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In 1999 the U.S. Institute of Medicine released what would become a touchstone report, *To Err is Human*, which estimated that between 44,000 and 98,000 people die in hospitals each year due to medical errors that could have been prevented. It brought the idea of building a safer health system to the forefront of the public's mind.

Since then, improving health care outcomes has become a central goal in everything from clinical training and research studies to government initiatives and political debate. Clinicians, hospitals, professional organizations, and researchers have made significant strides over the last decade and a half in improving patient safety. In many ways, patients today are safer than ever before. However, multiple independent reports have found that medical errors are still a pervasive problem, with recent research suggesting that preventable medical error is responsible for 3%–5% of hospital deaths, or 21,000–35,000 preventable deaths in the U.S. alone. While these figures continue to be scrutinized and improved, it's clear that there is more to be done to make patients safer.

Looking at surgery as an example, our research suggests that the road ahead for improving patient safety will look different from the road behind. We propose that older approaches to advancing surgical safety, focused on technical and structural improvements, have passed their peak; attention must now turn to innovations in how people enact their work "on the ground," or how they organize in real time for reliable surgical performance. Similar to how improvements in smartphones have shifted from increasing processor speed or screen resolution to focusing on better user experience, innovation in surgery has to shift from the technical or structural aspects to emphasizing how people, processes, and practices come together in the pursuit of patient safety.

Waves of Innovation in Surgical Quality and Safety

Nearly 65 million surgical operations were performed last year in the U.S., resulting in an estimated 200,000 deaths from complications or other post-operative issues. Ongoing innovation is of tantamount importance to improving these patient outcomes, and over the past several decades, we have observed three distinct waves of surgical improvement:

Technical advancements. The first wave of innovation centered around enhancements in surgical technique. Increasingly available high-quality surgical instruments, greater knowledge of potential complications, and widespread sharing of best practices made surgery more effective and efficient. At the same time, training techniques, including the use of high-fidelity patient simulators and surgical skills labs, enabled less experienced surgeons to refine their technical prowess with less risk to patients.

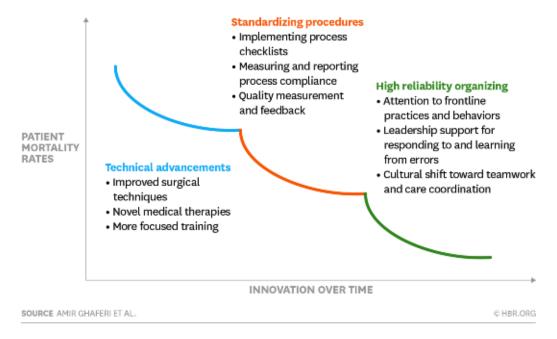
Arguably the biggest technical advance in surgery has been the advent of laparoscopic (minimally invasive) surgery, which allows surgeons to perform complex operations through tiny skin incisions. Older procedures required cutting large openings to operate on a patient (e.g., making a 4-6" incision in the abdomen to remove a gall bladder or repair a hernia). But in the 1980s surgeons began perfecting minimally invasive surgical techniques, where instruments can be inserted through much smaller incisions. Surgeons can now perform nearly every abdominal or thoracic operation using a high-resolution camera and specialized instruments through incisions less than ½ inch long. These smaller incisions typically lower the risk of infection and reduce recovery times, enhancing patient safety.

Technical advances have greatly reduced patient morbidity and mortality. However, as the surgical community continues to innovate and refine safe surgical practices, the benefits of continued technical improvements may be much more incremental, thereby having less impact on improving safety. In other words, the largest gains in patient safety (and reductions in mortality) may have already been realized now that these minimally invasive techniques are in wide use.

Of course, there are still many efforts to further improve surgical technology, including the use of 3D imaging and higher-resolution cameras to improve laparoscopic tools, or employing surgical robots to enable more precise procedures. However, the patient benefits of these advances have not been as clearly defined or demonstrated (especially relative to their extremely high cost). As we display in the figure below, we may have thus reached a flattening of the patient mortality curve regarding technical advancements.

