS' public reporting and value-based purchasing activities for hospitals, physicians, and other providers. Wachter also highlights that none of the 29 serious preventable events on the NQF list relate to diagnosis errors.

Despite some nascent attempts to give the problem policy respect, difficult-to-measure diagnosis errors remain a leading cause of avoidable disability and death, the leading cause of claims for professional liability, and a cause of major concern to clinicians and patients. Efforts to produce useful measures of diagnosis errors should become a priority for those with a direct interest in the problem—a group that surely includes medical specialty societies; the Patient Centered Outcomes Research Institute (PCORI); the many physician specialty boards and other professional associations; NQF; the National Committee for Quality Assurance; private payers and employers; professional

liability risk managers, and, importantly, consumer advocacy groups.

The most active, current initiatives that would help the problem of diagnosis errors gain policy traction in a somewhat cluttered quality and safety improvement agenda are being led by the Society to Improve Diagnosis in Medicine and the Institute of Medicine.

Society to Improve Diagnosis in Medicine: Given the vacuum of research and improvement activities focused on reducing diagnosis errors, AHRQ grants supported a group of mostly academic physicians and other health professionals who shared a common perception that it was time to get serious about the problem. They launched the first Diagnostic Errors in Medicine conference in 2008, and by the third annual conference they formally organized themselves to form the Society to Improve Diagnosis in Medicine. Much of the research cited in this paper was produced by individuals who became the core leaders of the Society. Earlier this year, they launched a new quarterly journal, *Diagnosis*, dedicated to research and to practice improvement on this issue. The Society's website is becoming a comprehensive reservoir of literature and publications on what is known about diagnosis errors and what to do to reduce their incidence and impact.⁹⁰

Institute of Medicine (IOM): A recently formed IOM committee is evaluating the existing knowledge about diagnosis error in medicine from a patient safety perspective more than a decade after IOM launched its flagship Health Care Quality Initiative, which includes the reports "To Err is Human: Building a Safer Health System" and "Crossing the Quality Chasm: A New Health System for the 21st Century." The committee will examine current definitions, epidemiology, burden of harm, and costs associated with diagnosis errors. It will also develop recommendations to reduce them. According to IOM, action items for key stakeholders may focus on medical education, the culture of medical practice, information technology, systems engineering, measurement approaches, reimbursement policies, and further research.^{91,iii}

ⁱⁱⁱ This study is sponsored by the IOM along with the Agency for Healthcare Research and Quality, Cautious Patient Foundation, Centers for Disease Control and Prevention, College of American Pathologists, The Doctors Company Foundation, and the Robert Wood Johnson Foundation.

Specific policy initiatives to address diagnosis errors

Public reporting of quality and value can be an important approach to assuring greater accountability, promoting consumer choice, and stimulating providers to improve their performance through quality improvement initiatives. In considering repealing the Sustainable Growth Rate, both houses of Congress adopted an approach referred to as value-based purchasing, which would provide substantial financial bonuses or penalties to individual physicians and physician groups based on their reported performance on specific quality and cost metrics. The draft legislation identifies specific measurement gaps that need to be filled to have a robust, comprehensive set of performance measures.⁹² The gaps list does not include the category of diagnosis errors, so possibly physicians could receive high ratings for the overall value of their services without any consideration of whether they make accurate and timely diagnoses.

As suggested, filling this particular measurement gap will be extremely difficult or impossible, at least in the near future. The clear implication from this and other gaps in what can be reliably measured is that public reporting and value-based purchasing can be approaches to promoting higher value for Medicare beneficiaries (and other patients), but not the only approaches. We believe there are many policy options to address this pervasive quality problem that do not rely on measuring performance, and further, that these options should be developed under the assumption that useful measures of frequency and severity of diagnosis errors will not be available, outside of special research studies.⁹³

Policy options for addressing diagnosis errors at this time need to be developed under the assumption that important measures of the severity and frequency of quality errors will not be available 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 are a number of ways public policy can emphasize the issue and use value-improving tools other than measurement to promote improvement. 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. Borrowing from approaches pioneered by The Dartmouth Institute, such research should include the study of practice variations in order to help identify approaches to minimizing diagnosis errors that the better performers use.

