Organizational Change and Learning

Paying the Piper: Investing in Infrastructure for Patient Safety

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Patient safety has been the focus of much discussion and debate since the Institute of Medicine published To Err is Human. Significant local, national, and international efforts have aimed at improving patient safety. In response, national efforts such as The Joint Commission’s National Patient Safety Goals and organizations’ own internal commitments to reduce preventable harm have prompted many organizations to invest in patient safety improvement efforts.

Because health care organizations lack a robust framework to evaluate progress in improving patient safety, it is difficult to assess the effectiveness and efficiency of these interventions. Moreover, as health care organizations develop a deeper understanding of how to implement and evaluate patient safety efforts, we all recognize that the road to improved safety is long and often bumpy. It seems that the deeper we delve into understanding safety, the more ineffective and inefficient our current efforts appear. Most of the challenges we face stem from a meager investment to advance the science and evidence base for patient safety.

Part of the effort to mature the field of patient safety has concentrated on organizing patient safety efforts. Although the boundaries between patient safety and the broader concept of quality remain poorly defined, we have organized patient safety efforts into the following domains: measuring progress in patient safety, translating evidence into practice, identifying and mitigating hazards, improving culture and communication, and identifying an infrastructure in the organization for patient safety efforts. Fundamental to improving patient safety is the ability to design systems of care that reliably deliver evidence-based interventions and reduce preventable harm. This objective will require a culture of safety and an investment of resources. Although clinical staff are often expert first-order problem solvers (for example, nurses scrounge for missing supplies, physicians troubleshoot poorly functioning equipment), they are less adept as second-order problem solvers (for example, organizing care to eliminate the hazard and reduce preventable harm instead of applying a superficial fix that does not

<table>
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<th>Article-at-a-Glance</th>
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| **Background:** Although the best allocation of resources is unknown, there is general agreement that improvements in safety require an organization-level safety culture, in which leadership humbly acknowledges safety shortcomings and allocates resources at the patient care and unit levels to identify and mitigate risks. Since 2001, the Johns Hopkins Hospital has increased its investment in human capital at the patient care, unit/team, and organization levels to improve patient safety.  

**Patient Care Level:** An inadequate infrastructure, both technical and human, has prompted health care organizations to rely on nurses to help implement new safety programs and to enforce new policies because hospital leaders often have limited ability to disseminate or enforce such changes with the medical staff.  

**Unit or Team Level:** At the team or nursing unit level, there is little or no infrastructure to develop, implement, and monitor safety projects. There is limited unit-level support for safety projects, and the resources that are allocated come from overtaxed department budgets.  

**Organization Level: Hospital Level and Health System:** Infrastructure is needed to design, implement, and evaluate the following domains of work—measuring progress in patient safety, translating evidence into practice, identifying and mitigating hazards, improving culture and communication, and identifying an infrastructure in the organization for patient safety efforts.  

**Reflections:** Fulfilling a commitment to safe and high-quality care will not be possible without significant investment in patient safety infrastructure. Health care organizations will need to determine the cost-benefit ratio of various investments in patient safety. Yet, predicating safety efforts on the mistaken belief in a short-term return on investments will stall patient safety efforts.
substantially reduce harm). In addition, some staff may have the leadership skills for second-order problem solving but not the power to make changes.

It seems that much of our efforts in health care to improve patient safety have been broad (a mile wide) and marginally effective (an inch deep). We must reverse our efforts and focus an inch wide and dig a mile deep to be effective. This will require second-order problem solving, and organizations need to provide the resources to accomplish this work.

