Making Healthcare Safer
The Culture Of Patient Safety
Teamwork And Communication
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Patient safety has changed the language of healthcare. Terms such as medication reconciliation, critical incident and safety briefing are now part of the daily conversations of clinicians and managers. These shifts in language reflect larger changes in thinking and working, underpinning the currency of patient safety as a critical component of Canadian healthcare.

This is the sixth issue of Patient Safety Papers, published by Longwoods. The first five issues, published since 2005, presented reports on research studies, demonstration projects and leading practices from organizations across Canada. In this issue, we assess our progress and examine the future. To do so, we asked a selection of patient safety experts from across this country to reflect on critical patient safety initiatives in specific domains.

Ward Flemons and Glenn McRae (2012) examine the use of reporting systems to enhance organizational learning. Reporting systems are the foundation of efforts to identify gaps and create safer systems; but their success is predicated on the development of an organizational culture that facilitates reporting, and mechanisms for translating incident reports into recommendations for safer care.

Failures in teamwork and communication contribute to many patient safety events. So it is not surprising that research in these areas has made an important contribution to safer care. Yet researchers have only begun to uncover the complexities of team communication and to identify strategies to improve teams' performance. Lorelei Lingard (2012) challenges researchers and practitioners to delve deeper into team practices to understand their dynamic complexities and contribution to safety. One important tool used in team communication is the checklist. Chris Hayes (2012) helped implement the Surgical Safety Checklist across Canada. In his article, he reviews the successes and continuing challenges of getting operating room teams to use the new tool in a way that ensures safer and more effective care.

Patient safety has married insights from many different disciplines with clinical and managerial sciences. Joseph Cafazzo and Olivier St-Cyr (2012) examine the impact of human factors engineering (HFE) in addressing patient safety challenges and highlighting the importance of design and the human-machine interface. While the tools and insights of HFE have created many opportunities, Cafazzo and St-Cyr note that HFE has not yet fully delivered on its potential impact on safer care.

Work design and service delivery models also hold great promise in creating safer and more efficient care. Patricia O’Connor and colleagues (2012) examine several healthcare systems where innovative work design has translated into better outcomes for patients and staff. Redesigning care processes and physical environments creates a context for safer care; but strong leadership and support are required to implement these changes.

Healthcare-associated infections (HAIs) are another large, high-profile and recalcitrant patient safety problem. Michael Gardam, Paige Reason and Leah Gitterman (2012) identify new approaches to reducing HAIs, including the use of positive deviance to engage and empower staff in developing workable solutions. Reinforcing the insights of other papers in this volume, the authors stress the importance of patient safety culture, teamwork and design in creating a context for safer care.

Patient safety solutions must focus on care between settings, not just within them. Medication reconciliation provides tools to address and prevent adverse drug events stemming from incomplete or inaccurate knowledge about patients’ medications as they are admitted, discharged or transferred. But, as Olavo Fernandes and Kaveh Shojania (2012) discuss, this solution has been difficult to implement effectively. They argue that greater efforts are needed to ensure reliable medication reconciliation. More broadly, Irfan Dhalla and colleagues (2012) examine the patient safety threats stemming from poor integration and communication across systems of care. Transitions are complex and varied, and potential solutions need to incorporate a range of interventions and multiple providers before discharges, during transitions and after patients return to the community.

Much of the focus in the past decade has been on problems identified in major national patient safety studies. But other important issues have also emerged. Pat Croskerry (2012) notes that diagnostic error has received limited attention although it is a major contributor to adverse events and malpractice litigation. Croskerry traces the source of diagnostic error to the psychology of decision-making and cognitive bias. He urges greater emphasis on diagnostic reasoning in medical education and a continuing focus on these skills in practice. Safety is an issue outside of institutional settings too. Lynn Stevenson and her colleagues (2012) argue that home care is fundamentally different from hospital-based care and that we need to develop patient safety practices that are client- and family-centred and adaptable to the broad range of settings in which home care is delivered.

Each of these papers provides a lens through which to view a critical issue. While their coverage is not exhaustive, together they offer a perspective on our achievements and the challenges we still face. In a paper examining the strategic elements for broadening our efforts on patient safety and quality of care, I argue that we need to emphasize the business case for safety, move current initiatives to a broader scale and invest in capacity for and capability of leadership and staff to improve (Baker 2012). The gains of the past decade have been impressive, but we need to hard-wire and extend these efforts in our current system to ensure their impact and sustainability.

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Partners in Patient Safety

Hugh Macleod and Wendy Nicklin

Patient safety in healthcare is, fortunately, not an isolated quest. As seen in the array of contributors in this edition of Healthcare Quarterly, Patient Safety Papers (the sixth in the series), there are many valuable players in this arena. The Canadian Patient Safety Institute (CPSI) and Accreditation Canada have come together to co-sponsor this edition since the sharing of knowledge and expertise is so crucial to success in the patient safety forum.

It is critical to acknowledge the role that partnerships of many national and jurisdictional organizations play in this quest for a safer healthcare system. The Institute for Safe Medication Practices, the Canadian Institute for Health Information, provincial health quality councils, the Health Council of Canada and others are dedicated to helping organizations and peers improve the safety of healthcare. Such partnerships foster a coordinated effort that minimizes duplication and promotes the very best in safety.

Within the realm of patient safety, Accreditation Canada sets the standards for quality healthcare, inclusive of the required organizational practices (ROPs). CPSI leverages research expertise and provides tools that allow healthcare organizations to meet some of those ROPs.

Accreditation Canada and CPSI play complementary roles. With quality healthcare come improved efficiency and better patient outcomes. Through the integration of accreditation within the organization’s quality improvement program, Accreditation Canada continues to play a role in enabling high-quality care and in ensuring that the patient safety focus is clearly fundamental to achieving this high-quality care. CPSI views accreditation as integral to a safer healthcare system. It develops and uses evidence-based procedures and products to help organizations put into place the necessary tools to enable safety.

In 2011, Accreditation Canada completed a comprehensive evaluation of its Qmentum accreditation program. Through the insights gained, Accreditation Canada has provided evidence proving that patient safety and quality healthcare are inextricably linked. In addition, an organization with a strong governing board achieved higher performance by incorporating the ROPs and the Patient Safety Culture Tool. With that in mind, Accreditation Canada recently developed the Patient Safety Strategy Phase Three, which builds on the work done in phases one and two. It also continues to strengthen the role of the accrediting process, as integrated with quality improvement programs, and is a catalyst for ensuring that patient safety strategies are incorporated into daily practices.

Through collaborative relationships, such as that between Accreditation Canada and CPSI, the implementation of key initiatives is enhanced, ensuring that client organizations and patients see results sooner rather than later.

Accreditation Canada’s 2011 Report on Required Organizational Practices (2011) revealed that the ROPs achieving the highest national compliance rates were related to infection prevention and control, suicide prevention, medication safety and communication at transfer points— all of which are areas where CPSI has focused its efforts in the recent past. The accreditation process and the resultant data provide invaluable insights that can help inform changes, not only for Accreditation Canada but also across healthcare. For CPSI, the accreditation process offers insight regarding where to expand products and services and where to focus research efforts.

Accreditation Canada and CPSI are proud to co-sponsor this important publication focusing on patient safety. We hope that the readers benefit in a marked way from the quality of the articles contained herein.

Hugh Macleod is president and CEO of the Canadian Patient Safety Institute.

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Reference
EFFECTIVE GOVERNANCE FOR QUALITY AND PATIENT SAFETY – RESOURCES FOR HEALTHCARE BOARD MEMBERS AND SENIOR LEADERS

The Canadian Patient Safety Institute (CPSI) and the Canadian Health Services Research Foundation (CHSRF) co-released the report, “Effective Governance for Quality and Patient Safety in Canadian Healthcare Organizations,” prepared by a research team lead by Dr. G. Ross Baker.

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The Challenges of Making Care Safer: Leadership and System Transformation

G. Ross Baker

Ten years ago, in September 2002, the National Steering Committee on Patient Safety delivered its report urging the development of the Canadian Patient Safety Institute and enhanced efforts to identify and reduce the risk of patient harm across the healthcare system. Two years later, the Canadian Adverse Events Study (Baker et al. 2004) provided data on patient safety in acute care – data that reported levels of harm far greater than most suspected. Today, virtually all Canadian healthcare organizations have goals around improving the safety and quality of care, and many have implemented reporting systems that identify patient safety incidents and track the implementation of recommendations to reduce hazards. In only a decade, patient safety has been transformed from the esoteric interest of a small number of champions to an essential component of healthcare performance across Canada. Today, patient safety is a fundamental prerequisite for the healthcare system: quality is impossible unless patients are protected from unintended harm.

Yet despite clear goals and considerable investments to improve patient safety, the gains have been limited. Healthcare-associated infections remain a major source of patient morbidity and mortality (Umscheid et al. 2011); adverse drug events continue to occur in hospitals (Classen 2010) and many other settings (e.g., Thomsen et al. 2007); and many other risks, such as pressure ulcers and patient falls, resist efforts to reduce their incidence. Although the problems are now well known, progress is slow. One study of a sample of hospitals in one US state showed little evidence of improvement over 10 years (Landrigan et al. 2010).

Even more troubling are the challenges of creating effective solutions. As Fernandes and Shojania (2012) report in this special issue, medication reconciliation offers clear benefits when implemented in a robust and effective fashion; but many organizations have created only a superficial and ineffective process. Efforts to improve hand hygiene gain traction in many settings, only to have compliance return to low levels when attention moves elsewhere. And the problems span organizational boundaries. Dhalla and colleagues (2012) explore the reasons why many patients experience adverse events following hospital discharge. The handoff between the hospital and the community fails due to inadequate plans or poor communication about follow-up visits or medications. Safe and effective care requires careful coordination between caregivers in multiple settings and quick, informed decisions based on new knowledge about a patient’s condition. As a result, the opportunities for failure are frequent. Patient safety in the home presents additional challenges: as Stevenson and her colleagues detail (2012), every home environment is different and the resources available to identify and respond to risks are limited.

High reliability in many industries comes from automating complex processes; however, healthcare remains a largely human endeavour – which is mostly a good thing. But humans are fallible, systems are imperfect and patient safety is elusive.

Still some progress is apparent. One of the important benefits of the emphasis on patient safety and quality improvement in the past decade has been the development of new approaches to clinical improvement. Patient safety “campaigns” beginning...
with the Institute for Healthcare Improvement 100,000 Lives Campaign and the Canadian Safer Healthcare Now! initiative have mobilized large-scale efforts and motivated greater engagement. While notable themselves for spurring action, often with defined timetables and goals, these initiatives incorporated several important and innovative features. First, they were designed around the Model for Improvement, a simple, effective strategy for setting aims, selecting measures and small-scale changes and then testing these changes in local settings (Langley et al. 2009). Although the logic for the Model for Improvement is rooted in a long tradition, many teams and organizations first used it as part of Safer Healthcare Now! and similar patient safety initiatives. Second, these campaigns incorporated an effective knowledge translation strategy that translated evidence around effective practice into “bundles” of specific recommended practices. In the bundle for central line care, for example, teams were asked to carry out five practices: hand hygiene; maximal barrier precautions; chlorhexidine skin antiseptic; optimal catheter-site selection, avoiding the femoral vein for central venous access in adult patients; and daily review of the necessity of central lines, with unnecessary lines promptly removed. Although there was evidence for the use of each of these elements, their prominent inclusion in a list of key practices and the highlighted experience of teams that were able to reduce central line infections using these practices provided considerable traction for local leaders who sought to engage teams in improving care.

The identification of effective practices and their “translation” into bundles has linked broader patient safety goals into daily clinical practice. But at the same time, the variation in the success of different teams in adopting these practices makes it evident that knowledge of effective practice alone is insufficient to improve performance. Improved patient safety relies not just on knowledge of safe practices but also on creating care environments that support individuals and teams to identify, adapt and spread these practices. In the Keystone project, which involved clinicians from 103 intensive care units (ICUs) in 55 Michigan hospitals in reducing the rate of catheter-related bloodstream infections (CR-BSIs; Pronovost et al. 2006), the evidence of effective practices was linked to a strategy to engage, educate and execute these practices in local settings and to evaluate their impact. Rather than assuming that knowledge of “what works” was sufficient, the project explicitly linked the new practices to efforts to improve local unit safety cultures and to engage organizational leaders in reviewing and supporting unit-based change. Borrowing from Ronald Heifitz’s useful distinction between “technical” changes based on scientific evidence and “adaptive” changes involving attitudes, values and culture (Heifitz 1994), Pronovost and colleagues (2006) recognized that the alterations in ICU practice incorporated in their efforts to reduce CR-BSIs were more than just changes in simple practice. These changes had to be rooted in the critical care unit culture and supported by leadership at the unit and organizational levels.

Implementing effective practices into daily routines is more than simply acknowledging culture; the dynamics of change are variable and complex. Some units absorb new tools and approaches such as the central line infection bundle or safe surgery checklist; others see these ideas as a challenge to existing routines and relationships. While patient safety practices have become accreditation requirements and publicly reported performance measures, these requirements are insufficient to overcome resistance in many settings—they can create superficial compliance rather than reliable practice.

Rosabeth Moss Kanter noted that “everything can look like a failure in the middle” (1999: 20). Sound ideas for improving patient safety and well-conceived plans to implement these changes may start enthusiastically, but they inevitably hit a plateau. Leaders must sell their ideas and engage staff, not expect blind obedience. Healthcare organizations are slow to change because they are complex professional bureaucracies and patterns of local work become deeply ingrained. Scepticism about change is rooted not only in a defence of professional autonomy but also in a need to assess whether new ideas are effective or possibly harmful. Over the past decade, there has been a growing recognition of the need to identify risks and create strategies to prevent or mitigate the potential harm that results from these risks. The challenge for the next decade will be to create integrated and sustainable strategies to incorporate safe practices and safety strategies into Canadian healthcare organizations. A small number of key elements will help to determine the effectiveness of these efforts.

**Strategic Elements for a Safer System**

Government budgets and recent reports, such as the Drummond report (2012) in Ontario, herald a new era of cost constraints in healthcare. These may undermine current efforts to implement patient safety practices; at a minimum, they will force organizations to take a harder look at their current investments in quality improvement and patient safety. While patient safety concerns have been a high priority for the past decade, moving forward, the realistic prospect is that patient safety advocates will need to be more disciplined in arguing the “business case” for safety. Poor-quality care is typically more expensive than good-quality care. But capturing the savings from new patient safety practices is often difficult. The ICU patient safety initiatives of Peter Pronovost and his colleagues translated into both a substantial improvement in care and large cost savings (Waters et al. 2011). Prioritizing efforts that offer considerable savings is an obvious strategy for preserving current investments in quality and patient safety staff and other resources. Rather than see cost containment and patient safety as competing goals, we should welcome the opportunity to reduce harm while limiting or reducing costs. An additional challenge is that Canadian hospitals are funded
largely through global budgets. Individual organizations may not garner savings from reductions in adverse events since their beds remain filled with other patients — so the challenge will be to reap those savings on a broader system level while maintaining a commitment to improvement at the local level.

Too many patient safety initiatives have had limited scope and, thus, minimal impact. But if the goal is to reduce harm and costs by focusing on high-frequency or high-cost events, patient safety interventions have to scale up. Sometimes the limits on scale stem from variable enthusiasm: for example, as Chris Hayes (2012) notes in this volume, some surgeons have adopted the surgical checklist while others avoid it. But if errors can happen to any surgeon in any operation, then ensuring widespread adoption is key to reducing harm and conserving resources. Testing new ideas and adapting improvements to local practice environments make sense given the differences between Toronto and Timmins, or Calgary and Cape Breton. However, when interventions prove effective, leaders must require commitment from those providing care. The test of effective patient safety is no longer success on individual units but, rather, the creation of reliable and safe care across large systems.

In many Canadian hospitals, the responsibility for clinical care is delegated to program or unit directors and clinical leads; but if patient safety and quality of care are truly strategic goals, they need to be embraced by senior leaders, with clear accountability from the board to the ward. New legislation in Ontario, the Excellent Care for All Act, has clarified the responsibilities of boards and senior leadership for quality of care; and the publication of quality improvement plans by all Ontario hospitals emphasizes both current levels of performance and the scale of hospitals’ quality goals. Yet, setting goals is only the beginning of the challenge. Aligning activities and investments on quality improvement strategies across executive portfolios can be difficult, as is creating a portfolio of projects that can address the quality goals. Recent work by Trillium Health Care in Ontario demonstrates how driver diagrams and other management tools can help to focus and align patient safety and quality activities in that organization (Cochrane et al. 2011).

Capacity and capability for change is another important issue. Helen Bevan identified capacity as “having the right number and level of people who are actively engaged and able to take action” and capability “means that those people have the confidence and the knowledge and skills to lead the change”(2010: 2). The growing pressures of daily work create a disincentive for staff to engage in improvement, and organizations faced with slow and uncertain improvement often employ external change agents to speed these efforts. However, while change consultants can help to start change, it is the ongoing capability of organizations to develop new ways of working that is key to enduring improvements (Parcell and Collison 2009, as cited in Bevan 2010). Canadian healthcare organizations have relatively few staff with expertise in quality improvement methods and patient safety. These staff are often burdened with multiple responsibilities and ambitious programs of work. Since the pace of change is limited by the capabilities of front-line units, supported by quality improvement experts, to make improvements, the pace is usually slow. Experience in a number of high-performing healthcare organizations, such as Intermountain Healthcare and the Henry Ford Health System in the United States and Jönköping County Council in Sweden, demonstrates that greater investment in this capability accelerates the pace of improvement (Baker et al. 2008; Baker and Denis 2011a).

