

# Risk-Based Patient Safety Metrics

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## Abstract

Patient safety programs require meaningful metrics. Dominant frameworks are based on two safety metrics: one that seeks to identify, measure, and eliminate error and one that seeks to identify, measure, and eliminate injuries. However, non-health care safety programs suggest a third framework, hazard- or risk-based measurement. Error measurement has many limitations, including the issues of error identification, hindsight bias, outcome-based judgment, and reinforcement of blame. Although injury-based metrics might aid the prevention of harm, limitations include poor discrimination of preventability, resulting in misdirected interventions, missed opportunities, and disregard for the systems-based nature of unsafe health care. In contrast, work in safety science allows for a third framework: risk-based patient safety metrics that are consistent with systems thinking in health care. These metrics focus on identifying the underlying hazards or risks in the system that ultimately lead to errors and injuries. In this article we explore the strengths and limitations of these frameworks and describe a practical application of risk-based patient safety metrics.

## Introduction

A valid, reliable, and usable system of metrics is integral to any patient safety program. Data related to patient safety can be used for a range of purposes, including the selection of improvement initiatives, measurement of the success of safety improvement efforts, enhanced transparency by public reporting, organizational accreditation, and even contracting and reimbursement. With the increase in patient safety data applications, the importance of the data has increased commensurately.

Several data attributes should be considered in the context of patient safety metrics. First, are the data feasible to collect? Are the collected data reliable and valid? Do the data support their intended use? What is the rationale for using a given patient safety metric? It is the rationale for using a given patient safety metric that underlies the focus of this article. The mere creation or use of patient safety measures does not assure that they will be useful for improving safety and reducing harm. Even worse, invalid measures can lead to poor decisionmaking, whereas measures that do not lead to safety improvements can be viewed as lost opportunity costs.

The two dominant frameworks for patient safety metrics focus on measurement of errors and measurement of injuries.<sup>1, 2</sup> While arguably there is a role for including both of these frameworks, a third model—i.e., metrics focused on hazards or risks—is based on safety science and human factors engineering.<sup>3</sup>

The following discussion explores the strengths and limitations of these frameworks with practical suggestions for the range of patient safety data consumers.

## **Error-Based Patient Safety Metrics**

The work of James Reason and others has clearly identified the role of errors in preventable harm to patients. In the context of patient safety, errors are defined as a failure of a planned action to be completed as intended—i.e., an error of execution—or the use of a wrong plan to achieve an aim —i.e., an error of planning.<sup>4, 5, 6</sup> These definitions are based on the premise that the goal of health care is to successfully execute the correct plan of care for any given patient. Thus, error-based metrics seek to identify deviations from this health care goal.

The measurement of errors in health care might appear like a reasonable means of assessing safety. First, errors in the delivery of health care are common. Studies of both pediatric and adult populations reveal that medication errors occur in 3.0 to 6.9 percent of inpatients.<sup>7, 8, 9, 10, 11, 12</sup> The relatively high frequency of errors leads to a second potential advantage of measuring errors in health care: errors seem easy to identify and measure. Finally, errors can guide improvements. If errors are the source of unsafe health care, then one needs to prevent the errors.

There are, however, significant limitations inherent in efforts to measure errors. One of the important limitations is the inability to create a meaningful metric or rate. To have a rate that is valid, reliable, and ultimately meaningful, both a numerator and denominator are necessary. In the context of errors, denominators are not necessarily problematic. Medication error rates might utilize denominators of patient days, number of medications dispensed, or number of patient admissions. However, it is entirely possible that an appropriate denominator might not be readily available for calculating an error rate. For instance, any attempt to measure the error rate in infusion pump programming requires a choice between potential denominators, including number of medications infused, number of pumps programmed, number of programmers involved, number of steps in programming process, or even the number of key punches involved in programming.

A greater limitation of error rates in patient safety is the inability to identify a valid and reliable numerator. If an error rate is:

| <b>Identified errors</b>                               |
|--|
| <b>Potential opportunities for that error to occur</b> |

then, the numerator is only as valid and reliable as the means of identification. Unfortunately, there is no valid and reliable means for identifying all errors.

Voluntarily reported events provide one means of identifying errors as a potential numerator. Yet, reported events, by definition, reflect only those events that individuals recognized as an error and then reported. Errors could go unrecognized, particularly by the person committing the error.<sup>13, 14, 15</sup> Reporting itself depends on the ease of use of a reporting system, the organizational culture and its attitude toward reporting of errors (including any consequences of reporting), and the competing demands on a potential reporter.<sup>16</sup> For example, nurses with multiple patient care demands might not realistically have time to report, independent of her/his belief in the importance of reporting.

Cultural issues are also critical to reporting rates. The fear of reprisal or legal action might lead to underreporting.<sup>17, 18</sup> Subsequently, any error metric that used reported events as a numerator would therefore be a rate of reporting and not a true rate of medical error occurrence.<sup>16</sup>

Two other means of identifying errors in health care have been described in the health care setting, although typically, these methods are limited to detecting medication errors and not other types of health care delivery errors: chart review and direct observation of the provision of care in different settings. Chart review has been used in a number of studies to identify errors as a numerator. In order for chart review to identify all errors, the following sequence of events must occur:

**Error occurs**

- Every error is recognized by a health care provider.
- Every error is documented by the provider.
- Chart in which errors were documented is reviewed.
- Reviewer recognizes each documented event during review.
- Error is attributed correctly.

