

## Framework for Patient Safety Research and Improvement

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Lapses in patient safety represent a significant global problem that results in preventable morbidity, mortality, and costs of care. In the 1999 landmark report *To Err Is Human*, the Institute of Medicine shocked the healthcare industry with estimates that up to 98 000 people die because of medical errors each year in the United States.<sup>1</sup> This glaring report was amplified by a 2003 RAND study that suggested that hospitalized patients in the United States on average receive only half the recommended therapies.<sup>2</sup> The impact of these reports damaged consumer confidence in the healthcare industry and galvanized broad industry support to improve patient safety.

Five years after the Institute of Medicine publication, there was increasing concern that little measurable progress had been made to improve patient safety.<sup>3-5</sup> Since then, the number of quality- and safety-related activities has grown steadily, but there is still minimal empiric evidence demonstrating progress.

Our inability to evaluate progress toward improving patient safety results from poorly articulated safety improvement goals and measures and the absence of a simple yet meaningful framework to identify and prioritize the most effective and efficient patient safety interventions. The present report presents a framework to help organize future patient safety research and improvement efforts.

### Framework for Patient Safety Research and Improvement

We sought to develop a framework for patient safety research and improvement that would address many issues emerging from an expanding international appetite for higher-quality and safer care. We acknowledge that the boundaries between safety and the broader concept of quality remain poorly defined. As we developed and revised this framework, we reflected on our experiences, revisited the Institute of Medicine's strategies for improvement, and studied the literature on knowledge transfer and diffusion of innovation.<sup>6-14</sup> The framework presented includes the following 5 domains (Table 1): (1) evaluating progress in patient safety; (2) translating evidence into practice; (3) measuring and improving culture; (4) identifying and mitigating hazards; and (5) evaluating the

association between organizational characteristics and outcomes.

Our goal in developing this taxonomy was to clarify the broad clinical and policy domains that link to a safety scorecard. Although we limit our examination to these domains, there are tools (eg, health information technology or simulation) that could be useful in both domains and warrant discussion. For example, simulation can provide clinicians with a better understanding of how to translate evidence into practice, or how to be more cognizant of and mitigate hazards. Unfortunately, examination of tools to support this work is beyond the scope of the present report. Our taxonomy does not include a separate category for diagnostic errors. This exclusion is not intended to diminish the importance of diagnostic errors but rather to recognize that they are a subcategory of our main categories.

Because patient safety research is an applied science, research and improvement are and should remain inexorably linked. As such, healthcare organizations must address technical (science) and adaptive (culture change) work; both are necessary to sustain improvements in patient safety.<sup>15,16</sup> Technical work involves activities with known solutions and science. Examples include stocking a unit with chlorhexidine for sterile procedures or training residents to intubate a patient. Adaptive work requires a change of values, attitudes, or beliefs. Examples include getting clinicians to reliably implement an evidence-based therapy or getting staff to report adverse events. In collaborative projects, the technical work is generally done by a centralized research team, whereas the adaptive work is done by the local team. The improvement team must do both well.

### Evaluating Progress in Patient Safety

The broad use of pay-for-performance has made hospital reporting on quality and safety measures a de facto mandate.<sup>17-19</sup> Despite the growth in quality of care and patient safety measures,<sup>20</sup> it is concerning that many measures are not supported by substantial evidence.<sup>21-23</sup> Patients, providers, and payers should have confidence that quality-of-care public statements are accurate.<sup>24</sup>

The exploration of measures of safety involves 2 tensions. One tension is balancing the desire for a global though more

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**Table 1. Framework for Patient Safety Research**