Although the best allocation of resources is unknown, there is general agreement that improvements in safety require an organization-level safety culture, in which leadership humbly acknowledges safety shortcomings and allocates resources at the patient care and unit levels to identify and mitigate risks.1,9

Although we believe that improved quality and safety will reduce waste and thus save money in the long run, we believe that health care has a current safety infrastructure debt to pay. Health care organizations need to invest substantial resources now to repay this debt and improve safety. We have reported efforts at the Johns Hopkins Hospital to improve the safety culture (primarily through the Comprehensive Unit-based Safety Program [CUSP]11,12), but we have not described our ongoing journey to allocate human resources for patient safety initiatives (Table 1, right). In this article, we describe our efforts since 2001 to increase investments in human capital at the patient care, unit/team, and organization levels to improve patient safety.

**Table 1. Time Line for Building of Infrastructure**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
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<tbody>
<tr>
<td>2001</td>
<td>Josie King and Ellen Roche adverse events</td>
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<tr>
<td>2001</td>
<td>Patient safety officer appointed (Johns Hopkins Hospital)</td>
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<td>2001</td>
<td>Patient safety committee convened (Johns Hopkins Hospital)</td>
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<tr>
<td>2001</td>
<td>Comprehensive Unit-based Safety Program (CUSP) piloted in multiple intensive care units</td>
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<tr>
<td>2002</td>
<td>Center for Innovations in Quality Patient Care formed (Johns Hopkins Medicine)</td>
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<td>2003</td>
<td>Patient safety coordinator hired (Johns Hopkins Hospital)</td>
</tr>
<tr>
<td>2003</td>
<td>Department of pediatrics creates director of quality and safety initiatives and allocates physician support</td>
</tr>
<tr>
<td>2004</td>
<td>Patient safety nurses hired (operating room and labor and delivery)</td>
</tr>
<tr>
<td>2004</td>
<td>Patient Safety Net (PSN; incident reporting system for Johns Hopkins Hospital) implemented, and system database administrator hired</td>
</tr>
<tr>
<td>2005</td>
<td>Risk management reorganization</td>
</tr>
<tr>
<td>2005</td>
<td>Patient safety analyst hired for PSN</td>
</tr>
<tr>
<td>2005</td>
<td>Medication safety officer hired (Johns Hopkins Hospital)</td>
</tr>
<tr>
<td>2006</td>
<td>Patient safety manager (Johns Hopkins Hospital)</td>
</tr>
<tr>
<td>2006</td>
<td>Human factors engineer hired (operating rooms)</td>
</tr>
<tr>
<td>2007</td>
<td>Pediatric medication safety officer hired (Children’s Center)</td>
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</table>

**Patient Care Level**

Much of the work to improve patient safety is new. Standardizing work and creating independent checks for key processes, identifying and learning from mistakes, and monitoring performance to improve patient safety are examples of tools that create new work. During the past several years, clinicians have had to adopt many tools or interventions in the name of “improved patient safety” or “quality improvement.” For example, medication reconciliation, addressed by The Joint Commission as a 2006 National Patient Safety Goal,13 is now mandated by The Joint Commission for all patients at hospital admission, transfer between units, and hospital discharge. This process requires the reconciliation of existing and newly written medication orders to ensure that patients receive appropriate pharmacologic therapies. Medication reconciliation adds significant new work for physicians and nurses.14–16

In addition, in an effort to reduce or eliminate central line-associated bloodstream infections, our hospital developed and implemented a checklist, whereby nurses advocate and ensure that physicians adhere to evidence-based practices when inserting central venous catheters. This intervention is now used in hospitals throughout Michigan, New Jersey, Rhode Island, Maryland, and Tennessee, among others.17,18 Although exceedingly effective, this checklist intervention requires that nurses be present during central line insertions, which was rare before this protocol was introduced. Another example is the requirement that operating room nurses double-check specimens to minimize labeling errors—all effective but time-consuming endeavors.19

Clinicians and administrators are struggling to absorb well-intentioned but burdensome new work. Nurses invariably step forward to carry the burden of new work and protect patients. An inadequate infrastructure, both technical and human, has prompted health care organizations to rely on nurses to help implement and enforce new policies because hospital leaders often have limited ability to disseminate or enforce such changes with the medical staff.
Although much of the new work for safety has fallen in nurses’ laps, it is generally not accompanied by an increase in nursing hours per patient day—a common measure of nursing resources—or dedicated time for physician oversight. Each new intervention may provide some benefit to patients; but there must be resources to support the new work. At Hopkins, we have a limited ability to add new interventions without increasing staff support or decreasing work loads, and our failure to do so will likely worsen the already critical nurse shortage. Health care organizations, regulators, and accreditation agencies must ensure that the new work they ask staff to do is both effective and efficient. Ultimately, society must decide how much it is willing to pay to improve patient safety.

