Patient Safety At Ten: Unmistakable Progress, Troubling Gaps

Robert M. Wachter

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Patient Safety At Ten: Unmistakable Progress, Troubling Gaps

ABSTRACT December 1, 2009, marks the tenth anniversary of the Institute of Medicine report on medical errors, To Err Is Human, which arguably launched the modern patient-safety movement. Over the past decade, a variety of pressures (such as more robust accreditation standards and increasing error-reporting requirements) have created a stronger business case for hospitals to focus on patient safety. Relatively few health care systems have fully implemented information technology, and we are finally grappling with balancing “no blame” and accountability. The research pipeline is maturing, but funding remains inadequate. Our limited ability to measure progress in safety is a substantial impediment. Overall, I give our safety efforts a grade of B−, a modest improvement since 2004.

Five years ago, on the occasion of the fifth anniversary of the Institute of Medicine (IOM) report on medical errors,1 I reviewed progress in patient safety in five areas: efforts to create and enforce new safety standards through regulation and accreditation; weaknesses in how health systems track and report errors; the disappointing uptake of promising information technology (IT) tools that promote patient safety; the lack of progress in reforming the U.S. medical malpractice landscape and fostering increased accountability among health care providers; and the paucity of physician and nurse engagement in patient safety efforts.2 Overall, I gave a grade of C+ to our early efforts. In this paper I update my assessment of the patient-safety field, again assigning grades representing this observer’s informed but nonscientific assessment of progress in each area.

The scope of the patient-safety movement has broadened since 2004, leading me to add five domains to the original set: research, patient involvement, provider organization leadership engagement, national and international organizational initiatives, and use of the payment system to drive safety. Exhibit 1 compares my grades during the 1999–2004 and 2004–2009 eras.

Areas Described In The 2004 Paper

REGULATION AND ACCREDITATION In my 2004 paper,2 I praised the Joint Commission’s efforts to create safety standards and enforce them through more robust inspections. It was during this early era that the Joint Commission first developed its National Patient Safety Goals, adopted the “tracer methodology” (talking to patients and caregivers around the organization during site inspections instead of focusing on reviewing meeting records and policies), and shifted from preannounced to unannounced visits. Since 2004, the Joint Commission has continued these initiatives, but it now confronts a common problem of regulators and accreditors: once the low-hanging fruit has been picked, their blunt tools become increasingly ill-suited to drive progress in complex, nuanced areas. Contrast Joint Commission National Patient Safety Goals released in the first and second eras: “sign your site” and eliminating high-risk abbreviations were typical of pre-2004 goals. More recent

<table>
<thead>
<tr>
<th>Safety category</th>
<th>2004 grade</th>
<th>2009 grade</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation/accreditation</td>
<td>A−</td>
<td>B+</td>
<td>An important early driver, but much of the low-hanging fruit has now been picked</td>
</tr>
<tr>
<td>Reporting systems</td>
<td>C</td>
<td>B+</td>
<td>Key intervention was the adoption of the NQF list to support error reporting; some improvement in analytical abilities at provider organization and state/national levels</td>
</tr>
<tr>
<td>Health information technology</td>
<td>B−</td>
<td>C+</td>
<td>Surprisingly low uptake over past 5 years; increasing evidence of health IT-related safety hazards and implementation challenges; new infusion of federal dollars should promote health IT adoption</td>
</tr>
<tr>
<td>Malpractice system and accountability</td>
<td>D+</td>
<td>C+</td>
<td>Increased pressure for accountability has led to more emphasis on “Just Culture”; more accountability at leadership level as well; practical approaches for balancing “no blame” and accountability still lagging</td>
</tr>
<tr>
<td>Workforce and training issues</td>
<td>B</td>
<td>B−</td>
<td>Limited but increased engagement by providers; evidence regarding impact of residency duty-hour limits mixed; nurse shortage eased but primary care shortage worse; few organizations adopting robust teamwork, culture change, or simulation programs</td>
</tr>
<tr>
<td>Research</td>
<td>−</td>
<td>B−</td>
<td>Stronger methods are emerging; moderate, but insufficient, increase in funding; still limited data on what works; field still debating fundamental questions regarding evidence standards for safety studies</td>
</tr>
<tr>
<td>Patient engagement and involvement</td>
<td>−</td>
<td>C+</td>
<td>Patient advocacy movements small; impact of “how can patients protect themselves?” efforts uncertain; significant progress on disclosure policies and practices</td>
</tr>
<tr>
<td>Provider organization leadership</td>
<td>−</td>
<td>B</td>
<td>Stronger focus on safety by boards, “C-suite,” as business case becomes more robust; uptake of strong leadership interventions (root-cause analyses, Executive Walk Rounds) improved but spotty</td>
</tr>
<tr>
<td>National and international</td>
<td>−</td>
<td>A−</td>
<td>Much stronger engagement by AHRQ, NQF, Joint Commission, ACGME, WHO, IHI, and others; better dissemination of tools, training, and requirements; some wide-scale change efforts (IHI campaigns, Michigan and WHO checklist studies) have illustrated capacity for broad engagement and measurable progress</td>
</tr>
<tr>
<td>National and international</td>
<td>−</td>
<td>C+</td>
<td>Impact of P4P in quality uncertain; P4P not yet applied to safety because of measurement challenges; Medicare’s “no pay for errors” is a provocative initiative; no evidence yet about impact and concerns regarding unintended consequences</td>
</tr>
<tr>
<td>Overall grade for progress in patient</td>
<td>C+</td>
<td>B−</td>
<td>Most striking improvements in reporting and leadership; gaps in IT and accountability are most concerning, but both areas should see significant progress, driven by new funding (IT) and emerging consensus (accountability)</td>
</tr>
</tbody>
</table>

