In *To Err is Human: Building a Safer Health System*, released in 1999, the Institute of Medicine (IOM) estimated that medical errors cause approximately 98,000 deaths in the United States each year; since then, we have learned that the number of patients who die needlessly is far larger. Preventable deaths are the third leading cause of death in the United States.
Patient safety is a monumental, but largely unrecognized, public health issue.

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The personal costs of these preventable events is immeasurable—a toll experienced as loss of life, disability, pain and suffering, lost or diminished productivity, psychosocial distress, and impact on loved ones. Additionally, medical errors incur financial costs estimated to be as high as $29 billion per year. Despite pockets of success and notable efforts, the United States has failed to significantly reduce preventable patient harms since the IOM’s highly publicized report was issued, over a decade ago.

THE TODDLER WHO LAUNCHED A MOVEMENT

The story of the Armstrong Institute for Patient Safety and Quality begins with the brief but important life of Josie King. In January 2001, 18-month-old Josie was admitted to Johns Hopkins Hospital after suffering first and second degree burns from a hot bath. She healed well and within weeks was scheduled for discharge. Two days before her expected return home, she died of severe dehydration and missed narcotics.

WHAT WENT WRONG?

After ten days in the pediatric intensive care unit, Josie’s central line became infected. Septic shock followed. Her mother, Sorrel King, began to notice signals that Josie was in distress—inseparable thirst, rolling eyes; nursing staff dismissed her concerns as unwarranted. In a night-marsh spiral of events, fueled by gaps in communication and culminating in a drug delivered at the wrong time, Josie’s life slipped away. This tragedy occurred under intensive care in one of the best hospitals in the world.

Josie’s story is not unique. What sets Josie apart from tens of thousands of other patients harmed by medical errors each year is not the chain of events ending in disaster, but the fact that her death set in motion an equally powerful chain of events resulting in substantial positive change, reduced suffering, and lives saved.

In 2001, Peter Pronovost, M.D., Ph.D., an anesthesiologist and critical care physician at Johns Hopkins, had recently completed doctoral work in medical education. He had long been concerned with the task of making hospitals safer for patients. The initiative started small, the efforts of one physician-researcher in close communication with Sorrel King. Support of Johns Hopkins leadership and a generous philanthropic gift led to the establishment of the Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine. The Institute’s goal is to eliminate preventable harm to patients and to achieve the best patient outcomes at the lowest cost possible, and to share knowledge of how to achieve this goal with the world. A research scientist himself, Dr. Pronovost understood that his ability to change practices among healthcare professionals, and within medical institutions, would depend on the credibility of his methods. His first patient safety initiative was pragmatic, its methods were scientific, and its target was compelling—Josie’s cause of death, central line-associated bloodstream infection (CLABSI).

“PROOF OF CONCEPT” THAT WE CAN IMPROVE PATIENT SAFETY AND SAVE LIVES

The Centers for Disease Control estimates that bloodstream infections contracted in the hospital claim the lives of 31,000 people each year, approximately the same number who die from prostate cancer or breast cancer. To avert deaths due these CLABSI, Dr. Pronovost envisioned a simple, pragmatic, replicable approach, one that prevented infection by ensuring that essential safety tasks take place before catheterization. The concept was that, by identifying and standardizing the most important safety measures, such that healthcare providers perform them routinely, errors could be

RISING TO THE CHALLENGE

A CALL TO ACTION

Rising to the Challenge: The Campaign for Johns Hopkins will raise unprecedented levels of support to attract, sustain, and further empower the people of Johns Hopkins—our students, faculty, and researchers—who through their work improve the lives of millions around the world. Together with our philanthropic partners we will:

ADVANCE DISCOVERY AND CREATIVITY through support of our exceptional faculty and researchers. Their innovative work drives the development of new knowledge, new forms of expression, and new ways to save lives and improve health, and furthers progress across our core disciplines in science and technology, the humanities and arts, and public health and medicine.

ENRICH THE STUDENT EXPERIENCE by investing in scholarships and fellowships, inspirational spaces for collaborative learning and social opportunities, and new programs that will enhance student-faculty interactions, ensure diversity on campus, link learning in the classroom to life after graduation, and strengthen connections between our students and our surrounding communities.

SOLVE GLOBAL PROBLEMS AS ONE UNIVERSITY by creating new cross-disciplinary solutions in crucial areas such as sustaining global water resources, revitalizing America’s cities, advancing individualized and population health, and understanding how we learn and teach.

The Armstrong Institute for Patient Safety and Quality is committed to playing a key role in the success of the campaign. Please join with us in this important mission.
eliminated and the number of CLABSIIs dramatically reduced. And so, “the checklist” was born. It is a brief but evidence-based and effective protocol: wash your hands; clean your skin with chlorhexidine; avoid placing catheters in the groin whenever possible; cover the patient and yourself while inserting the catheter; keep a sterile field; and ask yourself, every day and for every patient, if the benefits of catheterization exceed the risks.