**Unit or Team Level**

At the team or nursing unit level, there is little or no infrastructure to develop, implement, and monitor safety projects. Yet, each of these essential tasks must occur if we expect to improve patient safety. Team-level resources could be allocated at the department, division, or clinical unit level. There is limited unit-level support for safety projects, and the resources that are allocated come from overtaxed department budgets. In large, complex departments, resources would be better allocated at the division level. For example, the department of medicine at Hopkins encompasses 13 divisions and many clinical units; allocation of resources for safety at the division level would be a much easier scope to manage.

At Hopkins, many units have created safety nurse positions by allocating 0.2 to 0.5 nurse full-time equivalent (FTE) positions to oversee patient safety efforts and have provided a smaller amount of time for physician oversight. Many departments have also committed 0.5 to 1 nurse FTEs to oversee safety efforts. As these safety managers better understand the work underlying patient safety, they feel overwhelmed at the enormity of the task. Hundreds of clinical staff submit hazards through patient safety reporting systems and report how the next patient will be harmed through CUSP. The number of hazards to address is substantial, yet the methods to prioritize which hazards to address are immature. In addition, as managers better understand the principles of safe design, they recognize that second-order problem solving takes substantial effort. Unfortunately, only a handful of units or departments have individuals who can fill these essential roles.

Outside these safety positions, unit resources are generally used to manage daily patient care operations and support organizational priorities (for example, computerized provider order entry, service excellence). Safety tends to be dealt with reactively. Nurse managers generally have limited time or support to proactively identify and mitigate hazards on their units. Some managers, overwhelmed, are forced to limit the number of safety issues that staff can tackle, or they conduct cursory reviews of adverse events. Nurse managers are essentially the chief executive officers overseeing $1–$2 million budgets—as many as 100 FTEs and many hospital safety efforts—yet many do not even have a secretary. Like bedside nurses, they too are feeling the infrastructure crunch.

One example of the burden that nurse managers face is the hospital’s dependence on them to investigate incident reports. On the basis of our Web-based voluntary incident reporting system, a typical unit submits 10 to 15 incident reports per week. Nurse managers are expected to investigate and remedy each reported hazard. Because managers have little time to peel back the layers of their broken systems, investigations are often superficial, and deep system changes are rarely implemented.

Another example is the burden to develop, implement, and evaluate patient safety programs. Many units are held accountable for improving safety—work that often falls to nurse managers, nurse educators, or senior nurses. Current physician and nurse education programs are not producing caregivers with the skills needed to improve safety. Health care must train clinicians to be patient safety leaders and provide the time and resources they need to implement system improvements.

We do not yet know the optimum support required for a particular department or unit. But, such support could be a vice chairman for patient safety at the department level, and a 0.5-to-1-nurse FTE to collect data and manage safety efforts at the division or unit level. We have experienced the benefits when such resources are provided and the perils when they are not allocated.

In the following four examples of innovative safety roles, we found the same issue—the harder you dig into safety issues, the more problems you identify, and the more work you create:

1. In an intensive care unit (ICU), a staff nurse who has a proclivity for patient safety devotes 80% of her time to safety and 20% to clinical activities. In this role, she helps develop and implement safety interventions, monitors performance, provides staff feedback, and disseminates interventions to other units. Her role has been vital in improving safety in multiple ICUs.