Physician engagement is a particularly critical issue. No substantial change in clinical care is possible without the full involvement of physicians. Efforts to transform healthcare systems – improving safety and quality while limiting increases in costs – must engage informed physicians as part of the team. Yet this has been difficult in many settings. There are encouraging efforts in Saskatchewan and elsewhere in Canada to develop a physician cohort with expert quality improvement skills, but these initiatives need to be broadened. Leaders in healthcare organizations must recognize that developing the skills of a handful of physicians to assume leadership roles is no longer sufficient. Rather, leaders need to create a distributed network of physician champions as part of medical leadership strategies that facilitate broad-scale improvement among their physician colleagues (Baker and Denis 2011b). These physicians (and other clinicians) will become role models. Their insights into clinical processes linked with knowledge of quality improvement will provide the mechanisms for identifying and implementing sustainable quality gains.

Achieving higher-quality and safer care without increasing long-term costs requires the redesign of existing systems of care. Improvement starts with identifying waste and focusing on value. The current and growing interest in applying Lean thinking and Lean production ideas to healthcare stems from this need. Lean initiatives provide the tools to systematically examine work processes, identify improvements and implement new systems and environments. New programs, such as Releasing Time to Care: The Productive Ward, in Saskatchewan and Ontario offer systematic ways to examine and improve nursing care and patient unit environments, with the potential to improve efficiency, increase patient safety and quality, boost staff satisfaction and enhance the patient experience. Yet working on large-scale improvement is an enormous task, and the rate-limiting step is our ability to create capability – the skill, energy and insight– at the front lines to improve care. In a time of restraint, it might seem ambitious, or even foolhardy, to suggest that we need a broad investment in improvement skills in leaders, clinicians and managers. But this is exactly what the system needs. Rather than cutting education and support (as is usually done in times of restraint), we should
be investing in programs to build skills, provide resources to seek out and test innovative new ideas, and create the energy that helps to mobilize staff across the system. Large-scale changes, in healthcare or elsewhere, require mobilizing commitment, not just restructuring of pieces and programs (Bate et al. 2004; NHS Institute for Innovation and Improvement n.d.). Reports over the past 15 years have highlighted the critical issues facing the Canadian healthcare system. These issues remain, and recent reports, such as the Drummond report (2012), have reinforced their urgency. But there is still no detailed plan in most of Canada for how to execute the changes needed to improve safety and quality at a large scale across the continuum of care with the currently available resources. The costs of developing leadership skills and improvement knowledge and of investing in staff and innovation to achieve a sustainable healthcare system are relatively modest. The achievable outcomes that would come from such efforts are likely the only bridge from the current system – which wastes resources and breeds frustration in patients, staff and leadership alike – to a sustainable, accessible and safe healthcare system.

References


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THE CULTURE OF PATIENT SAFETY

Reporting, Learning and the Culture of Safety

W. Ward Flemons and Glenn McRae

Abstract

Systems that provide healthcare workers with the opportunity to report hazards, hazardous situations, errors, close calls and adverse events make it possible for an organization that receives such reports to use these opportunities to learn and/or hold people accountable for their actions. When organizational learning is the primary goal, reporting should be confidential, voluntary and easy to perform and should lead to risk mitigation strategies following appropriate analysis; conversely, when the goal is accountability, reporting is more likely to be made mandatory. Reporting systems do not necessarily equate to safer patient care and have been criticized for capturing too many mundane events but only a small minority of important events. Reporting has been inappropriately equated with patient safety activity and mistakenly used for “measuring” system safety. However, if properly designed and supported, a reporting system can be an important component of an organizational strategy to foster a safety culture.

Healthcare is not as safe as it should or could be: rates of adverse events, defined as situations where patients suffer harm from the healthcare they receive (or not receiving care that would have helped), in acute care have been shown to be high. For example, the Canadian Adverse Events Study found that 7.5% of patients admitted to a Canadian hospital suffered an adverse event (Baker et al. 2004). The National Steering Committee on Patient Safety listed the comprehensive identification and the reporting of hazards as one of “nine key principles for action” that served as a foundation for the committee’s recommendations to make Canadian patients safer (National Steering Committee on Patient Safety 2002). Further, the committee recommended the adoption of non-punitive reporting policies within a quality improvement framework. Recently, the National System for Incident Reporting (Canadian Institute for Health Information 2011) was established by the Canadian Institute for Health Information, whose focus at the present time is incidents regarding hospital-based medication and intravenous fluids. The development of reporting systems to enhance patient safety has been proposed as a strategy in other countries; examples include the Australian Incident Monitoring System (Runciman 2002) and the National Reporting and Learning System in England and Wales (Williams and Osborn 2006).

Reporting Defined

Reporting is described in The Canadian Patient Safety Dictionary as “an activity where information is shared with appropriate responsible individuals or organizations for the purposes of system improvement” (Davies et al. 2003). Reporting is sometimes confused with disclosing, informing and notifying. Disclosing is the imparting of information, by healthcare workers...
(and, in some situations, healthcare organizations) to patients or their significant others, pertaining to any healthcare event affecting (or liable to affect) patients’ interests (adapted from Davies et al. 2003). Informing, in this context, can be described as the sharing of safety-related information by an organization, or an individual healthcare provider, with stakeholders who are not responsible for the care of a particular patient or patient population (Figure 1). Reporting can be internal or external to a healthcare providing organization. Finally, notifying means to give formal notice (Merriam-Webster n.d.); in this context it would be providing notice to individuals in organizational positions of authority about an important safety event. Although voluntary sharing of patient safety incidents with provincial or national non-regulatory organizations is commonly referred to as reporting, using the definitions derived from *The Canadian Patient Safety Dictionary*, this voluntary sharing would more accurately, for the organization submitting the information, be referred to as informing.

**What Are We Trying to Accomplish?**

In addition to national strategies for incident reporting, internal systems are often set up locally; health system (e.g., health region, local health integration networks, groups of hospitals) and hospital-based incident reporting systems are ubiquitous. Is there a clear understanding of how reporting into these systems would translate into safer care? One goal of asking healthcare workers to submit reports of adverse events, close calls, hazardous situations or errors is to make possible the opportunity for a system to learn of vulnerabilities or weaknesses in care delivery processes. When reports of adverse events and close calls are submitted, the expectation is that reporting an event will lead to lessons learned; an analysis of the event will shed light on contributing factors, and interventions that address the system deficiencies that contributed to harm will be undertaken to reduce the likelihood of recurrence. Reporting systems can also be created for which the primary goal is accountability. Some organizations strive to hold healthcare providers more accountable for the care they provide by placing reports of close calls and adverse events in human resources files, which can then be used for performance assessment. Using reports to aid in assessing performance (negatively) is a strong motivation for healthcare providers to stop reporting, thus reducing the potential for organizational learning. Reporting systems with a primary purpose of accountability require the reporting activity to be mandatory; those systems with a primary purpose of learning are created so that the activity is voluntary and without repercussions for either not reporting or what is reported (with exceptions for criminal activity or gross negligence).

Reporting systems have been used for purposes other than learning and accountability. Some organizations use their reporting system data to track or measure safety in their system. For example, it is not uncommon for organizations to use reports of falls as their “falls rate” performance measure. But because the reporting is incomplete and not systematic, the events and issues that are captured do not reflect an objective estimate of the rate of adverse events; reporting systems are not helpful for estimating whether a healthcare system is becoming more or less safe.

Many organizations rely mostly on reports of adverse events as their source of information about system weakness and vulnerability. However, several studies have demonstrated that reporting systems capture only a minority of adverse events and close calls. Sari et al. (2007), in a large UK National Health Service hospital, compared the organization’s routine incident reporting system with a review of case notes in 1,006 admissions. Of the 324 patient safety incidents identified in 230 admissions, 83% were picked up by case note review only, 7% by the routine reporting system only and 10% by both. The case note review detected all 110 admissions in which a patient suffered harm; however, the reporting system detected only 5% of these. Similarly, Cullen et al. (1995) found that only three of 54 adverse drug events (6%) had a corresponding incident report filed. Reporting has also been criticized for capturing too many “mundane” events...
and for inappropriately being equated with meaningful patient safety activity (Vincent 2007).

**A Role for Reporting: Using Reporting Systems to Transform a Culture**

Sustained improvement in the provision of safe patient care requires an organizational commitment to a safety culture; reporting is an important contributor to this (Vincent 2007). Reason (1997) listed reporting and a reporting culture as one of four attributes of a safety culture. The other attributes are learning, flexibility and a just culture. Reason defined an organizational learning culture as “the willingness and the competence to draw the right conclusions from its safety information system, and the will to implement major reforms when their need is indicated” (1997: 196). He also suggested that the best safety information is derived from analysis of reports of incidents and near misses as well as from “proactive checks on the system’s vital signs.” A reporting culture is “an organizational climate in which people are prepared to report their errors and near-misses” (Reason 1997: 195). It is dependent on how an organization processes information and chooses to handle blame and punishment. Westrum (2004) described three archetypal organizational approaches for processing information: (1) pathological (messengers are shot/failure leads to scapegoating/novelty is crushed); (2) bureaucratic (messengers are neglected/failure leads to justice/novelty is problematic); and (3) generative (messengers are trained/failure leads to inquiry/novelty is implemented). Reason defined a just culture as “an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information – but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour” (1997: 195).

Important success factors for a reporting system to be effective – based on our review of the literature and our experience in implementing a new, electronic safety and learning reporting system in the former Calgary Health Region – are listed in Table 1. The contribution of reporting to high-quality, safe patient care and reporting system dependencies are shown in Figure 2.

### Experience Implementing a Region-Wide Safety and Learning Reporting System

In the former Calgary Health Region, external reviewers were asked to complete an analysis of the safety of Calgary’s health-care system following the death of two patients in 2004 (Baker et al. 2008). Among the multiple recommendations made for making care safer was a proposal to redesign the region’s incident reporting system to ensure that reports were used “as learning opportunities for the entire organization” and not as occasions for performance management. What existed at the time in the region was a paper-based reporting system that required staff to complete a detailed form and submit it to their direct supervisor. If the supervisor believed the report detailed an “incident,” he or she would submit the report, via internal mail, to a central safety office; copies were sometimes kept by supervisors and placed in personnel files. The average duration between the time an incident occurred and the report reaching the safety office was 30 days. Basic summary-type statistics were generated, but there was no systematic process for report analysis: managers assumed responsibility for reading reports and “closing the file.” The most common actions were to speak with the staff member(s) involved or to forward the report to someone else so that he or she could speak with the staff member(s). Rarely was a report received from a physician.

The decision was made to completely change the reporting system to complement a planned effort to evolve an existing bureaucratic attitude in the region toward a more generative attitude, with the ultimate goal of creating a safety culture. This was signalled by decommissioning the existing paper-based “incident reporting system” (incident was poorly defined and could refer to non–patient safety issues) and replacing it with an electronic safety reporting and learning system. An easily identifiable link to the reporting system was created on the region’s internal home page so that it was readily accessible.

The fundamental premise was that an increase in the number of reports would positively reflect a shift in attitude and culture. The tactics used to increase reporting rates included making the act of reporting (1) acknowledged, (2) worthwhile, (3) easy to use and (4) safe (no real or perceived repercussions). Reporters received an automatically generated message acknowledging their effort to report and thanking them for submitting. To signal that reporting was worthwhile, a formal communication

<table>
<thead>
<tr>
<th>TABLE 1. Important success factors for effective reporting systems</th>
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<tbody>
<tr>
<td><strong>Organizational</strong></td>
</tr>
<tr>
<td>• Generative approach toward information processing (Westrum 2004)</td>
</tr>
<tr>
<td>• Just culture (not a blame-free culture) (Reason 1997)</td>
</tr>
<tr>
<td><strong>Design of the system</strong></td>
</tr>
<tr>
<td>• Voluntary and confidential</td>
</tr>
<tr>
<td>• Easy to use</td>
</tr>
<tr>
<td>• Focus on the story (Morath and Turnbull 2005)</td>
</tr>
<tr>
<td>• Emphasis on close calls (near misses) (Morath and Turnbull 2005)</td>
</tr>
<tr>
<td>• Acknowledgement and feedback given to reporter</td>
</tr>
<tr>
<td>• Analysis by clinicians and someone able to analyze human factors and organizational issues (Vincent 2007)</td>
</tr>
<tr>
<td>• Visible action taken to mitigate important risks identified in reports</td>
</tr>
</tbody>
</table>

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strategy was launched that produced patient safety alerts, safer practice notices and patient safety information sheets, the genesis of which were in part from the reports received. The system was designed around simplicity – there were minimal screens for users to complete, with a minimal amount of required information; the focus was a narrative story rather than check boxes requiring users to “classify” the report.

To make the system safe, the practice of using reports for performance management was stopped, a changed endorsed by the region’s executives and board. A just and trusting culture policy was also introduced, based on a principle of appropriate accountability (i.e., not blame free), that declared that healthcare workers would not be punished for committing errors regardless of whether a patient was harmed or not, but maintained accountability at an individual level in other circumstances (i.e., rule breaking, intention to harm). Additional safety was designed into the system itself: in the new electronic system, the reporter’s name was required in order to submit a report but was kept confidential (supervisors were prevented from knowing the name of the reporter).

Initial pilot studies of the new system showed that old habits were hard to break; to maintain the past practice of performance management, some managers resorted to using patient identifiers, chronological information and staff rotation information to determine who the reporter was and/or which staff members were involved in the report. Therefore, the reporting system was redesigned with two important (and executive-approved) modifications. First, a daylong educational program, supported by tool kits and workbooks, was created and delivered to over 1,500 leaders. The program introduced them to the region’s four new safety polices: Reporting, Disclosure, Just and Trusting Culture, and Informing. These workshops provided leaders with a theory-based safety model for the changes being introduced and the rationale behind the new reporting system. Second, all possible identifiers (including those of the patient) were removed from the submitted reports. The premise was that the primary purpose of this reporting system was to serve as a safety culture carrier. Staff could tell their patient safety stories with the expectation that managers, by reviewing the substance of the reports, would target the system rather than individuals for change.

However, one of the unintended consequences was the alienation of many front-line managers who felt a disconnect between their responsibility for the care being provided in their area and their inability to use the new system to manage individual events (as described in reports). Managers were receiving reports signaling that something untoward had happened in their area of responsibility, and they felt disempowered in their attempts to manage the issues. The managers were still adhering to the prevailing culture, with the belief that each report required individual follow-up with a staff member, which was in conflict with a new safety culture that promised confidentiality to the reporter. Some managers created a workaround – the development of a parallel paper-based event management system (recreating the old incident report).

**FIGURE 2. Requirements for and role of an effective reporting system in the delivery of high-quality, safe patient care**

<table>
<thead>
<tr>
<th>Goal / Outcome</th>
<th>High-quality, safe patient care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous improvement</td>
<td>- processes of care</td>
</tr>
<tr>
<td>- structures</td>
<td></td>
</tr>
<tr>
<td>Measurement / evaluation</td>
<td></td>
</tr>
<tr>
<td>Prioritization</td>
<td></td>
</tr>
<tr>
<td>Reports from other healthcare organizations</td>
<td></td>
</tr>
<tr>
<td>Identified opportunities</td>
<td>- hazards / hazardous situations</td>
</tr>
<tr>
<td>- suboptimal quality issues</td>
<td></td>
</tr>
<tr>
<td>Reports from the healthcare literature</td>
<td></td>
</tr>
<tr>
<td>Analysis</td>
<td></td>
</tr>
<tr>
<td>Investigations of patient safety incidents</td>
<td>- adverse events</td>
</tr>
<tr>
<td>- close calls</td>
<td></td>
</tr>
<tr>
<td>Reports from healthcare workers / staff about</td>
<td>- hazards</td>
</tr>
<tr>
<td>- hazardous / error prone conditions</td>
<td></td>
</tr>
<tr>
<td>- close calls</td>
<td></td>
</tr>
<tr>
<td>- adverse events</td>
<td></td>
</tr>
<tr>
<td>Willing co-operation of healthcare workers</td>
<td></td>
</tr>
<tr>
<td>Just Culture - how the organization / system responds when a worker / provider:</td>
<td>- makes an error</td>
</tr>
<tr>
<td>- makes an error implicated in harm</td>
<td></td>
</tr>
<tr>
<td>- is noncompliant with (violates) rules / procedures</td>
<td></td>
</tr>
<tr>
<td>- intentionally harms a patient</td>
<td></td>
</tr>
<tr>
<td>Organization’s reputation for ‘responding’</td>
<td>- do they listen?</td>
</tr>
<tr>
<td>- do they make effective changes?</td>
<td></td>
</tr>
<tr>
<td>Ease of reporting</td>
<td></td>
</tr>
<tr>
<td>Reporting is safe</td>
<td>- voluntary</td>
</tr>
<tr>
<td>- confidential</td>
<td></td>
</tr>
<tr>
<td>Just Culture - how the organization / system responds when a worker / provider:</td>
<td></td>
</tr>
<tr>
<td>Acknowledgement for, &amp; feedback about reporting</td>
<td></td>
</tr>
</tbody>
</table>
In the final evaluation of the new reporting system, staff overwhelmingly asked that they be given the option of whether or not to leave their name on the electronic report that would be sent to their manager. Although the intent of the region’s quality and safety portfolio that led the implementation of the new reporting system was to make it completely voluntary and confidential, it was learned that it would take time to evolve to this ideal. In retrospect, the investment needed in change management and the requirement to also replace the non-safety uses of the legacy incident reporting system were underestimated.

The analysis of safety learning reports was well supported; this was an important factor for success. Centrally, there were two expert coders, and each one of the six clinical portfolios in the region had a patient safety leader who was responsible for (1) reading each report that originated within his or her portfolio; (2) scrubbing all identifiable information; (3) classifying and entering the report into the Safety Learning Database; (4) identifying those reports that required more immediate action and ensuring that timely notification was made available to responsible leaders; and (5) where appropriate, sending reports to members of “reading groups.” For example, an interdisciplinary group of medication experts would read reports of adverse drug events and determine, through electronic communication with each other, if there were particular reports that required action or themes emerging from groups of reports. This expert group reviewed multiple reports about the failure to remove timed medication patches from patients. They took a systems approach to addressing this hazard and published a patient safety alert and configured the region’s new patient care information system to provide electronic reminders for patch removal.