Dr. Pronovost and his team got to work, with Johns Hopkins Hospital as their learning laboratory. Infection rates at the start were high and many staff thought they could not be improved, but implementation of the checklist led to virtual elimination of these infections.

To Dr. Pronovost, positive results at Johns Hopkins were just the beginning. He immediately moved forward to ask: Can the checklist reduce CLABSI and save lives on a larger scale, including at other institutions, perhaps in a whole state? Working with 103 intensive care units in Michigan, in partnership with the Michigan Health and Hospital Association, the Armstrong Institute turned the CLABSI intervention into a team-based patient safety program that was tested in intensive care units across multiple hospitals. The program has three components: (1) the checklist for preventing CLABSI, (2) a strategy for translating this Evidence into Practice (TRiP), and (3) a strategy for changing the organization’s culture, the Comprehensive Unit-based Safety Program (CUSNP).

Results were dramatic: Within three months, hospital-acquired infections at typical intensive care units in the state dropped from 2.7 per 1,000 patients to zero. More than 1,500 lives were saved in the first 18 months. The results have been sustained for three years. The intervention not only prevented infections, it was associated with reduced mortality throughout Michigan, and with lower mortality rates among Michigan intensive care patients compared to similar patients in 11 surrounding states. Costs of care have also been reduced.

The program has now been implemented in more than 1,000 intensive care units in 47 states, with similar results. It is the only nationally successful quality improvement program. In the country as a whole, between 2001 and 2009, bloodstream infections were reduced by 60% while other types of harm continue unabated.

FROM EFFECTIVE TO TRANSFORMATIVE

With the CLABSI initiative, the Armstrong Institute solved one major problem in patient safety. Equally important was the proof that an effective patient safety innovation can be scaled from a single institution to groups of institutions, a state, and even a whole country. The CLABSI project worked because it was led by clinicians, informed by science, and guided by valid measures. It also changed culture, reframing CLABSI in the minds of clinicians and administrators from an inevitable problem to a preventable one.

There are, however, many hundreds and perhaps thousands of possible types of medical errors. Even when combined into broad categories—such as harm from blood tests, diagnostic errors, poor team-work, and decubitus ulcers (bedsores)—the scope is daunting. Clearly a piecemeal approach that addresses medical errors one by one will leave many critical areas untouched and many patients at risk. The science for how to prevent and measure these errors is immature.

Potential for error exists at every step in medical practice. As medical care becomes more complex—for example, by using genomic profiles to personalize care to the individual patient—the number of steps at which error can enter increases exponentially. In order to get at the root of all medical errors, we need an approach that identifies the causes, in the healthcare system, of medical error and that develops system-level methods for eradicating those causes.

Medical error is endemic to the current healthcare environment. To benefit a maximum number of patients through strategies that ensure their safety while reducing costs, we need more than effective interventions; we need to transform the healthcare system.

RETOOLING THE HEALTHCARE SYSTEM FOR PATIENT SAFETY

To inform both large-scale implementation of targeted patient safety interventions and healthcare system transformation, Dr. Pronovost and his colleagues in the Armstrong Institute distilled seminal lessons from the CLABSI initiative. They found that change only takes root, and improvements in patient care only result, when work is informed by science, guided by valid measures, modified to fit the local context, team-based, and led by clinicians. Past approaches to improving patient safety have focused on “silos” of cause and effect, such as the role of nurses or communication between patients and physicians; their impact has been limited. A successful strategy must engage all individuals involved in healthcare as partners; these individuals must be brought together around a shared goal—eliminating medical errors.

Change in medical practice requires change in the context of patient care, that is, in the internal culture of...
A learning healthcare system is, inherently, one with the capacity to prioritize patient safety. It is designed to continuously innovate, evaluate processes and outcomes, and, based on results, refine what it does.

It works simultaneously to optimize clinical outcomes, "patient-reported outcomes" such as symptoms, psychosocial well-being, and quality of life, and cost-efficiency.

Systems in healthcare are comprised, largely, of people. The people who deliver medical care will be those most likely to know where potential risks lie, and best able to devise solutions. Quality improvement programs that are developed with clinicians, rather than dictated to them, are thus more likely to be wise, effective, and implemented in actual practice.

