



Institute of Health Policy, Management and Evaluation
UNIVERSITY OF TORONTO

BEYOND THE QUICK FIX

Strategies for Improving Patient Safety

October 31, 2015

This report was developed with support from KPMG LLP in partnership with the
Institute of Health Policy, Management and Evaluation at the University of Toronto



Acknowledgements

This report greatly benefited from the valuable contributions and insights of several collaborators. Anu MacIntosh-Murray helped in interviewing Canadian leaders and patient safety experts, analyzing the key issues in these interviews. Christine Shea and Jocelyn Pang did a detailed review and analysis of the published Canadian literature and grey literature on patient safety from 2004 to 2014. Their contributions helped to shape the findings of this report.

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Introduction

The Canadian Adverse Events Study (CAES) – published in May 2004 (Baker, Norton et al. 2004) – provided one of the most comprehensive pictures of patient safety in Canada to date. The CAES reported that 7.5% of all hospitalizations in Canada had an adverse event that harmed patients.

Extrapolating from the 3,745 cases reviewed suggested that around 185,000 hospital admissions during the study period likely had adverse events of which close to 70,000 were potentially preventable. In the lead up to the release of the CAES, the federal government announced the creation of the Canadian Patient Safety Institute (CPSI). In the decade since the CAES, provinces have invested heavily in patient safety reporting, the CPSI launched *Safer Healthcare Now!* designed to improve the safety of care, and healthcare organizations across Canada have invested considerable energies in measuring and assessing adverse events, identifying ways to reduce such events, and investing in training, equipment, and reviews of current practice to reduce the likelihood of such events. While hospital acquired infections, surgical complications and medication errors have long been seen as important issues, the adverse events study helped to change the perspective on these and other incidents, introducing “patient safety” as a critical element of healthcare performance and a major focus for improvement work.

With ten years of activity and easily tens of millions of dollars invested in patient safety we should now have a much safer healthcare system. But do we? This report provides an overview of the impact of this new focus on patient safety, and offers an accounting of the progress made and of the challenges that remain. To provide a comprehensive picture of progress on patient safety we reviewed the Canadian and international literature on improvements in patient safety, spoke with international experts, and conducted structured interviews with 15 Canadian patient safety experts and health system leaders across the country between November 2014 and January 2015¹.

What became clear early on in our analysis is that ten years later, many Canadian healthcare organizations still struggle to address key patient safety issues. Harm experienced by patients, and the impact on families, staff and organizations continues despite better measures of the number and impact of these events, and efforts to change unsafe practices.

¹ A full summary of our methods and a bibliography are available on request.

Patient Safety Changed Perspectives on Healthcare

The concept of “patient safety” incorporates four fundamental propositions that are transforming mental models, conceptions of team and organizational performance, and broader expectations of clinical and system leadership in our healthcare system.

Many patient safety problems are preventable. Adverse events (or patient safety incidents) are negative, unintended consequences of care and care settings experienced by patients. These incidents range from infections in the ICU to medication overdoses on a medical surgical unit to falls in long-term care homes. Until recently these problems were viewed as unfortunate consequences of healthcare; they are now seen as failures in quality of care, many of which are preventable. Moreover, these preventable problems are measurable and could now be aggregated into measures of performance. As a result of measuring and aggregating these events it became evident that the incidence of such events was much larger and more widespread than most observers, even experts and researchers, had recognized or even anticipated. The classification of many adverse events as preventable and the publication of remarkably high rates of adverse events served as a call to action in the healthcare system.

Improving safety requires moving from a focus on blame towards a focus on improvement. Patient safety experts offered a new view on human error and its sources. Rather than viewing error simply as a result of poor individual decisions or knowledge, patient safety experts created a broader perspective.

Guided by the work of James Reason (Reason 1990), Jens Rasmussen (Rasmussen 1990) and others, this new view shifted the focus from individual decisions and practice and saw incidents as the result of both individual and broader system factors, including staffing patterns, equipment purchases, information systems, credentialing decisions and many more organizational issues. Patient safety events were not just the result of poor clinical practice and flawed decisions by individual practitioners; they represented failures by leaders in healthcare organizations to develop broader strategies and to make investments to ensure safer care. Instead of blaming individuals associated with “errors”, organizations now faced the more difficult challenge of designing systems of care that made it less likely that patient safety events would occur. Finally, as a result of the recognition of the incidence of such events and their source in both organizational and clinical actions, governments, accreditors and regulators started to hold governors and leaders accountable for patient safety performance and improvements to address patient safety issues and other quality of care issues. This whole new range of quality problems has become a concern for organizational leadership and governance, and system performance. If safety was indeed a property of healthcare systems, then those responsible for the performance of those systems needed to be held accountable.

Improving patient safety is a shared responsibility to design safer systems. The new view of error requires a new interprofessional approach to improvement. In the past the widely different types of adverse events had previously been the purview of different professional groups or teams (surgeons were responsible for surgical complications, infection control specialists for nosocomial infections, pharmacists for medication events, and nurses for falls and pressure ulcers). As already noted, the old view had been that these errors stemmed from poor judgment, inattention, incorrect diagnoses or treatment plans, or incompetence. Healthcare organizations and professions relied on blaming and shaming to ensure better performance (Leape 1994; Dekker 2014). The new view implicated

organizations and leadership in creating, or tolerating risky environments, setting the scene for failure. New solutions needed to be based not just on changing individuals, but changing the organization of care. Team based care and team performance were seen as important strategies for improving quality of care and patient safety outcomes (Weaver, Lyons et al. 2010). But teamwork alters existing relationships and practice and many organizations find this difficult. For example, efforts to implement a bundle of practice interventions to reduce central line infections in English ICUs failed in many hospitals where it was difficult to create an interprofessional leadership team to guide improvement efforts (Dixon-Woods, Leslie et al. 2013). Moreover, team-based efforts to improve front line care required organizational support and leadership. Organizational and clinical leaders needed to provide resources to redesign care, including not just new resources, but clear direction and a focus on the values underlying efforts to promote safer care.

Improving safety requires complex interventions, not simple solutions. Adverse events are a function of underlying unsafe systems but safer practice is rarely achieved easily. One important patient safety innovation was the development of improvement “bundles” -- sets of practices none of which were sufficient to reduce patient safety events, but which together created better outcomes. For example the effective response to clinically well-defined problems like ventilator-acquired pneumonias included several changes in clinical practice including elevation of the bed to 45 degrees, daily evaluation of readiness to extubate, the utilization of endotracheal tubes with subglottic secretion drainage, oral care and decontamination with Chlorhexidine, and initiation of safe enteral nutrition within 24 to 48 hours of ICU admission (Canadian Patient Safety Institute 2012). No single change was sufficient to improve care.

