SPECIAL ARTICLE

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Patient Safety:
Rejecting the Status Quo

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A little over five years ago, the National Academy of Science's Institute of Medicine (IOM) released its groundbreaking report on medical errors *To Err Is Human*.[1] The report, a product of more than a year's work by the Committee on the Quality of Health Care in America—on which I had the privilege to serve—was a startling indictment of the unsafe state of hospital care prevalent in the United States.

As this report was released there was an enormous media response, especially to the body count of patients that the IOM attributed to safety lapses (44,000 to 98,000 deaths in America's hospitals each year). The range of estimated fatalities meant that medical error was the fourth or eighth leading cause of death in the United States, and even more alarmingly, many of these deaths were said to be preventable.

Reaction to the IOM's *To Err Is Human*

To Err Is Human caused a firestorm of reaction, some of which was highly critical of specific conclusions or recommendations made by the committee. While few denied that there were safety problems, many took issue with either the IOM's assessment of the dimension of the problem or to its specific recommendations—especially those that proposed mandated changes in the ways that hospitals and health professionals went about providing care and how they were held accountable for the safety of patients.

There was, in general, an expression of gratitude for the IOM's leadership in bringing the problem to the forefront of national consciousness, and while many went back to business as usual, many other providers, professionals, and policy makers rolled up their sleeves to try to do something about the safety problem.

President Clinton pulled together an interagency task force to tackle safety within the federal healthcare system. Congress, heeding one of the IOM's principal recommendations, budgeted an extra $50 million to the Agency for Health Care Research and Quality (AHRQ) to be used to improve patient safety throughout the healthcare system.

That same year, a group of large employers formed the Leapfrog Group to discuss how they could work collectively to influence healthcare quality and affordability. The group promised (and threatened) to use their combined financial leverage to drive the system toward improved safety and better quality outcomes.

Hospitals began to plan for computerized physician-order entry systems (CPOE), bar coding, and the use of clinical pharmacists on rounds to reduce medication errors. Operative sites were to be marked for identification (or, was it the "non-operative" site that was to be marked?), and operating room "time-outs" were instituted to ensure that the right patient was getting the right operation for the right site. Three decades or more of plans for converting from paper to electronic medical records, digitizing films and test results, and other ways of sharing critical patient information in real time were dusted off. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) quickly developed accreditation standards that focused on patient safety, and the American Medical Association (AMA) founded the National Patient Safety Foundation. Legislatures in more than a dozen states began considering legislation aimed at attacking the patient safety crisis.

So, from early 2000, it appeared, at least to some observers, that patient safety was an issue whose time had come, and that perhaps the IOM's challenge to healthcare providers and professionals—to work toward a 50% reduction in medical errors by the end of 2004—was a real possibility.

Quagmire

But, there were some divisions that had begun to erode any unified sense of purpose and almost immediately began to slow forward motion. For example, there was a lot of push-back on the estimates of 44,000-98,000 patient deaths each year that the IOM said were linked to medical errors in hospitals. These estimates, which were based on two different studies by Harvard researchers,[2,3] were being challenged as vastly overblown. Critics agreed that there was a patient safety problem,

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but it was far less lethal than *To Err Is Human* claimed. And, they argued, "error" was a subjective, imprecise event that defied simple definition (i.e., many deaths attributed to error were more likely due to other factors outside of the control of providers and professionals). Thus, a protracted debate ensued about the lethality of medical errors in hospitals and, of course, some provider and professional associations (perhaps embarrassed by the sorry state of patient safety) seized on these critiques to argue that patients were not nearly as much in harm's way as the IOM report claimed, and that they (providers and professionals) had the situation well in hand.

I would have hoped that the numbers distraction would have evaporated more quickly, but it did not. As recently as last year the medical society of my home state, New York, characterized the IOM estimate as having been "discredited" by critics such as Troy Brennan, MD, JD, MPH, a physician, health services researcher, and lawyer from Harvard who is also, paradoxically, a co-author of both of the large studies of hospital patient errors that the IOM relied upon in its report. Brennan, however, while preaching caution, still believes the human toll of medical error is substantial:

> "Whenever you extrapolate from relatively small samples, you have concerns about the statistical precision of the estimates… although we don't know exactly how many people die from medical errors, there is no doubt it's at least 50,000 per year in hospitals and many additional outpatients."[4]

Focusing on Systems and Assuring Professional Compentency

One very key IOM recommendation disappeared from the radar screen almost instantly. It was a recommendation for establishing state-based, mandatory reporting systems for medical errors that caused serious patient harm. Even more contentious was the committee's belief that some of the information collected by states should be publicly disclosable. The IOM committee actually had the temerity to suggest that the healthcare system should be held publicly accountable for its safety performance.