The need for each of these additional steps to occur perfectly makes it less likely that chart review would provide a true numerator to establish an error rate.

Error identification by means of direct observation of health care workers has been reported as successful.<sup>19</sup> Similar to error identification through chart review, correct determination of a numerator of error rates through direct observation is contingent on another sequence of events:

**Error occurs**

- Every error occurrence during the observation period is witnessed by an observer.
- All errors are recognized by the observer as errors.
- Observer correctly attributes event as error.

The limited likelihood of absolute ascertainment of errors through direct observation suggests this method is also incapable of establishing a true numerator for error rates.

Two important findings have been made when reporting events and chart reviews, and direct observations of the medication process have been compared. First, the different techniques seemed to yield different results based on the phase of the medication process that was being measured.<sup>20, 21, 22</sup> Second, the events found by reporting, chart review, and direct observation appeared to be complementary, rather than redundant.

Ultimately, no valid or reliable method for establishing error rates is available in most health care settings. Therefore, patient safety programs that leverage error rates as their principal safety metric are operating on flawed data that could lead to incorrect prioritization of safety improvement efforts.

Multiple issues are associated with error-based metrics. “Hindsight bias” leads to simplified attributions of the cause of errors.<sup>23, 24</sup> Furthermore, incorrect or inadequate attribution of causality may create the potential for misguided actions to “solve” the wrong problem, resulting in more complicated and less safe systems.<sup>25</sup> This might result in what Cook has called the

“cycle of error,” or the medical equivalent of the arcade game “whack-a-mole”——events occur, inadequate evaluation leads to incorrect actions, which gives the misperception of fixing a problem until a new event, potentially created by the actions, pops up in a new setting.<sup>23</sup>

Steps can be taken to minimize hindsight bias, and there are positive benefits of this phenomenon in adaptive learning.<sup>24</sup> However, the use of retrospective analyses colored by hindsight could inadvertently increase a system’s complexity. As a result, “improvements” intended to decrease the risk of patient harm might only prevent the same adverse event from recurring, rather than improving overall system safety.

Another limitation of error-based metrics is “judgment based on the outcome of the events.” The perception of a sequence of events associated with the administration of anesthesia can be significantly influenced by the outcome of the case, regardless of the actual actions and judgments of the provider.<sup>26</sup> The fact that knowledge of an outcome might influence evaluations of the quality of a decision has very real implications for identifying errors as potential metrics.<sup>24</sup>

Another major limitation of error-based metrics is the emphasis on the performance of individuals without consideration of the larger system in which care is provided. As illustrated by the Systems Engineering Initiative in Patient Safety (SEIPS) model for systems in health care, providers are merely one of five systems elements.<sup>27</sup> Providers (1) attempt to perform tasks (2) using tools and technology (3) in a given environment (4) within the larger context of an organization (5). Any system outcome, whether it is an error or safe care, results from the performance of and interaction between the five system elements, and not solely the performance of the provider. Although an error may be proximally associated with an individual clinician, organizational factors create the circumstances in which the failure occurred.<sup>25</sup> These organizational factors have been identified as latent errors that foster an environment in which an active error is more likely to occur.<sup>28, 29</sup>

Error-based metrics can also be influenced by the psychological concept of attribution theory.<sup>30</sup> Well known biases, such as the self serving bias and fundamental attribution error, make it more likely that those in power are likely to blame the clinician on the “sharp end” when patient harm or an error occurs. At the same time, the clinician on the “sharp end” tends to blame the situation or circumstances surrounding the event.<sup>31</sup> Despite any disclaimer that unsafe health care is a “systems problem” of care delivery, the tendency to blame people for errors underscores a final reason why patient safety programs should move beyond a pure focus on error-based metrics.<sup>3</sup>

Finally, any discussion of error-based metrics would be incomplete without recognizing that the concept of “human error” is socially constructed and, therefore, may not be meaningful in many circumstances.<sup>32</sup> Indeed, people attribute causes of unwanted outcomes to “human error,” and people make such attributions with all of their biases and under different kinds of pressures. Therefore, calling something “human error” or “error” might not be factually meaningful. Full exploration of this perspective is beyond the scope of this article, but interestingly, it has led some safety scholars to call for “ditching human error.”<sup>33, 34</sup>

Despite these limitations, the identification of errors does hold value for a patient safety program. Identified errors can serve several important roles. First, trends in reported events, while not valid as rates of event occurrence, are a potential reflection of an organization’s patient safety

culture. Second, identified errors are learning opportunities that might allow for intervention prior to future harm to patients. It should be noted that even if a given hospital chooses to focus on error-based metrics in the face of the discussed limitations, the National Coordinating Council for Medication Error Reporting and Prevention issued a formal statement that there is no value in using error rates to compare hospitals and health care organizations.<sup>35</sup>

## **Injury-Based Patient Safety Metrics**

The second major framework for patient safety metrics focuses on patient injuries. It has been argued that because errors and harm are often unrelated in a cause-effect manner, a patient safety program should focus on the elimination of harm.<sup>1</sup>