Bundled interventions at the clinical micro-system level and arguably even at the system level (for example, in care transitions) have become the standard for improving safety and address the complexity of care (Guerin, Wagner et al. 2010; Costello, Morrow et al. 2008). These new changes included not only standardizing new clinical practices, but also new non-technical changes such as interdisciplinary rounds and improved reporting of events.

What Are the Results? Has Patient Safety Improved?

Medical injuries resulting from care have been acknowledged for some time (California Medical Association 1977) and the potential for error in diagnosis and screening has been recognized for 25 or more years (Eddy 1990). Despite the apparent shock of the adverse events study, the recognition of patient safety as an issue for system policy, organizational leadership and clinical practice had been building slowly over nearly twenty-five years. Lucian Leape, Troy Brennan and colleagues published several high profile publications in the early 1990s that documented the incidence of patient safety events in New York State. Yet these papers had little impact beyond the research community. Full recognition of the scope of the problem occurred only with the publication of the U.S. Institute of Medicine's report, *To Err is Human*, in 1999. That event unleashed a series of reactions that galvanized politicians, policy makers and healthcare leaders in the US. The following year, Liam Donaldson, then the Chief Medical Officer of the National Health Service in England, released a parallel report, *An Organization with a Memory*. That report had a similar impact on the health services in the UK, stimulating widespread discussion and activity, including the development of a new agency, the National Patient Safety Agency (NPSA) established in 2001 to monitor patient safety events and to assist the NHS in developing safer care.

In contrast with the US and the UK, Canada was slow to recognize patient safety as a system issue. In September 2001, the Royal College of Physicians and Surgeons created a Task Force chaired by Dr. John Wade² to recommend a pan-Canadian strategy for patient safety. The Task Force issued a report in 2002, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*. The key recommendation in that report was the creation of the Canadian Patient Safety Institute (CPSI). CPSI was formally established with funding from the Government of Canada in late 2003.

The Canadian Adverse Events Study (CAES) represented a critical turning point in recognizing and addressing patient safety issues in Canada. Although the study was published in the Canadian Medical Association Journal on May 25, 2004, the study funders, the Canadian Institutes of Health Research and the Canadian Institute for Health Information, had convened a series of roundtable knowledge translation efforts starting in the spring of 2002 that engaged national policy makers, including leaders from the major healthcare associations. Thus when the study was finally released there had been considerable planning about policy and programmatic responses. This planning, and careful media strategy led to considerable media coverage (Baker, Norton and Flintoft 2006). Among important follow-up efforts was that by Accreditation Canada to create a series of Required Organizational Practices addressing patient safety issues, and the development of a national campaign by the Canadian Patient Safety Institute - Safer Healthcare Now! - patterned on the Institute for Healthcare Improvement's 100,000 lives campaign in the US. Like the US campaign *Safer Healthcare Now!* used bundles of interventions to reduce preventable patient safety events, including medication errors and infections in surgical and intensive care patients.

Attention to patient safety was also spurred by a greater focus on general quality of care issues and performance reporting in many provinces. New bodies, including the Health Quality Council in Saskatchewan, the Cancer Care Ontario Quality Council and the BC Patient Safety and Quality Council

² Dr. Wade is a prominent physician leader and an anesthesiologist, former chair of the board of the Winnipeg Regional Health Authority and former Deputy Minister of Health for the province of Manitoba.

were created to foster improved performance. New performance measurement reporting provided increased transparency of quality of care and patient safety. A series of high profile investigations, including the Cameron Commission of Inquiry on Hormone Receptor Testing in Newfoundland and Labrador (Commission of Inquiry on Hormone Receptor Testing 2009) and the Report of the Manitoba Pediatric Surgery Inquest, also drew attention to major quality and safety concerns. However, attention to patient safety remained variable across provinces and across healthcare organizations. Somewhat surprisingly, despite these activities there was limited understanding of how or why patient safety was important and the dominant theme of health policy initiatives was access to care, not the safety or quality of care.

Canadian patient safety experts and healthcare leaders noted that the Canadian Adverse Events Study helped to create a more intensive focus on quality of care. One Ontario hospital CEO noted:

I would tie some pretty big changes system-wide to the adverse event study because I think that study did shine a big light on safety and it opened the doors for all sorts of important developments like the Canadian disclosure guidelines, apology legislation. I think it was understanding and having out there evidence on adverse events that let the system start talking about things like apology. I think it ultimately led us to Excellent Care For All [ECFA] in terms of legislation that now requires quality plans, a focus on quality improvement, publication of metrics.

One provincial organization's leader stated that awareness and the willingness to measure and hold organizations accountable have increased to the point that his province "is in an entirely different place", although he added that it would take more than ten years to solve most of the problems. The system view and need to ensure leadership and governance focus on patient safety is growing. He continued,

We didn't actually have at the board level 10 years ago discussion of patient quality at all other than what happened to be on the front page of the newspaper and most of those discussions occurred in the washroom! So I really think that we are in a different place. We have the measurement tools and we have the directional strategy from the Ministry of Health to do some of these things. That to me is fundamentally different...

Recognition that patient safety is an important quality issue has greatly increased; but has this recognition translated into effective efforts to create safer care?

Efforts to Improve Patient Safety: Better Measurement, Better Understanding, Improved Practice But Limited Results

Following the IOM report in the US, there were optimistic projections that concerted efforts could reduce the incidence of patient safety events by 50% or more within five years (Kohn, Corrigan et al. 1999). These US estimates were in line with data that showed a high proportion of adverse events was preventable (as have studies in Canada and elsewhere). But performance improvements have proved to be much more difficult. Despite the development of new organizations focused on supporting patient safety efforts, the development of training programs for leaders, front line staff and patient safety “officers” and substantial funding devoted to patient safety there is limited evidence of substantial improvement.

The impact of the wide range of activities that followed in the wake of the CAES study found wide reflection in our interviews with healthcare leaders across Canada. Many spoke of the “light” that had been shone on problems in patient safety, of increased awareness and understanding of the problems in patient safety, and a lot more measurement and public reporting of these problems. But the evidence on whether care has actually gotten safer is mixed; with closer and more careful examinations suggesting limited real improvement.