Domain	Description
Evaluating progress in patient safety	Develop valid and feasible measures to evaluate progress to improve patient safety; include these measures in a safety scorecard (see Table 2)
Translating evidence into practice	Develop and evaluate interventions that increase the extent to which patients receive evidence-based medicine
Assessing and improving culture	Strategies and interventions to improve safety culture and communication
Identifying and mitigating hazards	Use of retrospective and prospective analyses to identify and mitigate safety hazards at the microscopic level (unit or department, in-depth evaluation) and macroscopic (institutional, country) levels
Evaluating the association between organizational characteristics and outcomes	Evaluate organizational characteristics that help or hinder research efforts or patient safety practices, for example, the association between staffing and patient outcomes

biased measure of safety versus a more focused but less biased (robust) measure. In a desire for parsimony and simplicity, healthcare organizations want global measures of patient safety (eg, overall hospital mortality). Although this type of measure is potentially beneficial because it applies to all patients and may be efficient to collect, it has significant bias from inadequate risk adjustment and failure to account for patient preferences to limit care.<sup>25</sup> Conversely, a more specific measure, such as central line–associated bloodstream infection, targets a limited set of patients but is much more robust. But these specific measures will only address a limited patient population or a narrow set of processes and outcomes. Many specific measures will be needed to provide a sufficiently broad view of patient safety. Even so, a large group of measures may be difficult for consumers to interpret. To move the science of safety forward, efforts should ensure that all measures are robust. Invalid measures could result in incorrect inferences regarding progress toward improving patient safety.<sup>26</sup>

The second tension is finding a balance between a measure that is scientifically sound (valid and reliable) and feasible given existing resources. To date, many measures have focused on feasibility at the expense of being scientifically sound. For example, measures of deep venous thrombosis from administrative data are feasible to obtain but correlate poorly with data collected from the medical record and require greater resources.<sup>27</sup>

It is often difficult to develop and implement measures of patient safety. Such measures should be important to a variety of stakeholders, scientifically sound, feasible, and usable.<sup>28</sup> All of these attributes are difficult to achieve in 1 measure. For example, consumers and employers may perceive outcome measures as important, whereas clinicians, who are often concerned with the validity of outcome measures, may prefer process measures. There is no shortage of important measures, but the tension described above must be rectified.

Through our experiences with measurement, we found it was useful to reduce the quantity but not the quality of data collection. When conducting a study involving myocardial infarction rates, for example, a National Institutes of Health–funded randomized trial may collect many variables (eg, age and gender) to provide context for this outcome. Although they are interesting, these nonessential variables should not be collected in the patient safety project.

When evaluating whether measures are scientifically sound, it is important to consider validity of a measure at 2 levels. The first level involves the patient safety domain. If the domain is an outcome, does it represent an important aspect of quality, and does either variation in practice among organizations or interventions that improve the outcome demonstrate it is largely preventable? If the domain is a process measure, is there evidence that the intervention will improve patient outcomes?<sup>29</sup>

The second level of validity must consider how we measure that important domain of patient safety. To minimize bias, efforts should follow the measurement principles for clinical research. Clinical research studies typically have well-defined research protocols, explicit data collection tools, well-designed databases, clear quality control plans, and detailed analytic plans.<sup>29</sup> The limited evidence base in quality and safety is often rationalized as a study design issue, in which the “gold standard” randomized clinical trial is not feasible. Although this may be true, it does not preclude the opportunity to achieve robust results through other study designs.<sup>30</sup> Quality improvement studies can use cluster-randomized designs, a stepped-wedge trial design,<sup>31</sup> or a quasiexperimental (time series) design—observational study with the intervention and control groups evaluated over time. Because many safety and quality improvement studies use a pre-post design, it is especially important to control for historical bias or changes in performance over time.<sup>26</sup> Without controlling for historical and other biases that are commonly found in observational studies, the investigators may make incorrect inferences. Moreover, although study design issues often address selection bias, they do not address measurement bias, which is often significant in quality improvement efforts.<sup>29</sup>

A major obstacle in establishing rigor when developing measures to evaluate patient safety progress has been the difficulty in distinguishing indicators that can and cannot be measured validly as rates.<sup>22,32,33</sup> Parameters of patient safety are often inappropriately presented as rates, when it is nearly impossible to measure most as rates for several reasons: Events are uncommon (medication errors with significant harm or death) or rare (wrong-site surgical procedures), few events have standardized definitions, surveillance systems typically rely on self-reporting, denominators (populations at risk) are largely unknown, and the time period for exposure (patient-day or device-day) is unspecified. The creation of a measurement system free of the biases introduced by these limitations would be complex and costly.