Source: Author’s analysis. Notes: NQF is National Quality Forum. AHRQ is Agency for Healthcare Research and Quality. ACGME is Accreditation Council for Graduate Medical Education. WHO is World Health Organization. IHI is Institute for Healthcare Improvement. P4P is pay-for-performance. *Not ranked in 2004.

goals include requiring hospitals to have a process in place to identify and respond to caregivers who are disruptive or create a negative culture; improving hospital leadership, and promoting patient involvement in safety.

Moreover, several recent goals were released before there was robust evidence to guide implementation, leading to major missteps and wasted motion. For example, there is consensus that the 2005 National Patient Safety Goal requiring hospitals to reconcile medications at every patient transition was enacted without sufficient guidance about how to accomplish this complex task successfully. The Joint Commission’s recent announcement that it would no longer grade hospitals’ performance on reconciling medications is an acknowledgement of the goal’s many problems and an important cautionary note about the hazards of implementing national safety standards prematurely.

Some hospital leaders have criticized the Joint Commission for being overly aggressive. Nonetheless, after reviewing several instances in which hospitals that appeared to have chronic safety problems were not censured by the Joint Commission, in 2008 Medicare opened the hospital accreditation market to selected competitors. The impact of this change is not yet known. Notwithstanding these critiques, a large gap remains between the comparatively stringent accreditation standards for hospitals and nursing homes and the lax environment for clinics, doctors’ offices, and surgical centers—a gap that illustrates our continued relative inattention to safety in these settings.

Other accreditors are becoming involved in patient safety. The American Board of Medical Specialties (ABMS), representing physician accrediting boards, and the Accreditation Council for Graduate Medical Education (ACGME) have emphasized new “competencies” such as systems-based practice, leading to early efforts to
Recent experience has confirmed that health IT is harder than it looks, a concern I raised in 2004.

add such content to examinations and training programs. Undoubtedly, the ACGME’s most consequential initiative was its 2003 duty-hours limits, which have enhanced the quality of life of physicians-in-training but have not measurably improved patient safety. Although many public stakeholders seek even tighter limits on duty hours and housestaff supervision, hospitals and training program directors have pushed back, citing worries about costs, insufficient training experiences, and the creation of a shift-work mentality.

Many states have stepped up their oversight of hospitals and providers to promote safety. These efforts strike fear in the hearts of hospital leaders, but their impact on safety remains unclear. Some institutions report an undue focus on meeting a variety of detailed administrative requirements that feel somewhat arbitrary, leading to diminished provider enthusiasm and collaboration. On the other hand, state requirements that hospitals report serious adverse events appear to be prompting institutions to initiate more rapid and thorough analyses of such events—a positive development.

