By David W. Bates and Hardeep Singh

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Two Decades Since *To Err Is Human*: An Assessment Of Progress And Emerging Priorities In Patient Safety

David W. Bates (dbates@partners.org) is chief of the Division of General Internal medicine at Brigham and Women's Hospital, in Boston, Massachusetts.

Hardeep Singh is chief of the Health Policy, Quality, and Informatics Program, Center for Innovations in Quality, Effectiveness, and Safety, Michael E. DeBakey Veterans Affairs Medical Center, and a professor of medicine at the Baylor College of Medicine, both in Houston, Texas.

ABSTRACT **The Institute of Medicine's *To Err Is Human*, published in 1999, represented a watershed moment for the US health care system. The report dramatically raised the profile of patient safety and stimulated dedicated research funding to this essential aspect of patient care. Highly effective interventions have since been developed and adopted for hospital-acquired infections and medication safety, although the impact of these interventions varies because of their inconsistent implementation and practice. Progress in addressing other hospital-acquired adverse events has been variable. In the past two decades additional areas of safety risk have been identified and targeted for intervention, such as outpatient care, diagnostic errors, and the use of health information technology. In sum, the frequency of preventable harm remains high, and new scientific and policy approaches to address both prior and emerging risk areas are imperative. With the increasing availability of electronic data, investments must now be made in developing and testing methods to routinely and continuously measure the frequency and types of patient harm and even predict risk of harm for specific patients. This progress could lead us from a Bronze Age of rudimentary tool development to a Golden Era of vast improvement in patient safety.**

The Institute of Medicine's *To Err Is Human*[1] was transformational for patient safety. It brought the problem of medical errors into the public eye and highlighted why every health care organization in the US must consider safety as a priority. Before the report's release, many—including leaders in major health care organizations—simply did not.

The report made several major points: Errors are common, they are costly, systems-related problems cause errors, errors can be prevented, and safety can be improved.[1] Important changes resulted, including a significant increase in patient safety research sponsored mainly by the Agency for Healthcare Research and Quality (AHRQ) and hospital programs focused on measurement, accreditation, and regulation.[2] The number of studies to address safety gaps increased by more than 250 percent over several years,[3] and many occurred in areas that had not received previous attention.

What We Have Learned

In the years since the report's publication, it has become increasingly clear that safety issues are pervasive throughout health care and that patients are frequently injured as a result of the care they receive. The exact number of deaths that occur in the US is highly controversial and has been debated at some length.[4–7] This is

partly because methodologically questionable approaches have been used to estimate deaths, and in any given instance, it's often hard to determine whether an individual death could have been prevented. However, many experts believe that the number is probably in the hundreds of thousands annually, while many more patients are injured unnecessarily.

Early efforts to reduce hospital errors largely focused on hospital safety. Before the report, adverse events such as hospital-acquired infections were considered a cost of doing business. Central line–associated bloodstream infections (a type of hospital-acquired infection) represent a notable example. Peter Pronovost and his team from Johns Hopkins University showed that by following a bundle of safety procedures, they could reduce the incidence of these infections to nearly zero.[8] The bundle included steps to follow in central venous catheter insertion, the handling and maintenance of lines, and the prompt removal of unnecessary lines. Many felt that these initial results might be too good to be true, but Pronovost and colleagues were later able to replicate the results across the state of Michigan.[9] This resulted in a change in how people thought about harm, because even in situations in which no obvious error had been made, it was possible to dramatically reduce the risk of harm. Some of the principles behind such interventions were adopted from high-reliability industries[10] such as aviation, which use a more systematic approach to safety than health care does.

Subsequent safety targets included ventilator-associated pneumonia and catheter-associated urinary tract infection. Nearly all hospitals have implemented surveillance for the main types of hospital-acquired infections, including these two conditions, central line–associated bloodstream infections, and surgical site infections. Improved hand washing has also been an important part of this effort.[11] In fact, the number of hospital-acquired conditions fell from 145 per 1,000 admissions in 2010 to 115 per 1,000 admissions in 2015, as assessed by the AHRQ national scorecard.[12] The rate of central line–associated bloodstream infections appears to have fallen by about 80 percent since the publication of *To Err Is Human*.[13]