Several organizations have proposed indicators that are intended to identify injuries. Following administrative database analysis, the Agency for Healthcare Research and Quality (AHRQ) put forth a set of potential in-hospital complications that might represent patient safety events.<sup>36</sup> Similarly, the Institute for Healthcare Improvement's *100K Lives Campaign* focused specifically on strategies to reduce the incidence of specific patient injuries, including in-hospital cardiac arrest, acute myocardial infarction, adverse drug events, surgical site infection, central venous line infection, and ventilator-associated pneumonia.<sup>37</sup>

The goal of eliminating patient injuries makes injury-based metrics very attractive to a patient safety program. However, injury-based patient safety measures are not without shortcomings. By definition, identification, measurement, and analysis of injuries are reactive, taking place after an injury occurs. Consequently, they are subject to the same limitations as error-based patient safety metrics, including hindsight bias, incorrect attribution, blaming, and failure to consider the complexities of systems.

Additionally, not all patient harm is preventable. Unless a tool for identifying injuries is highly predictive for preventable events, resources might be spent identifying, analyzing, and trying to eliminate unpreventable injuries. There is scant literature on the positive predictive value of widely used injury-based measures, such as the AHRQ Patient Safety Indicators (PSIs). Study of these measures in a pediatric population led to AHRQ eliminating several measures from use in children and modifying other of the remaining measures.<sup>38</sup> These shortcomings illustrate an unintended consequence of injury-based metrics, which include events that are not preventable and thus not affected by improvement. In light of the pay-for-performance movement, evaluating hospitals by injury-based metrics—which include false-positive events—may cost the hospitals reimbursement dollars and lead them to misdirect improvement efforts, resulting in lost opportunity costs. For instance, if an injury-based metric identifies a falsely high rate of decubitus ulcers at a hospital, planned changes to Medicare reimbursement would have direct negative influence through incorrectly lowered payments.<sup>39</sup>

The risk to health care providers resulting from the use of injury-based metrics and pay-for-performance reinforces the problem of incorrect attribution of causation. The identification of many of these events depends on documentation and hospital coding in administrative data sets. Therefore, a hospital might admit a patient, preventable harm might occur, and then the patient might be discharged without accurate documentation and coding to reflect the harm event. If this patient were either transferred or admitted to a second hospital that correctly identified the event,

it would be this second hospital that would receive “credit” for causing harm. This limitation of incorrect attribution may disappear since Medicare has implemented a new billing form, the UB-04, to replace the prior UB-92 form and, with this change, a “Present on Admission” indicator has been added.<sup>40</sup> However, until this change in coding practices is fully implemented, hospitals that accept patients from other care facilities are at risk for having harm to patients incorrectly attributed to them.

These issues of false-positive/false-negative identification and incorrect attribution of causality potentially undermines the value of using injuries as a patient safety metric. Ideally, a patient safety program would use injury-based metrics to calculate an injury rate that could be trended. That rate would be:

$$\frac{\text{Identified injuries}}{\text{Potential opportunities for those injuries to occur}}$$

As with error measures, correct identification of injuries as a numerator may be inherently problematic. Similarly, defining potential opportunities as a reliable denominator may be challenging. Thus, changes in the rate might reflect true changes in the rate of injury occurrence or simply changes in the way the numerator or denominator are collected. The potential lost opportunity costs and inappropriately lower reimbursement under a pay-for-performance system illustrate very practical concerns about the value of injury-based metrics to a patient safety program.

The final criticism of measuring patient harm as a primary metric for patient safety efforts might be viewed as philosophical in nature. By design, the measurement of injuries requires that before anything can be measured and improved, a patient must first be injured. Medical injury is very much a reality in health care, but it is worth raising the question as to whether health care metrics should be based on waiting for harm to occur, rather than attempting to proactively prevent patient injury.

Despite the numerous limitations, the desire to eliminate preventable harm to patients reinforces the need to understand the limitations of injury-based metrics while still learning from injuries. A strategy that couples the improvement opportunities identified by error-based metrics with those identified with injury-based metrics might outweigh the limitations inherent to either method.

## **Hazard- or Risk-Based Patient Safety Metrics**

The term “risk” is used widely in health care. When obtaining informed consent for a procedure, risks may be presented as the chance of undesirable outcomes during the procedure. Risk ratios are used in epidemiology and medical literature to represent the likelihood of a disease or event occurring relative to an exposure. For instance, the risk of a central venous line-associated infection can be presented relative to whether sterile procedure was used during placement. Risk management is an intrinsic part of hospitals and health care organizations, although traditionally its focus has been on protecting organizations from financial loss.<sup>41, 42</sup> However, with a few notable exceptions, the concept of risk and risk-based metrics as understood by human factors engineers and safety scientists remains relatively unexplored in the specific context of patient safety.<sup>3, 43, 44</sup>

The lack of explicit recognition of risk in the context of patient safety does not mean examples are not available. One example that has been identified in both the medical and popular literature relates to central venous line-associated bloodstream infections (CVL BSI).<sup>45, 46</sup> These infections are costly, common, and result in significant harm, lending themselves to a potential injury metric. Historically, CVL BSIs were viewed as largely unpreventable, although a handful of interventions were known to decrease the risk of infection. By treating failure of compliance with these interventions as a risk factor for infections and by implementing a checklist to drive compliance with this “central line bundle,” significant reduction of CVL BSIs has been achieved.<sup>46, 47</sup>