Notwithstanding some of the challenges with the new Safety Learning and Reporting system, the initial evaluation of its implementation showed positive results: reporting increased by 200% (Figure 3); reporter perception of safety (in reporting) and ease of use increased significantly (Table 2); there was an

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**TABLE 2.**

<table>
<thead>
<tr>
<th>Level of Agreement</th>
<th>Pre-implementation (n = 309)</th>
<th>Post-implementation (n = 172)</th>
<th>p Value (Chi-Square)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff may be blamed unfairly when an incident report/safety learning report is submitted</td>
<td>Agree/strongly agree: 34.9%*</td>
<td>16.0%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>I don’t feel confident the incident report/safety learning report is kept confidential</td>
<td>Agree/strongly agree: 50.5%</td>
<td>27.3%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>The incident form/safety learning report takes too long to fill out</td>
<td>Agree/strongly agree: 58.6%</td>
<td>23.9%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>The incident report/safety learning report is complex and can be complicated to fill out</td>
<td>Agree/strongly agree: 48.8%</td>
<td>17.4%</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* For this response, n = 310.
increased percentage of submitted reports that described close calls and hazards rather than adverse events; and feedback to reporters increased (more than 260 reporters received feedback on substantive and demonstrable changes that had been made to the system as a result of their reports).

Before additional evaluations could be carried out, the region merged with other provincial regions in the creation of Alberta Health Services. This changed the direction of this system. However, the implementation of the Safety Learning and Reporting System demonstrated that it was possible to create an approach to reporting that was successful at meeting the requirements set out in Table 1 and thus supported a large healthcare organization’s goal to positively influence its safety culture.

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References


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… a reporting system can be an important component of an organizational strategy to foster a safety culture. See page 12.
Productive Complications: Emergent Ideas in Team Communication and Patient Safety

Lorelei Lingard

Communication is recognized as one of the central factors underpinning safe, high-quality teamwork in complex systems. Without effective communication, competent individuals form an incompetent team. Healthcare, traditionally predicated on the excellence and autonomy of the individual practitioner, has been somewhat slow to embrace this reality. It is only recently that we have recognized that both technical and communicative expertise are necessary for safe care.

The past decade has seen important advancements in our attitudes and knowledge regarding team communication. There is increasing evidence of an association between effective team communication and valued clinical outcomes (Alfredsdottir et al. 2007; Gawande et al. 2003; Mazzocco et al. 2009; Neilly et al. 2010; Nurok et al. 2011). Research in this domain has developed a knowledge base sufficient to drive international change initiatives, such as the World Health Organization’s Safe Surgery campaign (WHO 2010). Team communication is becoming a standard component of health professional education, recognized in competency frameworks (Royal College of Physicians and Surgeons of Canada 2005) and supported by a catalogue of validated measurement tools to track trainee performance (Mishra 2009; Yule et al. 2008).

Unquestionably, great strides have been made in what might be called the “first generation” of research regarding team communication and patient safety. However, some of the messier, murkier aspects of team communication remain poorly explored. In fact, one of the hallmarks of the first generation of team communication research is arguably an oversimplification of what is, at its essence, a highly complex phenomenon. Oversimplification may be a natural consequence of our efforts to make early headway in the face of a complex social phenomenon. However, the major contribution of the “second generation” of team communication research will be to build on these starting points through productive complications of what we already know. In what follows, three promising areas of study are sketched: the meaning of silence, the uptake of communication innovations and the phenomenon of intertextuality.

**The Meaning of Silence**
To date, team communication research has attended to the presence of speech: what team members are saying to one another, or what they should be saying to one another, in the course of their clinical work. The absence of speech, by contrast, has received little attention. The importance of this distinction is evident to anyone who has spent time with healthcare teams at work: there is much more being communicated in teams than simply what is being said. Teamwork is full of meaningful silences; so far, however, our research efforts and teamwork improvement initiatives have paid little attention to the silent end of the speech-silence continuum.

An exception is the literature on organizational silence, which
explores why team members may not “speak up” during or after dangerous clinical situations. This literature is concerned mainly with error reporting; silence in this context is conceived as the failure to report, and the research in this domain describes the organizational characteristics and professional attitudes that create such silences (Chamberlain 2008; Espin et al. 2007, 2010; Maxfield 2005, 2010; Tangirala 2009), the socially shared nature of silence as mutual censorship (Hart 2011) and “consensual neglect” to report, which may present a hidden threat to safety (Henriksen 2007). Overall, this literature on silence as “not reporting” shares an orientation toward silence as problematic and, once understood, ameliorable. This orientation is appropriate in the context of cultivating a culture of error reporting for quality and safety. However, not all silence is problematic.

Many kinds of silence punctuate the everyday communications of a clinical team. They include the matter-of-fact silence required for conversational turn-taking etiquette (Sacks 1974); the pregnant silence of a request that is unanswered (Gardezi 2009); the uneasy silence that descends when something unexpected emerges intra-operatively (Moulton et al. 2010); the face-saving silence when a junior team member cannot answer a teacher’s Socratic question (Lingard et al. 2003); and the comfortable silence of routine work among familiar colleagues. Silence is recently becoming recognized by communications experts, such as linguists, as a rich communicative resource (Kurzon 2011). While some recent studies point to the presence of silence as a meaningful marker in a team setting (Moulton 2010), few explore more fully its motivations and implications on hierarchical teams (Gardezi 2009) and its role in serving tacit purposes such as both patient and psychological safety in the operating room (Lingard et al. 2009).

An emerging literature is grappling with the meanings of silence for teamwork and safety. Fivush (2010) has laid out, using a feminist socio-cultural lens, the distinction between “being silent” and “being silenced”; the former may entail a shared understanding that need not be voiced, whereas the latter may entail an imposed loss of power. Working with similar attention to the complexity of silence, Gardezi et al. (2009) took a critical ethnographic approach to exploring the patterns of nursing silence on operating room teams. They described three forms of recurring silences – not sharing information, not responding to requests and speaking quietly – and found that these could be defensive or strategic. These authors argue that current improvement initiatives, such as preoperative team briefing, need to take into account the ways in which silence functions, both productively and problematically, in everyday team communications.

Silence in team communication can be functional or dysfunctional as far as patient safety is concerned; it depends on the team members involved, the particular situation and the broader organizational context. The second generation of team communication research is poised to more fully explore what silence is doing on teams, by tracing patterns of silence in particular work settings and describing their impact on patient safety issues such as situational awareness and adaptive flexibility in the face of emergent challenges.

The Uptake of Improvement Initiatives
Initiatives aiming to better team communication in order to improve patient safety have proliferated in recent years. This section focuses on one particularly popular effort: a checklist approach to support pre- and post-operative surgical briefings in operating room teams. Such checklists support a communication protocol that is designed to create a proactive, inclusive and non-hierarchical communication event that ensures the transfer and explicit verification of salient information about a surgical procedure (WHO 2010). A growing body of evidence testifies to the ability of surgical briefings to better patient safety by improving the timing of antibiotic prophylaxis (e.g., France et al. 2008; Lingard et al. 2011; Paull et al. 2010; Rosenberg et al. 2008) as well as other basic standards of care (Weiser et al. 2010); decreasing non-routine surgical events (Einav et al. 2010); and reducing rates of errors (de Vries et al. 2010), death and complications (Haynes et al. 2010; Weiser et al. 2010).

The development of this evidence base has supported a cultural shift in attitude, from the acceptance of a tradition of ad hoc communication among team members to the insistence that a surgical checklist is a necessary and straightforward approach to support pre- and post-operative surgical briefings in the face of emergent challenges. This literature is poised to more fully explore what silence is doing on teams, by tracing patterns of silence in particular work settings and describing their impact on patient safety issues such as situational awareness and adaptive flexibility in the face of emergent challenges.
Second, high compliance rates imply that good team communication has been achieved. Very few studies have measured the impact of the checklist on communication practices (Lingard et al. 2008). However, a positive association is commonly assumed. For instance, Weiser et al. (2010: 979) speculate that “team interactions and communication … were likely enhanced with use of the checklist,” although they present no data in support of this speculation. This lack of rich data regarding what happens to a team’s communication when checklists are introduced perpetuates the assumption that, if checklists are in place, then team communication must, of course, be better. This assumption signals a serious threat to safety, characterized by Bosk et al. as “the complacency induced when an organisation thinks that a problem is solved” (2009: 445).

The aura of simplicity around checklists is perhaps most starkly evident in the term itself. A checklist is a tool, a technical intervention, while a briefing is an activity, a socio-cultural intervention. Attention to checklists leads, quite naturally, to questions about whether boxes are being ticked. Attention to briefings, by contrast, leads to questions about what team members are doing – or not doing – when they take up this communication intervention. These questions cannot be answered by compliance rates; richer, ethnographic data are required, informed by socio-cultural, theoretical perspectives with a capacity to complicate the taken-for-granted assumptions that underpin safety interventions (Kitto 2011; Zuiderent-Jerak et al. 2009). Dixon-Woods (2011) argues that we need to better acknowledge the organizational and professional politics involved in a team’s uptake of a safety innovation in order to move the field beyond normative assumptions about how things ought to be, and toward describing how things are. For example, rather than assuming that the checklist ought to be easy, we can investigate the elaborate, interdependent processes that need to come together for a team to share a two-minute briefing at 8:00 a.m.

How teams brief is also a critical question elided by compliance rates. The normative assumption in the research literature is that, if teams brief, they ought to brief well. More attention is needed to workarounds or deviations – instances in which something is happening that gets checked off as “done” for checklist compliance but does not reflect the fundamental principles of briefing or is not recognized by all team members as constituting a briefing (Allard et al. 2007). Interestingly, while resistance and workarounds are commonplace in the stories of leaders, administrators and educators at the front end of implementing team communication innovations such as the WHO Surgical Safety Checklist, they are only rarely studied and formally reported (National Health Service 2010; Vats et al. 2011). More work is required to richly describe the complicated uptake associated with team communication innovations such as the briefing; examples are the emerging work regarding the role of staff attitudes toward safety in briefing implementation (Allard et al. 2011; Wolf 2010) or the phenomenon of poor briefings and their paradoxical effects (Whyte et al. 2008). This work reports good, bad and indifferent practices in the face of such innovation and studies the impact of these on the safety of the work they are intended to support.

The Phenomenon of Intertextuality

To date, research on the links between communication and safety has tended to focus on distinct communication practices such as oral handovers between clinicians (Arora et al. 2005; Catchpole et al. 2007; Leonard et al. 2004; Manser and Foster 2011) or medication reconciliation in discharge summaries (Grimes et al. 2011; Wong et al. 2008). Such focused study has advanced our understanding of particular communication events and their impact on quality and safety; however, rarely has research considered systems of such communication practices and how they invoke, imply and impact one another. This phenomenon is referred to as intertextuality. Intertextuality is not a new idea in disciplines such as literary theory (Kristeva 1980), genre theory (Devitt 1991) and linguistics (Fairclough 1992), where scholars have long been concerned with understanding how texts coexist, and how that coexistence produces multiple meanings and shapes interpretation. Intertextuality is only beginning to be explored in team communication research, but it has much to tell us about how communication events upstream can shape, often invisibly, patient safety events downstream.

Consider the example of communication practices of an internal medicine team in an academic teaching hospital that employs an extensive system of oral and written communication practices to care collaboratively during in-patient stays (Goldszmidt et al. 2011, May). Goldszmidt et al. explore how these communication practices, such as student case presentations, admission notes, test results and discharge summaries, influence one another. Early findings suggest that important concepts can get distorted as they move from one communication practice to another; that concepts can appear at one point in the communication system and then inexplicably disappear; and that some communication practices can exert an inappropriate, and apparently unnoticed, influence on others.

More research is needed that considers intertextuality within systems of team communication practices. Such work could be particularly helpful at “transition points” – admission, transfer between care settings and discharge – where poor transfer of information is responsible for as many as 50% of all medication errors and up to 20% of adverse drug events in hospitals (Institute
for Healthcare Improvement 2006). Attention to the system of team communication practices that feed into problematic transition points could offer critical insights. Other relevant examples include the issue of surgical briefings discussed earlier, which could be considered within the broader communication system in which they are situated: the daily case board in the operating theatre, the computerized procedural record completed by the circulating nurse during the case, the surgeon’s ‘pic list’ (their list of preferred instruments), the patient’s chart, the anaesthetist’s instrumentation protocols and the teaching discourse during the surgical procedure. The question of how coexisting communication practices influence the meaning of a particular communication event such as a briefing or handover has the potential to significantly advance our understanding of a communication event as a complex, situated practice with ripple effects that may influence the safety of patient care.

**Intertextuality has much to tell us about how communication events upstream can shape, often invisibly, patient safety events downstream.**

**Conclusion**

Considerable progress has been made in evidencing the links between team communication and patient safety. With the first generation of research in this domain having achieved strong consensus on these links, the major contribution of the second generation will be to productively complicate existing knowledge. The three issues presented in this paper – the meaning of silence, the uptake of communication innovations and the phenomenon of intertextuality – challenge us to avoid indulging in a sense of complacency as researchers, hospital leaders and policy makers. There is still much to be learned about how teams communicate and what their communication means for patient safety. Efforts to improve teamwork at the hospital management and policy levels need to acknowledge the complexity of the relationship between how teams communicate and the safety of the care they provide. Currently popular initiatives, such as team communication checklists, should be complemented with more sophisticated tracking measures than mere compliance. We should strive to understand the multi-faceted meanings and impacts of silence, and, rather than seeking to eradicate silence from team communication, we should educate practitioners to use and interpret silence wisely and safely. And, finally, efforts to improve single communication practices, such as handover, should, when possible, take into account their intertextual relationships with other practices in the clinical setting to ensure maximal impact and avoid unintended consequences in communication practices up- or downstream.

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About the Author

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In some respects, the use of human factors engineering (HFE) methods in healthcare has been transformative. However, as measurable progress has been limited in patient safety, these challenges continue. Where is HFE headed to address these challenges? We look at the progress and difficulties HFE faces in today's complex healthcare environment.

**Human Factors in Safety Research**

Applications of HFE principles to the domain of healthcare are relatively new. Although some references to human factors in healthcare date back to the 1980s and early 1990s (Leape 2004), it was the work of James Reason in 1995 that contributed to increasing the scope of HFE practices to healthcare systems.

Reason reviewed HFE contributions to the domain of healthcare and introduced the concepts of active and latent failures. The former are errors committed by users of the systems (e.g., a doctor administers the wrong medication). The latter are errors created at the organizational level of the design (e.g., inadequate procedures, incomplete training, poor labelling choices etc.) and may lie dormant for several days, months or even years until triggered by a collection of local factors. Among other things, Reason's work emphasized the importance of considering team and organizational factors in the design of safety critical systems as well as avoiding the culture of “blaming the users” and embracing a culture of understanding the root causes of adverse events (Reason 1995).

One of the early empirical demonstrations of the significant impact of using HFE design techniques on medical systems was shown in a redesign of the user interface of a commercially available patient-controlled analgesia (PCA) pump (Lin et al. 1998). The authors conducted an evaluation comparing their redesign to the original design. The results showed a significant decrease in programming time, a lower mental workload and fewer errors. These findings clearly demonstrated the applicability...
of HFE techniques in the healthcare domain and highlighted important design considerations for medical equipment.

It is important to understand that the use of HFE frequently extends to non-technological problems (Vicente 1998), such as hand hygiene, where human behaviour imperils safe practice. HFE often shows that the design of environments affects performance, cognition and behaviour: poor lighting can cause a nurse to misread a label, personal conflict can inhibit critical clinical communication, and a poorly located sink can result in low adherence to hand hygiene.

The Institute of Medicine’s report To Err Is Human (Kohn et al. 2000) was a further catalyst to the use of HFE in the healthcare domain. It led to a considerable understanding of actions needed to solve safety problems in the healthcare system.

A decade of great expansion in the field of HFE in healthcare followed. As healthcare became a domain of study for human factors practitioners, HFE principles became valuable tools for healthcare professionals. Many regulations, standards and guidelines (e.g., the Food and Drug Administration [FDA] regulations on human factors and medical devices, and the American National Standards Institute [ANSI]/Association for the Advancement of Medical Instrumentation [AAMI] HE75 standard on HFE and the design of medical devices) resulted from this increased attention and are now in place to help the healthcare industry catch up with other domains in which HFE principles and regulations have been common practice for many years. With this in place, what have we learned and what progress has been made in the past 15 years?

Our Understanding of Human Factors Today
HFE is still new to many in healthcare who seek methods for improving safety and efficiency. Certainly in recent years, other methods such as checklists (Gawande 2007) and Lean methods (De Koning et al. 2006) have received more attention.

Even as the discipline of HFE has made significant progress in addressing patient safety problems in healthcare, it often remains misunderstood and unfamiliar. The term human factors is somewhat of a misnomer, sometimes interpreted by the uninitiated as attributing the cause of an adverse event to human factors, that is, someone’s actions. However, regardless of the definition of human factors used, the discipline promotes a fundamental rejection of the notion that humans are primarily at fault when making errors in the use of a socio-technical system. The premise of this defence is that these systems are constructs of human invention and, hence, should be designed for humans to use them. Any error that occurs by the user is thus attributable to the design of the system; this recognizes that some aspect of human cognition, performance or behaviour was not fully considered in order to avoid the circumstance that led to the error. (Figure 1)

System Design versus Behaviour Change
As healthcare was accepting the sea change in patient safety to a “no blame” and just culture (Frankel et al. 2006), there was also a realization that progress in addressing patient safety issues has been limited (Classen et al. 2011; Landrigan et al. 2010; Leistikow et al. 2011). Through the lens of human factors, this

FIGURE 1.
Human Factors Considerations
outcome was not surprising. Many prior strategies have presumed behaviour change on the part of the practitioner, but dependencies on perfect human performance to ensure patient safety are both scientifically and practically unreliable. Humans err.