National Institutes of Health (NIH): The national research infrastructure mirrors the clinical specialty infrastructure, providing no natural home for research about diagnosis. The NIH is organized into disease-oriented or specific population-based (e.g., children, aged) institutes and currently provides no locus oriented to the diagnostic process, whether starting from symptoms that people have or the clinical presentation to emergency departments and primary care practices. The process of scientific review similarly emphasizes treatment of known diseases, with virtually no attention to the study of clinical diagnosis and, in particular, the role of cognitive biases and how to reduce their influence. Further, academic researchers have pointed out that investigator-initiated research proposals focused on symptoms or differential diagnosis are not readily funded.⁹⁴ A renewed focus on improving diagnosis and reducing related errors could provide a much-needed impetus into further research on this subject.

AHRQ: In 2007, AHRQ took notice of diagnosis errors, calling for research to support emerging literature on the problem resulting in “devastating consequences for patients, families, and health care professionals.” Though the funding was very limited, the new emphasis helped initiate an annual conference for experts in the field that eventually led to the formation of the Society to Improve Diagnosis in Medicine. In 2013, AHRQ reissued its 2007 funding call, this time for research on “improving diagnostic performance.”⁹⁵ However, AHRQ has still not earmarked funds to support these calls for proposals. Currently, only one study in AHRQ’s \$400 million research portfolio focuses on diagnosis, and none focus on diagnosis errors, while virtually the entire budget supports treatment-related research, including the \$66 million earmarked for patient safety research.⁹⁶

PCORI: Although “patient-centered” is included in the title of the Patient Centered Outcomes Research Institute, and harms from diagnosis errors is an outcome to be avoided if possible, our review of projects funded by PCORI shows little that explores the comparative effectiveness of reducing diagnosis errors, a problem that patients care about. In its few years of

existence, PCORI has assured that its priorities include, and are oriented toward, patient perceptions of what is important. Surely that orientation should result in an emphasis on comparative effectiveness interventions that are specifically aimed at achieving lower rates of diagnosis errors.

Given that this is one of the first attempts to produce policy approaches to reducing diagnosis errors, we do not suggest major organizational changes such as establishing an “Institute for Correct Diagnosis” at NIH. However, each of these organizations could help develop the science of diagnosis error and its prevention within their current structures by, for example, empowering a subset of interested researchers in developing research programs that could at some point solicit research addressing particular ways to reduce diagnosis errors, including reducing cognitive biases and improving systems for preventing error and harm. The former area would seem ripe for NIH-funded research, the latter for AHRQ and PCORI, which could also seek to fund research promoting patient-reported diagnosis errors.

2. Require enhanced conditions of participation in Medicare

The Society to Improve Diagnosis in Medicine has initiated discussions with the Joint Commission about including structural elements and performance measurement of certain processes related to diagnosis errors in their hospital accreditation standards.⁹⁷ CMS should explore similar provisions in its Conditions of Participation (CoPs)^{iv} for hospitals and perhaps other institutional providers for which CMS requires facilities to meet CoPs.⁹⁸

Perhaps the central Medicare initiative designed to meet the CMS’ “Three-Part Aim” of improving the patient experience of care—including quality and satisfaction, improving the health of populations, and reducing the per capita cost of health care—is promoting and testing Accountable Care Organizations (ACOs).⁹⁹ In its regulations for the Medicare Shared Savings Program for ACOs, CMS presented an

^{iv} The Centers for Medicare & Medicaid Services (CMS) develops Conditions of Participation (CoPs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. CMS regulates all hospitals that receive any type of federal reimbursement for care provided. Virtually all U.S. hospitals are affected and must take certain actions to remain compliant with CMS regulations.

approach to quality improvement that, if modified, could be the basis for increased focus on reducing diagnosis errors in ambulatory care as well as institutional care settings. Acceptance as an ACO in the Shared Savings Program requires organizations to indicate in detail how the ACO will assure that central quality topics—such as evidence-based medicine, shared decision-making, and beneficiary engagement—are given explicit attention.¹⁰⁰ How the ACO specifically plans to assess and reduce the high prevalence of diagnosis errors could be included in the short list of topics the ACO must address.