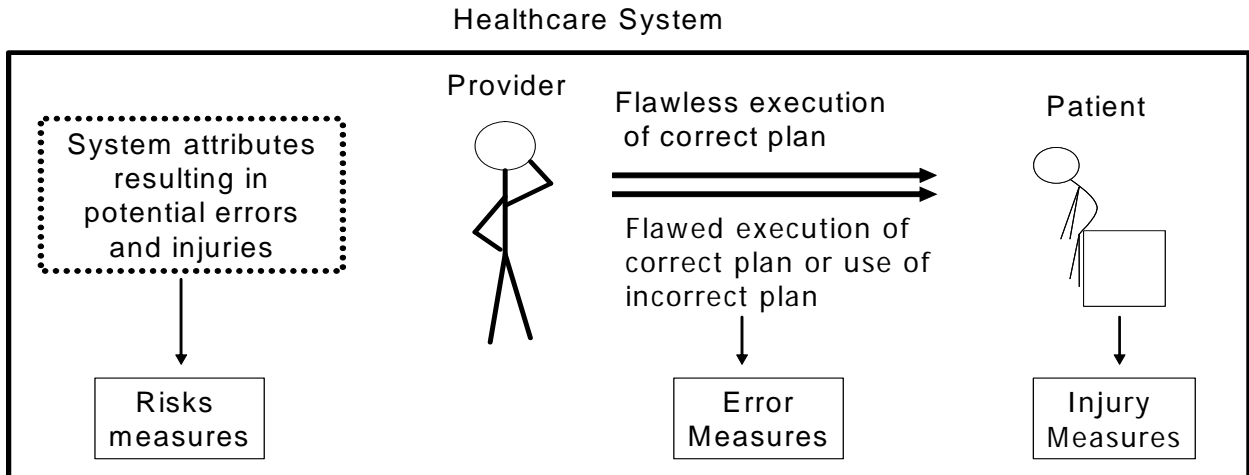
Many other known patient safety errors and injuries can be reframed similarly in terms of risks. Other hospital-acquired infections result from lack of proper hand hygiene. Thus, poor hand hygiene is a patient safety risk factor that can be reduced with a resultant decrease in infections. Wrong site surgeries are known to be preventable through use of the universal protocol.<sup>48</sup> Failure to comply with this protocol is a recognizable yet preventable risk; compliance, on the other hand, can reduce or prevent harm.

Outside of health care, safety risk factors are called hazards<sup>49, 50</sup> or the causes of, or circumstances leading to, unwanted outcomes, not the unwanted outcomes themselves (e.g., error or injury). The hazard identification and control approach is the preferred safety approach in non-health care safety programs, with injury surveillance as an important and complementary component. Although not typically viewed from this perspective, health care situations readily lend themselves to a similar risk identification and control approach.

Hazard identification and control is the basis for safety planning procedures for manufacturing. These procedures state, “The design phase of the proposed ISO (1991) safety strategy includes: (1) specification of the limits of parameters of the system, (2) application of a safety strategy, (3) identifications of hazards, (4) assessment of the associated risk, and (5) removal of the hazards or limitations of the risk, as much as practicable.”<sup>51</sup>

According to the U.S. Occupational Safety and Health Administration (OSHA), which enforces employee health and safety regulations for all industries, including health care, a successful safety program has four components: (1) management leadership and employee involvement, (2) worksite analysis, (3) hazard prevention and control, and (4) safety and health training. Regarding hazard prevention and control, OSHA states, “Management must provide the resources and authority so all personnel can find the hazards in the worksite and, once found, to eliminate or to control those hazards.”<sup>52</sup> Applying these approaches to a health care context, it follows that systematic efforts to identify risk of harm, assess these risks and, whenever possible, eliminate or reduce these risks are a necessary activity for patient safety programs.

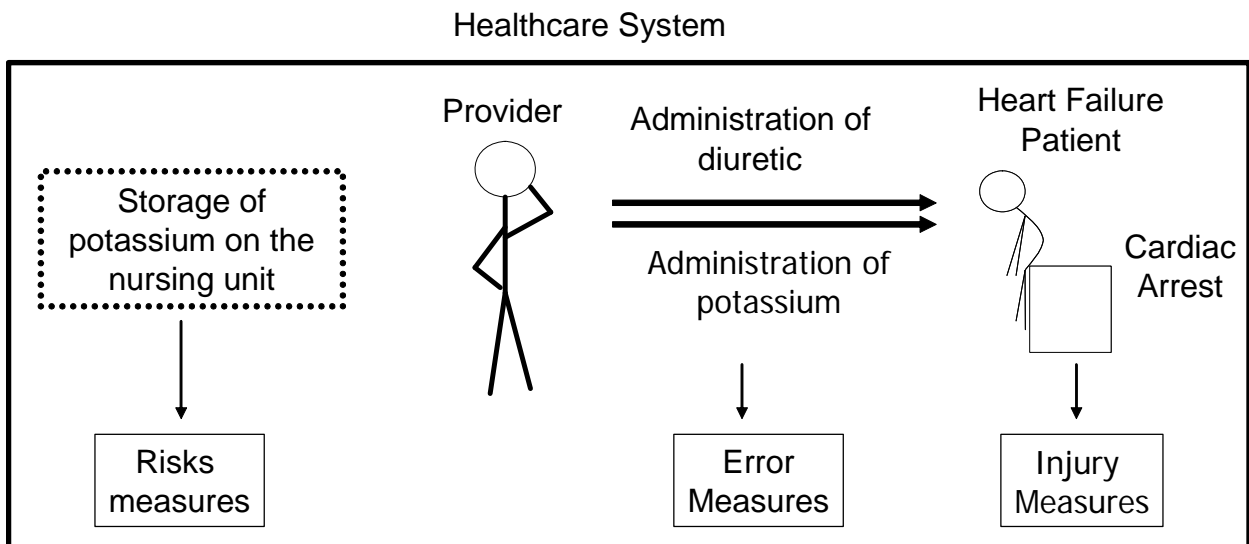
As previously mentioned, the concept of identifying risks in health care with subsequent design or redesign is not new to the patient safety literature. Prior publications have focused on the need to leverage these concepts of hazard and risk to achieve sustainable safety improvements.<sup>3, 53</sup> To fully understand these concepts, it is helpful to frame errors, injuries, and risks in the context of health care systems (Figure 1). Both errors and injuries are possible outcomes of the performance of, and interactions between, the five aforementioned systems elements. That is, while a provider attempts to perform a task using tools and technology in a given health care environment within