Human factors practitioners tend toward a more systemic approach for mitigating human error; the only truly reliable method for designing and creating socio-technical work environments involves minimizing the possibility for human error as well as the potential impact when error occurs. This means designing systems that elicit desired behaviours and help reduce errors (i.e., promote human behaviour shaping) as opposed to designing systems that force behaviour changes (Vicente 1998). Despite this view, in healthcare we tend to continue to rely on interventions that improve user performance through greater training and/or a behaviour change to reduce and minimize the impact of adverse events.

Dependency on human behaviour change as a means to mitigate use errors is illustrated by the current popularity of the use of checklists (Gawande 2007; Hales and Pronovost 2006). Although checklist use has recently made headlines in its ability to reduce adverse events in settings such as the operating room and intensive care (Haynes et al. 2009; Pronovost 2006), it remains unclear that an intervention so fundamentally reliant on human behaviour will be sustainable in the long term without constant enforcement (Bosk et al. 2009). Are all healthcare organizations able to create a culture for the sustained use of checklists? If this solution applies only to organizations that have the leadership and resources to maintain such a culture, checklists – and other solutions reliant on human behaviour – cannot be considered a systemic solution. Given how rare serious adverse events are to the total volume of healthcare encounters, a solution that applies to only a fraction of organizations cannot address this safety issue fully.

The Hierarchy of Intervention Effectiveness (Figure 2), a risk management theory, rates interventions related to human behaviour toward the bottom of its scale in favour of technological interventions, which are viewed as more reliable (Institute for Safe Medication Practices 1999). This should not suggest that human-based mitigation interventions (e.g., training, policy and checklists) are not without value. Indeed, a scenario where we are totally dependent on automation with little human intervention is not desirable when a centralized locus of control could propagate errors so easily across a system. Humans are still needed to make judgments at the point of care. However, what this reinforces is that no single mitigation strategy will totally eliminate use errors that lead to adverse events. A tapestry of strategies that have some scientific basis for success will likely be more successful.

FIGURE 2.
The Hierarchy of Intervention Effectiveness
Nonetheless, as healthcare providers, we tend to not create such strategies. We continue to seek silver-bullet solutions such as checklists, bar-coding and crew resource management (CRM), adapted from aviation. In medication administration in particular, the lack of holistic, systemic solutions has created a fragmented system of technologies, policies and training. No single company has a product that ensures a continuity of information and workflow for the administration of medication. Oddly, there is often no single administrative entity within the hospital overseeing this either, with a mixture of medicine, pharmacy and nursing leadership attempting to ensure the safety of medication administration. What is required from organizations is transcendence of organizational boundaries in order to produce a delivery system that ensures an integrated approach for the user, rather than dealing with multiple disparate systems to perform their critical tasks (Cafazzo et al. 2009).

**HFE in Evaluation**

If we are to note any significant progress in the use of HFE in healthcare, it must be in the evaluation of technology, if not the improvement of its design. HFE methods have been particularly effective in post-market identification of design flaws that have led to use errors (Chagpar et al. 2006; Chan et al. 2010; Jessa et al. 2006; Trbovich et al. 2010a).

In 2011, FDA issued an update to its regulatory approval guidelines (the first update in 10 years) for device manufacturers to support a far more rigorous human factors evaluation process during the pre-market phase (FDA, 2011). In particular, the guidelines are more prescriptive in defining product usability testing for final design validation to ensure a minimum of use errors.

The motivation for such strict new rules may be due to a growing awareness and recognition that human errors are often due to systemic issues. Specifically, recent high-profile disclosures of human error rates in medication administration using infusion pumps (ECRI Institute 2010; Trbovich et al. 2010a) and concerns over similar issues in radiation therapy delivery (Chan et al. 2010) have given regulators pause for how the industry is designing such products. However, some responsibility also lies in how we continue to purchase technology, as manufacturers argue that they are designing for the marketplace. Even today, healthcare organizations continue to demand the most advanced technology with the latest features to adorn their already-crowded displays. Procurement processes evaluate technology using a checklist culture, rating product quality by the number and completeness of features. This can drive device manufacturers to race to the bottom of product quality. Organizations opt for products bloated with features and that are far too complicated, creating an environment for forced, unintended errors.

The FDA’s new guidelines will not entirely remedy the quality of healthcare technology. By emphasizing testing in the final stages of validation, they do little to ensure that human factors methods are extended to the entire development process. While it is a step in the right direction, it is also a missed opportunity to include greater rigour of user-centred design in the earlier conceptual phases of product development.

At a local level, we can identify and mitigate risk by including HFE methods in the procurement process for high-risk technologies. Usability testing can be effectively applied to short-listed products to inform the procurement decision-making processes. The return on this modest investment of time and effort is the acquisition of technology that best suits the user needs of the organization (Cassano-Piché et al. 2010).

As well, computer systems that were intended to solve patient safety issues have revealed other potential sources of use errors (Koppel et al. 2005). HFE identified that software systems require even more attention than previously thought if they are to realize their potential (Beuscart-Zéphir et al. 2010). HFE has been used to mitigate interruptions of high-risk tasks (Trbovich et al. 2010b), to help develop team communication (Grogan et al. 2004) and to manage error at the organizational level (Reason 1997).

And this is where we sit. The full utility of human factors continues to be relegated to the evaluation aspects. We have become proficient at using human factors methods in identifying problems, often after it is too late. The questions we are faced with are whether we can find these problems sooner and how we can implement solutions once problems are identified.

**Human Factors and the Design Solution**

Human factors practitioners are often passionate in their determination to ensure the safety of systems. They can be combative; insisting that design flaws are at the root of adverse events and that not addressing these flaws directly will lead to more mishaps. They believe that local mitigation strategies such as additional training, new policy, reminders and checklists will not address the systemic problem. However, finding design solutions is not necessarily practiced by human factors professionals. Methods for identifying solutions in science and practice are clear and widely acceptable, whereas methods for finding solutions in design are much less so. We could argue that design is more a process of creativity and inspiration (which are ill defined), and this contrasts the precision of science and engineering. Nevertheless, design is where HFE practitioners can make further impact in the area of patient safety. There is fortunately a body of work in HFE that directly addresses design science with rigour, and this is outlined below.

**The Future of Design Practice: User-Centred Design and Ecological Interface Design**

User-centred design (UCD) is one of the most common methods that HFE practitioners use to create systems that
prioritize the need for ease of use. UCD defines an iterative process where concepts and prototypes employ user testing to inform and optimize the design of the system. It does not define how concepts and initial prototypes are achieved. UCD better defines the evaluation methods in the design process than the process of design ideation and implementation. What is missing then is a rigorous framework to inform design, leading to design solutions that adapt technology to people as opposed to requiring people to adapt to technology.

The human factors discipline promotes a fundamental rejection of the notion that humans are primarily at fault when making errors in the use of a socio-technical system.

Ecological interface design (EID) is one such framework for designing human-machine interfaces for complex systems (Vicente and Rasmussen 1992). The framework has been applied to a variety of domains, including healthcare (Vicente 2002). EID is based on the insight that major events in safety critical systems occur when users encounter conditions unanticipated by systems designers. Hence, one of the goals of EID is to provide design principles for human-machine interaction that will help users in unanticipated conditions while preserving their ability to exercise normal control (Vicente and Rasmussen 1992).

The EID framework is relatively new to most HFE healthcare practitioners. Given the complexity of today’s healthcare systems, it seems appropriate to consider EID as a systematic approach that could improve our understanding of such systems and lead to innovative design solutions. Recent applications for the framework in the domain of healthcare are encouraging. Examples include the use of EID to modernize the user interface of high-risk radiotherapy control systems (Chun et al. in press), as well as for systems for the detection, evaluation and treatment of cardiovascular risk (McEwen and Flach in press). These illustrate the viability of EID in healthcare and offer promising new applications.

With these methods established, HFE practitioners need to recognize that their value in ensuring patient safety will not be fully realized until they consider providing design solutions with scientific rigour, rather than simply evaluating and identifying issues.

Conclusions
Much of what we can learn from HFE is not in the methods themselves but in the cultural lens HFE provides healthcare practitioners. Working nurses should not assume that because they are having difficulty with a task, whether it involves technology or not, that it is necessarily the case that they are the problem. They should not assume that the designers of the system have fully considered the complexity of their working environment, understood the multi-tasking that is often involved, or realized that they are frequently interrupted when performing such critical tasks.

The positive news is that providers are finding their voice with respect to the quality of the systems they use. They are demanding of the tools employed to care for patients. Why can these systems not be as easy to use as the latest consumer electronics gadget?

HFE rigour has given healthcare better products, helped find the poor ones and provided insight into how our behaviour is impacted by our environment, among other critical safety issues. There are also more hospital practitioners of HFE methods in healthcare settings who can be advocates for providers by evaluating and identifying technologies, workflows and environments. The future lies with practitioners in using more advanced HFE methods to create the path to finding greater systemic solutions to the challenges in patient safety.

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Poor designs and outmoded systems of work set the workforce up to fail (Institute of Medicine 2001). Nurses spend too much time “hunting and gathering” and in other non-value-added activities and, ultimately, patients suffer from the ineffective use of valuable resources. To successfully cross this “quality chasm,” nurses and other professionals need to be working to full scopes of practice, engage in inter-professional collaborative teamwork and be provided with the technological and information infrastructure needed (Hendrich et al. 2008; Institute of Medicine 2011; Page 2004). Fundamentally, our work processes and physical environments significantly impede the delivery of safe, effective and efficient care (Baker et al. 2008).

Many organizations are struggling to find answers while controlling costs. Common solutions include skill mix changes – such as adding licensed practical nurses, physiotherapy aides, pharmacy assistants and unregulated workers – potentially affecting patient safety (Aiken et al. 2003, 2008; Dunton et al. 2004; Jiang et al. 2006) and employee satisfaction (McGillis Hall and O’Brien-Pallas, 2000). More creative and responsive solutions are needed. Many have advocated for increased interdisciplinary collaboration in the planning and delivery of healthcare, yet there is little empirical literature about what it takes to successfully create and sustain interdisciplinary work redesigns (Oandasan et al. 2006; Clements et al. 2007). While numerous complex factors influence the successful adoption of innovations by organizations, the role of leadership in improving system-level performance is pivotal (Baker et al. 2006; Nolan 2007; Stetler et al. 2007).

This article explores the challenges healthcare organizations face with outmoded and inefficient service delivery models, describes some examples of successful work redesign in the United States and Canada and discusses how lessons learned can be applied to improve efficiency, quality of care and quality of work environments in Canada.

These values are illustrated by SCF’s deliberate replacement of the word patient, with “customer-owner,” signalling the shift in balance of power to a system owned and managed by Alaska Native people.

The Search for Successful Innovations
A fellowship as a US Commonwealth Fund Harkness associate permitted the lead author (P.O.) to examine innovations in interdisciplinary work designs and service delivery models to identify solutions to these challenges. The goal of the research was to describe successful innovations in interdisciplinary healthcare...
work design, critical elements and strategic processes for innovation adoption and sustainability, and their impact on outcomes. In other words, how do organizations make it happen?

We used an explanatory case study design (Yin 2009) with individual and focus group interviews, document reviews and targeted observation. Three cases were selected from 19 organizations nominated by experts in healthcare. During four-day site visits, we interviewed stakeholders from all levels of each organization. Thematic content analysis was based on Pettigrew and Whipp’s (1992) framework of strategic change. Two of the cases are presented below, demonstrating the why, what and how of successful innovation.

Case One: Primary Care Transformation at Southcentral Foundation

Southcentral Foundation (SCF), a non-profit healthcare organization, serves Native and American Indian people living in south central Alaska. With a history of fragmented, emergency room-based care, long waits, no continuity, little respect and no customer involvement, SCF moved from federally controlled health services to Native ownership and management. Over the past decade, it gradually developed a relationship-centred model of primary care marked by profound changes in philosophy, structure and delivery of services. It introduced the NUKA system of care that guides all care processes and employee actions. Based on the vision of developing a Native community that enjoys physical, mental, emotional and spiritual wellness, the key elements include shared responsibility and a commitment to quality, family wellness and operational effectiveness. These values are illustrated by SCF’s deliberate replacement of the word patient, with “customer-owner,” signalling the shift in balance of power to a system owned and managed by Alaska Native people.

Innovative Redesign Elements at SCF

SCF’s model guided the development of several innovations, the most salient being the following:

- Care that is population-based, longitudinal and focused on family wellness. In moving from physician-based care to broad interdisciplinary teams (registered nurse [RN] case managers, family physicians, psychologist or social worker, medical assistant, dietitian, pharmacist and clerical staff), staff work at full scopes of practice, see customer-owners together and share assessments and decision-making. Advanced access programs ensure same-day appointments, and there is a systematic approach to reducing the morbidity and mortality associated with specific chronic illnesses.
- Use of technology linking remote regions. Automated telepharmacy dispenses medications and provides inventory control, and telehealth is available for remote villages.
- Introduction of novel roles. Residents in remote regions are trained as local healthcare aides and are supported by RN case managers, while traditional healers and family wellness warriors address situations of domestic violence, abuse and neglect.

Strategic Change Processes at SCF

Strategic change processes at SCF included the following:

- Alignment of the organization’s mission and core values with all activities. Core operating principles, developed through consensus seeking, guided all work (clinical, administrative, organizational development and quality improvement). Staff at all levels, as well as customer-owners, were clear about the priorities and expectations, reflecting the tight alignment around the vision.
- Cohesive, stable senior leadership team with a shared vision. The senior team has worked together for many years, resulting in increasing cohesiveness.
- An approach centred on customer-owners. Extensive, continuous customer-owner consultations use traditional and culturally sensitive methods. As explained by the chief executive officer (CEO): “We asked other Alaska Native people what they wanted, what they needed and what they valued. The system was built from the ground up based on that feedback. Still today, this is how we operate.” Continuity of care providers is a priority, and requests to change practitioners are explored to identify problems in care satisfaction.
- Building capacity for improvement. Staff training incorporates a set of guiding principles and tools to use in every interaction with customers and fellow employees to create healthy relationships. All staff engage in ongoing cultural awareness training and rapid cycle improvement processes. Monthly meetings, with peer coaching, occur with interdisciplinary teams, a physician senior leader and a manager to review performance on several clinical indicators. Physician leadership training with the Institute for Healthcare Improvement (IHI) and Intermountain Health targeted learning needs in administration and quality.
- A redesign of physical environments to support vision and practice changes. Ambulatory care spaces are designed to be responsive to the needs and values of the community, with extensive displays of Native artwork, areas for potlatches, dancing and singing and quiet spaces for dialogue. To increase collaboration, SCF has each interdisciplinary clinic team share one large office, rather than having profession-based space in “silos.”
- Leveraged information technology to support service delivery. Extensive clinical performance monitoring of preventive and chronic illness management is facilitated by an extensive “data mall” with monthly panel reports, and open reporting of results on the intranet.
- Physicians becoming salaried. This change has created
People.
the environment.
Redesign elements primarily focused on people, processes and environment.

Innovative Redesign Elements at ThedaCare
Redesign elements primarily focused on processes and the environment:

- **People.** Innovations include admission trios and joint care planning. At the bedside, a nurse, physician and pharmacist complete the admission assessments, including medication reconciliation and risk screens, and develop a single plan of care that is linked to practice guidelines for specific diagnoses. An anticipated discharge date is discussed with the patient and communicated on the white board near the patient’s bed. In daily bedside care conferences, clinical learning and exchanges occur in interaction with the patient, focusing on the latest progress and recommendations for the next 24 hours. Joint decisions about medication and other clinical changes yield no misunderstandings or delays in action. RNs work as case managers, with licensed practical nurses (LPNs) and nursing assistants performing most of the task-oriented care activities, including medication administration and bedside testing. Assignments are clear, with minimal overlap between RN and LPN functions. RNs focus on patient and family education, chronic illness management, psychosocial interventions and ensuring that there is no wasted time between diagnosis, testing, treatments and preparation for discharge.

- **Processes.** Planned diagnostic and treatment interventions as well as patient results are closely monitored by the RN in six-hour intervals (“tollgates”) to reduce delays in decision-making. Progress is noted on a visual control board. Integrated, electronic charting using evidence-informed clinical practice guidelines and standardized orders for all diagnoses supports clinicians in following the same pathways.

- **Environment.** Supply and medication cabinets (patient servers) have been built into every patient room, significantly eliminating the time spent looking for supplies and medications. Visual cueing is used extensively throughout the unit, improving efficiency and reducing the time for information transmission (e.g., new orders, notifications of medication delivery).

Outcomes at SCF
There was clear evidence of spread and sustainability at SCF. The outstanding outcomes included improvements in quality of care (100% same-day access, a 50% decrease in emergency room/urgent care and specialty care visits due to more comprehensive primary care services, a 30% decrease in admissions and in-patient days, greatly improved customer satisfaction and performance at the 90th percentile levels on multiple preventive care practices), quality of work environment (relatively high staff satisfaction, inter-professional collaboration and continuous efforts to act on staff feedback for workplace improvements) and costs (fewer admissions and specialty care reduced costs, and significant enhancement of revenue streams allowing for a doubling of the primary care capacity). Other jurisdictions, including the Saskatchewan Ministry of Health and First Nations, are working on transferring these lessons learned to their communities.

