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By Robert M. Wachter

Why Diagnostic Errors Don't Get Any Respect—And What Can Be Done About Them

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ABSTRACT The first decade of the patient safety movement achieved some real gains, focused as it was on adverse events amenable to systemwide solutions, such as infections associated with health care and medication errors. However, diagnostic errors, although common and often serious, have not received comparable attention. They are challenging to measure and less amenable to systemwide solutions. Furthermore, it is difficult to hold hospitals accountable, since diagnostic errors usually result from cognitive mistakes on the part of one or more members of the medical staff. Health information technology, better training, and increasing acknowledgment of the problem hold some promise. As approaches to measuring, preventing, and mitigating harm from diagnostic errors are proven to work, it will be important to integrate these approaches into policy initiatives to improve patient safety.

Robert M. Wachter (bobw@medicine.ucsf.edu) is a professor and associate chair of the Department of Medicine at the University of California, San Francisco.

A decade ago, the publication of a report on medical errors from the Institute of Medicine (IOM), *To Err Is Human*, launched the modern patient safety movement.[1] This report, which estimated that 44,000–98,000 Americans die each year from medical mistakes, led to a steady stream of initiatives designed to improve patient safety.

The topic of diagnostic errors has been strangely absent from the flurry of patient safety activity over the past decade.[2] This absence is particularly noteworthy given the frequency of these errors. Approximately one in ten autopsies uncovers some disease or condition that—had its existence been known when the patient was alive—would have altered his or her care or changed the prognosis.[3]

Across a wide variety of clinical conditions, diagnostic error rates average about 10 percent.[4] Ironically, efforts to improve the quality of health care, without taking into account diagnostic errors, sometimes make a bad situation worse. For example, the Centers for Medicare and Medicaid Services (CMS) recently changed its recommended "door-to-antibiotic" time for patients with pneumonia—after studies showed that many patients who rapidly received antibiotics, thereby meeting CMS's quality standard, ultimately proved not to have pneumonia.[5,6]

In this article I describe the reasons for the relative inattention to diagnostic errors in the field of patient safety. I also suggest some changes that would help elevate efforts to fight diagnostic errors to their rightful place among serious safety measures.

The Neglect Of Diagnostic Errors

The pattern of ignoring diagnostic errors began with *To Err Is Human*.[1] A search of the text of the IOM report finds that the term *medication errors* is mentioned seventy times, while *diagnostic errors* appears only twice. This is surprising, since the IOM's famous estimate of 44,000–98,000 yearly deaths from medical errors was drawn from the Harvard Medical Practice Study, which found that diagnostic errors constituted 17 percent of all adverse events—far more than medication errors.[7] Other studies have found

that diagnostic errors account for twice as many malpractice suits as any other type of error.[8]

Reasons For Lack Of Attention

Why did the IOM pay so little attention to diagnostic errors in its seminal report? First, the IOM committee that wrote the report was dominated by thoughtful individuals whose focus was on improving systems of care. That approach works better with medication errors and other errors of execution than with diagnostic errors.

Second, the momentum for the IOM report came from several high-profile errors that clearly demonstrated systemwide flaws, such as the 1994 death of the *Boston Globe* health columnist Betsy Lehman from a chemotherapy overdose, and the 1995 amputation of the wrong leg of a patient in Florida named Willie King. No diagnostic error had garnered similar public attention.

Third, the IOM wanted to focus on solutions, such as computerized provider order entry and other tools. It is far easier to find solutions for medication errors and other process errors than it is for diagnostic errors.

AFTER THE IOM REPORT The IOM report set the stage for collective inattention to diagnostic errors. Events of the following decade pushed this important subset of safety hazards even further behind the curtain.

Since 1999 and up to the present, a variety of policies have been implemented to promote patient safety and quality of care. Those policies include a more vigorous regulatory environment, increased scrutiny of health care organizations by accreditors such as the Joint Commission, and public reporting of safety and quality measures.

Additional pressure for change has come from employer coalitions such as the Leapfrog Group, which has recommended various strategies, such as the use of physicians called intensivists, who provide special care for critically ill patients. Other approaches include pay-for-performance initiatives and Medicare's recent "no pay for errors" policy.[9,10] Each of these efforts was designed to increase the penalty to hospitals and health care systems for failing to keep patients safe or to invest in safety programs.

STRUCTURE, PROCESS, AND OUTCOME Consideration to diagnostic errors was again largely absent from these initiatives. One key reason is the problem of measurement. For example, according to Avedis Donabedian's famous framework[11] for thinking about quality improvement efforts—structure, process, and outcome—each of these must first be measured before it can be improved.