**Figure 1.** Error, injury, and risk measures in the context of health care systems.

the larger context of an organization, the provider might commit an error that, in some circumstances, causes an injury to a patient.

Another clinical example that illustrates the relationship between systems, risks, errors, and injuries is the use of concentrated potassium on patient care units (Figure 2). A nurse might be directed to administer a diuretic to a patient who is in congestive heart failure on a medical unit. While attempting to obtain the dose of diuretic, the nurse might inadvertently obtain a dose of potassium chloride. Administration of this potentially lethal electrolyte could lead to a life threatening cardiac arrhythmia and cardiac arrest. In this scenario, a specific error might be measured—i.e., incorrectly obtaining and administering potassium chloride rather than a diuretic. Additionally, an injury occurred that might be measured—i.e., the cardiac arrest. However,



**Figure 2.** Clinical illustration of systems, errors, injuries, and risks.



patients with congestive heart failure may experience a cardiac arrest independent of medication dosing, and thus, the injury might not ever be correctly associated with the preceding error. Similarly, not every administered dose of potassium chloride will necessarily lead to an arrest. Thus, the error might occur and go undiscovered and unmeasured.

Central to this clinical scenario is the fact that the storage of concentrated potassium on patient care units presents a potential danger to patients, independent of whether a given hospital experiences and identifies a medication error of this nature and the resultant patient injury. That is, the design of a system of health care delivery that results in the storage of potassium on patient care units creates a potentially preventable risk that could be identified, analyzed, and eliminated, regardless of whether a hospital ever experienced either potassium-related errors or injuries.

A shift “upstream” from injuries and errors to safety risk factors (i.e., hazards) provides an alternative rate to the error and injury rates described previously. The risk-based metrics become:

$$\frac{\text{Assessed risks}}{\text{Identified risks}} \quad \text{and} \quad \frac{\text{Eliminated risks}}{\text{Assessed risks}} \quad \text{resulting in} \quad \frac{\text{Eliminated risks}}{\text{Identified risks}}$$

In the first statement, the denominator is limited only by identification of risks that are relevant to that organization. The numerator is clearer relative to those in error and injury rates. Either a risk has been assessed or not. In the second statement, all assessed risks become the denominator, with a numerator consisting of those assessed risks that have been eliminated. For the sake of simplicity, the first two statements can be combined to create the simple metric of eliminated risks over identified risks at a given health care organization.

Consistent with the limitations of error and injury rates, the denominators in these risk relationships are subject to the limitations of any discovery process used by a patient safety program and, therefore, will never represent all potential risks. The intent of this metric is different from those of errors or injuries. In the case of errors and injuries, the previously discussed metrics are attempts to reflect all errors or harm in a hospital. In the case of the proposed risk metric, the fact that the denominator is “identified risks” clearly suggests that there are other unknown risks. Rather than attempting to represent all risks, this measure instead emphasizes the need to first understand and then eliminate risks in a proactive manner.

Multiple potential implications are involved in adopting such a risk-based metric. First, in keeping with OSHA safety guidelines, organizations are charged with identifying and assessing potential risks. The identification of risks can be accomplished by use of a wide range of data sources. Errors—whether identified by report, chart review, and/or observation—can provide information on potential organizational risks. This is particularly true of “near-miss” and “no-harm” errors, which do not cause harm and yet might herald significant potential harm to patients. Identified injuries also become a source of risk identification, regardless of whether or not the injury is preventable. In using errors and injuries as sources for identifying risk, the rates of errors and injuries are irrelevant. Instead, in keeping with the work of Woods and Cook,<sup>43</sup> the stories behind errors and injuries can be explored with the intent of finding underlying risks.

Other potential sources of risk identification include the published literature, alerts of sentinel events, medical device recalls, and even anecdotal reports from colleagues. One potential source heavily leveraged in non-health care industries is the safety inspection by a safety expert.<sup>49, 50</sup> In other industries, safety and human factors engineers are routinely employed, and part of their job is to conduct periodic and formal hazard inspections, in which the goal is to identify hazards or risk factors for error and injury (e.g., potassium chloride on the unit or a difficult-to-navigate barcoded medication administration system). Health care delivery organizations have yet to embrace such a model.