Publicly available data on some patient safety measures such as hospital standardized mortality rates (HSMR) or potentially inappropriate prescribing in nursing homes do show improvement. Although often contested as a measure of patient safety, the overall HSMR has declined by almost 15 per cent between 2009 and 2013³. However, profound variation across provinces means that hospital death rates continue to be 4% higher in Newfoundland in 2013 than across Canada in 2009 while rates are 19% lower in BC in 2013 than across Canada in 2009. Other indicators, like inappropriate prescribing fell by a smaller proportion over the same time period (from 32% of all long-term care home admissions to just under 29%) (Health Quality Ontario 2015).

Yet other, more rigorous, studies in several countries that attempted to measure patient safety directly showed little real change. For example, a study of North Carolina hospitals published in 2010, reviewed a sample of 100 patients admitted to 10 hospitals in that state each quarter from January 2002 to December 2007. Using methods similar to the national adverse events studies, they identified harm experienced by patients and assessed changes in the incidence and severity of harm over this period (Landrigan, Parry et al. 2010). Results from their study indicated no significant changes in harm and little evidence of widespread improvement.

An even more stark demonstration of the persistence of harm comes from two studies carried out in the Netherlands. Researchers in that country repeated a large adverse events study to examine the changes resulting from a national program aimed at improving patient safety in hospitals in the Netherlands.

These researchers used methods similar to the Canadian Adverse Events Study to assess the incidence of harm in 21 acute care hospitals in 2004 and 20 hospitals in 2008. In their first study they

³ See the CIHI sponsored report on Hospital Deaths, accessed 29 April 2015 at <http://yourhealthsystem.cihi.ca/hsp/inbrief?lang=en#!/indicators/005/hospital-deaths-hsmr;/mapC1;mapLevel2;/>

found an overall incidence of 4.1% of patients were harmed, while in 2008, following concerted efforts to address patient safety in the Netherlands, the incidence showed a statistically significant increase to 6.2%, although the proportion of preventable AEs did not change. Moreover, with shorter lengths of stay in 2008, the number of incidents per 1000 patient days showed an even larger increase. Baines and colleagues concluded that “patient harm related to healthcare is a persistent problem that is hard to influence” (Baines, Langelaan et al. 2013).

The challenges of improving safety for patients in acute care began to draw commentary at the five-year anniversary of the IOM report. In a 2006 article several US experts noted specific challenges in the US: measurement of patient safety was difficult, there was limited evidence about effective interventions, and policies enacted to improve safety were written without a clear view of whether they could be understood or used in practice (Pronovost, Miller et al. 2006). Leape and colleagues (Leape, Berwick et al. 2009) described the problem more broadly. Too many healthcare organizations were hierarchical, lacked teamwork, transparency and mutual respect. These organizations continued to rely on blaming individuals as a solution for safety issues and lacked the ability to learn from the incidents that occurred within them.

Interestingly, our interviews showed the same understanding of progress. Healthcare leaders talked about better attention to and understanding of patient safety issues across Canada. Almost all noted the importance of reporting or new disclosure requirements. Several said that government attention to the issue was helpful in focusing boards and senior leadership on safety and a few talked about changing culture and acceptance of safety as a key priority. But almost all also talked to the fact that improving patient safety would be a long journey and many questioned whether care was in fact safer ten years after the CAES. It is also important that a few leaders argued that attention from above, that is from policy-makers, regulators, and accreditation bodies could also hold back innovation and could not substitute for leadership within organizations.

Why Are Patient Safety Improvements So Difficult?

One highly visible patient safety intervention to reduce adverse drug events provides a powerful illustration of the challenges of reducing patient safety events. Adverse drug events are a major category of patient safety events and unintended discrepancies between patients' medications on admission to and discharge from hospital are frequent. Up to 69% of patients admitted to hospital have unintended medication discrepancies (Tam, Knowles et al. 2005; Gleason, McDaniel et al. 2010) and as many as 80% of those discharged from hospital (Lehnbom, Stewart et al. 2014). In many cases these discrepancies are not clinically significant (Cornish, Knowles et al. 2005). But studies of care transitions find that medication issues are a common source of problems post discharge, including unplanned readmissions (Coleman, Smith et al. 2005).

Medication reconciliation, a process of comparing patient medications at key transfer points was developed as a strategy to reduce medication discrepancies and potential adverse drug events. This process has become a Required Organizational Practice by Accreditation Canada, although many organizations have struggled to implement effective medication reconciliation. Recent reviews suggest that medication reconciliation on its own may not have a large impact on readmissions; but when combined with other interventions, they may reduce the likelihood of post-discharge hospital utilization (Hansen, Young et al. 2011; Kwan, Lo et al. 2013).

An equally powerful illustration of the challenges of improving safety is provided by the example of the safe surgery checklist. Surgical checklists were heralded as an important tool for improving the safety of surgery and a widely heralded study of the use of the surgical checklist in 8 hospitals, including two Canadian facilities found that the safe surgery checklist reduced mortality by almost 50% and complications by more than one-third. These results, combined with other studies (Treadwell, et al. 2014) and efforts by the World Health Organization (WHO) to spur adoption of the checklist led to its widespread use. Accreditation Canada mandated the surgical safety checklist for hospitals and Ontario began public reporting of completion of surgical safety checklists at the hospital level, resulting in an immediate increase in reporting compliance. However, an evaluation of the impact of this reporting in Ontario by Dr. David Urbach and colleagues using administrative data revealed no real improvement in patient outcomes (Urbach, Govindarajan et al. 2014). This result is at odds with a recent review of the use of checklists to improve safety in operating rooms that found checklists could improve teamwork and communications, and result in a reduction of errors (Russ, Rout et al. 2013). But, as Charles Vincent, the English patient safety expert suggests “while checklists are valid and useful we need in the longer term to think more in terms of designing teamwork” (Vincent 2010). Lucian Leape was even more direct in an editorial that accompanied the Urbach article, saying, “the likely reason for the failure of the surgical checklist in Ontario is that it was not actually used” (Leape, 2014). Despite the failure of checklists in Ontario hospitals to reduce mortality and morbidity, they remain an important tool for team communication. Checklists have been shown to be effective in multiple settings, but they are complex interventions. Safety and team performance experts suggest that checklists are most valuable when they are a part of a larger strategy to improve care and not as an isolated intervention (Bosk, Dixon-Woods et al. 2009).