Case Two: In-patient Care Redesign at ThedaCare
ThedaCare, the largest healthcare provider in rural north-eastern Wisconsin, is composed of four hospitals, 21 primary care centres and a range of other services. Its intensive efforts in organizational transformation through in-patient interdisciplinary care redesign were aimed at producing value-added care and reducing errors and variability. ThedaCare’s Collaborative Care model of in-patient care delivery is based on changes in team roles and responsibilities, innovative work processes, and principles of error proofing and visual management. Its vision has nursing at its centre and focuses on maximizing the scopes of nursing and pharmacy practice, including redesigning the physical environment to support inter-professional collaboration, reduce waste, ensure safety and promote healing.

Strategic Change Processes at ThedaCare
Strategic change processes at ThedaCare included the following:

- **Senior leadership team commitment to improving performance.** The former CEO provided a clear message that filtered through the ranks: “We’re not going back, so let’s figure out how to improve together.” The senior team also visited top performers in other industries to learn how to reduce defects (safety errors) and improve quality and value. They further strengthened their resolve by inviting some of those executives onto their board.

- **The application of the principles and tools of the Toyota Production System to healthcare.** To develop capacity for completely redesigning in-patient care, staff were liberated for multiple value-stream-mapping events and trained to work at full scopes of nursing and pharmacy practice. The ThedaCare Improvement System introduced systematic quality improvement and error-proof training to staff at all levels. ThedaCare deliberately rotated trained facilitators into operational roles within 18 months of having developed expertise as quality advisors. There are weekly reports on improvement projects in a forum with the CEO, executive team and more than 200 staff.

- **A vision with nursing at its centre.** ThedaCare hospitals’ president, previously an administrator of large primary care practices, reflected on what she saw as the central core of in-patient care: “And what came to me was, it is 24-hour...
nursing care … the patient is in the hospital because … the nurses [are there].” To strengthen nursing, ThedaCare joined IHI’s Transforming Care at the Bedside (TCAB) program, which engages nurses to lead process improvement efforts aimed at improving patient outcomes and the work environment (Hassmiller and Bolton 2009). Evolving into the new Collaborative Care model, ThedaCare took redesign to a whole new level. Prior to implementation, protected staff release and training time were significant to prepare practitioners for new roles.

- **Considerable investments in information systems and measurement.** Realizing the critical need for reliable, useful data, ThedaCare has created a dependable data warehouse and electronic health records. These investments have built capacity for creating quality data that drive needed and effective improvements. It was striking to hear front-line medical and nursing staff on the alpha unit easily describe their quality performance processes and results vis-à-vis several relevant safety indicators.

**Outcomes at ThedaCare**

Two years after the launch of the Collaborative Care alpha unit, the results were striking. Physicians, pharmacists and nursing staff described the dramatic impact of these role changes. As one RN commented, “I feel I have grown more in the past two years than I did my first 17 years of nursing.” Other outcomes included improvements in the quality of care (a 20% decrease in lengths of stay; a 9.5% increase in admissions; better quality bundle compliance for pneumonia, congestive heart failure and falls; defect-free medication reconciliation; and very high patient satisfaction), the quality of work environment (high staff satisfaction and low RN turnover) and costs (a 21% decrease in cost per case and a return on investments that auto-financed a new wing expansion).

**Lessons Learned and Success Factors**

Despite varying in size, complexity and the factors motivating the changes, there was considerable similarity in the key contextual and strategic change processes used in the successful adoption and sustainability of innovations at SCF and ThedaCare:

- **Courageous, stable and cohesive leadership.** Buy-in and consistent leadership from all levels within the organizations, executive stewardship, the use of physician and other clinical leader champions and broad stakeholder engagement were key. Successful change also required stable and courageous leadership.

- **Alignment and clarity of vision, goals and activities.** A critical feature was the clear alignment of the organizations’ core values, vision, policy decisions and activities to advance the change agenda. Deep engagement of the boards of directors, whose members had expertise in organizational change and quality performance, in all steps of the transformation (particularly when there were problems) was critical and highly supportive.

- **Support, reinforcement and recognition of individual and organizational capacities.** Extensive staff training in the Lean methodology and other systematic improvement processes was coupled with the use of standardized evidence-informed care protocols to increase reliability and decrease variation. Significant investments in technological infrastructure greatly facilitated performance management. Staff received timely, relevant feedback about changes in performance, and recognition of successes and extensive communication of progress were hallmarks of their change efforts. In other words, these organizations paid huge attention to their social capital.

- **Support for involvement and staying with the program.** In both cases, there was a clear understanding that the transformations the organizations sought would involve significant amounts of time, resources and energy, as well as strategies to manage the naysayers and the overzealous. Both organizations committed to putting the patient/family at the centre of their redesign, continuously seeking input on how to improve the experience of care (value) and breaking down the traditional professional role silos. They took policy and converted it into an operational effectiveness that truly improves the lives of the community they serve, as well as those of the staff.

**ThedaCare’s vision has** nursing at its centre and focuses on maximizing the scopes of nursing and pharmacy practice.

**From Inspiration to Action**

Taking inspiration from both case studies, it was time to apply the lessons learned to our own organization. In mid-2010, the McGill University Health Centre (MUHC) partnered with IHI to launch the TCAB program on five units in three of our hospitals. TCAB was by then implemented in over 200 US hospitals but was relatively new to Canada. Based on our philosophy that a redesign of care processes must respond to the real needs of patients and families, our aim was to understand care “through eyes of patients” and to engage patients and staff in co-developing and testing new work processes. Multiple “patient representatives” volunteered to join each unit’s core TCAB team. Support from generous donors, a Canadian Health Services Research Foundation patient engagement grant and one from Canadian Institutes of Health Research to evaluate impacts on staff provided the critical resources to begin. The “how” of TCAB focuses on teaching front-line staff how to do rapid cycle improvement processes using Plan-Do-Study-Act, so that
they can become the owners and leaders of the improvements needed to achieve better outcomes. Each unit chose the areas for improvement and learned how to conduct simple tests of change, with pre- and post-measurements.

Results from the first year have been positive and largely sustained. Patient representatives have become very active collaborators. We have seen an 8% increase in the amount of RN time spent in direct care. The responsiveness of caregivers, as measured by the Hospital Consumer Assessment of Healthcare Provider and Systems Survey, has improved by 30%, reflecting better patient experiences, and patient narratives have provided rich feedback about what is good (or not good) in care delivery. Other results have included the following:

- A quiet zone for medication administration was introduced, which resulted in a 50% reduction in interruptions and a 60% reduction in transcription errors.
- Equipment re-location significantly reduced time spent hunting and gathering.
- Patient and staff redesigned a chemotherapy treatment room, reducing the time to start chemotherapy by 57%.
- A joint inter-professional admission process introduced in mental health reduced admission time from 4.3 hours to 1 hour, eliminating duplication and improving team communication and cross-discipline learning.
- Staff and patient representatives have been gaining skills in Plan-Do-Study-Act cycles, leading change, negotiations and communication.

Barriers faced have included ensuring protected release time for staff, securing support resources (project manager, facilitators, leadership training for managers) and managing expectations.

**Other Work Redesign Innovations in Canada**

In a bold policy move in 2009, the Saskatchewan Ministry of Health made significant investments to support the province-wide implementation of the Releasing Time to Care (RTC) program. With very similar goals to TCAB, this highly structured program for redesigning nursing care processes is being implemented on 14 units. Results have included increased time in direct care; improved patient and staff satisfaction; a reduction in falls, infections and pressure ulcers; and improved relationships with service departments. As part of a case study in February 2011 with Dr. Alain Biron, a Canadian Patient Safety Institute patient safety fellow, we witnessed considerable ministerial and executive buy-in, extensive leadership support and the degree to which front-line staff have assumed ownership in creating and spreading innovations. Since the summer of 2011, MUHC has partnered with the Saskatoon Health Region to share lessons learned in our respective quality improvement journeys. For details of the Saskatchewan experience, log on to the Health Quality Council’s website at www.hqc.sk.ca. A number of hospitals in Ontario also embarked on RTC starting in late 2009.

**Primary Care Redesigns**

There are now many examples of successful integrations of nurse practitioners, dietitians and pharmacists into primary care practices. Policy changes within provinces have broadened scopes of practice and provided financial incentives for such practices to evolve – key factors to their success and sustainability. In jurisdictions where the funding envelopes have not been adequate or sustained, the introduction of nurse practitioners has been challenging.

**Research to Action: Applied Workplace Solutions for Nurses**

Under the visionary leadership of Linda Silas, in 2008 the Canadian Federation of Nurses Unions partnered with the Canadian Nurses Association, the Canadian Healthcare Association and the Dietitians of Canada to support nurse-led innovations aimed at applying research evidence in practice to create healthier workplaces. Funded by Health Canada, the creative and sustainable solutions included a redesign of the nursing workforce and staffing models (e.g., the 80-20 model, in which staff are scheduled to have 20% of time for quality improvement or development activities), mentorship programs, e-learning in rural areas and broader access to professional development opportunities.

**Implications for Policy and Practice**

Inter-professional care teams focused on patient needs and system efficiency offer improved system performance. Redesigning care processes and physical work environments requires broad vision, quality and coherence of organizational policy, as well as consistent executive leadership support over time. Wide dissemination of real-time clinical performance information and infrastructure support to build capacity in quality improvement processes are critical to changing provider behaviour. Current policies and systems issues in Canada that act as barriers to team-based or inter-professional healthcare delivery are educational programs that train professionals in discipline-specific silos, systems that consider physicians independent entrepreneurs rather than members of hospital staff and incentives that encourage “procedural” care versus addressing health outcomes. As highlighted in
the *Future of Nursing* report (Institute of Medicine 2011), we will not realize the vision of a transformed healthcare system until nurses, as the largest healthcare workforce, are working at full scope of practice and acting as full partners in leading change.

### Acknowledgements

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### References


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Abstract
Healthcare-associated infections are a major cause of patient morbidity and mortality. Fortunately for patients and the healthcare system, there is increasing interest in this field and the growing realization that many of these infections are highly preventable. We explore some of the newer and more promising strategies for decreasing infections, including the use of practice bundles, behavioural change strategies, hand hygiene auditing, public reporting of infection rates and antimicrobial stewardship. We also identify several areas where improvement is needed, including empowering patients to prevent infections, building safer healthcare facilities and accepting the limitations of the evidence supporting some infection control interventions.

Healthcare-associated infections (HAIs) are infections that occur in patients as a result of their being treated for another, unrelated issue. For example, a patient admitted to hospital to receive a life-saving cardiac procedure may initially do well post-procedure, only to later succumb to an infection that developed as a result of an intervention such as the use of central intravenous line or ventilation. A patient may also develop a life-threatening infection such as *Clostridium difficile* colitis by first picking up the organism through contaminated healthcare worker hands or contaminated equipment, and then receiving antibiotics that wipe out the patient’s normal intestinal flora and allow *C. difficile* to thrive.

It has been estimated that well over 200,000 Canadians develop such infections each year, resulting in more than 8,000 deaths (Office of the Auditor General of Ontario 2008). While this number is shocking, it is perhaps telling that patient safety organizations only relatively recently began focusing on HAIs as preventable patient safety issues. While attempts to control infections date back to Florence Nightingale during the Crimean War, the antibiotic era resulted in an attitude shift in which treating infections received more focus than preventing them. For many decades, HAIs have been seen as “a cost of doing business” (Gardam et al. 2009). Fortunately for patients and our healthcare system as a whole, attitudes are slowly changing as more and more evidence points to different interventions that can profoundly decrease infection rates.

This renewed interest in HAIs has resulted in a number of promising new approaches. It has also, however, shone a light on the sobering fact that some traditional infection prevention and control approaches do not work very well. In this article, we highlight some of the promising new approaches as well as challenging areas where we believe the infection prevention and control community needs to rethink its approaches.
New Approaches
Practice Bundles
Practice bundles are groups of clinical or other practices that have been studied and found to have a positive impact on infection rates (Institute for Healthcare Improvement 2011). Research and real-world experience over the past 10 years has clearly shown that, for some types of HAIs, using the practice bundle approach can often have a dramatic impact (Jain et al. 2011; Resar et al. 2005). Typically, the individual practice changes are remarkably simple. For example, central intravenous line infections can be significantly reduced in part by choosing appropriate insertion sites; treating the line insertion as a true sterile procedure, that is, requiring sterile drapes and using chlorhexidine alcohol skin preparation; and removing the line when it is no longer needed (Safer Healthcare Now! 2009a). Similarly, surgical site infections and ventilator-associated pneumonias can also be reduced through clear-cut interventions (Safer Healthcare Now! 2009b, 2010). Often, the spread of bundled approaches has been facilitated by collaboratives, where teams from different organizations work together while implementing practice bundles to learn from each other, share practices and provide mutual support (Institute for Healthcare Improvement 2003).

However, practice bundles cannot be the only answer or approach to preventing HAIs. A central, necessary condition of the practice bundle approach is that the event or intervention can be isolated in time, controlled, standardized and audited to ensure compliance. While this approach makes sense for perhaps most causes of HAIs that fit this condition, it is less obvious how it might be applied to circumstances that are far less controlled, such as healthcare worker compliance with hand hygiene.

Adopting a Complexity Science Approach to Complex Infection Control Challenges
Hand in hand with the growing recognition of the power of practice bundles in bringing about improvements was the recognition that this approach is not applicable to all infection control challenges. Proven infection prevention practices have been known for years, yet most healthcare organizations have been unable to achieve consistently high rates of adherence to these practices. Traditional strategies typically involve the reinforcement of healthcare worker hand hygiene, environmental cleaning, surveillance for colonized or infected patients and varying forms of isolation when certain infections are detected. Some components of the control measures to prevent the spread of hospital “superbugs” between patients may be amenable to a practice bundle approach (i.e., standardizing how to clean a patient room), but many of the factors that influence spread are deeply rooted in behaviour and inherently non-linear (Gardam et al. 2009; Lindberg et al. 2008). Experience over the past several decades and the study of complex adaptive systems have identified that many of our traditional approaches to more simple problems, such as checklists and the implementation of “best practices,” do not work well in settings where “culture eats strategy for breakfast” (Gardam et al. 2010). Rather, approaches for such challenges need to recognize the need for local variation, acknowledge local culture and recognize the requirement for multiple small fixes rather than one big solution to a problem (Glouberman and Zimmerman 2002). Often, those attempting to implement a particular practice change hear from front-line staff, “That isn’t the way we do things here.” Rather than ignore this, complexity science suggests that this “social immune response” should be acknowledged and that staff be allowed to create an intervention that works in their setting.

Recognizing this different approach and the need for local solutions, engagement and empowerment of those who are deeply connected to the problem at hand often can yield surprising results. Positive deviance is one such front-line empowerment strategy that has been used with success in tackling complex infection control challenges such as hand hygiene (Marra et al. 2010). The Canadian Positive Deviance Project used this approach and other front-line engagement strategies termed liberating structures (Social Invention Group 2007) to help control the spread of superbugs in five acute care hospitals. These complexity science–based methodologies help to guide groups in the midst of a problem toward solutions that are situation appropriate and that work for them in their setting. It was found that the use of these approaches over an 18-month period not only decreased rates of methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE) and C. difficile by an overall average of 56%, but also had a significant impact upon how staff relate and interact with one another (Reason et al. 2012). Simply put, infections are prevented because staff act differently and implement their own solutions. Remarkably, these approaches rarely require significant financial investment.

Public Reporting of Infections
The measurement and feedback of data are central tenets of any improvement work: how do you know where to go if you don’t know where you are? The recent trend in mandatory public reporting of infection rates in several Canadian provinces has taken this to a higher level. Now, not only can a facility benchmark with itself and track its performance, it can also benchmark with other facilities. In our experience, public reporting in Ontario has helped improvement processes by drawing much broader attention to the issues at hand and by enabling facilities at the higher end of the infection spectrum to realize that they might have a bigger problem than they thought.

These positive effects must, however, be balanced by several caveats. Because public reporting data rarely control for known factors that influence infection rates, with the exception of hospital type and size, it is very difficult to meaningfully compare infection rates between facilities; yet the public and the media
do exactly that. The indicators used may be chosen because they are convenience rather than meaningful. For example, Ontario’s reporting on MRSA and VRE bloodstream infections, while simple and largely bias free, is not that helpful for quality improvement simply because there are very rare events in most organizations (Ontario Ministry of Health and Long-Term Care 2011). A consistent rate of zero can obscure the fact that many other more common infections are ongoing and causing harm. Finally, process measures such as hand hygiene can be quite problematic as public accountability measures because current auditing processes can introduce substantial biases into rates, making it appear that hand hygiene compliance is excellent when it may not be (Muller and Detsky 2010).

**Hand Hygiene Compliance Programs**

Although hand hygiene was identified roughly 150 years ago as a major means of controlling the spread of infectious agents to patients (Semmelweis 1861), only recently have multiple organizations and countries made improving hand hygiene a priority that requires specific resources, education and interventions. Part of the reason for this long delay may be that, while the act of cleaning one’s hands is simple, the behaviour that drives compliance (or non-compliance) is remarkably complex (World Health Organization 2009). It remains common for administrators and leaders to be shocked and disappointed about how difficult it is to make significant progress with compliance.

**Likely all of us have heard a physician say, “I’ll give you an antibiotic, just in case.”**

An abundance of literature suggests that improving hand hygiene requires a multi-faceted approach, combining elements of social marketing, human factors engineering, education, strong leadership support and data feedback (World Health Organization 2009). While a focused educational or awareness campaign often temporarily increases compliance, the increase typically dissipates unless behaviour and expectations fundamentally change.

As mentioned previously, measurement is central to any change process, yet hand hygiene compliance measurement involving human auditors is both costly and subject to substantial bias. Not only does being observed have the potential to temporarily modify behaviour during the auditing period (i.e., the act of measuring influences the results), but because it is costly and labour intensive, only small numbers of measures can be obtained over short periods of time. The knowledge that rates will be reported publicly only further inflates this bias (Muller and Detsky 2010).