Risk-based patient safety metrics also have other implications. Adoption of a risk-based metric shifts the focus from reactively evaluating errors and injuries (with all their associated limitations) to proactively seeking out and evaluating risks that might exist. Another implication is the potential value of involving frontline staff who could become part of the process for proactively looking for potential risks.<sup>54</sup> This strategy requires no education of employees of error taxonomies or classification systems of injury severity. At the level of senior management and leadership, using risk-based metrics has a potential psychological benefit. By their nature, the risk-based metrics have a positive connotation; the numerator represents positive acts that have ideally resulted in enhanced safety through the elimination of risk. In contrast, both error- and injury-based metrics essentially provide a count of organizational failures. It is not a great leap to imagine leaders who might value a metric emphasizing and reinforcing improvement over one that provides a reminder of system failures. In turn, shifting any culture of blame to one more consistent with high-reliability organizations has at least a hypothetical benefit.<sup>55</sup>

In each case, an organization can assess each identified potential risk for its relevance to their institution. This assessment might require additional data collection to verify whether the risk exists in the health care delivery setting, as in the case of determining whether a national infusion pump recall is a viable risk to their organization. Additionally, this assessment would likely require the involvement of clinical content experts. In the case of public reports of a type of bacterial infection outbreak in newborn nurseries, the clinical content experts might include infectious disease experts, neonatologists, and infection control specialists. In the case of a medication recall, the content experts might be the ambulatory clinic manager and clinic staff charged with tracking medication samples. Without the involvement of the clinical content experts, an organization might incorrectly determine that a specific risk was present. If a risk did not exist, the organization would have no further action to take beyond periodic surveillance to assure that the risk is not introduced later.

When a risk has been identified and assessed to be relevant to a health care organization, then the next step is elimination of the risk. The science of safety improvement is beyond the scope of this discussion. However, the human factors literature clearly indicates the need to design solutions into the care delivery system to achieve sustained elimination of risks.<sup>3, 53</sup> Although redesigning health care delivery systems is no small undertaking, a patient safety program that incorporated a risk-based approach to measuring and improving safety would be consistent with the existing safety science used in non-health care industries.

A risk-based framework might be nearly universal outside health care, but evidence that it has been attempted in health care is limited. As a result, the conventional wisdom of focusing on errors and/or injuries might win out over what could be viewed as a theoretical argument for

broadening the approach to address risks. However, one illustration of the benefit of systematically focusing on hazards or risk has been published.<sup>54</sup> In this study, the use of a traditional incident reporting system over 5 years yielded a total of 200 reported events, all of which came from nursing. In contrast, a system of identifying hazards (safety risk factors) on the same study units resulted in 359 reports in 12 weeks. At the same time, the range of types of problems reported using the hazard-based system increased significantly, with much greater physician involvement: zero physician reports of incidents during the 5-year period, compared with 29 percent physician reports when the system was changed to a hazard-reporting system. Although generating more reports was not the goal *per se*, the incorporation of a risk-based framework led to greater proactive identification of problems in their hospitals, which in turn, by preventing future harm, allowed for a positive effect.

## **Additional Applications of Risk-Based Patient Safety Metrics**

The proposal of using risk-based patient safety metrics is entirely consistent with learning from identified errors and focusing on the elimination of injuries. As described, a patient safety program that adopts a risk-based approach is also consistent with the science of human factors. However, there are additional potential applications for an organization that adopts a patient safety framework centered on the identification, assessment, and reduction of risk.

One practical application of adopting a risk-based framework is the refocusing of all patient safety activities. Specifically, the primary functions of a patient safety program then become:

1. Identifying risks.
2. Assessing risk through analysis and clinical interpretation.
3. Reducing and eliminating risk through a range of efforts.

Any activity undertaken by the patient safety program can be evaluated in light of these three functions. Education of staff and patients is entirely consistent with risk identification and reduction. Noncompliance with accreditation requirements, such as the Joint Commission's National Patient Safety Goals or the Leapfrog criteria, is also an organizational risk. Thus, assessment of a hospital's performance relative to these goals and steps to correct any deficiencies are entirely consistent with the risk-based framework.

A second practical application of the risk-based approach to a patient safety program is the implementation of patient safety competencies among hospital staff and physicians. A set of patient safety competencies that has been introduced at multiple organizations reinforces the risk-based framework (Personal communication, Nancy Kimmel, PharmD, March 2004). The competencies include: (1) report what you find; (2) fix what you can; and (3) communicate to your supervisor those things you cannot fix.

Essentially, health care staff are encouraged to actively seek out potential risks, even though those risks might not have led as yet to an error or injury; communicate the risks; and eliminate them whenever possible. The competencies can be readily evaluated as part of employee performance review, simply through statements such as, "Tell me about something you reported in the last 3 months"; or "Tell me about a time when you fixed a risk to patients, families, or employees." The continual reinforcement of this process of risk identification, assessment, and

reduction at the individual employee level arguably is consistent with high-reliability organizations.