Overall, I give a grade of B+ to this category. Although the increased involvement of the ACGME, the ABMS, and states is net positive, the fall in grade from 2004 is attributable to the challenges faced by accreditors like the Joint Commission as they turn to knottier problems involving culture and communication.

**Reporting Systems** In part because of the successes of the Aviation Safety Reporting System in promoting airline safety, in the early years of the patient-safety movement, many individuals and institutions believed that creating vigorous reporting systems for medical errors and near-misses would be equally critical. However, in 2004 I criticized early institutional (such as “incident reporting systems” in hospitals) and extra-institutional (such as systems that require that hospital error reports be submitted to government agencies) reporting efforts, particularly those that admonished, or required, caregivers and hospitals to “report everything.” I felt that such efforts risked collecting massive amounts of data without promoting much learning or improvement.

The key development in reporting has been a shift from reporting “everything” to reporting a manageable list of serious, and partly preventable, adverse events. Such a list (commonly called “never events,” a misnomer because many of the events on the list are not fully, or even substantially, preventable) was launched by the National Quality Forum in 2003 and soon became the scaffolding for more useful reporting requirements. Twenty-seven U.S. states now require hospitals to report “never events,” a requirement that has begun to force hospitals to adopt much more powerful and nimble strategies to analyze errors. At my hospital (University of California, San Francisco, Medical Center), for example, the pressures of state reporting led to the creation of a standing weekly two-hour Root Cause Analysis (RCA) meeting, during which we promptly analyze serious adverse events, assign work groups to implement solutions, and review the resulting follow-up reports to learn lessons and troubleshoot problems. Although this is a more robust practice than that found in many other hospitals, it illustrates the emerging focus on error analysis and system improvement driven by new reporting requirements.

Interestingly, in contrast to the quality world, where public reporting has been a central theme (“transparency”), public reporting of safety outcomes remains unusual (most of the state “never event” reports described above are not made public). The difference lies in our continued reliance on provider self-reports to count most safety outcomes (versus quality performance, which can often be ascertained by reviewing existing clinical or administrative records). The major exception to this—health care-associated infections—has, not surprisingly, become the focus of several safety-related reporting programs.

Overall, my grade for safety reporting is a B+ (up from 2004’s C), the improvement reflecting the emergence of the National Quality Forum “never events” list as the basis for more useful error reporting systems, along with modest error reporting and analysis capacity building within some provider organizations.

**Health Information Technology** Politicians often laud health IT as the cure for medical errors, but most experts realize that it represents only part of the solution. Nevertheless, the promise of health IT is real, which makes its low uptake so disappointing: only 17 percent of hospitals have functioning computerized order entry, and fewer than 2 percent have completely integrated systems.
systems that include computerized provider order entry, electronic medical records, and decision support on all clinical units.\textsuperscript{12}

Moreover, recent experience has confirmed that health IT is harder than it looks, a concern I raised in 2004.\textsuperscript{2} Several major installations of vendor-produced systems have failed, and many safety hazards caused by faulty health IT systems have been reported.\textsuperscript{13,14} Although some provider organizations have implemented health IT systems and report major improvements in safety-related areas,\textsuperscript{15} overall progress has been stunningly slow.

The most hopeful development is federal engagement. After years of complete reliance on the private sector, the federal government recently made $19 billion available to support health IT implementation in doctors’ offices and hospitals. Although there are sure to be missteps, this massive infusion of federal money is critical, since health IT’s glacial adoption curve clearly represents a market failure.

Overall, I give health IT a lower grade (C+) than I did in 2004, mostly because its failure to fulfill its promise is even more jarring when juxtaposed against information technology’s overwhelming impact on our lives outside health care. But we seem poised to take important leaps, and I will be surprised if we do not see many exciting developments soon.

**THE MALPRACTICE SYSTEM AND ACCOUNTABILITY**

Sadly, the intellectual work on medical malpractice that characterized the early years of the patient-safety movement\textsuperscript{16,17} has all but disappeared. This is probably because there has been virtually no movement toward modifying the U.S. tort system, undoubtedly owing to intractable politics.