In the health care system, a relevant "structure" could be a system for computerized provider order entry, and the measurement would be its presence or absence. An example of a measurable process is whether there was a "time out" before surgery, to double-check that the procedure would be performed correctly. And an example of an outcome measurement is tracking and reporting the rate of bloodstream infections associated with central venous catheters, called central lines.

To date, the safety and quality movements have focused mostly on processes, or activities known to be associated with better outcomes. For certain safety targets, process measurement works well. It is relatively straightforward to measure a series of processes—now popularly called a bundle—to prevent bloodstream infections related to central lines and to encode these processes in a checklist that can be widely disseminated.[12,13] But diagnostic errors mostly reflect cognitive miscues, such as failing to adequately consider alternative diagnoses. No comparable series of processes (or structures) has been identified to prevent them.

If there have been few structure or process measures that convincingly correlate with diagnostic errors, why not use outcomes? While outcomes seem attractive as a safety target (they are, after all, what patients are most interested in), they are harder to measure than processes or structures, and the science of case-mix adjustment—which would allow outcomes to be calibrated according to patients' severity of illness—is insufficiently advanced to compare apples to apples in many cases.

Moreover, when it comes to outcome measurement, diagnostic errors present additional challenges. Measuring diagnostic errors generally requires a sophisticated review of a patient's chart; even then, expert reviewers often disagree. Such errors also frequently require lengthy follow-up. For example, a missed diagnosis of lung cancer might not be apparent for years.

Two lists of adverse event outcomes form the core of most national and state systems for reporting medical errors: the National Quality Forum's list of "never events,"[14] and the Agency for Healthcare Research and Quality's (AHRQ's) Patient Safety Indicators.[15] Not a single diagnostic error appears among the combined total of fifty adverse events or outcomes.[2]

ADDITIONAL FACTORS There are several other reasons why diagnostic errors have failed to receive the attention they deserve. With a few exceptions, such as missed myocardial infarction, diagnostic errors often do not elicit the visceral dread that accompanies wrong-site surgery. This

is probably because these errors frequently have complex causal pathways and might not be revealed for months or even years.

As mentioned above, none of the examples of medical errors that produced an uproar in the media has involved a diagnostic error. Rather, these high-profile cases have tended to involve terrible medication errors such as the one that led to Betsy Lehman's death or surgical errors such as the amputation of the wrong body part.[16]

One famous medical error, the death of Libby Zion at New York Hospital in 1984, was attributable at least in part to a diagnostic error. But that became known as a death caused by overworked residents and poor supervision, not as one caused by a diagnostic error.[17]

The Problem Of Solutions

The fact that many other types of medical errors can now be paired with relatively easy-to-understand solutions, some of which are supported by evidence, has helped make them high priorities for action. For example, some prescribing errors can be prevented by computerized provider order entry; medication administration errors by bar-coding and so-called smart pumps; failure to get rote processes right by the use of checklists; and infections associated with health care by infection control practices, such as thoroughly washing or disinfecting the hands.

In contrast, we do not have much evidence so far that the proposed solutions to diagnostic errors work, partly because they have been so little studied.[18] In general, the solutions fall into two main categories.

BETTER THINKING The first might be called "better thinking." This involves appreciating the risks of certain cognitive shortcuts called heuristics, and scrutinizing one's own thinking—a process called metacognition—to try to avoid falling into one of a number of common cognitive traps.[19–21]

For example, the heuristic known as "premature closure" occurs when a clinician decides on a single diagnosis and fails to fully consider other diagnostic possibilities.[22] Proposed solutions involve what Pat Croskerry has called "cognitive debiasing,"[21] such as asking oneself: "What else could this be?" or "What is the worst thing that could be going on?" Another solution includes building in mechanisms to receive systematic feedback on one's diagnostic decisions, such as by receiving notice when a patient discharged from the hospital is subsequently readmitted with a different diagnosis.[20–23] Such solutions may be effective. However, they are not easily implemented through the creation of a checklist or a "bundle," or through measurement, transparency, or pay-for-performance efforts.