A final application or benefit of risk-based metrics is reinforcing the alignment between patient safety, risk management, and quality activities at an organization. The coordination of safety, risk management, and quality activities might be unclear within any given health care organization.<sup>56</sup> A patient safety program built around identifying, assessing, and eliminating risks is consistent with existing models of quality improvement and might result in more efficient use of organizational resources.

## Conclusion

The practice of patient safety improvement has evolved significantly over the last decade. This evolution reflects both primary patient safety research in the health care setting and a growing appreciation for safety science developed in non-health care settings. In turn, the health care community has applied safety research findings from health care and non-health care settings through changes in care delivery and the introduction of patient safety-oriented technologies. Arguably, sufficient evidence is available to merit similar advancements in the practice of patient safety metrics, with a move beyond reactive measures of systems outcomes (i.e., errors and injuries) to measures of systems risks that ultimately cause the undesirable systems outcomes.

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## References

1. Layde PM, Cortes LM, Teret SP, et al. Patient safety efforts should focus on medical injuries. *JAMA* 2002; 287: 1993-1997.
2. McNutt RA, Abrams R, Aron DC. Patient safety efforts should focus on medical errors. *JAMA* 2002; 287: 1997-2001.
3. Karsh B, Holden RJ, Alper SJ, et al. A human factors engineering paradigm for patient safety – designing to support the performance of the health care professional. *Qual Saf Health Care* 2006; 15(Suppl I): i59-i65.
4. Reason J. *Human error*. New York: Cambridge University Press; 1990.
5. Reason J. Human error: Models and management. *Br Med J* 2000; 320: 768-770.

6. Reason J. Beyond the organisational accident: The need for "error wisdom" on the frontline. *Qual Saf Health Care* 2004; 13: 28-33.
7. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991; 324: 370-376.
8. Dean BD, Allan EL, Barber ND, et al. Comparison of medication errors in an American and British hospital. *Am J Hosp Pharm* 1995; 52: 2543-2549.
9. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997; 277: 312-317.
10. Bates DW, Boyle DL, Vander VM, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *JAMA* 1995; 274: 29-34.
11. Nelson KM, Talbert RL. Drug-related hospital admissions. *Pharmacotherapy* 1996; 16: 701-707.
12. Folli HL, Poole RL, Benitz WE, et al. Medication error prevention by clinical pharmacists in two children's hospitals. *Pediatrics* 1987; 79: 718-722.
13. Blavier A, Rouy E, Nyssen A-S, et al. Prospective issues for error detection. *Ergonomics* 2005; 48: 758-781.
14. Kanse L, Van der Schaaf TW, Vrijland ND et al. Error recovery in a hospital pharmacy. *Ergonomics* 2006; 49: 503-516.
15. Kontogiannis T. User strategies in recovering from error in man-machine systems. *Safety Sci* 1999; 32: 49-68.
16. Holden RJ, Karsh B. A review of medical error reporting system design considerations and a proposed cross-level system research framework. *Hum Factors* 2007; 49: 257-276.
17. Wu AW, Folkman S, McPhee SJ, et al. Do house officers learn from their mistakes? *JAMA* 1991; 265: 2089-2094.
18. Hobgood C, Weiner B, Tamayo-Sarver JH. Medical error identification, disclosure, and reporting: Do emergency medicine provider groups differ? *Acad Emerg Med* 2006; 13: 443-451.
19. Barker KN, Flynn EA, Pepper GA, et al. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002; 163: 1897-1903.
20. Barker KN, McConnel WE. The problems of detecting medication errors in hospitals. *Am J Hosp Pharm* 1962; 19: 360-369.
21. Shannon RC, De Muth JE. Comparison of medication error detection methods in the long term care facility. *Consult Pharm* 1987; 2:148-151.
22. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm* 2002; 59: 436-446.
23. Cook RI. A brief look at the new look at complex system failure, error, safety, and resilience. Chicago, IL: Cognitive Technologies Laboratory; 2005. Available at [ctlab.org/documents/BriefLookAtTheNewLookVerAA.doc.pdf](http://ctlab.org/documents/BriefLookAtTheNewLookVerAA.doc.pdf). Accessed March 25, 2008.
24. Henriksen K, Kaplan H. Hindsight bias, outcome knowledge and adaptive learning. *Qual Saf Health Care* 2003; 12: 46-50.
25. Karsh B, Brown R. The impact of organizational hierarchies on the design and analysis of medical error research. *Proceedings of Human Factors in Organizational Design and Management-VIII*; Santa Monica, CA: IEA Press; 2005. p. 293-298.
26. Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. *JAMA* 1991; 265: 1957-1960.
27. Carayon P, Hundt AS, Karsh B, et al. Work system design for patient safety: The SEIPS model. *Qual Saf Health Care* 2006; 15(Suppl I): i50-i58.
28. Reason J. Understanding adverse events: Human factors. *Qual Health Care* 1995; 4: 80-89.
29. Reason J. Safety in the operating theatre - Part 2: Human error and organisational failure. *Qual Saf Health Care* 2005; 14: 56-60.
30. Kelley HH, Michela JL. Attribution theory and research. *Ann Rev Psych* 1980; 31: 457-501.
31. DeJoy DM. Managing safety in the workplace: An attribution theory analysis and model. *J Safety Res* 1994; 25: 3-17.
32. Hollnagel E. Why "human error" is a meaningless concept. Position paper for NATO Conference on Human Error; Bellagio, Italy; 1983. Available at [www.ida.liu.se/~eriho/Bellagio\\_M.htm](http://www.ida.liu.se/~eriho/Bellagio_M.htm). Accessed March 25, 2008.
33. Kohn LT, Corrigan JM, Donaldson MS. To err is human: Building a safer health System. Washington, DC: National Academies Press; 2000.
34. Hollnagel E. Human reliability assessment in context. *Nuc Eng Tech* 2005; 37: 159-166.
35. Council recommendations: Statement from NCCMERP - Use of medication error rates to compare health care organizations is of no value. National Coordinating Council for Medication Error Reporting and Prevention; 2002. Available at [www.nccmerp.org/council/council2002-06-11.html](http://www.nccmerp.org/council/council2002-06-11.html). Accessed March 25, 2008.