Even with the assumption that we have valid measures, it is often challenging to select appropriate goals for benchmarking. Program goals and measures of performance will differ for benchmarks set on relative and absolute perfor-

mance.<sup>17</sup> For example, rewarding relative performance penalizes organizations that are already performing well. Rewarding absolute thresholds may fail to recognize poorly performing organizations that make substantial improvements. A balance between the 2 will be needed for benchmarking.

We developed a model to measure patient safety progress that considered the above limitations. It is built on Donabedian's structure and process influences outcomes measurement paradigm. Our model includes 4 categories of measures. Two measures are feasible to capture as rates with minimal bias: (1) How often do we harm patients, and (2) how often do clinicians provide appropriate, evidence-based interventions? Two measures are crucial to measure progress but are inappropriate for rate-based reporting: (3) Have clinicians learned from mistakes (defects), and (4) how successful are clinicians and healthcare organizations at improving and maintaining a culture of safety?

This model addresses current challenges in patient safety research and public reporting. For measures of harm, clinicians should be accountable for outcomes that we can measure and prevent with known science. For example, we can validly measure and most often prevent central line-associated bloodstream infections. The opposite is true of overall hospital mortality. Although commonly measured, mortality rates are subject to insufficient risk adjustment, inability to control for patient preferences to limit care, and an unknown degree of preventability.

Capturing and reporting compliance with evidence-based practice is equally important, because the omission of evidence-based interventions may result in patients sustaining preventable harm. Mandatory public reporting of hospital performance on a small set of these measures is now a requirement for Medicare participation.<sup>34</sup>

Our understanding of the 2 non-rate-based measures is informed by characteristics from high-reliability organizations.<sup>35</sup> High-reliability organizations have high levels of safety despite being hazard-prone industries. These organizations value a culture of safety, use redundancy in mission-critical processes, have flexible and decentralized operational decision making, and support a "preoccupation with potential failure."<sup>35</sup>

Although most mistakes (events) in patient safety are too rare to measure as rates in a single institution, we must evaluate the extent to which we have reduced the risk of a recurring mistake. To accomplish this, we can assess 3 things (organized from least to most valid and resource intensive): Did we create a new policy or procedure; does staff know about the policy or procedure; and does staff use the policy or procedure as intended? The last question generally requires an audit of behaviors.

It is often challenging to develop valid and reliable behavioral markers. Much like safety measures, there are 2 levels of validity for behavioral markers. First, the behavior must be associated with the outcome of interest. Second, we must measure that behavior in a valid and reliable manner. This requires training and calibration of observers to assess nontechnical (eg, cognitive and interpersonal) skills using psychometrically sound instruments and processes.<sup>36</sup>

**Table 2. Integrative Model to Translate Evidence Into Practice**

Strategy	Actions
Summarize the science	Identify interventions associated with outcome Select interventions with strongest evidence and lowest barriers to use Convert interventions to behaviors
Measure performance	Select measures (either process or outcome) Develop and pilot test measures Measure baseline performance
Understand the current process and context of work	Walk the process to identify breakdown in the process Research the context of current work to identify barriers in providing the intervention
Ensure all patients reliably receive the intervention	Implement approach to improve reliability Approach engages, educates, executes, and evaluates; involves senior hospital leaders, interdisciplinary team leaders, and frontline staff

Finally, regulatory and accreditation pressures to validly measure and improve culture are intensifying research efforts to understand the cultural context of care within healthcare organizations.<sup>37–39</sup> Further discussion of this measure occurs in domain 3 of this framework.

### Translating Evidence Into Practice

To date, the majority of research funding and efforts have focused on understanding disease mechanisms and identifying effective therapies, with comparatively little research funding to identify effective, efficient, and safe delivery of therapies to patients.<sup>40</sup> Thus, errors of omission (failure to provide evidence-based therapies) that result in substantial preventable harm represent a significant challenge in health care.<sup>41,42</sup>

Multiple approaches seek to increase the reliable delivery of evidence-based therapies to patients.<sup>43</sup> These approaches include evidence-based medicine and clinical practice guidelines, professional education and development, assessment and accountability, patient-centered care, and total quality management. However, most approaches focus exclusively on changing individual physician behavior. Yet physicians are part of a healthcare team, and little research has assessed how an entire team can improve the reliability of care.