Many patient safety interventions add work for clinical teams. For example, a recent study estimated that nurses have to spend an extra 115 minutes per patient per day to complete the tasks in the ventilator-associated pneumonia bundle (Branch-Elliman, et al. 2013). The willingness of clinicians to adopt and reliably perform this work relies on their capability to integrate this increased

workload as well as their perceptions that these interventions will improve patient outcomes, reducing the risk of harm. Many clinical teams have been asked to adopt numerous patient safety interventions without a full assessment of the impact of these interventions on their workload. Greater attention to the work resulting from these efforts will help to ensure that teams are capable of integrating these new routines into daily practice. Chris Hayes has analyzed this challenge, suggesting that both workload and the perceived value of new interventions are important considerations for ensuring their sustainability. Improvement efforts that add substantial work are less likely to be sustainable over time, while those that do not add (or can reduce) workload and have high perceived value are more likely to be sustainable (Hayes 2014).

Paradoxically, while patient safety experts have extolled the need to focus on a systems view of safety, moving beyond the role and responsibility of individual providers whose actions are associated with patient harm, the growing numbers of patient safety interventions have been added to the work of front line teams without assessing whether these teams can integrate these new routines into daily practice. Accreditation mandates and greater public reporting of the incidents they are intended to prevent reinforce these new patient safety practices. But stressing the system to increase safety will not yield sustainable results. A broader view is needed to create the environments that support safer patient care.

What Does It Take To Create Safer Care?

The challenges of medication reconciliation and the failed broad-scale implementation of safe surgery checklists in Ontario are illustrative of the broader difficulties of improving patient safety. The lessons of the last 10 years suggest that improving safety is more complex than simply identifying effective interventions and spreading the word to clinicians practicing in relevant areas. Evidence based interventions are critical to safer care; but they are insufficient if the environments in which these interventions are introduced are not receptive. In other words, efforts to create safer care need to be broader than identification of “what works”. Rather, we need to understand how we can create supportive environments that enable implementing, sustaining and spreading effective interventions to improve safety. This more comprehensive approach requires not only multiple interventions focused on specific safety events but also a broader “sensitivity to operations” (Weick and Sutcliffe, 2006). Karl Weick, Kathleen Sutcliffe and others who have studied high reliability organizations (HROs) suggest these organizations perform well because they are attentive to patterns and problems of work on the front line and cultivate “situational awareness” that allows front line workers to make adjustment to prevent errors from leading to events. Sensitivity to operations translates into a concern for anomalous events; and clinicians anticipate and act to contain risks. David Woods and Richard Cook in a prescient analysis published in 2001 suggested that the organizations wanting to develop safer care had to shift from reporting to learning from incidents, from counting events to a search for patterns in these events, from looking backward at events to anticipating future risks and shifting from a focus on error to a focus on complexity (Woods and Cook, 2001). Woods and Cook don’t discount reporting and learning from patient safety event. But the current approach to these practices may be insufficient to create safer clinical environments.

Creating high reliability organizations is not easy; they require new ways of thinking and acting and openness to new ways of working. The failure of organizations to be receptive to new practices is a common theme in the organizational change literature in healthcare and more generally (Armenakis, Harris et al. 1993; Kotter 1996; Kirch, Grigsby et al. 2005). One way to frame this issue is to focus on “readiness for change”. This idea has substantial face validity: organizations that are successful in improving are those whose staff are ready to change. Researchers suggest that readiness to change depends on two factors: first the willingness or motivation of staff to undertake the change, and, second, the capability of the unit or organization to support the change (Weiner, Amick et al. 2008). The capability of a group includes the expertise, resources and opportunity possessed by individuals, as well as the support provided by the organization. Another, more granular perspective on the factors influencing the success of improvement initiatives is offered by Mary Dixon-Woods and colleagues who reviewed improvement programs funded by the Health Foundation in the UK (Dixon-Woods, McNicol et al. 2012). They identify 10 factors that span the process of implementing improvement interventions, from design stages to sustainability and spread (see Table 1). These 10 factors combine the aspects of willingness and motivation with the capability elements included in readiness for change, and draw attention to several key elements that can limit effective improvement and patient safety initiatives: measurement and data; clinical and senior leadership, organizational culture and context, teamwork and organizational support. There has been considerable research and experience on these issues that bears on the capability to create safer, high quality care, which we will explore further below.

Creating an environment that supports safer care was a theme that a number of our interviewees identified. One CEO emphasized that clear organizational values were needed to develop a safety culture.

It all comes down to creating a culture that embraces and focuses on safety... We believe very strongly that there is a correlation between culture and safety. Culture we define as the way in which we work on a day-to-day basis. If you say that an organization has a culture – and organizations do have cultures even if they don't recognize that they have a culture - it is important to communicate to team members what the culture of the organization is. So it has to be visible, it has to be identifiable, so we say the culture is how we do things on a day-to-day basis but it is grounded in our core values.

The CEO illustrated the linkage between the core values and safety with the example of improvements to hand hygiene through positive peer pressure.

Take hand hygiene; how did we go from roughly 70% to 90-95%, we did that by honouring our commitment, so aligning with our core values in the organization is part of empowering the culture of safety and quality. We use data to drive the success and we do 40,000 manual hand hygiene audits a year and we have auditors out throughout the hospital. I know that there are technologies that can do this but we don't like the technological solution. To us, culture is all about people. We want to create an environment where everyone can speak up.

Table 1: Strategies for meeting common challenges in improvement work

Design and Planning of Improvement Interventions

1. Use hard data and stories to convince staff there is a problem
2. Provide clear evidence that the solution is effective
3. Invest in data collection and monitoring systems
4. Set realistic goals and avoid giving the impression that this is only a 'project'

Organizational and Institutional Contexts, Professions and Leadership

5. Make sure the improvement goals are linked to organizational priorities, and ensure that staff have sufficient time and support
6. Clarify who owns the problem and solution, agree on roles and responsibilities, work to common goals and use shared language
7. Ensure effective leadership. "Quieter" leadership oriented toward gentle explanation and persuasion may be more effective
8. Rely on intrinsic motivations; but be prepared to use harder measures judiciously to encourage change

Sustainability, Spread and Unintended Consequences Design and Planning of Improvement Interventions

9. Avoid effort that are seen as short term project, or those reliant only on particular individuals
10. Be vigilant in detecting unanticipated consequences and be willing to learn and adapt

Adapted from Dixon-Woods, McNicol, et al., 2012

Measurement and Data

Creating and using measures to assess patient safety enables trustees, organizational leaders and staff to gauge current performance and target improvement efforts. There are a growing number of patient measures that have been developed in the last decade, but limited guidance is available to direct the choice of measures at both an organizational level and in front line care. At both organizational and unit levels no single measure of safety is sufficient. Big dot measures, including the Hospital Standardized Mortality Ratio (HSMR) and composite measures of patient safety events on a monthly or quarterly basis are useful for assessing current levels of safety. But front line teams require more granular measures and more frequent reporting.