In my mind this was not a radical suggestion. After all, industrial plants post the days without an employee work-related accident in plain view—why shouldn't hospitals and doctors? I debated two successive presidents of the AMA over this issue, and, arguably, their position against mandated reporting of serious harm and any public disclosure of that harm, has for the most part carried the day.

A good part of the IOM's message was that, even more important than individual behavior, there is a lack of effective systems to prevent the epidemic of medical mistakes. The very title of the report, *To Err Is Human*, was, after all, recognition that human error is almost inevitable, especially in complex, constantly evolving environments like healthcare. And so, the essential task, the IOM concluded, is to build systems that are sensitive enough to recognize the conditions that are antecedent to error and that are adept at preventing patient harm from actually occurring. This "de-individualized" approach was seen as transformational—a turning away from a tradition of blame and shame and mostly punitive approaches to error prevention that had so clearly failed in the past. Needless to say this move from a focus on individual provider or professional responsibility to a "systems approach" was *welcomed* by the "players" in hospital care—perhaps *embraced* would be a better description. For the most part, I agree that a systems approach has great merit (the recommendations of an IOM committee are the result of a consensus process), but I worry about the wisdom of a too enthusiastic rush to dismiss the importance of a professional's competency in the patient safety equation.

Ironically, it was the "it's the system approach" permeating the IOM report that may have helped doom the recommendation that there be mandatory reporting of serious error accompanied by some public disclosure. That theme was fodder for critics of an error-reporting mandate to characterize it as antithetical to a non-punitive, systems-based approach to safety improvement. This partly explains why that essential IOM recommendation dropped off the table. Another reason for the disappearance of reporting mandates from ensuing discussion was that many who wanted meaningful improvement in safety and quality to move forward rapidly worried that such efforts would fail to gain traction if there was a fractious break with providers and professionals over a requirement to report harm.

The airline industry's approach to error became the role model for the patient safety movement. Of course, the fact that pilots happen to be the first to hit the ground when serious errors are committed in the cockpit, does not detract from the industry's seriousness of purpose in its safety efforts. Nor that serious harm to pilots and crew, their passengers, and their aircraft is always announced in a very public manner. It is also well-established public policy to invest almost unlimited resources in a painstaking forensic analysis of the causes of any flight failure that is performed by an independent, highly skilled agency. And the lessons learned from the root cause analysis often are used to mandate airline safety improvements. This is not at all analogous to how attempts to understand what went wrong play out in a highly secretive, mutually protective healthcare system, a system that is comfortable with having mistakes remain ambiguous in origin and that historically lacks a culture of safety. The airline analogy also fails to consider that, unlike healthcare professionals (who are more often than not licensed in perpetuity), cockpit crew licensees are tested for competency routinely throughout their careers and in addition, are required to prove competency as they take any different responsibilities, either as to aircraft or crew position.

In healthcare, except for the hit-or-miss, often misdirected employee firing, loss or reduction of credential or privileges, monetary fine, lawsuit or action against a license, there is really no program in place that demands understanding and accountability for unsafe practices.

I did then, and still, take issue with two reasons often used to bolster the benefits of voluntarism and anonymity in reporting: that it produces more and better quality reporting. I think there is little or no evidence to support these claims and, in fact, we

seem to have some evidence quite to the contrary. For example, New York State's hospital incident reporting system, known as NYPORTS, which was cited as an example of mandated reporting by the IOM, receives many times more reports of events that meet a sentinel event definition than the total number reported to JCAHO by hospitals across the country. And, the Food and Drug Administration's (FDA) MedWatch system for collecting adverse drug reactions (ADRs) is estimated to receive only from one-to-ten percent of the number of ADRs that actually occur. Even though the FDA has no interest in or any authority to punish those professionals or organizations that report an ADR, there is still vast under-reporting.