Quality improvement programs that are developed with clinicians, rather than dictated to them, are thus more likely to be wise, effective, and implemented in actual practice. To engage people in changing practice, and ultimately in transforming the healthcare system, the Armstrong Institute has developed a program for cultivating and supporting clinical communities. The program entails a series of educational conference calls or webinars for clinicians followed by a series of educational conference calls or webinars for clinicians followed by a one day, face-to-face meeting in which the group discusses ways to reduce harm, potential barriers, successes and success factors, and data related to training, measurement, and outcomes. Subsequent conference calls match each hospital’s team with a coach from the technical core. The Institute has partnered with state associations and the American College of Surgeons to invite hospitals to participate in clinical communities, which can be scaled to include hospitals, health systems, or even states.

In current parlance, “big data” refers not only to massive datasets such as those accruing in healthcare, but also tools for data collection, management, storage, access, mining, sharing, analyzing, interpreting, and visualizing. These features are critical in an information-rich environment. A learning healthcare system will need strategies for collecting all information relevant to patient safety, analyzing the data in a timely way, and helping clinicians make sense of the results—so that the wealth of data actually helps clinicians provide high-quality care, rather than further complicating their jobs. To this end, Armstrong Institute faculty are working with colleagues at Johns Hopkins in the Whiting School of Engineering, Applied Physics Laboratory, and Bloomberg School of Public Health to develop big data methods that happen “behind the scenes” of clinical practice.

To support rather than stress clinicians, a learning healthcare system must provide guidelines and algorithms appropriate to the patient at hand, and must invisibly perform crosschecks and other safety-ensuring measures in the background, alerting appropriate people immediately when problems arise. With vast quantities of potentially relevant data and evidence, and numerous decision points and steps in any patient’s care, contemporary medical care is exceedingly complex. Other industries, such as telecommunications, banking, and transportation, have recognized the complexity of the systems in which they

organizations such as clinics, hospitals, healthcare institutions, and provider or institutional networks. Medical culture must learn to incorporate teamwork and problem-solving. At its core must be a belief that harm is the result not of individual failure but of a social, contextual, systemic problem that can be fixed.

1. CREATE A LEARNING SYSTEM FOR PATIENT SAFETY

Drawing upon the concept of a “learning healthcare system,” a model developed by the IOM and advanced by agencies such as the Personalized Medicine Coalition and National Cancer Policy Forum, the Armstrong Institute is working to revision the healthcare environment in a way that builds patient safety into the system. In a learning healthcare system, (1) processes of care are standardized, based on the latest research evidence; (2) each patient’s care is routinely documented in an electronic health record; (3) patients’ data are secure, standardized, and interoperable; (4) clinicians have ready access to real-time data and other information relevant to each patient’s care; (5) outcomes of care are regularly assessed to evaluate effectiveness and to identify opportunities for improvement; and (6) the system “learns” by refining its activities and functions based on results.

A learning healthcare system is, inherently, one with the capacity to prioritize patient safety. It is designed to continuously innovate, evaluate processes and outcomes, and, based on results, refine what it does.
worked, and the possibility for different components not to cooperate with one another, in their fields, as in healthcare, technology was outstripping human ability to master it. These industries tackle the problem with systems engineering, an approach to complexity that manages logistics, coordination, and automation to ensure that many tasks are done well, consistently, and efficiently. The same needs to occur in healthcare. Through applying systems engineering to healthcare, the medical field can ensure that the right care is provided to the right patient at the right time. Armstrong Institute faculty is working with experts in human factors engineering, systems integration, and public health to apply systems engineering to patient safety.

2. TEST THE PATIENT SAFETY SYSTEM IN A LEARNING LABORATORY

While striving to eliminate all medical errors through system-wide transformation, the Armstrong Institute is simultaneously addressing targeted needs. For this, Johns Hopkins Medicine is essentially the Armstrong Institute’s “learning laboratory.” Here the Institute will develop, test, and refine high-impact patient safety interventions before bringing them into the larger arenas of other health systems, states, the country, and the world. Having already worked with several thousand hospitals, and having partners who span a wide array of fields—basic and clinical sciences, medicine and nursing, human factors engineering, psychology, anthropology, public health, organizational sociology, epidemiology, biostatistics, informatics, health services research—the Institute has developed a distribution channel and methods for large-scale implementation.

Four types of medical error are targeted in the near future. One is venous thromboembolism (VTE), a condition in which a blood clot lodges in a vein; when a VTE breaks away and travels to the heart or lung, the obstruction can be deadly. VTE is common, lethal, recurs frequently, is often overlooked, and results in long-term complications. Pulmonary embolism, a type of VTE, is the most common preventable cause of hospital-related death, resulting in 100,000 deaths annually. Also targeted are surgical site infections (first in colon cancer, then in other cancers), pulmonary complications, and readmissions. For each of these challenges, the Armstrong Institute plans to adapt the approach used to reduce CLABSI, then scale and disseminate the safety intervention to maximize the number of patients who benefit.