2. The department of pediatrics supports 50% of a physician’s time to serve as director of quality and safety initiatives and 25% of another physician’s time to oversee information technology for quality and safety efforts in the Children’s Center. These roles have been vital in implementing...
numerous safety efforts during the last several years. The resulting quick increase in the work load necessitated the hiring of a second physician at 50% time in 2006 to work on safety and quality in the Children's Center.

3. The Hopkins liability insurer funds one full-time FTE in the operating room and one in labor and delivery to serve as patient safety nurses. Their role is to educate staff about patient safety, identify hazards, design interventions that focus on improving culture, and monitor performance. Although this role is relatively new, it has been warmly received by clinicians and department leaders.

4. As our understanding of safety hazards increased, we became increasingly concerned about the prevalence of equipment and device errors. We recognized that our ability to identify and mitigate these risks could be improved. Therefore, we hired a full-time, doctorally prepared, human factors engineer to safety-proof equipment and devices in the operating room. This role's success has prompted surgery to hire two human factors engineers for the operating rooms; the emergency department has hired one engineer, and anesthesiology also plans to hire one.

Organization Level: Hospital Level and Health System
As our understanding of patient safety grew, so did our need for an improved infrastructure at the organization level. Earlier in this article, we noted our categorization of patient safety efforts into several domains: measuring progress in patient safety, translating evidence into practice, identifying and mitigating hazards, improving culture and communication, and identifying an infrastructure in the organization for patient safety efforts. Infrastructure is needed to design, implement, and evaluate these domains of work. For example, resources are needed to do the following:

- Identify hazards, typically through an incident reporting system
- Conduct root cause analyses and implement their recommendations
- Develop measures of patient safety, then monitor and report progress back to clinicians
- Design, implement, and evaluate new interventions
- Comply with the ever-growing list of regulatory and accreditation requirements
- Educate clinicians regarding safety efforts
- Monitor and improve safety culture

Some of these tasks represent new work, and some are increased work above current activities. The role of the patient safety officer/director/manager [L.P.] for our hospital is to strategically package the above activities.

In the early years following To Err is Human, our organization responded slowly. Early in our efforts, the dean/CEO appointed a vice president for quality improvement for Johns Hopkins Medicine. This person was charged with developing a strategic direction and providing oversight for safety, service, and quality improvement initiatives across all affiliated Johns Hopkins Medical Institutions. In addition, a vice president for medical affairs [B.J.R.] was appointed as the patient safety officer for the Johns Hopkins Hospital in 2001, and a patient safety committee was subsequently established and became part of the quality improvement infrastructure. Although these organizational structures have proven to be very important, they were initially limited in their ability to effect broad system change because little was known about methods to improve patient safety; accountability for improvement still remains diffuse.

Fortunately, the scholarly interests of a few patient safety researchers [P.J.P.] at our organization implemented some early and small-scale interventions that reaped significant results. With these data, the institution committed to viewing patient safety as a science and to broadly implementing safety interventions that focused on improving safety culture. The vehicle to accomplish this was CUSP; it became the cornerstone of our safety program and was coordinated by the patient safety committee. CUSP started in several ICUs in 2001, spread to other units, and was soon in great demand. However, there were limited central resources to meet the demand for CUSP.

In 2003, the activities of the patient safety committee accelerated and quickly became overwhelming for the generous efforts of volunteer members to coordinate. Funding for a patient safety coordinator position was secured, and the position was filled by a nurse with diverse clinical and administrative experiences within the organization. This role was initially 30% of an FTE but is now 100%. The patient safety coordinator also manages several additional safety support staff. With the additional staff, we were able to move forward and roll out CUSP in 30 clinical units at Hopkins.

One of the patient safety coordinator's first accomplishments in 2003 was the creation, with the collective input of an interdisciplinary group of frontline caregivers and administrators, of a comprehensive strategic assessment and plan for safety. The plan was disseminated broadly and has served as a guiding document for the patient safety committee and the hospital for the past five years.