36. Patient safety indicators overview. AHRQ quality indicators. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Available at: [www.qualityindicators.ahrq.gov/psi\\_overview.htm](http://www.qualityindicators.ahrq.gov/psi_overview.htm). Accessed March 25, 2008.
37. The 5 Million Lives Campaign. Cambridge, MA: Institute for Healthcare Improvement. Available at [www.ihl.org/IHI/Programs/Campaign/](http://www.ihl.org/IHI/Programs/Campaign/). Accessed March 25, 2008.
38. Scanlon MC, Miller M, Harris JM, et al. Targeted chart review of pediatric patient safety events identified by the AHRQ PSI methodology. *J Patient Saf* 2006; 2: 191-197.
39. CMS announces payment reforms for inpatient hospital services in 2008. Baltimore, MD: Center for Medicare & Medicaid Services. [Press release]. [www.cms.hhs.gov/apps/media/press/release.asp?Counter=2335&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cbOrder=date](http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2335&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cbOrder=date). Accessed March 25, 2008.
40. Are You Ready for the UB – 04? Chicago, IL: Health Information and Management Systems Society. Available at: [www.himss.org/content/files/200612\\_UB-04\\_FAQs.pdf](http://www.himss.org/content/files/200612_UB-04_FAQs.pdf). Accessed March 25, 2008.
41. Bryant JM, Hagg-Rickert S. Development of a risk management program. In: Carroll R, ed. *Risk management handbook for health care organizations*, 3<sup>rd</sup> edition. San Francisco, CA: Jossey-Bass; 2001. p. 46.
42. Vincent C. Introduction. In: Vincent C, editor. *Clinical risk management*. 2<sup>nd</sup> edition. London, UK: Br Med J Books; 2001. p. 1.
43. Woods D, Cook RI. Nine steps to move forward from error. *Cognition Tech Work* 2002; 4: 137-144.
44. Cook RI, Woods D, Miller C. A tale of two stories: Contrasting views of patient safety. National Health Care Safety Council of the National Patient Safety Foundation at the AMA; 1998. p.1-86. Available at [www.ctlab.org/documents/A%20Tale%20of%20Two%20Stories.pdf](http://www.ctlab.org/documents/A%20Tale%20of%20Two%20Stories.pdf). Accessed March 25, 2008.
45. Gawande A. The checklist. *The New Yorker*; 2007 Dec 10; 1-8. Available at [www.newyorker.com/reporting/2007/12/10/071210fa\\_fact\\_gawande](http://www.newyorker.com/reporting/2007/12/10/071210fa_fact_gawande). Accessed March 25, 2008.
46. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006; 355: 2725-2732.
47. Berenholtz SM, Pronovost PJ, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004; 32: 2014-2020.
48. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. Oakbrook Terrace, IL: The Joint Commission; 2003. Available at [www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal\\_protocol.pdf](http://www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf). Accessed March 25, 2008.
49. Smith MJ, Carayon P, Karsh B. Design for occupational health and safety. In: Salvendy G, ed. *Handbook of industrial engineering: Technology and operations management* 3<sup>rd</sup> ed. New York: John Wiley and Sons; 2001. p. 1156-1191.
50. Smith MJ, Karsh B, Carayon P, et al. Controlling occupational safety and health hazards. In: Quick JC, Tetrick LE, editors. *Handbook of occupational health psychology*. Washington, DC: American Psychological Association; 2003. p. 35-68.
51. Karwowski W, Warnecke HJ, Hueser M, et al. Human factors in manufacturing. In: Salvendy G, ed. *Handbook of human factors and ergonomics*, 2<sup>nd</sup> ed. New York: John Wiley and Sons; 1997. p. 1899-1900.
52. Safety and health management systems e-tool. Overview of system components. U.S. Department of Labor, Occupational Safety & Health Administration Available at: [www.osha.gov/SLTC/etools/safetyhealth/components.html](http://www.osha.gov/SLTC/etools/safetyhealth/components.html). Accessed March 25, 2008.
53. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care* 2003; 12: 2-7.
54. Morag I, Gopher D. A reporting system of difficulties and hazards in hospital wards as a guide for improving human factors and safety. Paper presented at the Human Factors and Ergonomics Annual Meeting. San Francisco, CA; 2006.
55. Weick KE, Sutcliffe KM. *Managing the unexpected*. San Francisco, CA: Jossey-Bass; 2001.
56. Institute of Medicine. *Crossing the quality chasm*. Washington, DC: National Academies Press; 2001.