While effective prevention strategies are now available, infection rates remain too high. For example, 75 percent of US hospitals had a standardized infection ratio above the Leapfrog Group's standard in one recent evaluation.[14] Much of the remaining variation in hospital infection rates is believed to result from inconsistency in the use of prevention techniques. Approaches such as peer-to-peer assessment appear to hold potential for reducing the rates.[15]

Medication errors have also been found to be one of the most common causes of harm.[16] However, effective interventions have been developed. Specifically, computerizing the ordering of medications and delivering computerized clinical decision support to the ordering provider has been found to reduce rates of adverse drug events.[17–19] Decision support includes checking orders for allergies and flagging drugs with risky interactions or out-of-range dosages and then making corrective suggestions to providers in real time. Another intervention, the bar coding of patients and medications, has reduced error rates both at the point of care[20] and in the pharmacy.[21] In 2009 the federal government implemented incentives to adopt computerized order entry with decision support as part of electronic health record (EHR) meaningful-use attestation, which increased the adoption of these technologies across the US. However, recent data suggest that clinical decision support in EHRs is not delivering the benefits seen in earlier studies, and that it might not be having any impact at all as currently implemented—which makes this a critical priority to address.[22] Work-arounds remain a pervasive issue with technologies such as bar coding: People employ work-arounds to save time in part because they might not appreciate the safety benefits. More generally, variability in the implementation and use of technology affects its impact. Much of this relates to disregard of the "sociotechnical" factors involved—nontechnical factors such as work flow, training, and organizational issues.[23]

Surgical injuries have also been a major cause of harm. To address this, Atul Gawande and his team at Brigham and Women's Hospital developed a surgical checklist for the operating room, which resulted in a 36 percent decrease in the rate of adverse events and a 47 percent decrease in the mortality rate in a multinational study.[24] Yet postimplementation success rates have been variable in this area, too. It is likely that several contextual factors[25] influence the success of an intervention, and while effective tools have been developed, their impact on safety in the real world is often determined by how those factors are addressed. For instance, leadership support and local safety culture are important determinants of whether there is adequate uptake and effect of an intervention that looks good on its face. Moreover, errors related to human cognition or behavior in or out of the operating room might not be targeted by the checklist, which suggests the need for more work to understand and address surgical safety.

Additional types of hospital errors that need addressing include errors during handoffs be-

tween units, failure to rescue, misidentification of patients, pressure ulcers, and falls. Safety gaps from discontinuous care have been addressed by a standardized intervention bundle called I-PASS (for illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver),[26] which is now being implemented in hundreds of hospitals across the US and internationally. Failure to rescue, defined as the death of a patient after one or more potentially treatable complications, is being used as a surgical quality indicator to account for potentially preventable postoperative complications.

At the organizational level, safety improvement is closely related to good management and the effective implementation of a safety culture.[27] A consistent and salient safety culture is a critical determinant of the success of safety interventions, and many organizations now measure their safety culture over time using a validated instrument available from AHRQ, the Hospital Survey on Patient Safety Culture. Organizations are unable to take on newly identified safety issues when they are still struggling to manage old ones whose solutions have not been sustainable because of culture issues. Hand washing is an example of an unsustainable intervention at many hospitals. Many leading organizations have also embraced the concept of a high-reliability safety culture, which has been defined as "professional leadership attitudes in a High Reliability Organization that manage potentially hazardous activities to maintain risk to people and the environment as low as reasonably achievable, thereby assuring stakeholder trust."[28] These institutions are trying to move from addressing each individual adverse event and type of adverse event to addressing safety systematically within an integrated management system for safety.[29]

An important part of safety promotion involves the scaling of successful interventions. Several organizations have been involved in scaling, including the Institute for Healthcare Improvement and the National Patient Safety Foundation (NPSF). The institute's 100,000 Lives campaign made notable strides, engaging hundreds of hospitals in adopting safety solutions. The NPSF formed the Lucian Leape Institute, a think tank that identifies novel approaches to improve safety and identifies risk areas that need system-level attention, as well as supporting both education related to safety in training and work on disclosure and apology.