Measurement for improvement at the front line is both simple and challenging. Quality improvement experts suggest that improvement projects need to collect small samples of process measures to assess the impact of the changes that teams are testing to improve key processes (Pronovost, Nolan et al. 2004; Langley, Moen et al. 2009). This guidance is a core element for safety improvement efforts in Canada, for example in the development of patient safety metrics for each intervention in *Safer Healthcare Now!* and in patient safety campaigns in the US and the UK. But this approach faces important cultural and logistical barriers. Many clinicians have been educated to seek carefully analyzed evidence to support changes in practice; so the apparent reliance on small, non-random samples to test new ideas can seem reckless. In a study of physician engagement in quality improvement, Parand noted that some doctors were reluctant to become involved in safety and quality improvement programs because they saw the methods as unscientific; they quote one informant who said that “doctors are having heart failure ...with the idea of ‘quick and dirty’” (Parand, Burnett et al. 2010). Just as important as the culture issues are the more tangible resource questions. Many organizations are unprepared to support local measurement. Their information systems are not capable of collecting and reporting data on a weekly basis, nor do they have the personnel to support clinical teams in doing manual collection and reporting. The time, skills and knowledge needed to support such measurement are often lacking (Burnett, Benn et al. 2010). At the same time, policy-makers may not be sensitive to requests for support for more data because of poor experiences with eHealth solution implementation.

So what does effective measurement for patient safety look like? The English expert, Charles Vincent, in a recent report (Vincent, Burnett et al. 2014) asserts the need for five dimensions of patient safety measures for a scorecard on patient safety (see Table 2).

The dimensions provide information on five fundamental questions:

- 1 Past harm: Has patient care been safe in the past?
- 2 Reliability: Are our clinical systems and processes reliable?
- 3 Sensitivity to operations: Is care safe today?
- 4 Anticipation and preparedness: Will care be safe in the future?
- 5 Integration and learning: Are we responding and improving?

Table 2: Measurement Dimensions and Illustrative Measures

Dimensions	Illustrative measurements and assessments
Past Harm	<ul style="list-style-type: none"> Patient safety indicators Global trigger tool Morbidity and mortality Incidence of falls
Reliability of safety critical processes	<ul style="list-style-type: none"> Observation of safety critical behavior Monitoring of vital signs Monitoring of stroke care bundle Assessment of suicide risk
Sensitivity to operations	<ul style="list-style-type: none"> Safety walk rounds and conversations Talking with patients Ward rounds and routine reviews of patients and working conditions Briefings and debriefings
Anticipation and preparedness	<ul style="list-style-type: none"> Structured reflection Risk registers Safety culture assessment Anticipated staffing levels and skill mix
Integration and learning	<ul style="list-style-type: none"> Aggregate analysis of incidents, claims and complaints Feedback and implementation of safety lessons by clinical teams Regular integration and review by clinical teams

Source: Vincent, Burnett, et al., 2014

Vincent and colleagues have tested this approach in workshops in the UK and received positive responses (Vincent, Burnett et al. 2014). Pronovost has also suggested a series of measurement principles (Pronovost, Berenholtz et al. 2007) and developed a multi-dimensional scorecard framework for ICUs and other patient units (Pronovost, Holzmueller et al. 2006). These approaches provide a broader assessment of current performance and a local guide to focus improvement efforts.

Clinical and Senior Leadership

Government, boards and top organizational leadership set directions for healthcare organizations. But all improvement is local. New accountabilities for improving performance in quality of care and patient safety cannot be achieved or sustained unless organizations have developed distributed leadership that helps to translate organizational goals into action across microsystems. The Institute for Healthcare Improvement calls out the importance of leadership in developing improvement capabilities: investing in people, providing resources to local initiatives and visibly supporting efforts to improve care. Those organizations that have developed distributed leadership supporting local improvement efforts throughout their organizations have an enormous advantage in efforts to improve performance (Swensen, Pugh et al. 2013).

The development of distributive leadership in healthcare organizations is a relatively new idea. However, there is growing recognition of the need for strong physician and other clinical leadership, not just at senior levels but also within programs and microsystems. Many large healthcare systems in the US have developed clinical leadership development programs, and some Canadian organizations (e.g., The Ottawa Hospital and the Interior Health Authority in British Columbia) have developed internal programs to create a physician leadership cohort. Professional organizations have also recognized the critical importance of clinical leadership. The new CANMEDs competency framework for specialist physicians developed by the Royal College of Physicians and Surgeons of Canada identifies “leader” as a critical role for physicians, “contributing to the development and delivery of continuously improving health care” (Frank, Snell et al. 2015).

Quality and patient safety initiatives are a natural environment for physician engagement because such efforts are closely connected to the underlying values and motivations of physicians to improve patient care. Moreover, involving physicians in patient safety efforts may initiate a broader engagement in organizational changes, overcoming the traditional difficulties of recruiting physicians into leadership roles.

There has been little empirical research on the factors that encourage physician engagement and involvement in quality and patient safety activities. But the limited physician (and other clinical) leadership in traditional hospital (and other healthcare) organizational structures has fostered a culture of work-arounds and quick fixes, rather than a structured search for underlying causes and more systemic problem-solving (Edmondson 2004). Strengthening clinical leadership and supporting local improvements in patient safety and quality of care have reinforcing benefits. The work culture in many hospitals still discourages speaking up and challenging the authority gradient, key behaviors in a safety culture. Stronger clinical leadership may facilitate greater attention to improved communication and teamwork behavior, and an investment in clinical improvement. In turn, these efforts may shift local work cultures from defensive and reactive, to open and proactive.