We have described an integrative model to improve reliability of care<sup>33</sup> that focuses on systems (how we organize our work), engages an interdisciplinary team to assume ownership of the improvement project, is based on evidence and performance measurement, and creates a collaborative culture that is essential for sustaining results. This model includes the following steps (Table 2)<sup>32,44</sup>:

1. Summarize the science. Assemble an interdisciplinary team to prioritize and decide where to focus patient safety



efforts. The team should review the evidence using a standard evidence-based approach (such as that provided by the Centre for Evidence-Based Medicine, [www.cebm.utoronto.ca](http://www.cebm.utoronto.ca)) to identify interventions with the biggest impact on their outcome. Then, select the top interventions (maximum of 7) and convert these into practice behaviors.<sup>45,46</sup>

2. Measure performance. Once an intervention has been chosen and practice behaviors have been developed, measure performance to evaluate how frequently patients who should receive a specific therapy actually receive it (process measures), or evaluate whether patient outcomes have improved (outcomes measures). The importance of process versus outcome measures has been debated.<sup>47,48</sup> Process measures require less risk adjustment, allow for frequent feedback to clinicians, and have higher face validity for clinicians than outcome measures. Also, there are few valid outcome measures, and a larger sample is required to provide a truer estimate of performance. Thus, clinician feedback is infrequent and often challenged owing to insufficient risk adjustment. Clinicians must balance scientific rigor with feasibility when deciding whether to measure a process or outcome.

The steps to development of safety measures have been described in section 1 of this framework.<sup>28,49</sup> A rigorous process for developing and collecting patient safety measures will help reduce selection, measurement, and analytic bias. Pilot testing will ensure the validity and feasibility of measures, data collection forms, and databases before baseline performance is measured.<sup>33,49</sup>

3. Understand the current process and context of work. To understand work as a process, physically go through the steps with clinicians (walk the process) to appreciate what they actually do to provide evidence-based care to a patient. This can identify where defects occur or where systems do not support evidence-based practice. In addition, investigate the context in which work occurs. Ask clinicians why it is difficult to comply with recommended practices and what they believe they will gain or lose from participating in the improvement effort.
4. Ensure all patients reliably receive the intervention. This step is typically the most difficult to accomplish. Interventions to redesign care must reflect each hospital's current system, culture, and resources. Although there is no formula for redesigning care processes, there are tactics that appear to be effective.<sup>50–54</sup> Informed by our experience and the literature,<sup>13,14,46</sup> we developed the following approach to improve reliability, which targets 3 levels of leadership: senior hospital leaders, interdisciplinary team leaders, and patient-care leaders (frontline staff).
  - a. *Engage* by telling patient stories and providing an estimate of the number of deaths attributable to the outcome targeted.
  - b. *Educate* by providing evidence supporting the intervention in the form of concise summaries and slide presentations.
  - c. *Execute* the intervention by walking the process, talking to reluctant clinicians, and pilot testing the intervention before broader implementation.<sup>55</sup>
  - d. *Evaluate* progress in improving patient safety by measuring performance (process) and/or the impact on the outcome.

This approach only applies to the initial implementation phase of an intervention. Sustaining and spreading an inter-

vention can prove difficult. As such, we added “endure” (sustain) and “extend” (spread) to our reliability model; both will need a structured approach.

### Assessing and Improving Safety Culture

After the *To Err Is Human* report,<sup>1</sup> the National Quality Forum and the Joint Commission recommended improving the culture of safety. Efforts to improve safety culture addressed the following: What is it? How do you measure it? How do you use it? How do you improve it?