Major national policy and practice initiatives have also built momentum to address safety in US hospitals. The Patient Safety and Quality Improvement Act of 2005 authorized the creation of Patient Safety Organizations (PSOs). These organizations bring groups together to improve wider learning by sharing data from voluntary reporting under privacy and confidentiality protection.[30] Often they coalesce around a specific domain such as health information technology (IT) safety. Organizations (often hospitals or integrated delivery systems) submit information about errors and adverse events to their PSO. While submitting organizations participate variably, with some reporting a great deal and others largely observing, the PSOs can play a valuable role in providing information on safety patterns and trends back to the reporting organizations.[31] A national initiative of the Centers for Medicare and Medicaid Services (CMS), the Partnership for Patients, is also investing resources to reduce preventable harm through the Hospital Improvement Innovation Networks.

The health care system has begun to draw on scientific approaches to safety from areas outside of traditional medicine.

In 2008 CMS stopped reimbursing hospitals under Medicare for certain hospital-acquired conditions, including pressure ulcers, in-hospital falls, and infections.[32] While this certainly stimulated hospitals to work on these problems, both the measurement of hospital-acquired conditions and the safety impact of this policy remain controversial.[33,34] Measurement of these conditions has varied substantially across hospitals, and some of the metrics appear unreliable. Perhaps more important, large hospitals that care for sicker populations and hospitals that care for poorer populations have higher rates of hospital-acquired conditions, and they believe this relates to the fact that their patients are at higher risk and of lower socioeconomic status than patients at community hospitals.

The health care system has begun to draw on scientific approaches to safety from areas outside of traditional medicine, including human factors engineering, psychology, the social sciences, patient-centered approaches, culture and teamwork, and design of the physical environment. These disciplines have improved the

health care system's understanding of safety and served as the basis for developing novel strategies within health care to address safety problems. For example, evidence-based design in relation to the built environment[35,36] plays a major role in infection prevention and improvement of other safety issues. Regarding infection, examples include designing rooms to eliminate cloth curtains (which hold bacteria) and eliminating corners in rooms (which are difficult to sterilize). More work is needed to translate systems and human factors engineering principles to design safer systems in health care environments.

Emerging Priorities In Patient Safety

Many new issues have emerged within the purview of patient safety that require systematic safety-based solutions. In this section we highlight the problems of diagnostic error, outpatient safety, and safety related to health IT because we believe they are especially pressing.

DIAGNOSTIC ERROR Although exact inpatient numbers are unknown, about 5 percent of US adults in the outpatient setting experience a diagnostic error every year, and about half of these are potentially harmful.[37] Standards for accuracy and timeliness of diagnosis are ill-defined for most conditions, and providers must constantly balance diagnostic accuracy against the judicious or appropriate use of tests or procedures. Errors involve common diseases or conditions, not just infrequent or rare ones, and often result from breakdowns in data gathering and interpretation of patient history and exam or in follow-up of abnormal diagnostic tests.[38] A 2015 report by the National Academies of Sciences, Engineering, and Medicine titled *Improving Diagnosis in Health Care* thrust diagnostic error into the mainstream conversation on patient safety.[39]

The past decade revealed more advanced understanding of diagnostic error—its frequency, harm, and contributory factors.[40,41] No single physician's knowledge and decision making are sufficient to ensure an accurate diagnosis, especially when a diagnosis evolves across time and place and involves interactions among numerous team players. Research has highlighted the need to account for the complex interaction of multiple contributory factors, both system (such as breakdowns in communication, coordination, or teamwork or the lack of robust policies and procedures) and individual (such as failures in data gathering or interpretation, overconfidence in diagnostic judgment, and lack of knowledge).[42,43] This underscores the rationale for a more systems-based approach to addressing the diagnostic process instead of simply focusing on whether the diagnosis was right or wrong.

The National Academies and other organizations have made recommendations for addressing diagnostic error that are consistent with other areas of safety and health care improvement: improving teamwork and patient engagement; providing adequate time and reimbursement for cognitive work; reforming malpractice standards; using technologies to support patient care, such as clinical decision support—which sometimes involves artificial intelligence; and providing research funding to accelerate the science of diagnostic errors and develop preventive strategies.[44,45] While AHRQ in particular is sponsoring research on how to better measure the problem,[46] several high-risk areas are ripe for policy and practice initiatives to reduce diagnostic error, and health systems could lead these efforts. These include clarifying responsibilities for follow-up of abnormal clinical findings among different care team members, identifying at-risk patients for reliable tracking or "closed-loop" follow-up—for example, ensuring that a patient who has received an important specialist referral gets to see the specialist, improving doctor-patient communication and relationships, and monitoring follow-up of high-risk abnormal test results (such as those suspicious for cancer).[47–49]