Emerging technological approaches to hand hygiene auditing involving the use of radio frequency identification and other technologies have the potential to profoundly alter our understanding of hand hygiene compliance (Edmond et al. 2010; Levchenko et al. 2011). Through small transmitters worn by staff, these technologies can capture hand hygiene compliance at every moment of the day, thus providing potentially thousands of data points per day. Some systems incorporate reminders into the system so that staff are prompted to clean their hands should they miss an opportunity. Provided that these hand hygiene data are reported back to healthcare workers in ways that encourage improvement, these technologies have the potential to help identify problem areas and encourage behavioural change.

**Antimicrobial Stewardship**

Simply put, antimicrobial stewardship programs attempt to ensure that patients receive the right antibiotic at the right time for the right duration (Dellit et al. 2007). This is not a new concept; however, there is considerable renewed interest in this field, fuelled by the spread of highly drug-resistant and difficult-to-treat organisms such as carbapenemase-producing gram-negative bacteria (Moellering 2010) and antibiotic-associated diseases such as *Clostridium difficile* diarrhea (Kelly and LaMont 2008). These significant threats to patient safety stem at least partially from the widespread use and misuse of antibiotics that occurs in all healthcare sectors. Unfortunately, the prescribing of antibiotics has been viewed as a benign intervention, and likely all of us at some point have heard a physician say, “I’ll give you an antibiotic, just in case.” While this behaviour comes from concern about missing a treatable bacterial infection, there needs to be greater recognition that antibiotics can cause harm. In addition, some antibiotics are quite expensive and, yet, are being given for questionable indications.

The current stewardship model relies heavily on intervention by trained pharmacists and specialty physicians; however, most healthcare settings, including hospitals, do not have access to such resources (Johannson et al. 2011). Stewardship needs to evolve from an intervention that only academic and large community hospitals can afford into a far more flexible program where different aspects of stewardship can be implemented in almost any setting, including long-term care and outpatient clinics.

**Continuing Challenges**

**Patient Engagement**

Despite some progress, patients and families remain largely sidelined from the infection control process: in general, rather than patients being engaged in creating and implementing policies, control measures are done to patients by healthcare workers. Patients and their families are seen as potentially mobile sources of contagion, rather than people who may well have insights into possible solutions. Fortunately, there are some examples of settings where these individuals are becoming more involved (Bittle and LaMarche 2009).

Furthermore, there continue to be confusion surrounding
what carrying a hospital “superbug” means, an inconsistent application of control measures across healthcare settings and vagueness surrounding the risks to patients and others upon discharge. Indeed, infection control measures often stop upon exit from the hospital, even though patients likely access ambulatory care. Patients want to know what the transmission risk is to their family members, how long they will potentially carry the organism etc. More work needs to be done to address these gaps and inconsistencies in practice across the continuum of care. This can start with a simple conversation with patients and their families, answering questions and providing education, and allowing them to be a part of the solution, not just passive recipients of care.

**Never-Ending Search for a Common Approach**

Unfortunately, much of infection control practice is not black or white but, rather, many shades of grey. For example, there is some literature indicating that alcohol-based hand rubs (ABHR) do not kill *Clostridium difficile* spores, leading some to argue that one should only clean one’s hands with soap and water when caring for patients with this infection (Jabbar et al. 2010; Oughton et al. 2009). Others argue that while it is true that ABHRs do not kill *C. difficile* spores, insisting upon soap and water washing will dramatically decrease hand hygiene compliance since it takes longer and is more drying to the hands, and often sinks are not readily accessible. Both of these are valid points of view and, not surprisingly, various expert bodies have released differing recommendations (Ontario Ministry of Health and Long-Term Care 2010; Siegel et al. 2007). Similarly, rings have been shown to harbour potentially pathogenic organisms, even after one performs hand hygiene (World Health Organization 2009). Requiring rings to be removed prior to handwashing would solve this problem but, again, would likely decrease compliance with hand hygiene.

Searching for the “correct” answer when there isn’t one can lead to a stalemate. We have stated before that HAIs have perhaps more in common with social problems such as littering than with our traditional perception of an adverse event, which tends to have a more linear association between cause and effect. During a typical week-long hospital stay, patients are literally exposed to thousands of diverse human and environmental contacts that may lead to them acquiring a hospital superbug or developing a device-related infection – the hospital is a truly complex environment. While there may only be one exposure that ultimately leads to infection, it is nearly impossible to determine which one was responsible.

Thus, all pieces of the healthcare system have the potential to harm patients and, importantly, the power to protect them. Fortunately for our patients, once we acknowledge the central role of culture in patient safety, we can begin to successfully address problems by using approaches that work with culture rather than against it.

**Healthcare Design**

Despite considerable, robust evidence that healthcare design has a large role to play in preventing the spread of communicable agents, Canada has been slow to adopt single-patient room design standards that have been accepted in other countries such as the United States (American Institute of Architects 2006). It has been shown that having roommates is a very potent risk factor for acquiring a communicable organism (Hamel et al. 2010). Furthermore, single-patient rooms have been shown to have multiple other patient safety and comfort benefits that ultimately result in decreased lengths of stay and better outcomes (Ulrich et al. 2008). All told, it is estimated that the upfront capital costs are rapidly recouped over the lifetime of the facility (Ulrich et al. 2008). Fortunately, the Canadian Standards Association has recently released new guidelines that support the use of single-patient rooms (Canadian Standards Association 2011).

**Healthcare Culture**

Perhaps the most central factor that continues to drive the spread of infectious agents in hospital is healthcare worker culture. As mentioned previously, until recently HAIs were not seen as patient adverse events. Even today, there is far more innate comprehension by both healthcare workers and patients themselves that a critical medication error (e.g., giving the wrong dose of chemotherapy) is tragic and preventable, than there is that a fatal case of *C. difficile* diarrhea resulting from poor environmental cleaning and antibiotic misuse is tragic and preventable (Gardam et al. 2009).

**Searching for the “correct” answer when there isn’t one can lead to a stalemate.**

We have stated before that HAIs have perhaps more in common with social problems such as littering than with our traditional perception of an adverse event, which tends to have a more linear association between cause and effect. During a typical week-long hospital stay, patients are literally exposed to thousands of diverse human and environmental contacts that may lead to them acquiring a hospital superbug or developing a device-related infection – the hospital is a truly complex environment. While there may only be one exposure that ultimately leads to infection, it is nearly impossible to determine which one was responsible.

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**Conclusion**

The field of infection prevention and control is maturing, thanks to renewed interest by the healthcare community and patients and the realization that effective, low-cost strategies to prevent infections exist. New approaches to data measurement and feedback are emerging that may help shine a light on current problems that contribute to an unsafe environment.

While there will always be a necessary role for command-and-control approaches during dangerous outbreaks, it is our hope that this field will continue toward a model where all those involved in the problem will be recognized as part of the
solution. We have witnessed the ability of front-line empowerment to enable significant positive change on multiple occasions throughout Canada. Every organization has individuals who are fed up with the status quo and who have ideas on how to make things better, yet our traditional hierarchy does not allow them to have a voice. By traditional leadership allowing these individuals to lead change, encouraging others to try their ideas, and learning to step back and move toward a facilitation and support role, it is possible to achieve what we were unable to accomplish with our usual approaches.

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Medication Reconciliation in the Hospital
WHAT, WHY, WHERE, WHEN, WHO AND HOW?

Olavo Fernandes and Kaveh G. Shojania

Abstract
Medication reconciliation arose as the solution to the well-documented patient safety problem of unintentionally introducing changes in patients’ medication regimens due to incomplete or inaccurate medication information at transitions in care. Unfortunately, medication reconciliation has often been misperceived as a superficial administrative accounting task with a “pre-occupation with completing forms,” resulting in the implementation of ineffective processes. In this article, the authors briefly review the evidence supporting medication reconciliation but focus more on key practical questions regarding the elements of an effective medication reconciliation process: what it should consist of, where and when it should occur, who should carry it out and how hospitals should implement it. The authors take the why of medication reconciliation to consist not just of the professional obligation to avoid causing harm, but also of a rational self-interest on the part of healthcare leaders. The authors argue that, rather than wasting time implementing a nominal reconciliation process, we should invest time and energy in a more robust and effective strategy, and they address specific practical questions that arise in such an effort.

At the monthly management meeting of a large urban hospital, the head of patient safety announces: “We had a critical incident last week. A patient was readmitted two days after discharge with severe hypoglycemia. The treating team discharged the patient on a new insulin regimen without realizing that the patient also had insulin 30/70 at home. The patient continued to take her previous regimen as well as the new one, and was found unresponsive by her husband. She’s in the ICU and probably will have permanent neurological deficits.” After various sighs and exclamations from the executives around the table, the chief medical officer asks, incredulously, “Why didn’t this get picked up by medication reconciliation?” Before anyone can answer, the executive adds: “We had that other case six months ago in which a patient was discharged without restarting his Coumadin, and he ended up having a stroke. We implemented medication reconciliation last year: why is this still happening?”

The answer to this executive’s question is that care transitions represent such an error-prone process that, even with robust medication reconciliation, catastrophic cases such as these can still occur. Moreover, the vast majority of hospitals do not have a robust medication reconciliation process in place, so these events can continue to occur with considerable frequency.
In this article, we use the existing literature, as well as results from our own research and experiences as clinicians, as pharmacist (O.F.) and a physician (K.S.) to address key practical questions regarding effective medication reconciliation: what it should consist of, where and when it should occur, who should carry it out and how hospitals should implement it. In terms of why, we do not formally review the evidence supporting medication reconciliation; however, we do briefly summarize key studies that indicate the likely impact on patient safety.

Why Implement Medication Reconciliation?

Transitions from one healthcare setting to another – whether from an intensive care unit to a general ward or from a rehabilitation facility to the patient’s home – increase the risks of adverse drug events and can contribute to avoidable hospital visits (Dedhia et al. 2009; Fernandes 2009; Jack et al. 2009; Ong et al. 2006). For instance, incomplete or inaccurate medication information can introduce changes to patients’ outpatient medication regimens that were not intended by hospital-based physicians. Two common unintended medication changes are omissions – pre-admission medications are omitted from hospital orders and therefore not continued after discharge – and commissions – previous medications that patients discontinued prior to admission are inadvertently re-initiated in the hospital and therefore continued upon discharge (Tam et al. 2005). In one study of 151 hospitalized medical patients (Cornish et al. 2005), 54% of patients had at least one unintended discrepancy between their hospital and outpatient medication regimens, and 39% of these discrepancies were judged to have the potential to cause moderate to severe discomfort or clinical deterioration. Because many unintended medication discrepancies are relatively minor, the better studies have assessed the likely clinical impact of the discrepancies identified by medication reconciliation (Gleason et al. 2004; Lalonde et al. 2008; Nickerson et al. 2005; Schnipper et al. 2009; Varkey et al. 2007; Vira et al. 2006). Despite varying definitions of clinical impact, these studies all identify a category that might be called “clinically important” discrepancies – unintended changes...
to patients’ medications with a reasonable risk of some harm. Rates for these clinically important unintended discrepancies range from a low of 0.25 per patient to a high of 0.97. The best study to date—the only randomized controlled trial comparing medication reconciliation with usual care with an intervention that involved interprofessional process redesign from admission to discharge (Schnipper et al. 2009) — reported a relative reduction in potential adverse drug events of 28% (95% confidence interval 1.0–48%).

These studies of the impacts of medical reconciliation on clinically significant events all involve key roles for pharmacists. Accreditation standards do not stipulate involvement by pharmacists (Accreditation Canada 2011, Joint Commission 2011), and staffing constraints probably limit the degree to which pharmacists perform medication reconciliation outside academic medical centres. Thus, medication reconciliation as implemented in most hospitals does not correspond to the intervention for which the literature provides support.

What Is Medication Reconciliation?

Initial conceptions of medication reconciliation have evolved into a robust system for reducing potential adverse drug events and risks for unnecessary subsequent care (Figure 1 [High 5s 2009]; Fernandes 2009; World Health Organization 2006). Unfortunately, medication reconciliation has often been misperceived as a superficial administrative accounting task with a “pre-occupation with completing forms” (Boockvar et al. 2011). When conducted as intended, medication reconciliation is a conscientious, patient-centred, inter-professional process that supports optimal medication management (Greenwald et al. 2010).

The best possible medication history (BPMH) provides the cornerstone for medication reconciliation. It differs from a routine medication history in that it involves (1) a systematic process for interviewing the patient (or family) and (2) a review of at least one other reliable source of information (e.g., a provincial medication database, an inspection of medication vials or contact with the community pharmacy) to obtain and verify patient medications (prescribed and non-prescribed) (Safer Health Care Now! 2011). In practice, however, medication histories fall short of these recommendations, with clinicians skipping the time-consuming step of actually speaking with the patient to verify medications. Reconciling a suboptimal medication history with medication orders does nothing to improve care and may even “hard-wire” unintentional discrepancies. Finally, efforts to obtain a BPMH face the many challenges associated with patients who maybe unfamiliar with their medications.

The number and intensity of medication reconciliation activities may legitimately vary between hospitals and even clinical areas within a hospital. Table 1 outlines a proposed continuum of varying levels of medication reconciliation intensity, from bronze—just a BPMH and reconciliation, the current national accreditation indicator in Canada (Accreditation Canada, 2011)—through to silver, gold, platinum and diamond. The more advanced levels of medication reconciliation involve progressions in inter-professional collaboration, integration of medication reconciliation into discharge summaries and prescriptions, and the delivery of more comprehensive medication education to patients. In principle, individual patients might appropriately receive different levels of medication reconciliation, from bronze

### TABLE 1.
Medication reconciliation in varying levels of intensity, as seen in published studies

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<thead>
<tr>
<th>Level</th>
<th>Key Components</th>
<th>Published Examples</th>
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<tr>
<td>Bronze</td>
<td>BPMH with admission reconciliation</td>
<td>Cornish et al. 2005; Kwan et al. 2007</td>
</tr>
<tr>
<td>Silver</td>
<td>Bronze level + reconciliation at discharge by prescriber only ± electronically generated discharge prescription</td>
<td>Schnipper et al. 2009; Wong et al. 2008</td>
</tr>
<tr>
<td>Gold</td>
<td>Silver level + discharge reconciliation is inter-professional (e.g., prescribing physician and pharmacist collaboration) + electronically generated discharge prescription</td>
<td>Cesta et al. 2006; Dedhia et al. 2009; Schnipper et al. 2009</td>
</tr>
<tr>
<td>Platinum</td>
<td>Gold level + attention to broader medication management issues (e.g., appropriateness of agents, safety and effectiveness assessment) + medication counselling prior to discharge (including discussion of medication changes) + provision of patient-friendly reconciled medication schedules upon discharge</td>
<td>Al-Rashed et al. 2002; Dedhia et al. 2009; Makowsky et al. 2009; Murphy et al. 2009; Nazareth et al. 2001</td>
</tr>
<tr>
<td>Diamond</td>
<td>Platinum level + additional elements, such as • post-discharge follow-up phone call to patient by hospital clinician (e.g., nurse or pharmacist) • communication of medication changes with rationale directly to community pharmacy and primary care physician</td>
<td>Gillespie et al. 2009; Jack et al. 2009; Karapinar-Çarkıt et al. 2009; Schnipper et al. 2006; Walker et al. 2009</td>
</tr>
</tbody>
</table>

BPMH = best possible medication history.
to platinum, given their different risks for adverse drug events. In practice, hospitals may choose a specific degree of medication reconciliation for all patients in a given clinical area.

Where Should Medication Reconciliation Occur?

Literature on medication reconciliation in ambulatory settings has begun to emerge (Bayoumi et al. 2009; Fernandes 2009; Varkey et al. 2007), but most studies remain focused on the hospital.

Within the in-patient arena, should hospitals target any specific clinical area first? The extent to which patients in some clinical areas benefit more from medication reconciliation than patients in others (e.g., general medicine versus surgery) remains unclear. (Realistically, the potential benefit probably depends on the number and type of medications taken by patients, not the clinical service.) Thus, rather than choosing to focus on clinically defined patient groups, many hospitals choose to target patients admitted through the emergency department and elective patients, typically in surgery. Focusing on elective patients offers the advantage of proactively conducting the BPMH in a controlled setting such as a pre-admission clinic (Kwan 2007). That said, the emergency department represents a much larger gateway for hospitalized patients, and the strategies used for medication reconciliation in a pre-admission clinic may not translate well to the busy, time-pressured setting of the emergency department.

When Should Medication Reconciliation Occur?

Should hospitals first target admission, discharge or internal transfers? Some studies have highlighted serious medication risks at internal transfer points, such as from intensive care to a ward (Santell 2006). Realistically, though, most hospitals initially choose to target medication reconciliation at admission or discharge. Both options involve implementation issues, and determining the optimal choice for a particular hospital is challenging. Ultimately, some form of discharge reconciliation needs to be present – after all, the main purpose of medication reconciliation is to avoid unintended medication errors created by hospitalization. The key challenge faced by discharge reconciliation is integrating it into the general discharge process, which already involves multiple activities on the part of physicians, nurses, pharmacists and other health professionals. It may be tempting to simply provide a medication reconciliation form or letter with a summary of medication changes. However, disconnecting medication reconciliation from related discharge processes, such as preparing discharge summaries and prescriptions, may minimize its full benefit and give rise to the false impression that medication reconciliation is not a clinically relevant process and just adds to clinicians’ work.

Reconciliation at admission avoids the complexities of the discharge process, but the time pressure at admission, especially for acutely ill patients, presents challenges for obtaining a BPMH. In practice, hospitals deal with the time pressure issue by expanding “on admission” to mean within 24–48 hours of admission. This solves the time pressure problem but misses the opportunity to have the medication reconciliation support the process of creating medication orders at admission. As with the discharge process, not integrating medication reconciliation into a relevant clinical process (e.g., creating orders at admission) may foster the misperception of medication reconciliation as extra work that exists for purely administrative reasons.