3 Waves of Innovation in Patient Safety

Technical and procedural improvements have made surgery safer, but future innovation will focus on reliably organizing the work of patient care.



Standardizing procedures. A second wave of surgical innovation – inspired in large part by *To Err is Human* – has focused on structural improvements to make patient care more consistent. The logic was rooted in the idea that if hospitals could only do to patient care what Henry Ford did to automobile production – standardization – then patients would see drastic improvements in safety. Hospitals began identifying key processes that needed to be conducted the same way every time (such as the preparation and insertion of a central venous catheter), and set up reward and punishment systems for compliance, including standard quality metrics to evaluate provider performance.

One key standardizing innovation was the implementation of the checklist, used by providers to help recall and document the steps for best performing a complex procedure. Instead of relying on each individual care provider to develop their own approach to performing certain procedures, checklists formalized a standard order of operation. The checklist, created from research evidence and providers' best practices, routinizes the tasks involved in a given procedure so that it is performed and documented the same way every time. Research has shown that the systematic use of checklists by medical care teams has yielded significant reductions in patient mortality and other adverse outcomes, such as infections.

These structural improvements addressed many problems of patient safety, but over time they have also seen their utility diminish somewhat. Although enacting standard procedures works consistently in settings such as manufacturing, the complexity and case-by-case nature of providing patient care seems to have pushed the medical community to the point of diminishing returns with process compliance, checklists, and quality measurement. For example, the Surgical Care Improvement Project (SCIP) aimed to improve adherence to protocols for reducing surgical infections, blood clots, and heart attacks, through checklists and other interventions. But while adherence rates increased, there was little evidence of improved patient outcomes.

High Reliability Organizing: The Third Wave

Our research points to a new wave of innovation in patient safety where significant strides are still being (and have yet to be) made: improvements in how health care providers organize for highly reliable performance.

High reliability organizing rests on the notion that in order to achieve high performance – especially under trying conditions – we have to pay attention to how individuals interact with one another and organize their day-to-day work. Contrary to technical or structural innovations that aim to reduce variation and dictate one way of operating, organizing emphasizes the varying actions that can affect patient safety.

Indeed, pursuing a perfectly standardized system ignores the fact that each patient is different. High reliability organizing recognizes that over-standardizing can also increase risks. Therefore making patients safer involves standardizing when possible, but also embracing variation, instead of simplifying patients into one category, and honing practices for responding to a range of encounters.

What Is High Reliability Organizing?

High reliability organizing has its roots in studies of organizations across many industries where failure has drastic consequences and coordinated efforts are needed to ensure safe outcomes (e.g., commercial aviation, nuclear power, and naval aircraft carrier operations).

It demands that people coordinate their attention and action to continually improve the functioning of the organization, while acknowledging that there is always room for further improvement.

Our research has revealed that high reliability organizations fuel a culture of trust, foster strong relationships, and tend to demonstrate five key characteristics that help them maintain reliable performance, even in the face of ongoing change:

- 1. Preoccupation with failure
- 2. Reluctance to simplify interpretations
- 3. Sensitivity to operations
- 4. Commitment to resilience
- 5. Deference to expertise

Organizing for high reliability involves attending to not only the culture of a surgical team or health care organization (i.e., their shared values and beliefs), but also to the actual behaviors, practices, and interactions that unfold between people as they care for patients and manage the organization.

For years, surgeons have sought to reduce the rates of surgical complications – errors or unusual events that occur during or after surgery – in order to lower patient mortality. However, some of our research has found that hospitals with high mortality rates and those with low mortality rates actually have very similar rates of surgical complications. This means that differences in mortality cannot be simply attributed to reducing the rates of complications. Instead, it seems that health care providers in certain hospitals are better able to recognize and "rescue" patients from these complications, which may be driving the lower mortality rates.

In other words, it isn't only about standardizing or improving techniques to reduce complications, but it is also about how health care providers organize their work so that they recognize when something is *going* wrong (before it has already *gone* wrong) and can adapt to rescue patients. As renowned author and surgeon Atul Gawande summarized, "This is what distinguished the great from the mediocre. They didn't fail less. They rescued more."