#### What Is Safety Culture?

Norms, beliefs, attitudes, and values define safety culture, but the lay definition of “the way we do things around here (nursing unit or clinical area)” is both practical and succinct. Culture is typically associated with anthropologists and ethnographers who undertake a lengthy study of 1 culture or group. In contrast, healthcare organizations need scientifically sound yet feasible methods for regular assessments of safety culture. The sudden demand for relatively low-cost, quick, annual assessments of safety culture has resulted in a reliance on climate questionnaires, which measure a snapshot of the larger culture through multiple dimensions such as safety climate or teamwork climate.<sup>37,38</sup>

#### How Do You Measure Safety Culture?

Safety culture assessments evaluate staff members' attitudes toward patient safety. To date, the most thoroughly validated and widely used instrument to assess safety culture in health care is the Safety Attitudes Questionnaire.<sup>37,39,56–58</sup>

Safety culture responds to interventions<sup>33,59</sup> and elicits attitudes previously associated with length of stay and error rates.<sup>60</sup> The Safety Attitudes Questionnaire groups staff perceptions into 6 factor-analytically derived scales (domains): safety climate, perceptions of management, teamwork climate, job satisfaction, stress recognition, and working conditions.

We use a robust process to sample individuals. The criteria for participant inclusion are all clinical and nonclinical staff with a  $\geq 50\%$  commitment to 1 clinical area for at least 4 consecutive weeks before survey administration. In addition, we require a  $\geq 60\%$  response rate for accurate interpretation of results; our Safety Attitudes Questionnaire administrations average an 80% response rate.<sup>61,62</sup> Typically, Safety Attitudes Questionnaire assessments are annual.

We use the clinical area (unit) to group and interpret Safety Attitudes Questionnaire results, because unit cultures within a hospital vary 6-fold more than cultures among hospitals (Bryan Sexton, PhD, personal communication, December 14, 2007). However, a unit-level focus may pose risks when assessing complex services that span multiple units or departments, such as door-to-balloon time for cardiac patients.<sup>63</sup> Nevertheless, we believe a culture of safety must initially exist within a unit. After this, organizations can address complex services by linking related units.

#### How Do You Use Safety Culture Results?

Assessment of progress toward improving safety culture involves 2 goals: Achieve or maintain a unit-level climate score of at least 60% agreement, and improve last year's climate score by 10 points or more (100-point scale). To

interpret results on a hospital or health system level, hospitals can report the percent of units above the 60% threshold. A focus on unit-level results helps hospitals recognize units that need resources or leadership support and helps health systems identify hospitals that are struggling versus those that are thriving.

#### ***How Do You “Improve” Safety Culture?***

In our experience, culture is local, and improvements must occur at the unit level. Nevertheless, our understanding of how to improve safety culture is immature, albeit growing rapidly. We developed and use the comprehensive unit-based safety program to improve safety culture.<sup>59,60</sup> Briefly, the comprehensive unit-based safety program assesses safety culture, involves staff in identifying and mitigating safety hazards, assigns a senior hospital leader to support unit-level safety activities, and provides tools to improve communication and teamwork.<sup>51,60,64–66</sup> Human factors analysis and systems designs<sup>67,68</sup> were incorporated into these programs and used in other projects such as the Systems Engineering Initiative for Patient Safety.<sup>69–71</sup>

#### **Identifying and Mitigating Hazards**

The identification and mitigation of safety hazards is an important aspect of patient safety research and practice. Efforts to identify hazards involve analysis of the healthcare system at multiple levels (unit, department, and hospital) to determine where potential or known risks of patient harm can occur. Analyses can occur retrospectively (analyze past adverse events) or prospectively (study the system or healthcare process for potential hazards).

#### ***Retrospective Identification of Hazards***

Most patient safety research involves retrospective analysis of medical errors. On a unit or departmental level (microscopic), this involves in-depth analysis of sentinel events. Analyses may be formal (eg, root-cause analysis) or informal (eg, case review by a departmental safety or quality improvement committee). The purpose of an analysis is to identify the causes and contributing factors associated with an adverse event, then plan and implement strategies to prevent the event from recurring.