IMPROVED TECHNOLOGY The second category of proposed solutions for diagnostic errors involves improved health information technology (IT) systems, including forms of computerized decision-support systems. Early systems such as DXplain[24] and Iliad[25] were initially received with enthusiasm, but they quickly fell out of favor when none lived up to expectations.[26]

Some,[27] although not all,[28] modern computerized decision-support systems are demonstrating positive results and beginning to generate interest. Many observers believe that the systems will take a giant leap forward when more day-to-day clinical work is documented electronically. Once providers no longer have to input data into the system outside the normal course of documenting care, effective decision-support systems will be able to provide them with meaningful guidance.

IMPROVED DIAGNOSTIC ACCURACY As Gordon Schiff and David Bates recently emphasized, health IT has the potential to improve diagnostic accuracy in ways other than through computerized decision-support systems.[29] Among the features they call for are better ways to filter and organize clinical information, functions that promote provider-to-provider communication, more dynamic problem lists, and the incorporation of diagnostic checklists into the electronic record.[29] Moreover, Schiff, Bates, and others have observed that many diagnostic errors, particularly missed diagnoses of cancer in outpatients, may be reduced by systemwide improvements that will allow clinicians to see relevant patient care information from other settings, such as freestanding ambulatory laboratories and imaging centers.[22,23,29,30]

Unfortunately, although all of these features may decrease diagnostic error rates, there is little empirical research on their actual impact. In addition, few of today's commercially available IT systems include any of the features discussed.

POTENTIAL FOR MORE ERRORS Interestingly, even as some experts focus on the computer as a fail-safe mechanism, others have emphasized the possibility that increased computerization could cause even more diagnostic errors. In both professional[31] and lay[32,33] publications, concerns have been raised that today's electronic health records promote the copying and pasting of clinical information, instead of its thoughtful analysis;[34] foster a focus on completing computerized checklists and templates rather than detailed probing of the patient's history;[32,33] and support less thoughtful diagnostic reasoning and more automatic behavior on the part of caregivers.[31]

As with the potential benefits of health IT for diagnostic accuracy, research regarding these

hazards is relatively sparse. Nevertheless, the concerns seem well founded.

It is clear that solutions for diagnostic errors—whether new ways of training people to think or the use of advanced health IT systems—cannot compete very effectively in the battle for resources and attention against less controversial, more easily implemented, and better-researched solutions to other safety problems, such as bar codes, checklists, and standardization.

The Problem Of The Accountable Entity

One final disadvantage for diagnostic errors is the absence of an accountable entity with resources to spend on improvement. Partly because hospitals are scrutinized by accreditors such as the Joint Commission, payers such as CMS, regulators such as state departments of health, and the media, they can be held accountable for errors.

That accountability prompts them to invest time and money in creating safer systems of care. Hospitals have supported the collection of adverse event reports and the performance of root-cause analyses by taking actions such as hiring patient safety officers and installing electronic health records.[9]

But how can a hospital be held accountable for diagnostic errors, which usually represent cognitive mistakes on the part of its medical staff? Even if it can be held accountable, what can we expect it to do when no solution has been convincingly demonstrated to be effective?

Additionally, there currently is no mechanism to measure and promote diagnostic skills on the part of practicing physicians. Board certification could help accomplish this goal, but it is not mandatory, and physicians are reassessed quite infrequently during the process of recertification. Most boards require physicians to pass a certifying exam only once every ten years, and many older practitioners have been grandfathered out of even this requirement.

What Can Be Done?

If diagnostic errors are to be included under the broad umbrella of patient safety, where they can garner the attention and resources they deserve, a variety of stakeholders will need to take concerted action.

ENCOURAGE RESEARCH First, we need to encourage research on diagnostic errors. Are there training models for physicians that lead to fewer diagnostic errors? Do any existing computerized tools really help? How can we measure diagnostic errors without expensive reviews of patients' charts? These are important questions, and research on them should be supported by federal agencies and foundations that award grants in the area of patient safety.

In the past few years, a group of academic physicians and researchers with an interest in diagnostic errors has begun to promote this research agenda, and AHRQ has provided seed funding for the study of these errors.[4] Medical journals should encourage these early research efforts by publishing their findings and otherwise highlighting the importance of diagnostic reasoning. One excellent example is the Interactive Medical Cases series recently launched by the *New England Journal of Medicine.*

PROMOTE ACTIONS THAT REDUCE ERRORS Second, regulators and accreditors should follow this research and promote activities that decrease the probability of diagnostic errors. For example, if studies show that certain types of training are strongly associated with improved diagnostic performance, hospitals should be required to offer them or ensure that their medical staffs participate in them.