In most instances, deaths after surgery are the culmination of a cascade of events, beginning with an initial "seminal" complication (such as a leak after colon surgery), followed by escalation of care (where the patient must return to the operating room or be transferred to an intensive care unit) and additional "domino" complications (such as pneumonia or kidney failure), that ultimately lead to the patient's death. This "failure to rescue" – when a health care team fails to recognize and treat these complications – represents a significant opportunity for improving patient safety through better organizing.

This failure to rescue is driven by elements of the broader hospital environment (e.g., the systems or structures in place for guiding care), by characteristics of individual providers (such as their knowledge, awareness, and attention), and by the micro-system of post-operation patient care (i.e., the culture and shared practices of nurses, physicians, and other staff in a particular hospital ward or intensive care unit where the patient is being treated). However, previous research in this area has focused almost exclusively on factors in the first category. But continuing to improve on patient safety requires focusing more on the micro-system level, where teams of clinicians (nurses,

technicians, administrators, surgeons, and physicians) are coordinating to rescue patients after complications, and where interpersonal dynamics, such as whether people are comfortable speaking up about potential errors, matter greatly.

This is why our colleagues at Johns Hopkins Medicine and the Armstrong Institute developed a comprehensive unit-based safety program comprehensive unit-based safety program (CUSP) to train frontline clinical team members in better teamwork, knowledge sharing, learning, and communication. It has already yielded significant gains in patient safety (for instance, leading to a 33% reduction in surgical site infections among colorectal surgery teams).

Similarly, a 2016 study by Timothy Vogus and Dawn Iacobucci at Vanderbilt University analyzed the reliability-enhancing work practices and organizing efforts of 1,685 nurses across 95 units in 10 hospitals. They found that more mindful organizing processes among nurses in a unit (e.g., being attentive to mistakes and how to learn from them, and relying on the team's pool of expertise, rather than hierarchical leaders, to resolve issues) was associated with significantly fewer medication errors and patient falls in that unit.

Identifying future levers for improving health care and patient safety will require a stronger focus on how people, process, and practice come together in patient care, rather than solely on technical or structural innovations. For instance, the PERFECT (Perioperative Enhancement of Rescue by Fostering Engagement, Communication, and Teamwork) Initiative at the University of Michigan seeks to "build the ideal rescue system" by shedding light on how health care organizations can better organize their efforts to sense, cope with, and respond to the unexpected. This more effective organizing, both at the bedside and among health care leaders, makes people more aware of risks, harmful deviations, and errors earlier, allowing them respond more quickly and appropriately, ultimately reducing harm to patients.

Safe and highly reliable patient care is the ultimate target of any improvement effort. However, we must recognize that patient safety is a dynamic, moving target, and our approaches for reaching it must continue to evolve to keep pace.

Amir A. Ghaferi is an assistant professor of surgery and business at the University of Michigan. He is a practicing surgeon and health services researcher focused on understanding the relationship of organizational culture and design to quality and efficiency with the ultimate goal of improving care locally, regionally, and nationally.

Christopher G. Myers is an assistant professor at the Johns Hopkins University Carey Business School and Armstrong Institute for Patient Safety & Quality. His research explores organizing processes that support individual learning, development, and innovation in dynamic work environments.

Kathleen M. Sutcliffe is a Bloomberg Distinguished Professor at the Johns Hopkins University with appointments in business, medicine, and the Armstrong Institute for Patient Safety & Quality. Her research focuses on how organizations and their members cope with uncertainty, team and organizational learning, and how organizations can be designed to be more reliable and resilient.

Peter J. Pronovost is an intensive care physician and the C. Michael and S. Ann Armstrong Professor of Patient Safety at Johns Hopkins University. He serves as the Johns Hopkins Medicine Senior Vice President for Patient Safety and Quality and the Director of the Armstrong Institute, and helps to lead patient safety efforts globally.