A number of our expert interviewees pointed to the importance of leadership in improving safety, and the need for local, distributed leadership to influence local microsystem cultures and focus. Many participants pointed out that the culture and way of doing things at the front line have not changed enough to make safety improvement an expected, accepted and supported part of daily work. Why? Some stated that it has not been a part of longstanding professional cultures. Others note the lack of education and training of providers and leaders combined with poor role models who do not take responsibility for change. One medical leader made two telling observations; “We haven’t built this into the souls of our professions,” and “I think we’re dealing with such a large culture change that we have underestimated the resistance and lack of interest within the culture.”

One system-level director noted that despite the safety resources now available, these had not permeated to the frontline clinical microsystems.

Not being totally negative, there are resources being devoted to patient safety that there never were in the past; we have mechanisms for patient safety alerts now, we have patient safety courses; we have a lot of resources but we are not actually moving beyond the structural type of resources – the point people, the patient safety officers, the courses that are offered – we haven't moved beyond to really realize that this is about the local culture and the local leadership at the clinical microsystem level...Of course senior leaders do need to influence this journey but definitely can't direct what happens at the clinical microsystem. It needs to be resourced and supported and brought alive at the clinical microsystem or unit level or program level.

The CEO of a national organization was also concerned about leadership capabilities and preparation:

The issue is the competencies and do we have the right competencies in the leaders to take us forward, both existing leaders and leaders coming into the system. Because I think with the increasing complexity of the environment, the leader of today is not the leader of five years ago.

More evidence on strategies supporting effective physician leadership comes from a study of 10 high performing hospitals in the US. The authors examined the approaches these systems used to engage their physicians in quality and patient safety and identified 6 critical levers: engaged leadership, a physician compact that clarified roles and responsibilities, appropriate compensation, realignment of financial incentives, data support and valuing physician leadership in academic promotion (Taitz, Lee et al. 2012).

Teamwork

Gaps in communication or poor teamwork are frequently noted as contributing factors to many patient safety events. There is a considerable body of evidence on teamwork in healthcare and several reviews have identified specific aspects of team performance, including effective communications, shared mental models and situational awareness, which are related to better patient outcomes (Weaver, Dy et al. 2014; Schmutz and Manser 2013). In the last decade many organizations have incorporated teamwork training, particularly in high-risk environments, as a patient safety and clinical effectiveness strategy. For example, the Veterans Health Administration developed and implemented a Medical Team Training program for operating room and ICU staff (Neily, Mills et al. 2010). However, most teamwork training programs offered in healthcare organizations are short duration with concomitantly limited effects (Salas and Rosen 2013). While these programs have been shown to have impact (Weaver, Dy et al. 2014) they are unlikely to have a broad and lasting influence on team performance. Some studies have shown that longer training continues to demonstrate improved performance (Neily, Mills et al. 2010), but many organizations settle for more limited benefits.

Continued benefit from team training requires ongoing reinforcement and the development of supportive processes such as team meetings. In a study of team training in a US intensive care unit, Brodsky and colleagues report improvements in communication, situational awareness and staff satisfaction (Brodsky, Gupta et al. 2013). Teamwork improves performance but, like other

interventions, the impact of teamwork training is dependent on the broader workplace environment, sometimes referred to as “teamwork climate”. Strong leadership and continued reinforcement of teamwork skills is key to teamwork climate. Salas and Rosen point out “if team training is viewed solely as training, real change is not likely to happen” (Salas and Rosen 2013:371). Teamwork has both direct and indirect benefits for patient safety. Excellent communication among team members reduces the likelihood of patient safety events. Moreover, improvements in teamwork climate create a more receptive context for patient safety interventions. For example, one study on the use of the WHO surgical safety checklist found that those sites that experienced the greatest improvements in teamwork (as measured by the Safety Attitudes Questionnaire) had the greatest improvements in surgical morbidity and mortality (Haynes, Weiser et al. 2011). Paradoxically, while teams with poor skills may have the greatest need, teams that already have better teamwork skills are more likely to seek and receive further training, a phenomenon that sociologist Robert Merton (Merton 1968) has labeled as the “Matthew effect”⁴.

Although competencies in teamwork have been included in the core skills required for physicians in the US, Europe and Canada, and despite the development of innovative approaches for developing high performing clinical teams, there is still a lack of attention to team training. Brock, et al. (2013) found that interprofessional team training programs contribute to improved attitudes and knowledge about teamwork and they argue that such programs need to be integrated more broadly into professional education to promote effective teamwork skills early in professional training. Continued interprofessional education and a commitment to local, less formal interprofessional team learning in daily work is also seen as critical for maintaining team skills (Weaver, Rosen et al. 2010). However, it is worth noting that efforts to improve team performance may be displaced not only by resource constraints but also by the continuing focus of health professional regulation on the assessment of individual competence, rather than the development of effective teams.

Organizational Capability

Clinical units, even those with strong teamwork, ongoing measurement, and a commitment to improvement will struggle to change without the leadership and improvement skills needed to change practice. A recent report from the Health Foundation in the UK lamented the “fragmented and unfocused” state of the NHS improvement infrastructure” seeing it as a “major impediment to the type, extent and pace of change now needed” (Jones and Woodhead 2015). In the aftermath of the Francis Inquiry on the deaths and poor patient experiences at the Mid Staffordshire NHS Foundation Trust and other reports detailing deficiencies in the quality and safety of care in English hospitals, a number of prominent English clinicians have argued for building additional improvement capability across the NHS and integrating such skills into the professional training of all clinicians (Woodhead, Lachman et al. 2014).

High performing healthcare organizations invest in improvement and leadership skills as a critical resource for their organizations. Intermountain Healthcare, an integrated healthcare delivery system in Utah has offered their Advanced Training Program (ATP) of improvement and leadership skills for more than 25 years. All leaders in the system are required to complete the 21-day program (although there is a shorter course for physicians). The training provides a common set of tools to

⁴ From the biblical passage, “For unto every one that hath shall be given, and he shall have abundance: but from him that hath not shall be taken even that which he hath.” Matthew 25:29, King James Version.

front line and system leaders across Intermountain, and supports the work of their clinical program and improvement infrastructure (Baker, MacIntosh-Murray et al. 2008; James and Lazar 2007). Other leading organizations such as Cincinnati Children's Hospital and Clinics have adapted the Intermountain program to their clinicians and leaders (Kaminski, Schoettker et al. 2014). The Ontario IDEAS (Improving and Driving Excellence Across Sectors) program now in operation is also based on the foundation of the Intermountain ATP.