The various approaches (presented on page 4) for measuring errors can provide some approaches ACOs might adopt as part of specific quality improvement projects to reduce diagnosis error. A recent paper provides three case studies based on initiatives at Kaiser Permanente, the Maine Medical Center, and the U.S. Department of Veteran Affairs to highlight innovative approaches health care organizations could adopt in reducing diagnosis errors.¹⁰¹

Unfortunately, it seems that once ACOs have presented an action plan to address the important core elements of care, CMS no longer monitors future progress. To make this approach work, CMS would have to give more weight and ongoing attention to the specific work plans that ACOs commit to in order to accomplish improvements in these areas, rather than just relying on the ACO's performance on the 30 or more measures ACOs have to meet to be eligible to keep any shared savings.

3. Quality improvement and collaboration

The Partnership for Patients,¹⁰² which CMS initiated through the Affordable Care Act (ACA), was designed specifically to reduce preventable readmissions through improved care transitions, and to make care safer by reducing hospital-acquired conditions. The approach is to create and sustain a broad collaboration among health professionals, employers, patients and their advocates, and private and government payers. This model should be extended to address particular problems found under the broad rubric of diagnosis errors. For the purposes of fostering a collaborative partnership, it would be necessary to develop objective markers of improvement, even if not true measures of diagnosis errors.

Patient Safety Organizations: In 2005, Congress passed the Patient Safety and Quality Improvement Act

that required AHRQ to create Patient Safety Organizations (PSOs), intended to promote reporting of safety-related errors to facilitate analysis and suggest areas for improvement in a nonpunitive manner.¹⁰³ PSOs were to be made up of independent, external experts who would provide the framework by which hospitals, doctors, and other health care providers would voluntarily report information to PSOs, on a privileged and confidential basis, for the aggregation and analysis of patient safety events. Providing confidentiality to allay liabilities was considered a crucial factor that could lead to the success of these PSOs. The concept was straightforward: clinicians would receive feedback on how they could reduce errors, the nation would learn from analysis of the large number of errors confidentially reported, and patient safety would improve.

Now, almost a decade later, AHRQ lists 79 PSOs operating in only 30 states.¹⁰⁴ Little is known about what they actually do, much less whether they are effective in improving patient safety.¹⁰⁵ It would seem that because hospital participation in PSOs has not been mandatory, and because of uncertainty and apprehensions around legal protections to hospitals and doctors in reporting these errors, the take-up of PSOs among hospitals has lagged.

To address this, the ACA required that hospitals with more than 50 beds wishing to contract with a Qualified Health Plan (QHP) selling on the state or federal exchanges needed to fulfill certain criteria, including participation in a PSO by January 1, 2015. Hospitals that wanted to serve those insured through the exchanges would have had to develop a patient safety evaluation system to send data to their PSO. But in December 2013, HHS acquiesced to the concern that hospitals and PSOs were unprepared, and that implementing the requirement could seriously hamper access to care for patients served by QHPs. HHS has proposed a delay of two or more years in the PSO participation requirement.¹⁰⁶

Although PSOs are developing too slowly and out of policy view, they remain an important potential mechanism for developing the epidemiology of diagnosis errors and providing useful feedback to clinicians and organizations trying to improve quality and safety. In describing some areas of PSO interest, AHRQ has identified readmissions, falls, health care-associated infections, medication errors, pressure ulcers, blood or blood products, deliveries, and HIT,

but not diagnosis errors. There needs to be a policy-based review of whether a revitalized PSO program could address diagnosis errors, as well as these more commonly identified safety problems.