Our work at Hopkins has been balanced and accomplished centrally by the hospital and peripherally by departments.
While we have gradually established a modest but still insufficient centralized infrastructure, departments have been working on unit and service-line efforts to improve safety. The correct balance between centralized and decentralized support remains elusive.

To identify our major risk areas, in 2004 the hospital implemented the Web-based incident reporting system mentioned earlier. The entire hospital uses this tool as the sole vehicle to report adverse events. A full-time FTE was hired in 2004 to help educate staff on the use of this system. We soon became the victim of our own success; we received 11,000 incident reports in the first year and 14,000 in the second but had no support to monitor all events in a timely fashion. In response, we hired a second full-time FTE in 2005 to analyze low-harm events, distribute results to appropriate hospital staff, and follow up on significant events and near misses. Risk management reviews the most harmful events. An active area of investigation now is to prioritize hazards identified from these events and effectively and efficiently allocate scarce resources to mitigate risks to patients.

The hospital has also invested resources to improve medication safety by creating a new medication safety officer position in 2005 and by supporting point-of-care pharmacists in all clinical areas. In 2007, a pediatric medication safety officer pharmacist was added to the safety infrastructure of the Children's Center. In addition, we are supporting the implementation of provider order entry by allotting time for physicians, nurses, and programmers to write protocols and standard order sets. The amount of work for this latter project is daunting. However, it appears exceedingly inefficient, not to mention unsafe, for each hospital to build unique order sets and decision supports. It equates to each airport creating a different air traffic control system.

In addition, Hopkins has also expanded personnel in the risk management department to conduct more thorough root cause analyses (RCAs) and to monitor the extent to which recommendations are implemented. As the organization gained knowledge of the science of patient safety, our RCAs have become more informative in identifying and, hopefully, mitigating hazardous systems deeper within the organization. Yet, such thorough reviews require increased time, often from multiple staff, and recommendations are often difficult to implement and monitor. This work increased from one FTE in 2003 to three, and staff continue to struggle with the work load of this ever-expanding role.

The hospital is investing ever-increasing resources to monitor the rate-based measures of quality and safety, nearly all of which are required by the Centers for Medicaid & Medicare Services, The Joint Commission, or insurers. Three FTEs have been added; one for data abstraction and two to work directly with the clinical services on the inpatient units to monitor outcomes and provide timely feedback for “real-time” interventions. Despite this investment, the lack of relational databases limits our ability to provide feedback to clinicians regarding performance.

We have also added resources to our hospital epidemiology and infection control department. Given the national and local focus to reduce health care-acquired infections, we added staff to assist with surveillance, data management, and training.

The hospital also recognized that it needed an institutional entity to innovate and coordinate quality improvement efforts. Accordingly, in 2002 it created the Center for Innovations in Quality Patient Care. Although the Center does not exclusively focus on patient safety, approximately half of the eight FTEs in the Center were hired for safety roles.

Because safety is recognized as an institutional priority, many capital budget requests that previously would have been in a department bucket are now packaged as institutional safety requests. Although the hospital now has a dedicated budget for patient safety, the requests for safety exceed the available funds by 10-fold.

Finally, we recognized that the safety issues faced by the Johns Hopkins Hospital are also faced throughout our health system. As such, we are investing resources to create a new corporate level of safety, service, and quality improvement that will provide infrastructure to support safety efforts in our three acute care hospitals, home care company, outpatient settings, and community physician practices. Although not yet fully articulated, this will likely include staff positions and support for information technology.

**Reflections**

**Investment in Infrastructure**

In our experience, fulfilling a commitment to safe and high-quality care will not be possible without significant investment in patient safety infrastructure. As our understanding of how to improve patient safety has grown, so has our realization that the current safety infrastructure is insufficient. As a result, many patient safety efforts fail to achieve their intended goal. To improve safety, it is essential (1) to ensure that sufficient numbers of qualified clinicians are staffed to provide care and (2) to create mechanisms to train clinical leaders and administrators in the science of improving quality and safety.