Helen Bevan, who has been a key leader in the transformation of the English NHS over the last decade, describes the changes needed as rooted in a fundamental shift in mindset around improvement capabilities, and the larger capacity of the system to support this learning. The new mindset requires all clinicians and managers to see improvement as part of their role, the integration of improvement into daily work and the commitment of clinicians and managers to shepherd healthcare system resources and be agents of change (Bevan 2010).

These themes were echoed by a number of our experts in interviews. One CEO described his organization's well thought out approach to improvement, which engages many staff in improving safety and quality of care. He noted "We have a very lean organizational structure and that allows people close to the front line to be the designers as well as the implementers of improvements and change." Most crucially, the leaders and staff are trained in problem solving, lean methods, and emotional intelligence.

So we've spent a lot of time giving frontline staff, managers, medical leaders' tools and skills in problem solving, lean methodology, emotional intelligence... So that approach of putting as much of that skill and knowledge and spreading it throughout the hospital has been really, really helpful in shifting the culture. And it's not training that takes a lot of [resource], like we do a lot of this training in-house.

Another participant underscored the importance of making sure the front line staff are trained and able to carry out improvement work as an expected part of their day-to-day responsibilities, not just on a project- by-project basis.

Maybe one of the advantages of lean initiatives is that people will be able to do this, I think it's so fundamental that we just don't think about it and we're still sort of stuck in the project mentality, and that's the problem. If you are doing a project that has a beginning and an end, that's why it's not sustainable. You have to have something that never ends.

Patient Safety Culture and Reliability: Breaking the Vicious Cycle

As noted above, most patient safety initiatives focus on implementing interventions to improve specific care processes and use checklists or other tools to ensure their reliability. There is limited information on the reliability of care more generally, in patient units or across hospitals or other organizations. However, Burnett and colleagues (Burnett, Franklin et al. 2012) studied the reliability of four clinical systems (clinical information in surgical outpatient clinics, prescribing for hospital inpatients, operating room equipment and the insertion of peripheral intravenous lines) in seven UK hospitals. Overall reliability of these systems ranged from 81% to 87% or, to put it more starkly: these important clinical systems failed 13% to 19%, nearly one in five times. Performance varied widely across the clinical systems and individual hospitals. For example the availability of equipment in operating rooms varied from 63% to 88% and the clinical information in the surgical clinics from 73% to 96%. Thus there was missing or faulty equipment in as many as one in three operations and missing clinical information available for up to one-quarter of patients seen in clinic. Not all of these issues compromised patient safety; the researchers estimated that one in five failures represented a potential threat to the safety of patients. However, the failures made care slower and led to cancellations, new appointments or other additional work.

The sources of poor reliability in these hospitals are rooted in a number of issues, including the work environment (how are equipment and supplies stored?), accountability for key systems (who is responsible for ensuring equipment is available and usable in operating rooms?), team factors (poor or inconsistent communication between pharmacists and physicians about medication orders) and task factors (is there a standard process for prescribing or discontinuing medications?) In some cases there were individual factors, including limited training or lack of familiarity with the clinical environment. And, some clinical systems were perceived by staff to be overly complex with few standard work processes. Perhaps most disturbing was that over time staff in these units had come to accept poor reliability as the norm. They had stopped reporting problems, including some issues that were potential threats to patient safety.

Staff acceptance of poor reliability as normal creates further problems. Staff learn that such first order problem solving is a core element of their work and this becomes a source of satisfaction as they resolve issues. Moreover, the focus on resolving problems displaces efforts to make systems more reliable. The focus on immediate problem solving displaces broader organizational learning. Short-term successes reduce the motivation or interest of staff to examine and redesign key work processes, and data that illustrate problems is lost as staff move on to additional “firefighting” (Tucker, Edmondson et al. 2002).

While some “workarounds” can be a source of resilience and overcome local inefficiencies, in most cases they subvert standardization and broader improvement efforts. Quick fixes resolve immediate problems but jeopardize the quality and safety of care: they mask existing deficiencies and further undermine standardization of care. A review of the empirical literature on workarounds noted that most studies focused on negative implications of these practices, including threats to patient safety (Debono, Greenfield et al. 2013).

The unpredictability of care environment has broader implications beyond workflow. The lack of standardization translates to safety concerns as well as efficiency. Many healthcare clinicians and other staff practice frequently in unsafe conditions, or observe risky practices by colleagues. And the

continual need to see and treat patients creates production pressures often accompanied by staffing shortages and other challenges. While external observers might expect such an environment to increase efforts to enhance safe practice, Amalberti notes (Amalberti, Vincent et al. 2006) that many clinicians become used to working in circumstances where staffing levels are unsafe, equipment is missing or defective, and there are pressures to “cut corners” to get work done. These conditions may exist for some time without any evident impact on outcomes. As a result staff come to accept these conditions as normal and routine, but the system has “migrated” to a level where adverse events are more likely to occur. Thus, we can see a vicious cycle emerge where – despite well-intentioned efforts focusing attention on patient safety – overall performance on patient safety does not improve.

Weick and Sutcliffe (Sutcliffe 2006) see collective mindfulness as critical to high reliability. Such collective mindfulness is reflected in 5 key components characteristic of high reliability organizations. These include an ongoing preoccupation with the possibility of failure; deference to expertise rather than hierarchy; a refusal to simplify observations about current performance which assists in making an early assessment of threats; a commitment to resilience in the face of unexpected events, identifying errors and correcting them before they have major impacts; and a sensitivity to operations, including deviations from expected performance (Sutcliffe 2006). High reliability is seen as characteristic of nuclear power plants, aircraft carriers, and other operating environments where failure is catastrophic. Yet, healthcare stands apart. Chassin and Loeb assert that few US hospitals observe these high reliability principles in practice. Indeed, “hospitals and other health care organizations behave as if they accept failure as an inevitable feature of their daily work” (Chassin and Loeb 2013) p. 463.