Providers have less of a problem with the other half of the IOM reporting recommendation—one that called for a national *voluntary* system of *anonymous* reports of so-called near misses that occur in hospitals. The model for this system has usually been the NASA-run "incident" reporting system used in the airline industry. That system collects anonymous narrative reports of "incidents," which, in airline talk, are "near misses." The reports are reviewed by retired pilots and controllers to spot important lessons to be learned; and these, in turn, are published so as to improve performance.

But, to-date no such voluntary system exists. Bills purportedly addressing this omission passed in both the houses of Congress last session, but failed to reach a conference to settle differences between them. These bills miss the mark and would mainly serve only to protect hospital patient errors, even those causing serious harm, from any outside discovery. The proposals, rather than build on existing organizations such as the federally funded Quality Improvement Organizations (QIOs), would create a new type of entity, Patient Safety Organizations (PSO), to collect, protect and analyze the safety information that hospitals voluntarily submit. The bills set no data standards, no criteria for judging the success of the PSOs in improving patient safety, allow hospitals to opt out of reporting safety data, and add yet even more expense to a healthcare system steadily marching toward 1.8 trillion dollars in annual costs.

Another key IOM recommendation, one that addressed new responsibilities for licensing and credentialing agencies and organizations in assuring professional competency and knowledge of patient safety practices, went almost unnoticed. But, the concept of periodic, routine competency assessment is gaining traction, especially among medical specialty societies.

This encouraging development can inform the work of other health professions and those providers that credential or privilege professionals. It would seem logical to assume that routine assessment of professional competency could have a substantial positive impact on patient safety and healthcare quality. And by making it routine, it becomes a *systems approach*, not a punitive one.

Why am I spending so much time on the past when what's really important is to understand where we are today? An appreciation of the history of professional and provider reactions to the IOM errors report (what was accepted and what was not) helps us understand how we arrived where we are today.

The Situation Today

Three years after the IOM report was published, author and journalist Michael Millenson had this to say in the March/April 2003 issue of *Health Affairs*:

"…the silence within much of the healthcare community about the true dimensions of the crisis caused by poor quality has changed only modestly over time. Many continue to avert their eyes."[5] Millenson, author of *Demanding Medical Excellence; Doctors and Accountability in the Information Age* went on to say:

"There is a world of difference between calling for a revolution and actually leading one. (And, yes, the latter is far riskier to one's professional well-being.) That difference is why the quality improvement movement, it pains me to say, remains essentially a sideshow for most providers and most of the public."[5]

Millenson's words ring as true today as they did in 2003. There is a profoundly disappointing lack of urgency and unified sense of national purpose to support immediate, forceful steps to significantly reduce and eventually eliminate preventable patient harm.

Consider this: if medical errors kill approximately 50,000 patients each year in hospitals alone, then as many as 250,000 patients may have died since the IOM report was published—a greater toll of human lives than that of the recent tragic December 20, 2004 tsunami. One essential difference, however, is that lethal patient error is not a natural disaster for which we have had little or no warning and no way to prevent.

According to a Kaiser Family Foundation poll released in November 2004, four in ten people surveyed believe the quality of care has gotten worse in the last five years.[6] One in three report that they, or a family member, have experienced a medical error at some point in their lives, and for one in five Americans, the error had "serious health consequences" such as death (8%), long-term disability (11%), or severe pain (16%).[6] Remember the immediate, visceral provider and professional opposition to IOM's recommendation of mandatory, publicly reported error tracking systems? Perhaps not surprisingly, nine out of ten of those surveyed said that reporting of serious medical errors should be required, and two out of three wanted this information to be public.

Patient Body Counts Move Public Policy

Patient "body counts" make providers and professionals uncomfortable, but they are necessary to move public policy in the right direction and to have it stay the course. Talking about preventable death puts a face on what is otherwise a "wonkish" debate and is a necessary element in convincing policy makers and the public that improvements in patient safety are critically needed.