The evidence threshold to promote or mandate practices to improve diagnostic safety should be no different than for other safety solutions. When troubling data appeared regarding medication errors at the time of patient transitions between hospitals and other sites, the Joint Commission required hospitals to implement medication reconciliation—the formal process of identifying the most complete and accurate list of medications a patient is taking—even before there was ironclad evidence that the process reduced such errors. A similar bar should be set for low-risk activities that address key types of diagnostic errors.

USE TECHNOLOGY Third, with an estimated $20 billion in federal support on the way under the 2009 federal stimulus legislation to promote implementation of health information technology, CMS recently announced regulations for what constitutes "meaningful use" of the technology.[35] When evidence emerges that certain types of health IT can decrease diagnostic errors, that technology should be considered in setting criteria for meaningful use.

For example, if evidence links certain types of computerized decision-support systems to improved diagnostic performance, the presence of this technology could be used as a criterion for hospitals' and practicing physicians' receiving federal funds for health IT.

IMPROVE MEDICAL TEACHING Fourth, accreditors of training programs for physicians, such as the Accreditation Council for Graduate Medical Education and the Liaison Committee on Medical Education, should ensure that residencies

and medical schools teach diagnostic reasoning[36] and make more creative use of model patients and simulations in that training.

Medical students and residents must be taught not to miss certain key diagnoses. Training programs should not rely on serendipity, trusting that every student and resident will happen to see just the right mix of patients under today's apprenticeship model of clinical training. Rather, diagnostic education should be covered as part of a formal, well-planned curriculum, accompanied by robust evaluation methods.

EMPHASIZE BOARD CERTIFICATION Finally, turning to practicing physicians, the certifying boards have a key, perhaps a dominant, role in reducing diagnostic errors. In the absence of process or outcome measurements linked to diagnostic accuracy, the best assurance that the public can have of a physician's competence in diagnostic reasoning is that he or she is board certified and maintains that certification.[37]

The boards need to focus on this unique role, ensuring that their initial certification and maintenance-of-certification programs emphasize key elements of diagnostic accuracy. These include whether a physician has the knowledge base to make correct diagnoses, can use electronic resources effectively to find information, has mature clinical judgment, and can engage in appropriate metacognition. Certifying boards need to include more realistic simulations and allow the use of electronic tools, such as online searches, during portions of their examinations to test all of these competencies.

Conclusion

As the quality and safety movements continue to accelerate, the need to elevate diagnostic errors to their rightful place among safety hazards grows ever more pressing. As one vivid example of how far we need to go, a hospital today could meet the standards of a high-quality organization and be rewarded through public reporting and pay-for-performance initiatives for giving all of its patients diagnosed with heart failure, pneumonia, and heart attack the correct, evidence-based, and prompt care[38]—even if every one of the diagnoses was wrong. Clearly, this anomalous treatment of diagnostic errors must be changed. ■

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ABOUT THE AUTHOR: ROBERT M. WACHTER

Robert M. Wachter is a professor at the University of California, San Francisco.

Robert M. Wachter is professor and associate chair of the Department of Medicine at the University of California, San Francisco, where he holds the Lynne and Marc Benioff Endowed Chair in Hospital Medicine and is chief of hospital medicine. He is also chief of Medical Service at UCSF Medical Center.

Widely recognized as a leader in the patient safety movement, Wachter has authored two acclaimed books on this topic: *Internal Bleeding: The Truth behind America's Terrifying Epidemic of Medical Mistakes* (2004) and *Understanding Patient Safety* (2008). He has also published more than 200 articles on quality and safety. In 2004 Wachter received a John M. Eisenberg Award, the nation's top honor in patient safety, sponsored by the Joint Commission and the National Quality Forum. He also was recently named the tenth most influential physician-executive in the United States by *Modern Physician* magazine.

Wachter long ago recognized that patients in the hospital are vulnerable to lapses in care, poor care coordination, and treatment errors rooted in hand-offs from one care provider to another. He is credited with coining the term "hospitalist" in a 1996 *New England Journal of Medicine* article in which he outlined the critical role that this on-site physician can play in improving hospital care delivery and coordination.

As the editor of *AHRQ WebM&M*, the Agency for Healthcare Research and Quality's case-based patient safety journal on the Web, and *AHRQ Patient Safety Network*, the leading federal patient safety Web site, Wachter has been privy to detailed accounts of many egregious quality and safety failures that are discussed in general terms on those sites. He also writes a popular blog, *Wachter's World*, in which he comments on emerging health policy issues, including patient safety and hospital quality measures and regulatory developments.