Compounding the pressures of unsafe work environments is the still limited information on the numbers and nature of patient safety events, particularly for staff at the front line. Despite considerable investments in reporting systems, levels of reporting are often limited. Staff, particularly, physicians, fail to report events because they are worried about being blamed (Lawton and Parker 2002, Shojania 2008), receive little or no feedback about their reports (Evans, Berry et al. 2006), feel that reporting is unlikely to result in changes, or see reporting as facilitating closer managerial or regulatory scrutiny of practice (Waring 2005). Reporting systems capture only a portion of patient safety incidents. In many instances practitioners do not report incidents or near misses because they develop local “fixes” to underlying problems (Hewitt and Chreim 2015) that remove the impetus to file reports. Many incident reporting systems identify only a small number of problems, and many of the reported events focus on clinically insignificant issues. By 2009 virtually all US hospitals (and presumably the same is true in Canada) had incident reporting systems, but only 65% of these hospitals distributed summary reports of incidents widely (Farley, Haviland et al. 2012). The goal of event reporting and analysis is to understand and learn from current patient safety threats. But a recent study in an Ontario hospital suggested that many front line staff when confronted with a problem, “fix and forget it” rather than reporting the problem. (Hewitt and Chreim 2015)

The hope that healthcare would create reporting systems as effective as aviation and other high-risk industries remains an unrealized, and perhaps unrealistic goal. While most reporting efforts have focused on facilitating the reporting of patient safety events, fewer have created systems that provide useful information for making care safer. The large number of events, the tendency to analyze each separately, instead of aggregating similar events and looking at common themes, and the challenge of identifying feasible and sustainable changes in care processes make learning from patient safety events much more challenging than was anticipated 10 years ago (Clarke 2006; Vincent, Burnett and Carthey 2014).

Many interview participants commented that the lack of data (e.g., outcome measures) and inadequate data collection capacity had to be addressed to move patient safety improvement forward. One expert stated,

I think the biggest gap still here 10 years on is a lack of systematic and reliable outcome measures. It's very difficult to improve if you don't know what you are improving. So if you don't have risk-adjusted outcomes for all your population that are being treated you are not actually going to be able to improve.... I don't see, particularly in acute care settings, how we can improve safety if we don't have any real reliable outcome measures.

A further challenge for healthcare has been the lack of investment in coordinated safety strategies. While many healthcare organizations have dedicated staff with quality improvement and patient safety roles, the numbers of these staff are often limited. In Canada these individuals serve a variety of functions, including supporting front line improvement teams, writing reports for accreditation and external regulators, staffing quality improvement meetings of senior leadership and the board and other roles (Gagliardi, Majewski et al. 2010).

Creating Safer Healthcare Environments

The patient safety efforts of the last decade have emphasized safer practices, but the broader solution to improving patient safety require creating healthcare environments that support safer care. These environments need to incorporate aspects of high reliability, including team practices that support team awareness, shared responsibilities, and adaptability to changing patient needs and staff responses (Xiao and Moss 2001; Baker, Salas and Day 2006). Clinical teams perform better in work environments with reliable clinical processes that develop standardized approaches to diagnosis and treatment, but where sensitivity to patient needs permits responsive and appropriate customization. Clinicians need to be able to assume that the necessary equipment, supplies, information and staff are available to meet current and emerging needs. The design of work, including the physical layout of patient care units, the composition of care teams, and the patterns and processes of daily practice should support effective, safe practice. Quality improvement efforts that review and improve current practice should be supported by clinical and improvement experts who facilitate these improvements.

What feasible changes are needed to create these environments? We end this paper with a set of recommendations building on our analysis of the shortcomings in the current approaches.

Recommendation 1: Healthcare organizations should develop a patient safety and quality improvement strategy that incorporates investments in local improvement capabilities and leadership as well as targeting specific patient safety events or practices.

Recommendation 2: Better measurement is needed to support patient safety initiatives both at an organizational level and at a team or microsystem level. These measures should include patient safety outcomes and measures of processes and operations that contribute to patient outcomes. Dashboards of key measures should be developed for selected microsystems and aligned with organization performance measures. Measurement of current patient safety outcomes should engage front line clinicians in determining which problems are priorities.

Recommendation 3: Patient safety event reporting and analysis should be focused on identifying key gaps in care and ensuring that recommendations are feasible and implemented. Reports from these systems need to be integrated with other quality and safety measures to create a broader picture of current safety challenges.

Recommendation 4: Since patient units with strong teamwork and leadership capabilities have superior patient safety performance, investments in improving work climate and processes are likely to help create receptive environments for patient safety practices. Lessons from high reliability efforts in healthcare and other industries will be helpful in developing teamwork, shared awareness and reliable processes. These investments are important adjuvants in the implementation of patient safety practices.

Recommendation 5: Involving patients and caregivers in patient safety and quality improvement will offer new insights on existing practices and alter current team dynamics that can limit the changes made to existing ways of working.

Recommendation 6: Increased investment in quality improvement infrastructure, including expert facilitation of patient safety and quality improvement teams, data collection and analysis and executive sponsorship of local projects will increase local support for these efforts and the

likelihood of meaningful results. Organizations should review their current investments in quality improvement capacity and target new resources where performance improvement is needed.

Recommendation 7: Leadership development is critical to improved performance in patient safety and quality improvement, as it is in other areas. The development of a talent management plan, including educational opportunities for leadership in quality and patient safety and the creation of opportunities for emerging leaders to develop and practice leadership skills in different settings are critical to improved performance.

Recommendation 8: Collaboration across organizations in efforts to improve patient safety and quality performance helps to stimulate local efforts, broaden insights on successful approaches and benchmark performance. Quality improvement collaboratives and hospital leadership networks offer low cost learning environments that facilitate greater engagement for front line clinicians as well as senior leaders.

Recommendation 9: While the governance of quality and patient safety has taken important steps forward in the last 5 years, governing boards need additional assistance in monitoring performance and understanding the returns from investments in organizational improvement capacity, better and more timely measurement and improved teamwork.

Recommendation 10: Concerns about privacy and legislation have limited information sharing about patient safety events. Currently there is currently very limited information about patient events and solutions shared across organizations and between provinces. Pan-Canadian information systems that enable better information exchange will ensure that effective responses do not have to be rediscovered in many different settings.

Conclusion

More than a decade since the Canadian Adverse Events Study, there has been a growing understanding of the safety threats facing patients and providers, and important efforts made to identify safety practices and patient safety measures. In the next decade these efforts need to be broadened and linked to efforts to improve care and care environments. Safer healthcare systems are environments where providers and managers anticipate threats and can respond effectively with limited decrements in performance. Patient safety is a critical health system issue, but the fundamental basis for improving safety lies in creating more effective work environments and high performing teams, not just selectively introducing new interventions into poorly organized settings.

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