Remember the $50-60 million dollars that Congress was providing to AHRQ for patient safety? Without commenting on whether it was money well spent or the miserliness of allocating only $50 million for safety in a 1.5 trillion dollar healthcare economy, the fact is that the money now competes with other

needs [e.g., health information technology initiatives (IT)]. The shift of AHRQ funding from "safety" to "IT" tells me that without a body count to vividly remind us of the magnitude of havoc created by unsafe healthcare; adequate, sustained support for improvement is unlikely.

Upon discovering the lack of attention paid to the considerable human costs of preventable harm that occurs in our healthcare system, Millenson describes himself as at first stunned, then depressed, and finally outraged. That outrage is the appropriate response to the lack of progress toward saving lives evident at the five year anniversary of *To Err Is Human*.

The fall 2004 issue of *Health Affairs* published an article by Robert Wachter,[7] which was commissioned by the Commonwealth Fund for a quality improvement colloquium and marked the fifth anniversary of *To Err Is Human* in November 2004. Dr. Watcher's assessment is that the healthcare system deserves only a "C+" over-all grade for the progress it has stimulated in addressing patient safety. That's not great news, considering the costs of not getting an "A." As if a C+ grade is not bad enough, this report card's grading is highly subjective. The reality is—a reality confirmed by all those attending the November quality colloquium—that we do not have an effective safety data collection system to track medical errors (beyond internal systems in place in many hospitals) and; therefore, cannot say whether things are better, the same, or worse than five years ago. How is this state of affairs acceptable when tens of thousands of lives are at stake, and how did it happen? Remember that the IOM recommendation about tracking medical errors causing serious harm was abandoned not very long after it was made.

For the record, it has not been abandoned everywhere. Some states have subsequently legislated reporting and public disclosure. Minnesota, for example, has just published a report on hospital errors that is the result of a law passed in 2003.[8] Because we have no baseline medical error rate and no way to count errors across systems, we cannot measure the progress made overall in meeting the IOM's error reduction challenge.

In *his* answer to the question "Are we making progress?" Wachter writes: "after hearing of yet another sentinel event in their institutions, every patient safety leader I know laments how little headway we've made in the last five years." He goes on to say "… signs of progress are unmistakable." He illustrates this assessment by telling us that when he asked 400 hospitalists (i.e., physicians who spend the bulk of their practice caring for inpatients) for their views about progress in improving patient safety, 45% of them said things were better than five years ago, 38% said they were the same, and 17% said things had gotten worse.[6] Wachter admits this is only anecdotal evidence, but, inexplicably, he finds it "instructive and reassuring." My problem is two fold: (1) it is not credible evidence because we do not have a valid tracking system; and (2) even anecdotally, more than half of those asked said there has been no progress.

These anecdotal responses of the hospitalists are alarmingly *instructive* and certainly not reassuring. Consider the apparent disconnect of the majority of the hospitalists' somewhat-rosy view that things were better, or at least no worse, with the considerably more pessimistic view of the public surveyed by the Kaiser Family Foundation—that the system is no safer or less safe than five years ago.

Bob Wachter is certainly one of the best in the patient safety and quality improvement movement, but he, like most healthcare professionals, is probably troubled by the truth—that tens of thousands of patients continue to die because healthcare, and all its constituent parts and players, have not applied forceful enough pressure to stop the bleeding caused by safety lapses.

That said, it would be unfair not to point out the hard work that is being done by many around the country to make patients safer every day and the great successes in improving safety that have been achieved through dedicated hard work in individual hospitals, clinics, delivery systems, and other settings. That's the "good news." Patient safety does not have to be an intractable or inevitable problem in healthcare. Providers and professionals do care, and they are able to substantially reduce patient harm if and when they put their shoulders to it. On the other hand, the fact that the healthcare field often knows what to do, what will work (either gleaned from first-hand experience or the lessons provided by others) and still it isn't done consistently or at all (think: hand washing) adds to the frustration of those who believe patient safety has not been made the national priority it should be.

The failure of the healthcare system and policy makers to squarely address the crisis in patient safety and, thus, to allow tens of thousands of preventable deaths each year should be viewed as morally unacceptable public policy. It must be a violation of the ethical standards of every healing profession to be knowingly involved in the delivery of substandard, dangerous care. This should not imply that healthcare workers, as individuals, make conscious decisions to harm patients. Rather, the point is that considerable threat to patient well-being occurs in everyday practice, and these dangers are well known to all the players.