“...even if not measureable, diagnosis errors often are memorable, leading physicians to learn from their mistakes.”

4. Follow-up and feedback¹⁰⁷

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.¹⁰⁸ Some experts have suggested that patients take a more active role in ensuring the reliability of the diagnostic process and to report breakdowns.¹⁰⁹ Even if not measureable, diagnosis errors often are memorable, leading physicians to learn from their mistakes. There is, of course, concern that physicians could react to even accurate feedback through an availability bias, for instance, overreacting to a recent, vividly recalled or major adverse event.¹¹⁰ Yet, it would be better to work on mitigating the cognitive bias response than not having information about the error in the first place.

Another potential concern is that patient reports would not always accurately reflect true errors. Because of that issue, such reporting would seem better targeted at promoting quality improvement efforts by providers rather than for use in public reporting and provider report cards, especially given the likely low numbers of reports filed. Similar to patient reporting, routine physician reporting of diagnosis errors they encounter offers significant promise and is consistent with the peer review duties found in most discussions of the expectations of professionalism. In initial studies, researchers were able to promote reporting of severe errors that otherwise would have escaped detection.¹¹¹

Therefore, a good first step would be collegial feedback, as it would be received as less threatening.¹¹² 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.¹¹³ Currently, there are many factors standing in the way of systematic feedback on diagnosis outcomes and error such as physicians’ lack of time, the threatening nature of critical feedback, and fragmented or discontinuous

care.¹¹⁴ Some physicians, at least, would be amenable to change and delivery system reengineering. A major rationale for this approach is that diagnosis errors are those that physicians remember the most and often consider the most serious in their career.¹¹⁵

There is growing interest in promoting patient-reported outcomes, with much of the leadership coming from NIH.¹¹⁶ Policy-makers should not only consider including reports of diagnosis errors in patient-reported outcomes surveys, but also promote direct feedback about particular errors to hospitals, physician practices, ACOs, and other entities that have responsibility to take action to reduce the likelihood of recurrence by improving the systems that support clinical care.

5. Fundamental medical malpractice reform

Although most of the focus of state-based tort reforms has emphasized limiting economic and noneconomic damages and enacting other barriers to bringing suits, more fundamental professional liability reform could change the current adversarial nature of court-based adjudication and instead promote enhanced disclosure of errors with more automatic compensation to injured patients. Although not specific to diagnosis errors, because such errors are the leading cause of suits and judgments,¹¹⁷ fundamental liability system reform could theoretically make a big dent in the diagnosis error problem.

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—to learn how to develop systems that serve to prevent error and reduce or eliminate patient harm and prevent recurrence. 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,¹¹⁸ and in so doing bringing out errors into the open for study and improvement rather than protecting against their disclosure, a result of the current adversarial system.¹¹⁹

6. Improved technology and EHRs

Earlier, we described the potential of EHRs to support diagnosis accuracy, especially from increasingly sophisticated decision support software, verging into artificial intelligence. Further, HIT can improve the diagnostic process by enhancing communication and

providing ready access to progress and referral notes, test results and other diagnostic information. Once providers no longer have to input data into the system outside of the normal course of documenting care, effective decision-support systems should be able to provide them with meaningful guidance to make timely and accurate diagnoses.¹²⁰ Yet, it is becoming increasingly clear that clinicians find current demands of EHRs overly burdensome and that their potential is more theoretical than real.

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, although 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, simultaneously 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.¹²¹ It is surely time to retire the documentation guidelines. But the problem of inappropriate up-coding has not disappeared.¹²² That problem needs to be addressed as part of payment reform. If CMS could bring in these 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

While it is a worthy aspiration to shift from volume-based to value-based payment to physicians, hospitals, and other providers, no payment system by itself can prevent medical errors or assure high quality. This may be especially true for diagnosis errors, which cannot be measured reliably to be included in pay-for-performance schemes (if such approaches prove successful—the jury is still out).¹²³

However, overdue improvements in payment systems that provide compensation for activities rather than results 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.¹²⁴ This payment skew in turn contributes to productivity pressures and the kind of cognitive biases and mistakes that lead to diagnosis errors.¹²⁵

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. Some contend that this requirement 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.