We need tools to aid the in-depth analysis of sentinel events and to evaluate the efficiency and effectiveness of strategies for mitigating risks to patients. The “Learning From Defects” tool provides one way to improve the efficiency of a root-cause analysis and increases the number of events investigated and mitigated. Details of this tool have been published previously.<sup>66</sup>

More common tools that the Institute of Medicine has advocated for identifying hazards are incident reporting systems.<sup>1</sup> These systems are used at the local, hospital, and national levels (macroscopic), and they target broad or specific event types or clinical areas. For example, MEDMARX (US Pharmacopeia) collects data on medication errors in the United States, the Intensive Care Unit Safety Reporting System collects data on all events in an intensive care unit, and the National Reporting and Learning System (National Health Service) collects data on all event types across the United Kingdom.<sup>72–74</sup>

Several challenges prevent us from fully realizing the potential of incident reporting systems to improve patient safety. First, although strategies for individual case analysis are well developed, methods to analyze groups (in this case, millions) of events, especially with very messy data, do not exist. Second, strategies to help healthcare organizations prioritize where their greatest hazards lie are underdeveloped. Third, we have exerted little effort on reducing hazards; most efforts have encouraged clinicians to submit reports. Finally, we have a limited ability to evaluate reduction of risks to patients.

#### ***Prospective Identification of Hazards***

Ideally, identification of hazards in the medical system would be prospective, before patient harm occurs. Unfortunately, prospective evaluation of hazards is limited by institutional resources and a capacity to accomplish this task. Failure mode and effects analysis, currently used by the National Aeronautics and Space Administration and the automotive industry, is a tool to identify hazards prospectively<sup>75,76</sup>; however, there is limited evidence regarding the validity and reliability of using failure mode and effects analysis, or its effectiveness. Also, individual hospitals conduct few such analyses each year, because they are resource intensive.

An alternative or supplement to failure mode and effects analysis is simulation. Research using simulation to identify and mitigate hazards is growing rapidly and holds promise to help improve patient safety. For example, simulation of resuscitation during cardiac/traumatic arrest or mass casualty events frequently identifies hazards in the process of care.<sup>77</sup> Although a common approach, simulation is also resource intensive.

#### ***Mitigating Hazards***

Although state laws require institutions and governing bodies (Joint Commission) to investigate sentinel events thoroughly, whether these investigations lead to safer care for patients is unclear. Largely, these investigations tend to focus on fact-finding rather than mitigating hazards. Healthcare organizations must take this information and make concrete system changes to achieve the goal of actually making care safer. One example of a strong system change is the pin-index system, which prevents clinicians from misconnecting oxygen and nitrous oxide, a potentially lethal mistake.<sup>78</sup> Efforts to evaluate the extent of risk reduction from other system changes are virtually nonexistent.<sup>66</sup>

#### **Evaluating the Association Between Organizational Characteristics and Clinical Outcomes**

Organizational concepts and characteristics play into many pieces of the research framework presented here (Table 3). Some of these pieces include how to translate evidence into practice; what resources to dedicate toward improvement efforts; and how to mistake-proof day-to-day operations. In health care and elsewhere, the purpose of an organization is to align and coordinate the work and personal goals of job roles and people to achieve the organization’s mission. In fact, social and structural characteristics of the work setting strongly influence employee behavior (sometimes enabling, sometimes constraining).

**Table 3. Variables to Consider When Evaluating the Association Between Organizational Characteristics and Patient Safety**

Level of Organization	Organizational Topics
World Health Organization	Social networks among nations/international societies and organizations
Nation/national societies or groups	Mechanisms for organizational learning
State hospital association	Identification of the locus of most reliable safety improvement State regulations and resources implementing, sustaining, and disseminating QI efforts
Hospital	Effective leadership for quality improvement Spreading quality improvement to other units
Unit	Perception of unit-level safety climate and teamwork Sustainability of interventions
Quality improvement team	Team effectiveness
Individual healthcare provider	Motivation to implement quality improvement
Patients	Structural inputs to patient-centered care

Important organizational variables that can affect patient outcomes include organization-wide culture; organizational design; policies, procedures, and requirements; rewards and incentives; readiness to change and orientation toward quality improvement, reliability, and patient-centeredness; monetary resources, staffing, infrastructure, and management of operations; formal and informal communication networks within and outside the organization; and skills, knowledge, and dedication of leaders. These variables may be important for organizational resiliency and the ability to succeed and sustain quality improvement efforts.<sup>63</sup>

Even the basic drive of the organization to perpetuate itself and expand could affect patient safety (eg, unit disruption from reorganization). These effects may operate directly on patient outcomes or, more often, act through the performance of staff members who directly interact with patients.