We believe that investments in infrastructure must occur at
multiple levels of the health care organizations. At the patient care level, organizations will likely need to increase the nursing hours per patient day to accommodate the myriad of new work to improve patient safety. At the unit level, we believe the role of the nurse safety manager should continue to grow. We are in the process of establishing core competencies for this position and developing training programs to ensure staff have the appropriate skills. We are still uncertain about the scope of these roles and the time requirement. For example, should each ICU have a safety manager or should one oversee all ICUs?

Departments—or for smaller hospitals, the entire hospital—should have, in addition to unit-level managers, a qualified safety director who understands the technical aspects, including measurement, and leadership aspects of improving patient safety. There is unfortunately no short cut in obtaining these skills. Competency cannot be obtained through a weekend- or week-long course, but likely requires master’s-level training in public health, followed by mentored research time on projects.

Health care organizations will need to determine the cost-benefit ratio of various investments in patient safety. If there is a business case, to whom does it accrue and when? To evaluate this, we will need to fully support the infrastructure required to evaluate the impact of interventions on clinical and economic outcomes. Outside of focused projects, we are a long way from fully evaluating the business case for safety. In the long run, society, employers, and insurers will likely benefit from improved patient safety. The financial impact on provider organizations, especially in the short term, is less certain. Yet, predicing safety efforts on the mistaken belief that we will see short-term return on investments will stall patient safety efforts.

**Launching of New Patient Safety Goals and Programs**

Regulators and accreditors such as The Joint Commission should have a more robust understanding of the risks and benefits of specific patient safety goals or programs before recommending or requiring implementation. We recommend the establishment of a “learning laboratory” to evaluate the program; to design, pilot test, and broadly implement interventions; and to design, pilot test, and evaluate the effectiveness and efficiency of those interventions. Far too often in the United States, the tendency has been to jump from a sound concept for improving patient safety (for example, medication reconciliation or operating room time-out) to a national practice or policy without a strong scientific basis of the causes of the underlying problems or the effectiveness and costs of the recommended solutions. Patient safety goals and programs, which can have an enormous impact on hospital work load, should be informed by strong scientific evidence.

**Making Up the Infrastructure Deficit**

Health care organizations need to recognize that we have a deficit to make up. The cost-cutting history during the past decade has resulted in an incapacity to meet the growing demand to improve patient safety. It takes considerable resources to conduct second-order problem solving. This will require people with the skills to do the work, which will require a training program, and time for them to do the work. It will also require an organizational structure that connects with and draws from other organization resources. The Securities and Exchange Commission developed standards for financial accounting, and most health care organizations have invested substantially in valid measurement efforts to meet these standards. Patient safety will likely require a similar investment. This will require following explicit rules to reduce bias in reports, qualified professionals to supervise the reports, a method to audit reports for validity, and a mechanism to hold health care organizations accountable for the reports.

Current federal efforts to improve quality of care and patient safety have focused on accountability with pay-for-performance and public reporting and have not yet grappled with this infrastructure debt. Given the costs to develop robust patient safety programs, including the development of measures to evaluate the process of improving safety and data architecture for collecting and reporting on performance, the public and private sectors will likely need to develop such infrastructure for broad use.

**Safety as a Continuous Variable**

We need to start thinking of safety as a continuous variable (in degrees), rather than as a dichotomous variable (safe or not safe). In doing so, we can more clearly articulate the cost and benefits of patient safety efforts. Yet, making and evaluating progress in patient safety will require a much more rigorous science than is currently used. In the nine years since the publication of To Err Is Human, we have increased awareness of patient safety and implemented local efforts to improve safety, yet empirical evidence of progress toward reducing preventable harm is limited. We hope the next decade focuses on maturing the science of patient safety and improving the effectiveness and efficiency of our patient safety efforts. Comprehending the human capital needed to make these improvements is a critical first step.
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References