On the other hand, interest in balancing a systems-oriented focus (accompanied by efforts to resist the natural tendency to blame individuals for errors) with accountability is blossoming, which is a critical development. The mental model for patient safety in the first five years was “no blame” and “it’s the system, stupid.”\textsuperscript{18} This mantra helped engage reluctant providers and undoubtedly generated substantial progress. But starting about five years ago, leading thinkers in the safety field, including Lucian Leape, began arguing the need for consequences for failure to adhere to safety rules.\textsuperscript{19,20} David Marx’s “Just Culture” has become a popular model for differentiating “human error” (inadvertent slips by good workers, which should be managed with “no blame” and systems change) from blameworthy acts (conscious disregard of unreasonable risks, which should be managed through remedial or punitive action).\textsuperscript{21}

Despite this recent emphasis, enforcement remains lax, even for willful violations of reasonable safety standards such as hand hygiene. Peter Pronovost and I recently argued that it is time to penalize physicians and others who fail to follow such standards.\textsuperscript{22} The degree to which these arguments will influence practice and culture is not yet clear.

I give this area a C+, a full grade higher than 2004’s D+, largely because we have finally begun to grapple with the tension between “no blame”/systems thinking and accountability. Future grades will hinge on our success in striking this crucial but elusive balance.

**WORKFORCE AND TRAINING ISSUES**

This area has been surprisingly inert in recent years. Although physicians’ involvement is crucial for patient safety, many—perhaps most—practicing physicians remain unengaged. Such physicians’ engagement in safety is probably greatest in large integrated organizations, where the organization’s increasing accountability is keenly felt by employed or highly aligned physicians.\textsuperscript{23} Even in organizations that lack tight integration, some physician groups—most notably hospitalists—have emerged as key leaders in safety, largely because they receive compensation from their hospital and thus partly share their hospital’s accountabilities.

Progress in nursing safety had also been surprisingly sparse. Particularly striking is the slowdown in research linking nursing characteristics and training to safety.\textsuperscript{24,25} On the positive side, public reporting of certain “nursing-sensitive” safety problems, such as bedsores and patient falls, has provided a focus for nursing safety, and some new models for nurse-physician communication (most notably, training nurses to use a structured format, known as SBAR [“Situation, Background, Assessment, Recommendation”] to report their concerns) have become popular.\textsuperscript{26}

Finally, although the nurse shortage has eased a bit, a primary care physician shortage has wor-
hospitals would achieve high scores on their practices in a bundle, making it more likely that might promote adherence to all of the required experts hypothesized that the use of checklists kinds of infections could be nearly eliminated,32 ("all-or-nothing strategies; a new conceptual model promoting event could be prevented by a series of achievable adverse event; research demonstrating that the surable, highly prevalent, morbid, and expensive or-none fit) are inappropriate or set too high a bar for areas as complex as those found in patient safety.38,39 The results of this fundamental debate will influence safety research for decades to come.

Overall, I give research in patient safety a B−. We have made progress in key areas, but funding is still far too limited, knowledge gaps in crucial areas remain, and the ongoing debate on evi-
dence standards must be resolved. Ultimately, we depend on research to drive progress in safety—there is no shortcut.

**Patient Engagement and Involvement** Over the past decade, a few patient-safety advocacy groups have emerged, often led by people who have personal experience with medical errors. These groups have helped put a human face on the patient-safety issue and ensure that the voices of patients and their loved ones are considered as policies are being crafted. Unfortunately, their small size and paltry funding have limited their impact.

Another recent trend might be called the “What can patients do to prevent medical mistakes?” movement. Although informing patients of their tests and medications is unquestionably worthwhile as a general practice, patient engagement as an error-prevention strategy remains unproven, and concerns have been raised about it on two grounds. First, because patients and families will vary in their capacity to participate in ensuring their own safety, some safety experts have argued that patient engagement might be ineffective or even counterproductive. Second, patients or families often feel guilty after errors occur, a feeling that might be inadvertently promoted by an expectation that they could have prevented the error.

In recent years, momentum has grown to support error disclosure to patients, bolstered by research demonstrating that disclosure does not raise the risk of malpractice suits and might even decrease it. Disclosure has also been promoted by state laws preventing plaintiffs from using apologies in subsequent litigation, a Joint Commission National Patient Safety Goal on disclosure, an influential Harvard guideline, the National Quality Forum’s decision to endorse disclosure as a “safe practice,” and the emergence of programs and tools to educate providers on effective disclosure practices.