OUTPATIENT SAFETY The high volume of outpatient care and the need for collaboration and communication across the continuum of care increase the potential for errors in outpatient settings. Furthermore, problems and strategies identified in the inpatient setting might not be applicable or relevant to outpatient care.[50] Outpatient clinicians have fewer resources and less infrastructure for patient safety activities than inpatient clinicians do. In addition, regulatory and accreditation agencies have not prioritized outpatient safety to the same extent as they have inpatient safety. The result is that knowledge in this area is nascent, and there are only a few generalizable interventions.

Recent reports from AHRQ, the American College of Physicians, the Organization for Economic Cooperation and Development, and the World Health Organization highlight potential next steps,[51–54] including the systematic measurement of safety and harm to inform action; learning from patient reporting of adverse events; more incentives for team-based care and patient engagement; research into both quantifying problems and intervention development; and strategies to address underlying contributory factors such as physician stress, burnout, and culture.

HEALTH INFORMATION TECHNOLOGY AND SAFETY Health IT can help prevent many types of patient safety errors. These include medication and diagnostic errors,[55] patient identification errors,[56] poor data accessibility for both pa-

tients and providers, and ensuring that issues like abnormal laboratory tests and important referrals are followed up appropriately.

But it has also become clear that health IT invariably introduces new problems. Emerging priorities for patient safety related to this technology include ensuring the safety of the technology itself; the safe use of the technology by clinicians, staff members, and patients; and the effective use of it to improve patient safety.[57] The latter entails using the technology to identify and monitor risks and safety events and intervening before harm occurs.

Examples of safety issues that have emerged include software bugs and system crashes;[58] copying and pasting inaccurate information;[59] signing autopopulated information supplied by the computer that shows abnormal clinical findings; and overlooking important abnormal lab or medication interaction alerts, often amid handling other alerts that are inconsequential.[60] Problems with EHR usability—including burdensome documentation methods, awkward workflow arrangements, and lack of interoperability with other patient record systems—cause provider frustration and burnout, with potential implications for safety.[61]

Policy Implications

While improvements have been made, unacceptably high frequency of patient harm remains. Additional safety priorities continue to emerge as new care approaches are implemented. Moreover, even well-thought-out interventions inevitably create new challenges and unforeseen safety issues.

A major priority must be to stimulate and support multidisciplinary scientific progress in both understanding the complexity of safety and developing and evaluating interventions. AHRQ has long been the federal leader in supporting multidisciplinary research in this area and needs to continue support for research on emerging safety threats and ongoing harm, because harm rates continue to be too high. Safety research should also be supported by the National Institutes of Health, whose institutes could expand their portfolios to include safety in the areas they address.

In addition, health systems must start to measure harm in a consistent and reliable way, using standard definitions, and they should publicly report harm rates. For this to happen, researchers must overcome methodological challenges, and robust metrics must be developed. Metrics are needed that can be reliably extracted from EHRs with limited burden on institutions, and measures must be judiciously tested for validity. When measures are inaccurate, as was the case with many of the Patient Safety Indicators,[62] public reporting of harm rates can provide the wrong picture of which organizations are delivering safe care, which can lead patients to make the wrong choices and adversely affect the organizations.

Penalties for certain patient safety events should be carefully considered. Policies that prevent payment when harm occurs make sense on their face but can have perverse consequences, as organizations may simply under-code harms to avoid payment disincentives.[63] The hospital-acquired condition program has been quite controversial, with large academic hospitals arguing that they have been unfairly penalized.[64] Moreover, payment-based penalties can drive too much institutional attention to measures tied to payment, shifting attention and resources away from other safety issues.