The timidity with which we (those who make public policy or, like myself, try to influence it) have approached providers and professionals alike, to beg, cajole, and entice a meaningful, unwavering devotion to fixing our patient safety crisis must change. Keeping patients safe can no longer be just one more request made of a healthcare provider or professional to improve care. It must become the pass/fail condition of continuing to practice and to serve patients.

A Positive Step

I would be remiss if I did not end on a more positive note. It is my opportunity to issue you a challenge to make things better—to provide a "how to do better" along with my outrage about what has not happened five years after *To Err Is Human*. So, I would like to call to your attention to a courageous and critically important initiative just begun by Dr. Donald Berwick and the Institute for Healthcare Improvement (IHI) —the campaign to save 100,000 lives.

I call it "courageous" because, for the first time, someone of great influence in the safety and quality movement is willing to mention the body count, albeit in a positive framework of

prospectively saving lives. I call the campaign critically important because, if successful, it could actually save tens of thousands of lives in a relatively short period of time, and wouldn't that be a wonderful turn of events? It's also important because, by joining, healthcare providers and professionals admit both ownership of the tragic error problem and the ownership of working toward hopeful solutions.

The campaign aims to enlist at least 1,500 hospitals across the United States to commit to six key evidence-based, safety and quality improvements that have the potential to save 100,000 lives over the next 18 months—and beyond. These key improvements are:

(1) *Rapid response teams* (RRTs). These are teams that can respond, assess, and take action quickly at the first sign of a patient's decline. RRTs were pioneered in Australia, and studies have reported they can reduce hospital mortality rates by 27%.
(2) *Prevention of central line-associated bloodstream infections*. While not rocket science, this safety intervention can be almost 100% effective. The bundle consists of five steps; hand hygiene, barrier precautions, proper skin antisepsis, proper site care, and no routine replacement. All five, the "bundle," must be delivered to be optimally effective.
(3) *Prevention of surgical site infections*. Again, there is emphasis on the use of well-understood processes of good care, which include the appropriate selection, timing, and duration of antimicrobial prophylaxis; glucose control; proper surgical site hair removal technique; and other basic prevention strategies. These strategies can cut surgical site infections in half.
(4) *Prevention of adverse drug events*. Implementation of proven safety measures (e.g., standardizing and implementing core medication processes in high-risk areas) and learning from many successful examples of what works from innovating hospitals around the country prove it is possible to reduce fatal adverse drug events and even to eliminate them.
(5) *Improved care for acute myocardial infarction (AMI) patients*. The so-called AMI "bundle" of five specific interventions: beta blockers at admission, aspirin at admission, an ACE inhibitor, reperfusion, and beta-blockers at discharge has been shown to reduce AMI mortality by 40%.
(6) *Prevention of ventilator-associated pneumonia* (VAP). The ventilator "bundle:" elevation of the patient's head by 30 degrees, peptic ulcer prophylaxis, deep venous thrombosis (DVT) prophylaxis, "sedation vacations," and strict hand-washing can eliminate cases of VAP altogether.

I think this initiative is worth your careful consideration as a very public way to show that your organization or your profession: (1) recognizes that there has been and will continue to be a significant loss of life as long as healthcare is not safe care; (2) recognizes that much has been learned about how to do things safer and better and these procedures have been tested in settings not unlike your own; (3) makes a public commitment to refocusing current work on patient safety in ways that will demonstrably and almost immediately begin to save lives; and (4) willingly agrees to having progress tracked and fed back to your organization or profession for comparative purposes (although at this point not publicly disclosed).

Berwick concluded his announcement of the 100,000 lives campaign in December 2004 with these words:

"…the patients whose lives we save can never be known, and though they are unknown, we will know that mothers and fathers are at graduations and weddings they would have missed, and that grandchildren will know grandparents they might never have known, and holidays will be taken, and work completed, and books read, and symphonies heard and gardens tended, that without our work, would have never have been….the point is, lets get started…"

I hope that Berwick's words help to inspire you to make patient safety the priority that those who come to you for care deserve. As we remarked in *To Err Is Human*: "The status quo is no longer acceptable and cannot be tolerated any longer." **NCMJ**

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