More fundamental payment reform—which is encompassed in the concept of value-based payment—would move from activity-based payment made separately to individual and often independent practitioners and facilities, to population-based payment to an organization responsible for the full continuum of care, including ambulatory, hospital, and post-acute care. The population-based payment concept inherently promotes greater attention to care coordination across clinicians and institutional providers and calls for much greater attention to systems’ solutions rather than relying on individuals trying to do their best, but in isolation. Under the more robust payment models that shift risk to providers, missing a diagnosis or making an incorrect one can produce wasteful spending. Organizations receiving such payments should have reason to tackle the diagnosis error problem directly.

“...diagnosis errors should no longer be viewed as inevitable and, therefore, an acceptable—if regrettable—by-product of even high-quality health care.”

8. Medical education reform

Given the central role that a strong knowledge base, an ability to find relevant information when needed, and management of cognitive biases play in avoiding diagnosis errors, education reform must be a strategy. For the most part, medical education reform efforts have been outside the public policy arena. The one area in which Medicare policy directly affects education of health professionals is graduate medical education. The Medicare Payment Advisory Commission has proposed using some of the indirect graduate medical education funds, which currently overpay teaching hospitals by

nearly \$4 billion per year, to support a new approach of rewarding residency programs that support national priorities in improving the quality and efficiency of health care delivery.¹²⁶ The Medicare Payment Advisory Commission did not identify reduction in diagnosis errors as part of the package of educational reforms that would be fostered with a restructuring of the indirect medical education payments, but it fits well with other priorities, such as attention to effective use of information technology, evidence-based medical practice, and quality measurement and improvement.

Conclusion

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. For some physicians, making diagnostic judgments constitutes the largest part of the work they do. Yet, the issue of diagnosis error gets little attention as the major quality and safety issue it has long deserved to be. Recent work by a relatively small, dedicated group of researchers strongly suggests 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.

We will eventually learn whether the growing Congressional commitment to value-based purchasing

is money well-spent or counterproductive, as some, including us, predict. Whatever the evidence ultimately shows about its value and for addressing the problem of diagnosis errors, the fact is we lack metrics to assess a clinician's or an organization's performance or to use them as the basis for rewarding or penalizing providers based on measured performance. Fortunately, 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. What remains lacking is an ability to demonstrate that specific activities seeking to reduce clinician cognitive bias, improve work processes, and implement needed systems' approaches to health care delivery can reliably reduce the frequency of diagnosis errors, and can be successfully scaled for wide application and adoption.

We have presented a range of potential levers public policy has available to stimulate needed action. There are surely others. We present these not as a prescription that needs to be taken, but rather in hopes of stimulating attention and discussion about finally taking on the problem.

To read the summary of this 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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About the Authors and Acknowledgments

Robert A. Berenson, MD is an institute fellow; Divvy K. Upadhyay, MBBS, MPH is a research associate at the Urban Institute's Health Policy Center in Washington D.C.; and Deborah A. Kaye, MD is a visiting fellow at the Center and a physician at the Brady Urological Institute, Johns Hopkins Medical Institutions, Baltimore. The authors thank Mark Graber, MD, senior fellow, RTI International and founding president of the Society to Improve Diagnosis in Medicine; and Lawrence Casalino, MD, PhD, chief of the Division of Outcomes and Effectiveness Research and an associate professor at Weill Cornell Medical College for their helpful comments on this paper. This research was funded by the Robert Wood Johnson Foundation and was reviewed at the foundation by Andrea Ducas, MPH, Emmy Hall Ganos, PhD, and Tara Oakman, PhD.

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