Overall, I give this category of C+, largely on the strength of the disclosure trend. The impact of patient advocacy groups remains small, and we await evidence on the effectiveness of patient engagement.

**Engagement of Provider Organizations’ Leadership** This area is crucial, since much of the action in patient safety flows from decisions made by leaders of hospitals, group practices, and health care systems. Many such activities are prompted by changes in other categories; in fact, I’d argue that the most important force promoting hospital safety has been the creation—via regulatory and accreditation standards, public reporting, and more—of a business case for safety.

Recently, boards and top executives have been subject to even more direct pressure. The IHI’s “5 Million Lives” campaign included a plank titled “Boards on Board,” and a recent Joint Commission National Patient Safety Goal targets leadership engagement. As a result of these focused initiatives and more general pressures, many boards and leaders are increasingly involved in safety work. New strategies have emerged to support this work, including Executive Walk Rounds (programs in which senior executives walk onto clinical units to elicit safety concerns), the creation of governing board patient-safety subcommittees, and a recent Joint Commission National Patient Safety Goal on disclosure, an influential Harvard guideline, the National Quality Forum’s decision to endorse disclosure as a “safe practice,” and the emergence of programs and tools to educate providers on effective disclosure practices.

Overall, I give this category of C+, largely on the strength of the disclosure trend. The impact of patient advocacy groups remains small, and we await evidence on the effectiveness of patient engagement.
Overall, I’d give the efforts of large national and international organizations an A−. In fact, their successes have created a new problem: the profusion of activities now makes harmonization increasingly crucial. For example, situations may soon arise in which hospitals are being required to collect different data or implement varied solutions for the same problem (such as preventing hospital-acquired infections) by state regulators, the Joint Commission, and the National Quality Forum. I fear that without harmonization, providers and administrators will be buffeted by (and ultimately rebel against) competing initiatives and requirements.

PAYMENT SYSTEM INTERVENTIONS There is great interest in the use of the payment system to drive quality improvement, and early experiments have been mildly supportive of “pay-for-performance” (P4P) strategies.49 In contrast, the use of P4P in safety has been limited by the measurement problems described earlier. The problem is seen most vividly with hospital incident reporting systems, where increased numbers of reports (a “reporting culture”) and decreased numbers of reports ("fewer errors") are both often interpreted as evidence of progress.50,51

Serendipitously, a feature of Medicare’s hospital reimbursement system created an opportunity to use payment policy to drive patient safety. The diagnosis-related group (DRG) system provides an extra payment (averaging about 30 percent) for “complicating conditions,” some of which are on the National Quality Forum’s “never events” list. This coincidence created an opportunity for Medicare to withhold the extra payment if the “complicating condition” was one of ten “preventable adverse events.”52 The “no pay for errors” policy, launched in 2008, has increased hospitals’ focus on preventing certain adverse events (despite relatively trivial payment cuts to date).54 However, concerns have been raised about fairness (particularly since many of the events on the list are not known to be substantially preventable)53 and unintended consequences (such as keeping hospitalized elderly patients in bed in a misguided effort to prevent falls).54

For now, I give this category a C+, with some points awarded to Medicare’s new policy for being a clever way to begin reshaping the reim-