On balance, starting the medication reconciliation process at or soon after admission may ultimately save time. Even if admission reconciliation does not directly generate admission orders, the discharge process will be more accurate and efficient if a BPMH already exists. Also, the Accreditation Canada indicator, a natural incentive, is currently focused on admission. Importantly, these ideas are not mutually exclusive. A “phased-in” approach that starts on admission, sustains gains throughout hospitalization and finishes at discharge may make the most sense.

The Who’s Who of Medication Reconciliation

Should hospitals target all admitted patients or “high-risk” patients only? With limited human resources and hospitals struggling to fully implement medication reconciliation across the continuum, it may seem natural to target patients who will most benefit from medication reconciliation. However, evidence-informed criteria for high-risk patients’ medication reconciliation remain unclear at this time. Some authors have suggested that medication reconciliation candidates can be focused by age (over 65 years old) or number of medications (more than four) (Coffey et al. 2009; Gleason et al. 2010). Others have proposed that “high risk criteria” include factors such as frequent hospitalizations, high-alert medications, chronic diseases prone to frequent medication changes and patients with a large number of in-hospital medication changes (Rumball-Smith and Hider 2009). Narrowing the scope of medication reconciliation promises a “quality job” for targeted patients versus a “superficial effort” for all.

Despite the plausibility of this approach, an important practical argument in support of medication reconciliation for all patients is that accurately identifying high-risk patients (e.g., based on the number or type of medications) often requires a proper BPMH process. Moreover, in some settings (e.g., medical wards), screening for a high-risk status may not practically eliminate many patients. Finally, patients who are considered low risk at admission may have changes made to their home medication regimens later in their hospitalization that would elevate their risk status. For all these reasons, Accreditation Canada’s focus on applying medication reconciliation to all admitted patients seems reasonable. That said, a given hospital may recognize that...
certain wards generally treat patients with short medication lists and for whom few changes in pre-hospital medications occur. In such cases, a lower-level version of medication reconciliation (see Table 1) may be justified.

Who should optimally lead medication reconciliation activities? Some argue that, based on their educational training and expertise, hospital pharmacists are uniquely positioned to lead and support patients and inter-professional teams with medication reconciliation (Fernandes and MacKinnon 2008) and that this may result in better accuracy and clinical and economic outcomes (Bond and Raehl 2007; Carter et al. 2006; Coffey et al. 2009; Kaboli et al. 2006; Tam et al. 2005). Karnon et al. (2009) conducted a cost-effectiveness analysis suggesting that pharmacist-led reconciliation yields the highest expected net benefits and a probability of being cost-effective of more than 60% by a quality-adjusted life year value of £10,000.

However, there can be problems with pharmacists leading reconciliation. First, many wards do not have clinical pharmacists, and most hospitals do not have 24/7 pharmacy service or enough pharmacist resources to complete and sustain medication reconciliation at all interfaces. Limited pharmacist resources may thus result in a target of only complex patients. A feasible alternative adopted by some hospitals is the use of pharmacy technicians and students to support medication reconciliation (Lam et al. 2009; Mersfelder and Bicketl 2008; van den Bernt et al. 2009). Regardless of the profession, a key factor is having the clinician receive formal practical training on how to systematically and efficiently conduct a BPMH (Boocvkvar et al. 2011; Greenwald et al. 2010; Safer Health Care Now! 2011).

Regardless of which professionals carry out medication reconciliation, patients remain essential partners in the process.

Formal BPMH training also promotes professional “trust” in this critical shared information.

Second, if pharmacists lead, there is a danger that other health disciplines will divest themselves of the patient responsibility linked to this critical activity. Interviews with staff at hospitals across Canada as part of an ongoing study conducted by one of us (K.S.) confirmed this concern in some hospitals: the focus on the pharmacists/pharmacy technicians risks losing sight of medication reconciliation as a shared inter-professional accountability. A recent US panel of stakeholders, representing professional, clinical, healthcare quality, consumer and regulatory organizations, achieved consensus that hospital-based medication reconciliation should employ an inter-professional team approach as the ideal (Greenwald et al. 2010). Moreover, a coordinated, inter-professional process can improve efficiency by reducing redundancy in the traditional approach of physicians and nurses all conducting individual medication histories. Regardless of which professionals carry out medication reconciliation, patients remain essential partners in the process. Even completely perfect reconciliation will serve little purpose if patients do not understand their new medication regimens. Thus, the higher levels of medication reconciliation shown in Table 1 include discharge medication counselling to patients. Other advanced features include the use of patient portals/kiosks to actively engage patients in the BPMH process and support a patient-accessible medication record (Bassi et al. 2010).

How to Implement Medication Reconciliation

One of us (K.S.) has led a study of the experiences of 25 adult and pediatric healthcare institutions across Canada with implementing medication reconciliation. The formal analysis of the interviews with 74 nurses, pharmacists, physicians, patient safety officers, project managers and senior executives has not yet been published, but some key themes are summarized here. First, what counts as medication reconciliation varies widely. Areas of variation included who conducted the medication history and how it was taken, the number of histories completed, the role of the medication order and which patients’ medications were reconciled. Some of this variation reflects understandable decisions in response to local implementation challenges. However, some variation included clearly suboptimal processes, such as the absence of a systematic approach to history taking and obtaining medication information from more than one source.

The focus of this study, however, was on the practical challenges encountered in implementation. These barriers included the following:

- Substantial underestimation of the time and resources required to implement medication reconciliation
- Resistance from front-line staff due to impacts on workload and work flow (physicians sometimes resisted even independent of such impacts)
- A lack of implementation/change management experience
- Turnover on the core implementation team
- Limited resources for ongoing education and support to sustain the implementation
- Too rapid implementation, as a result of pressure due to accreditation, resulting in a poorly configured process

Not surprisingly, interviewees repeatedly identified that real support from senior management in appropriately resourcing teams and implementation efforts was key to success. Other facilitators included having physician “champions,” inter-professional implementation teams and contact with other institutions to share and learn from implementation efforts (e.g., a formal collaborative, such as Safer Healthcare Now!)
<table>
<thead>
<tr>
<th>Question and Position Considered</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
</table>
| Where? Where should hospitals implement medication reconciliation? | • ED is the most common gateway for admissions in most hospitals  
• Unclear whether one clinical service has clear benefits over another, so makes sense to look at all patients admitted through ED gateway  
• Absence of published evidence of clear medication reconciliation benefit for non-admitted ED patients over admitted patients | • Starting in surgical pre-admission clinics for elective surgery patients allows for “pro-active” medication reconciliation for most patients (BPMH completed in advance of admission orders) vs. “reactive” medication reconciliation in the ED  
• May be better to pick a clinical service with a high rate of medication-related readmissions vs. all admitted patients in the ED |
| When? Which patient transition of care should hospitals target first: admission, discharge or internal transfer? | • Prevent discrepancies in hospital and beyond — discrepancies on admission are propagated through hospital stay to discharge so better to correct them from the beginning  
• Saves time: quality discharge medication reconciliation more efficient and accurate if a BPMH already exists  
• Accreditation Canada national indicator focuses on medication reconciliation | • May be better to target select patients at discharge interface rather than all admitted patients  
• Discharge medication reconciliation may reduce clinically meaningful outcomes such as readmissions  
• Patients may be at higher risk for adverse events outside the confines of hospital setting  
• Limited evidence that mortality risk is higher at internal-transfer interface (Santell 2006) |
| Who? Should hospitals target all admitted patients or “high-risk” patients only? | • Targeting all patients may save time — takes extra time and effort to screen for “high-risk” criteria (time better directed to medication reconciliation care)  
• Often can only truly ascertain appropriate risk after a proper BPMH (i.e., number of medications or high-alert drugs)  
• Accreditation Canada’s focus is on “all admitted patients”  
• Risk stratification point may only account for risk factors on admission, but other important risk factors may occur later (i.e., number of changes in hospital to home regimen) | • With limited resources, better to target medication reconciliation resources to patients who will derive the most benefit  
• Clear, evidence-informed “high-risk” patient populations for medication reconciliation–related adverse drug events are unclear at this time, but more definitive evidence evolving in this area |
| Who? Which healthcare discipline should optimally lead medication reconciliation patient activities? | • Pharmacists may lead admission reconciliation, with prescribers (physicians and nurse practitioners) leading discharge  
• Limited studies to suggest improved accuracy with pharmacist medication reconciliation | • Danger that if pharmacists lead, other health disciplines divest themselves of the responsibility linked to this critical activity  
• Not enough pharmacist resources to complete and sustain medication reconciliation — consider nurses or pharmacy technicians or healthcare students  
• Pharmacists often not available 24/7  
• Limited pharmacist expertise should be more appropriately targeted only to complex and high-risk patients |
| How? Should hospitals use paper-based or electronic-based resources for medication reconciliation? | • Electronic systems may save clinicians time and lessen tedious work  
• They allow for quick “conversion” of BPMH to admission orders  
• Information may pre-populate admission or discharge prescription orders  
• Easy patient tracking for team regarding who has received medication reconciliation and for monthly hospital reporting  
• System may facilitate “electronic reconciliation” to trigger identification of discrepancies  
• Aligns medication lists from different points in time on one screen to visualize together | • Electronic systems often require full CPOE implementation — which most hospitals do not yet have in place  
• They introduce unique risks and may create a false sense of accuracy — “hard-wire” mistakes  
• May have to address multiple system integration issues to be effective  
• May add unnecessary complexity vs. a simple paper form to facilitate medication reconciliation |

BPMH = best possible medication history; CPOE = computerized physician order entry; ED = emergency department.

**TABLE 2.**

Summary of pros and cons for key issues in medication reconciliation in acute care
Our interviews also revealed that, despite the accreditation requirement, many hospitals have not yet fully disseminated admission to discharge medication reconciliation beyond one or two pilot units, a finding confirmed anecdotally in discussion with colleagues across the country. Many of these implementation lessons thus remain relevant as hospitals struggle to spread and sustain quality medication reconciliation. Two specific practical decisions related to implementation also merit consideration, namely, whether to turn the medication reconciliation document into the admission orders (or the prescription at the time of discharge) and whether to strive for an electronic process. Table 2 presents some of the pros and cons related to these issues. Overall, hospitals should recognize that the successful implementation and maintenance of high-quality medication reconciliation practices, to the degree that they effectively prevent actual patient adverse events, require careful inter-professional and organizational planning along with effective change leadership. A number of hospitals in North America have published their successful medication reconciliation implementation journeys and valuable practical lessons learned (Coffey et al. 2009; Murphy et al. 2009; Schnipper et al. 2009).

Conclusion

Doing the bare minimum when it comes to medication reconciliation – just putting in place enough of a process to meet accreditation standards – will do little to prevent catastrophic cases, such as the ones described at the outset, from continuing to occur. Moreover, the occurrence of such cases will cause frustration (never mind risk management issues), given that implementing even a fairly superficial medication reconciliation process consumes substantial institutional time and resources. We argue that, rather than wasting time implementing a nominal medication reconciliation process, hospitals should invest additional time and energy in a more robust effective strategy, considering the issues we have outlined with respect to the what, where, when, who, why and how of implementing medication reconciliation.

Acknowledgement

Our thanks go to Michelle Baker, BScPhm, of the University Health Network, for developing Table 1.

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Olavo Fernandes and Kaveh G. Shojania  *Medication Reconciliation in the Hospital*
The Institute of Medicine (IOM) report *To Err Is Human* (Kohn et al. 1999), published at the turn of the century, signalled the beginning of the modern era of patient safety. Although a variety of good work followed, in hindsight what appears to have been missing at the beginning was sufficient pause to ask which of the many possible directions should be taken to achieve the most value for effort; only recently has this question been framed (Pronovost and Faden 2009). At the outset, it was understandable that the focus should be put on the tangible, obvious and most easily fixed problems. Medication error, for example, was quickly identified, and considerable work followed in this area. Other less tangible areas attracted less attention. Diagnostic failure appears to have been a major oversight and remains a major threat to patient safety. Wachter (2010) notes that the term *medication error* is mentioned more than 70 times in the IOM report (Leape et al. 1991), whereas *diagnostic error* appears only twice – even though physician errors that lead to adverse events are significantly more likely to be diagnostic (14%) than medication related (9%) (Leape et al. 1991). In both Canada (Canadian Medical Protective Association, personal communication, 2011) and the United States (Chandra 2005), diagnostic error is the leading cause of malpractice litigation. At the end of a long career in medical decision-making, Elstein (2009) estimated that diagnostic failure across the board in medicine was in the order of 15%.

The Invisibility of Diagnostic Failure

A major part of the problem is the inherent obscurity, complexity and irreducible uncertainty associated with human illness. In turn, the diagnostic process that attempts to identify it is similarly obscure. These issues have been well articulated by Montgomery (2006). As she notes, if illness were to follow scientific rules, our difficulties in this area would have been solved long ago. Instead, physicians often have to deal with a process that has “mushy but unavoidable ineffabilities” (Montgomery 2006). This is the process that takes place at the dynamic interface between the patient’s and the physician’s thoughts, feelings, reasoning and decisions.

Part of the problem, too, has been the tight control that physicians have exerted over diagnosis as well as an attendant culture of silence and secrecy – both have led to further obfuscations of the process. Other healthcare workers have been largely excluded, sharing little or no responsibility or accountability, with hospitals usually more than willing to distance themselves from the decisions of their physicians. From a medical-legal standpoint, diagnosis is largely a physician responsibility. Another important reason has been the invisibility of diagnostic error. At the outset of the modern patient safety era, its impact was obscured through the principal methodology used in the benchmark studies (Brennan et al. 1991; Thomas et al. 2000; Wilson et al. 1995), retrospective chart review, which did not readily permit the detection of diagnostic failure. Whereas
medication errors or failed surgical procedures are often clearly visible using this methodology, diagnostic errors are not. They would not be discussed in progress notes or discharge summaries, and there are few triggers that would help reviewers detect them. Even today, the Global Trigger Tool developed by the Institute for Health Improvement (Classen et al. 2011), acclaimed as a more sensitive and efficacious method of detecting adverse events, does not capture diagnostic error. A variety of reasons can be posited for the failure to recognize the important role of diagnostic failure in patient safety (Table 1).

The Psychology of Decision-Making
A major factor in diagnostic error has been that understanding the complex psychological processes that underlie clinical decision-making has not been seen as relevant to medical training. There remains a tacit belief by medical educators that becoming a well-calibrated decision-maker is a process that occurs through exposure to the decision-making of mentors or other exemplars and through experience, but there is usually no specific training. While sound formal training does exist for analytical, quantitative, rational decision-making of the type described by Rao (2007), there is little available on intuitive decision-making, where clinicians spend most of their time (Figure 1). Parenthetically, rational decision-making must also include, although it is rarely acknowledged, a consideration of the elements of argumentation, logic and critical thinking that are implicit in sound reasoning (Jenicek and Hitchcock 2005).

A further problem has been that rational clinical decision-making is far more amenable to experimental testing than is intuitive reasoning. The properties of rational thought are easily described, conforming as they do to fundamental laws of science, objectivity and probability. They have scientific rigour and are reproducible. In contrast, intuitive decision-making is often much more dependent on the individual, non-scientific, unpredictable and less reproducible. It is difficult to re-create in a laboratory the rich, complex context under which many clinical decisions are made. It is not surprising, therefore, that rational decision-making has emerged as the main focus of medical decision-making researchers.

Neither have there been adequate models of decision-making to explain the process of diagnostic reasoning, until quite recently. The history of clinical decision-making in medicine has followed a fairly conservative and sterile path, largely confining itself to a respectable, orthodox, rational approach. Unquestionably, this is an important part of decision-making; but given that we spend most of our thinking time in the intuitive mode (Lakoff and Johnson 1999), there is now a strong imperative to better understand its nature and consequences and to incorporate it into a more comprehensive approach toward medical decision-making.

Two important developments have facilitated our understanding of medical reasoning and provided insight into diagnostic failure. They came about through the “cognitive revolution” in psychology in the latter part of the past century, where “mental processes” were rediscovered and seen fit for study. The first was an important new way of looking at everyday thinking, termed heuristics and biases (Tversky and Kahneman 1971, 1974). A substantial literature has revealed that much of our thinking is vulnerable to a variety of affective and cognitive biases that exert their influence, particularly under conditions of uncertainty, when we are using heuristics (thinking shortcuts). This is an inherent feature of human reasoning. An example is illustrated in the sidebar.

However, initial efforts to apply the findings of psychologists to medical decision-making did not attract sufficient interest in the broader clinical community; they were viewed as lacking in ecological validity and therefore clinically irrelevant (i.e., experimental studies in the laboratory were too far removed from clinical reality). A turning point came with the publication of a book on clinical reasoning in which two prominent internists showed how psychological findings could be directly applied in the clinical context (Kassirer and Kopelman 1991).

The second development was the emergence (Dawson 1993; Elstein 1976) and progressive refinement (Evans and Frankish 2009) of dual process models of thinking; these held that the multiple varieties of thinking could be organized into two main modes: intuitive decision-making, where we spend most of our time, and analytical thinking, which is used more explicitly for deliberate problem solving. Over 35 years ago, the important distinction between rational and intuitive approaches was well articulated as a statistical-clinical polarization by Elstein (1976) in an article prophetic of modern dual process theory.

Most of our thinking occurs in the intuitive mode (Lakoff and Johnson 1999), where heuristics predominate (Gilovich et al. 2002). Dual process theory proper was introduced into medicine in the early 1990s (Dawson 1993) and subsequently provided a useful platform for a universal model for diagnostic reasoning (Croskerry 2009). Experienced clinicians make much of their diagnostic decision-making quickly and effectively in the intuitive mode using pattern recognition, but need to access the analytical mode for novel, ambiguous and more challenging cases. The particular operating characteristics of the dual process approach in diagnostic reasoning have been described (Croskerry 2009). In the past decade, there has been an increased willingness from medical quarters to accept the relevance and importance of the research findings of cognitive psychologists (Redelmeier 2005).