An especially difficult challenge is diagnostic errors, for which new methods of identification, data collection, and rectification will be needed. How do we know when a patient has been misdiagnosed? Does this information even get collected? Can we identify patients at risk, or risk-ridden clinical scenarios? What are the process steps that need to be taken to arrive at an accurate diagnosis?

An effective intervention in any one of these targeted areas will save many thousands of lives per year. Across institutions, states, the United States, and other countries, the cumulative
The Armstrong Institute for Patient Safety and Quality

HOW YOU CAN HELP
The Armstrong Institute has achieved large-scale impact because of a compelling and sweeping vision, one driven rapidly forward by a willingness to “think big.” This sort of creative, visionary thinking is the essence of great leadership. However, it is not supported by traditional research grants, nor can it be funded through clinical revenues or other institutional resources. Indeed, the federal government spends two pennies on patient safety research for every dollar it spends finding new genes and new drugs.

Philanthropy is our hope. A gift of any size is likely to reap returns that exponentially exceed the investment—returns seen in lives saved, function preserved, suffering averted, and quality of life upheld. A contribution to the Armstrong Institute for Patient Safety and Quality will, in a direct way, give to many individuals their health, and even their life.

RISING TO THE CHALLENGE

The Institute uses rigorous scientific methods in demonstration and evaluation of its strategies.

impact of these interventions—not only in deaths and suffering prevented, but also in reduced costs—is immense.

3. BUILD CAPACITY FOR TRANSFORMATION
The Armstrong Institute operates a well-developed web platform that serves to educate and support healthcare providers. Clinicians at participating hospitals have access to (1) elearning modules, (2) social networking, through which they share successful practices and protocols, and (3) methods of measurement, with feedback provided. They learn to use checklists of evidence-based practices, to self-evaluate and iteratively improve their practices, and to change their internal culture. This platform serves clinicians in learning and also helps them respond to the ever increasing regulatory requirements to document their involvement in patient safety efforts.

Already, through the web platform, clinical communities program, and coaching, the Armstrong Institute can train multiple hospitals at once. This approach facilitates transformation at the local level. It cannot, however, accommodate the huge number of clinicians and institutions around the country needing to be retrained in order to transform the healthcare system, to make the entire system safer for patients.

Transformation requires system-level capacity building, the purpose of which is to weave learning about patient safety into the fabric of the healthcare system. The Armstrong Institute is actively working to design capacity-building mechanisms. One strategy is a new degree program—a combined nursing degree (RN) and masters in systems engineering, focused on healthcare—which the Armstrong Institute is developing in collaboration with the Johns Hopkins Whiting School of Engineering.

Capacity building can occur at three levels. At Level 1, all healthcare staff acquire a critical basic foundation of patient safety knowledge. Level 2 imparts the content required for unit-level safety leaders, and includes a certificate in patient safety (approximately 40 hours of training). At Level 3, a leadership level, capacity will be built through formal degree programs such as the one under development with the Whiting School of Engineering, or a future joint program with the Bloomberg School of Public Health.

WHY THE ARMSTRONG INSTITUTE FOR PATIENT SAFETY AND QUALITY?
In combating medical error, no other organization in the United States, and likely no other in the world, is as likely to succeed as the Armstrong Institute. The Institute achieved phenomenal success in reducing a major type of medical error, standardized the approach, implemented it in progressively larger areas up to a national scope, and documented its impact. It has turned this stellar success into a templated program that can now be applied to other types of medical error.

The Institute uses rigorous scientific methods in demonstration and evaluation of its strategies. This grounding in research not only garners “buy-in” from highly trained academic physicians, research scientists, policy makers, and other persons of influence, but also assures that robust evidence of effectiveness underlies its patient safety interventions.

The Armstrong Institute takes a holistic approach, addressing the total environment of care rather than siloes within it. Broad participation in patient safety innovation is intentionally encouraged through providing a role for all stakeholders, promoting teamwork, and guiding culture change.

The Institute has developed an implementation model that builds success factors (effective interventions, proven implementation processes, evaluation methods, culture change) into local environments so as to support and sustain change. Implementation includes helping organizations adapt patient safety interventions to the specifics of their institution.

The Armstrong Institute has developed a national dissemination network, and an educational platform that can readily be adapted to support system-level intervention. Institute faculty have built key partnerships across a constellation of synergistic fields, drawing upon multi-disciplinary strength residing at its home institution, Johns Hopkins. Collaboration with these partners ensures that all aspects of the immensely complex problem, patient safety, are addressed.

And most importantly, the Armstrong Institute possesses a vision for the future, one in which healthcare system transformation results in elimination of virtually all medical errors. The Institute, directed by Dr. Pronovost, is poised to lead this transformation.