There are a number of methodological hurdles to understanding the association between healthcare organizational characteristics and patient safety. First, valid measures of patient safety are difficult to obtain. Second, many organizational variables lack a standardized definition, which could introduce misclassification and measurement bias. For example, there is wide variation in hospital and unit definitions of nurse turnover that limit our ability to evaluate the association between safety culture and nurse turnover.

### Challenges for Patient Safety Research

The framework we present is intended to be practical and to apply to both researchers and healthcare organizations working to improve patient safety. Nevertheless, significant challenges remain for patient safety research and improvement efforts. These include the need to build capacity among

researchers, create a research infrastructure, and evaluate the cost-benefit ratio of safety improvement efforts.

### Build Capacity

Given the magnitude of the patient safety problem, the number of researchers with the knowledge and skill (technical and adaptive) needed to improve patient safety is shockingly small. To build capacity in patient safety research, we need to provide trainees with formal coursework in research methods, mentorship, and a structured research experience. Trainees are encouraged to obtain a formal master’s or doctoral degree in their area of expertise. Although this is most commonly public health, it also includes biostatistics, informatics, economics, sociology, and psychology, among others.

Well-designed programs, such as K-awards, exist for basic and clinical researchers, but there are few career development awards in patient safety. Although day-long or week-long patient safety seminars may provide concepts for improvement, they do not provide the evaluation skills necessary to advance this field. In addition to building capacity in technical skills, we also need to build capacity in communication and teamwork skills (adaptive). To accomplish this, we hold seminars and coaching sessions on effective communication, including how to change communication styles to suit the audience (eg, scientists versus hospital administrators).

### Create Research Infrastructure

Another challenge is creating an organizational structure to link the multitude of clinical and methodological disciplines needed to conduct patient safety research. The goal is to create a research structure that allows clinicians to connect with methodologists and vice versa. To accomplish this, we hold weekly research meetings to bring together clinical (eg, surgery) and methodological (eg, epidemiology) disciplines, similar to a mixing bowl in which required ingredients are added. When discussing a project that requires a particular discipline, we invite experts to join the meeting. The goal is to develop the most scientifically sound yet feasible interventions by obtaining diverse and broad input on projects.

### Evaluate the Cost-Benefit Ratio of Improvement Efforts

Efforts to improve patient safety require resources; at some point, the economics will just not be feasible. For example, we can improve safety by placing an intensivist and a nurse at the bedside of every patient.<sup>79–81</sup> However, even if we could hire these clinicians, it would not be feasible for a hospital. Researchers need to articulate the costs and benefits of safety interventions so senior hospital leaders and regulators can make informed decisions before implementing or mandating a safe practice. To date, economic evaluations of patient safety efforts have been rare. National policy or accrediting body mandates (eg, Joint Commission national patient safety goals) should require balanced consideration of evidence regarding benefits and costs of proposed interventions. Defining the balance is an important research topic.

### Summary

Efforts to improve patient safety have become an international priority in health care. Despite focused efforts, patient



**Table 4. Future Directions**

## Recommendations

1. Develop valid measures to evaluate patient safety progress.
2. Develop methods to reliably translate evidence into practice; garner funding from federal government and insurers.
3. Study the link between culture, behaviors, and patient outcomes.<sup>82</sup>
4. Evaluate teamwork and leadership behaviors.
5. Use simulation to:
  - evaluate teamwork and technical work
  - train staff to translate evidence into practice
  - identify and mitigate hazards
6. Coordinate national-level efforts to investigate and implement industry-wide changes (eg, Commercial Aviation Safety Teams).
7. Explore ways to efficiently and effectively use patient safety resources at the unit, department, hospital, and health system levels.
8. Advance the science of how to measure and reduce diagnostic errors in health care.
9. Develop patient safety measures that provide a more comprehensive view of the safety and quality in a product line (eg, cardiac surgery).

safety is still a nascent science. This framework provides a scientifically sound yet feasible approach to evaluate progress in patient safety, a model to guide translation of evidence into practice, a method to assess and improve culture, a dialogue for identifying and mitigating hazards, and a connection between specific organizational characteristics and patient safety outcomes. In Table 4, we suggest future directions to help patient safety improvement efforts progress.

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## Framework for Patient Safety Research and Improvement

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