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**EXHIBIT 2**

**Milestones In The First Decade Of The Patient-Safety Movement**

<table>
<thead>
<tr>
<th>Year</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>Release of the IOM report <em>To Err Is Human</em> creates a media sensation and launches the modern patient-safety movement</td>
</tr>
<tr>
<td>2000</td>
<td>U.K. National Health Service releases another major report, <em>An Organisation with a Memory</em></td>
</tr>
<tr>
<td>2001</td>
<td>IOM releases its <em>Quality Chasm</em> report</td>
</tr>
<tr>
<td>2001</td>
<td>AHRQ receives $50 million from Congress to begin a patient-safety research and improvement program</td>
</tr>
<tr>
<td>2002</td>
<td>Joint Commission releases its first National Patient Safety Goals, followed by dozens more over the next 7 years</td>
</tr>
<tr>
<td>2002</td>
<td>NQF releases its initial list of serious adverse events, commonly called the “never events” list</td>
</tr>
<tr>
<td>2003</td>
<td>ACGME institutes duty-hours regulations, limiting residents to 80 hours per week</td>
</tr>
<tr>
<td>2003</td>
<td>17-year-old Jessica Santillan dies at Duke University Medical Center as the result of a mismatched heart-lung transplant; the error receives international media attention</td>
</tr>
<tr>
<td>2003</td>
<td>Minnesota becomes the first U.S. state to create a statewide error-reporting system based on NQF list of serious adverse events; 26 states would follow suit over the next 6 years</td>
</tr>
<tr>
<td>2004</td>
<td>U.S. government creates the Office of the National Coordinator for Health IT (ONC), the first federal initiative to computerize health care</td>
</tr>
<tr>
<td>2004</td>
<td>IHI launches its first national campaign (100,000 Lives Campaign) to promote the use of patient-safety interventions</td>
</tr>
<tr>
<td>2005</td>
<td>WHO forms the World Alliance for Patient Safety (later renamed WHO Patient Safety)</td>
</tr>
<tr>
<td>2005</td>
<td>U.S. Congress authorizes the creation of “Patient Safety Organizations” (PSOs)—voluntary associations of health care entities to promote error reporting and shared learning; implementation of PSOs is delayed until detailed guidelines are released in late 2008</td>
</tr>
<tr>
<td>2006</td>
<td>Publication of the Michigan ICU study in the <em>New England Journal of Medicine</em>, demonstrating remarkable reductions in catheter-related bloodstream infections through the use of a checklist and associated interventions</td>
</tr>
<tr>
<td>2007</td>
<td>Twin children of actor Dennis Quaid nearly die after a massive overdose of heparin at Cedars-Sinai Medical Center in Los Angeles, CA</td>
</tr>
<tr>
<td>2008</td>
<td>Medicare launches its “no pay for errors” initiative, the first use of the payment system to promote patient safety</td>
</tr>
<tr>
<td>2009</td>
<td>U.S. Congress appropriates $19 billion to promote implementation of electronic health records and health IT, partly to improve patient safety</td>
</tr>
</tbody>
</table>

burelement system to promote patient safety.

Where Are We Now In Patient Safety?
As we mark the tenth anniversary of *To Err Is Human*, some commentators and consumer organizations have criticized the safety field for having made insufficient progress.\(^5\)\(^,\)\(^6\) These harsh reviews have been abetted by “data” demonstrating static or increasing numbers of adverse events. However, many of the cited event rates are flawed,\(^1\) particularly those that depend on provider reports or those that were developed for purposes of screening rather than comparative measurement.

In my view, the activities chronicled in this paper represent unmistakable progress, even though hard evidence of improved outcomes remains elusive because of our rudimentary measurement capacity in safety. Unfortunately, the Harvard Medical Practice Study—\(^7\) the blockbuster from which the IOM’s now famous estimate of 44,000–98,000 deaths per year from medical errors was drawn—is unlikely to be repeated because of cost and complexity, leaving us unsure of the impact of our efforts in reducing true harm.

My own assessment is that our progress deserves an overall grade of B−, a slight improvement on my 2004 grade of C+. In a field as complex and massive as health care, a decade is a relatively short time, and incremental progress is probably the best we can hope for. In fact, if anyone had asked me in 1999 how much change in patient safety–related areas would be possible within a decade, I would have greatly underestimated our actual accomplishments. Most of our changes have constituted real progress, and even our missteps have yielded valuable lessons. Moreover, in a further sign of the field’s maturation, previously unaddressed areas (such as diagnostic errors) are being placed on the safety field’s agenda, and we are beginning to consider how to prioritize safety interventions.

The next decade will undoubtedly build on this progress and take advantage of these lessons. As for today, impatience is understandable, critical reflection is essential, and much remains to be done. Yet we should take some pride in the progress we have made in patient safety, progress that reflects enormous commitments of time and passion by caregivers, leaders, and health care organizations.

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**NOTES**


17. Bismark MM, Brennan TA, Davis PB, Studdert DM. Claiming beha-