Patient safety policies should ideally support a "learning health system" approach to safety, in which measurement on the front lines of care creates evidence for improvement. The evidence should be used in an ongoing way to develop interventions that are incorporated into practice. Health systems should conduct more embedded research,[65] creating learning labs to understand safety problems, advancing the science, and pilot-testing improvement strategies. Policy makers must promote knowledge sharing, such as through the creation of a national clearinghouse or coordinating center to promote rapid knowledge exchange among health systems. After pilot-testing, accelerated implementation of best practices could be spread to other settings through large multi-institutional quality improvement collaboratives.[66] The Veterans Affairs (VA) National Center for Patient Safety offers an example of a learning health system. The center not only promotes organization-wide learning in the VA but also funds patient safety centers of excellence nationally that focus on research and implementation, bringing to the bedside practical tools to improve safety.[67]

Health systems must start to expand their patient safety capacity and infrastructure to meet the demands of emerging safety issues, address recommendations from policy makers and other national stakeholders, and implement newly developed best practices. In a number of high-risk areas, scientific progress and evidence-based tools and strategies to improve safety still have not been translated into practice.[68] Recently, AHRQ and the Institute for Healthcare Improvement launched a new National Steering Committee for Patient Safety to create a national action plan for preventing harm, which could address institutional capacity, priority setting, and

thorny implementation issues that thwart progress in safety.

With the move to a health care system enabled by health IT, legislative or regulatory policies should be enacted to enable and encourage health systems to better use their EHR data for improving safety. Not only should EHR content such as clinical decision support and user-interface presentation be improved for safety purposes, but health systems should also extract key clinical and administrative data into enterprise data warehouses. This would facilitate complex, cross-patient queries to help identify areas for improvement and monitoring. Data scientists can help create condition-, location-, and procedure-specific dashboards to help clinicians and health systems monitor their performance in real time and predict which patients are most vulnerable to adverse events. Then increased monitoring could be done by front-line providers to prevent harm to patients who are at high risk.

Policy levers should also create mechanisms for shared responsibility for safety between health systems, care providers, industry, and relevant public and private agencies. One such mechanism would be a national safety center that leverages public-private partnership. The creation of a national center that would focus on health IT–related safety and enable key knowledge sharing has already been proposed.[69] Such a center could help modify barriers to knowledge sharing contained in EHR software license agreements, nondisclosure provisions, and intellectual property protections. Loosening these provisions would enable better sharing of data related to patient safety.[70]

Conclusion

The period since *To Err Is Human* was published[1] could be considered a Bronze Age in patient safety, when new tools—which may now be considered primitive—were developed and led to advances. Much has been learned about the epidemiology of safety, and while several effective solutions have been developed for some safety issues, their implementation and practice has been inconsistent. Despite progress in hospital-acquired infections and medication safety, there remain substantial opportunities for improvement—far more than any individual organization can afford to test or adopt. Progress in the prevention of patient harms such as pressure ulcers, deep venous thrombosis and embolism, and falls has been variable, even though some effective solutions are available. Even "never events" such as wrong-patient and wrong-site surgery still occur with disturbing frequency. Emerging priority areas include addressing harm related to outpatient care, diagnostic error, and health IT, as well as using newly available electronic data to improve safety

The next challenge in patient safety is the development and implementation of tools and strategies that enable organizations to measure and reduce harm both inside and outside the hospital, continuously and routinely. And as their effectiveness is demonstrated, policies that encourage and—when appropriate—require organizations to use these tools and strategies across multiple health care settings could lead us to the Golden Era of patient safety. ■

David Bates consults for EarlySense, which makes patient safety monitoring systems. He receives cash compensation from CDI (Negev), Ltd., a not-for-profit incubator for health information technology start-ups. He receives equity from ValeraHealth, which makes software to help patients with chronic diseases. He receives equity from Intensix, which makes software to support clinical decision making in intensive care. He receives equity from MDClone, which takes clinical data and produces deidentified versions of it. His financial interests have been reviewed by Brigham and Women's Hospital and Partners HealthCare in accordance with their institutional policies. Hardeep Singh's research has been funded by the Veterans Affairs (VA) Health Services Research and Development Service (HSR&D) (CRE-12-033 and the Presidential Early Career Award for Scientists and Engineers USA 14-274), the Agency for Healthcare Research and Quality (R01HS022087 and R18HS017820), the VA National Center for Patient Safety, the Houston VA HSR&D Center for Innovations in Quality, Effectiveness, and Safety (CIN 13-413), and the Gordon and Betty Moore Foundation. Authors' views do not represent those of any of the funders. An earlier version of the manuscript was presented at a working paper review session in Washington, D.C., April 10, 2018, organized by *Health Affairs* and supported by the Gordon and Betty Moore Foundation.

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