Knowledge Gaps or Thinking Deficits?
A strong consensus has emerged that thinking failures occur predominantly in the intuitive mode, having their origins in failed heuristics and the maladaptive influence of cognitive
**TABLE 1.**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Discussion</th>
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<tbody>
<tr>
<td><strong>Amorphous nature of many illnesses</strong></td>
<td>Illness and disease do not follow precise rules. While some illnesses are straightforward, many are complex and have covert features that are difficult to detect and quantify. A &quot;scientific&quot; approach is not always possible.</td>
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<tr>
<td><strong>Invisibility</strong></td>
<td>Critical parts of diagnostic failure are the physician’s clinical reasoning and decision-making processes, which are largely covert and poorly understood.</td>
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<tr>
<td><strong>Accountability</strong></td>
<td>Diagnosis, for the most part, is the responsibility of physicians. There is little incentive for others to concern themselves about the process if they are not immediately involved or have no direct accountability.</td>
</tr>
<tr>
<td><strong>Attitude of silence and culture of silence</strong></td>
<td>Historically, it has been relatively easy for one group (physicians) to control and suppress information about a specific topic, especially when not to do so might reveal weakness or incompetence. Generally, physicians are not forthcoming about their failures and are unwilling to discuss those of their colleagues. The result is that diagnostic failure has not reached the light of day. This is now improving, with morbidity and mortality rounds taking a more open approach toward error.</td>
</tr>
<tr>
<td><strong>Denial: discounting and distancing</strong></td>
<td>When diagnostic failure occurs, physicians are often unwilling to confront their own failings; they use various forms of denial: discounting the failure by blaming the illness or circumstances they could not control, or blaming the patients (for failing to give a full history, non-compliance etc.), other healthcare workers or the system.</td>
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<tr>
<td><strong>Non-disclosure</strong></td>
<td>A significant proportion of diseases resolves spontaneously or is “cured” through placebo effects. Disclosing failures to diagnose might reduce the confidence of patients in their doctors and weaken the power of the placebo. Thus, diagnostic failure is generally not sufficiently broadcast.</td>
</tr>
<tr>
<td><strong>Investigation</strong></td>
<td>The main methodological genre for investigating adverse events has been retrospective chart review. However, diagnostic failure is often not apparent from what is recorded in a hospital chart. Trigger tool methodology is similarly flawed due to the invisibility of diagnostic failure. Thus, diagnostic failure has been less visible and has attracted less attention.</td>
</tr>
<tr>
<td><strong>Natural course of illness</strong></td>
<td>Of the 12,000 or so diagnostic entities that currently exist, probably more than 80% resolve without the help of physicians. Even if a physician has the wrong diagnosis and prescribes an inappropriate treatment, the patient’s illness might still improve. Thus, diagnostic performance often looks better than it is, and people have more faith in it than is actually warranted. Alternative medicine owes much of its popularity to the natural course of most illnesses to resolve.</td>
</tr>
<tr>
<td><strong>Lack of awareness</strong></td>
<td>Outcome feedback has traditionally been poor in medicine, and physicians may be unaware that they have failed in their diagnosis, especially if their patients go to another institution or provider or, worse still, die. Patients themselves may “protect” well-liked physicians to spare their feelings.</td>
</tr>
<tr>
<td><strong>Lack of understanding of the decision-making process</strong></td>
<td>The psychological aspects of decision-making are not formally addressed in medical undergraduate curricula. Physicians receive little or no training on decision-making or on the influence of cognitive and affective biases. They do not generally reflect upon or view introspectively their own decision-making behaviours. There has been little incentive to change something that is poorly understood.</td>
</tr>
<tr>
<td><strong>Unavailability of tangible solutions</strong></td>
<td>Whereas other sources of error have been amenable to tangible solutions (checklists in surgery, computerized order entry for medications, safety bundles for specific error-prone practices), there are few options currently available for improving diagnostic performance, although some current clinical decision-support systems and other strategies (e.g., cognitive debiasing) show promise.</td>
</tr>
<tr>
<td><strong>Tolerance</strong></td>
<td>True costs of diagnostic errors are difficult to assess, and it has been easy for healthcare systems and payers to quietly tolerate them providing that physicians are not producing wild outliers.</td>
</tr>
<tr>
<td><strong>Poor business case</strong></td>
<td>Historically, healthcare systems and insurers have seen the investigation and remediation of intangible and obscure diagnostic adverse events as a poor business case, preferring to develop interventions in other areas of medical error. This may change with new data emerging that show that diagnostic adverse events may increase hospital stays by more than 80%.</td>
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</table>
and affective biases. As Stanovich notes (2011), there is now a voluminous psychology literature on the topic, to which can be added a recently burgeoning medical literature (Berner and Graber 2008; Croskerry 2005; Lawson et al. 2011; Neale et al. 2011; Pennsylvania Patient Safety Authority 2010; Redelmeier 2005; Scott 2009; Wachter 2010; Zwaan et al. 2010). An important study by Graber et al. (2005) implicated cognitive factors in about 75% of diagnostic errors; and in a subsequent and very much larger population-based Dutch study, this was estimated at 96% (Zwaan et al. 2010). Efforts to challenge this consensus are few, being largely confined to proponents of naturalistic decision-making (NDM; Klein et al. 1993) and others (Norman and Eva 2010). Researchers in NDM have relied on cognitive field research methods to study skilled performance and have largely dismissed the heuristics and biases approach as a laboratory artifact (Klein et al. 1993). They have placed a strong emphasis on intuitive decision-making, despite repeated demonstrations of its vulnerability to failure (Kahneman 2011). In view of protean demonstrations of heuristics and biases in all walks of everyday life, it is extremely unlikely that similar phenomena do not prevail in medical decision-making (Ruscio 2006; Whaley and Geller 2007), and the once popular criticism that they are only found in the laboratory has become a “caricature” (Kahneman and Klein 2009).

The view has also been advanced that diagnostic failure may be explained by physicians’ knowledge deficits (Norman and Eva 2010), although this too is unsupported by clinical findings. In a study of 6,000 patients in primary care who were cared for by mostly internal medicine residents, diagnostic errors were found in “a wide spectrum of diseases commonly seen in an outpatient general medical setting” (Singh et al. 2007). And

### Diagnostic Failure Due to Intuitive Biases

A 28-year-old female patient is sent to an emergency department from a nearby addictions treatment facility. Her chief complaints are anxiety and chest pain that have been going on for about a week. She is concerned that she may have a heart problem. An electrocardiogram is routinely done at triage. The emergency physician who signs up to see the patient is well known for his views on “addicts” and others with “self-inflicted” problems who tie up busy emergency departments. When he goes to see the patient, he is informed by the nurse that she has gone for a cigarette. He appears angry, and verbally expresses his irritation to the nurse.

He reviews the patient’s electrocardiogram, which is normal. When the patient returns, he admonishes her for wasting his time and, after a cursory examination, informs her she has nothing wrong with her heart and discharges her with the advice that she should quit smoking. His discharge diagnosis is “anxiety state.” The patient is returned to the addictions centre, where she continues to complain of chest pain but is reassured that she has a normal cardiogram and has been “medically cleared” by the emergency department. Later in the evening, she suffers a cardiac arrest from which she cannot be resuscitated. At autopsy, multiple small emboli are evident in both lungs, with bilateral massive pulmonary saddle emboli.

**Comment:** This case illustrates several intuitive biases that lead the physician to an inadequate assessment of the patient and, ultimately, an incorrect diagnosis. First, he stereotypes and labels the patient, failing to provide the assessment that he might otherwise do for a non-addicted patient. He focuses on the disposition of the patient rather than the circumstances that have led her into addiction (fundamental attribution error); she has had a long history of physical and sexual abuse. These biases lead to premature closure of his diagnostic reasoning process. Further, his anger at the patient produces visceral arousal and distracts him from his usual practice of reviewing medications and noticing on her triage chart that she is on a birth control pill and is a smoker – both risk factors for pulmonary embolus.

The biases described in this case reside in the intuitive mode of reasoning and lead to diagnostic failure. An accurate diagnosis is more likely in the analytical mode; but in order to get to it, the physician must decouple from the intuitive mode through the process known as cognitive debiasing.
in a population-based Netherlands study involving close to 8,000 patients, the majority of diagnostic errors were associated with common conditions such as pulmonary embolism, sepsis, myocardial infarction and appendicitis (Zwaan et al. 2010). Further, in a study by Schiff et al. (2009) that surveyed experienced clinicians, it was found that the top 20 missed diagnoses were common, well-known illnesses. At the top of the list was pulmonary embolus (PE), the pathophysiology of which, and its associated risk factors, are very well known to clinicians. Yet, PE appears particularly difficult to reliably diagnose; in a study of fatal cases of PE, the diagnosis was not suspected in 55% of cases (Pidenda et al. 2001). In my experience of three decades of attendance at morbidity and mortality rounds in emergency medicine, at which the majority of cases concern diagnostic failure, a knowledge deficit is very rarely identified as a reason for missing a diagnosis. Thus, it seems clear that how physicians think and not what physicians know is primarily responsible for diagnostic failure. This is an important distinction because it directs us to where remedial action should be taken to improve the calibration of diagnostic reasoning and patient safety.

**Extent of Diagnostic Failure**

Given that diagnostic failure is usually associated with physicians’ reasoning and thinking, it is present in every domain of medicine where decisions are required. It would be expected that diagnostic failure would be highest where uncertainty and ambiguity are high, and this appears to be the case. In the benchmark studies of medical error, diagnostic error was found to be high in emergency medicine, family practice and internal medicine (Brennan et al. 1991; Thomas et al. 2000; Wilson et al. 1995). In contrast, it would be expected to be lower in those areas where there is less uncertainty and ambiguity and clinical presentations are more pathognomonic, such as dermatology, orthopedics and plastic surgery. In an extensive review, Berner and Graber (2008) concluded that the overall rate of diagnostic failure in medicine is probably around 15% but that in the perceptual specialties that rely on visual interpretation (pathology, dermatology, radiology), it is considerably lower, at about 2–5%. Interestingly, the overall failure rate accords well with an ecologically valid study using standardized patients in a general internal medicine outpatient clinic in which the diagnostic failure rate was 13% (Peabody et al. 2004).

**Where Are We Now?**

The first articles specifically focusing on clinical diagnostic error and cataloguing it began to appear in the 2000s (Croskerry 2002, 2005; Elstein and Schwarz 2002; Graber et al. 2005; Redelmeier et al. 2001) and by the end of that decade were more robust (Berner and Graber 2008; Croskerry and Nimmo 2011; Schiff et al. 2009; Singh et al. 2007; Zwaan et al. 2010). In 2007, the Agency for Healthcare Research and Quality identified diagnostic error as an area of special emphasis, and much of the activity on its web-based morbidity and mortality site (http://webmm.ahrq.gov/) deals with cases containing diagnostic errors. In 2008, a working group of the World Health Organization Alliance for Patient Safety identified diagnostic error as a research priority, and in the same year the *American Journal of Medicine* produced a special supplement on the topic (Berner and Graber 2008). The first international conference on Diagnostic Error in Medicine was held in Phoenix, Arizona, in 2008 and the conference has been held annually since. The first conference on diagnostic error in the United Kingdom was held in 2011 in Edinburgh, Scotland. Society to Improve Diagnosis in Medicine (SIDM), has recently been established.

**Not all cognitive biases are created equal, and different cognitive pills might be needed for our different ills.**

**Where Do We Go from Here?**

For the multiple reasons outlined here, it is not surprising that diagnostic error has attracted insufficient attention in patient safety. Its covert nature and complex features have made it a tough problem to solve. One of the major impediments lies in medical education, where the theory and practice of decision-making have not been adequately addressed. However, the problem is now unmasked, and a variety of initiatives are under way. The next steps involve finding appropriate solutions to avoid failure, which remains a tall order. Diagnostic reasoning is mostly an invisible process—we infer failure usually after the fact. We can, however, offer plausible explanations, as well as combine what we know from research in cognitive psychology. A primary goal should be the development of a variety of educational initiatives aimed at teaching about decision-making, specifically, cognitive debiasing, advancing critical thinking and educating intuition (Croskerry and Nimmo 2011; Hogarth 2001).

Given that most diagnostic errors are due to cognitive failure, strong efforts should be made to develop a variety of debiasing strategies to mitigate the adverse consequences of cognitive and affective biases. We should acknowledge that not all cognitive biases are created equal and that different cognitive pills might be needed for our different ills (Keren 1990). Cognitive biases reside mostly in the intuitive mode of decision-making, and their power should not be underestimated. We should be aware that simplistic approaches toward debiasing are unlikely to be effective. Except in cases of significant affective arousal, we cannot expect that one-shot interventions will work (Lilienfeld et al. 2009) or that one particular type of intervention will be sufficient; many biases have multiple determinants, and it is unlikely that there is a “one-to-one mapping of causes to bias or
of bias to cure” (Larrick 2004). It seems certain that successful debiasing will inevitably require repeated training using a variety of strategies – the initial cognitive inoculation should be followed by repeated booster shots and will probably require lifelong maintenance.

Nevertheless, we can get on with improving those conditions known to be associated with cognitive failure – cognitive overload, fatigue and sleep deprivation/sleep debt. All of this work should be strongly embedded in the clinical context of patient safety. Additional strategies such as using checklists (Ely et al. 2011), forcing functions, algorithms, cognitive tutoring systems (Crowley et al. 2007) and other clinical decision support all require further research and development. As Thomas and Brennan (2010) note, the first chapter on diagnostic adverse events is now written: we know they are there and how important they are. The next chapter should focus on understanding the cognitive roots of diagnostic failure, its prevention and the improvement of patient care.

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Ely J, Graber M, and P. Croskerry. 2011. “Checklists to Reduce Diagnostic Errors.” Academic Medicine 86:307-313. (This paper inspired the Perioperative Interactive Education (PIE) group at the Department of Anesthesia at Toronto General Hospital to develop an interactive Diagnostic Checklist website at http://pie.med.utoronto.ca/dc.)


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Introduction and Background
I recently had the opportunity to work in the kitchen of one of the top-rated restaurants in Canada. In addition to satisfying a culinary dream, the experience allowed me to observe a high-functioning team outside of healthcare and reflect on attributes contributing to this team’s success. Let’s set the stage: This was a stressful and productive environment, focused on delivering high-quality and reliable outcomes. There were many team players, all with their unique set of roles and responsibilities and all working toward a common goal – to satisfy the customer. Hierarchy was present, with different grades of expertise and authority, and the executive chef orchestrating the group toward his expectations of perfection. We have seen this orchestration on food network television – often from a tyrannical leader; however, in the case of this top performer, the team members were respected for their skill sets, encouraged to excel, given opportunity to develop and provided with valuable feedback. Although the tyrannical approach can produce high quality, it comes at the cost of increased staff turnover, workplace stress and dissatisfaction and unnecessary variability and error (Donaldson-Feilder et al. 2011; Lloyd 2009).

Jump now to the aviation industry. Although considered an exemplar of a high-reliability organization, its team approach to safety was not always as central as it is today (Salas et al. 2010). Prior to the 1990s, the primary focus in pilot training programs was on individual development of technical skills, with little education on team development within the cockpit (Salas et al. 2010). Although the flight crew performed safety checklists, they did so independently. After several high-profile commercial airline accidents in the 1970s, root cause analysis of flight recorder data revealed that human factors and team dynamics were the cause, not equipment failure (Stone and Babcock 1998). As a result, the airline industry developed and introduced its first Cockpit Resource Management (CRM) program into its training in 1979 (Helmreich 2000). CRM teaches teams to use all available resources (equipment and people) to achieve safe flight operations. Initially, CRM was offered only to captains, with the intent of fostering open communication in the cockpit and flattening hierarchy; however, it was expanded to all flight crew members in the 1980s upon learning that there remained a reluctance among other crew members to “speak up,” contributing to airline accidents (Helmreich 1992). As such, CRM was changed to stand for Crew Resource Management. Although, there is no controlled evidence showing that CRM has resulted in the aviation industry’s ultra-safe status, most aviation sectors have seen a significant reduction in accident rates since its introduction (Diehl 2001; Helmreich 2000).

Whether the culinary or aviation industry, there is general consensus that high-performing teams produce more reliable and quality outcomes (Baker et al. 2006). A team is defined as “two or more individuals, who have specific roles, perform interdependent tasks, are adaptable and share a common goal” (Baker...
et al. 2006: 1578). However, since teamwork is more than task work, merely forming a group with the above characteristics does not ensure that a team will function effectively. Teamwork is defined as a “set of interrelated knowledge, skills and attitudes that facilitate coordinated performance,” and effective teams are those that demonstrate a shared commitment to that set (Baker et al. 2006: 1579). Within healthcare, it is well known that communication failures and ineffective teamwork have led to patient safety incidents and patient harm (Sutcliffe et al. 2004). In a review of over 3,500 reported sentinel events (those resulting in death or severe injury), the Joint Commission (2004) in the United States determined that the root causes were failures in communication and teamwork/training in over 60% and 50% of cases, respectively. Furthermore, a breakdown in communication was highlighted as the number one contributor to cases of wrong site surgery (Joint Commission 2001). Given the prevalence of adverse events related to surgery (Baker et al. 2004) and the huge number of surgical procedures performed annually, in 2008, the World Health Organization (WHO) launched its second Global Patient Safety Challenge, Safe Surgery Saves Lives (SSSL), in an attempt to reduce the morbidity and mortality associated with surgical complications (WHO 2009).

The Surgical Safety Checklist

This brings us to the now well-known Surgical Safety Checklist (SSC; WHO 2009). With evidence underscoring communication issues in surgery (Lingard et al. 2004) and the positive impacts of checklists in aviation and medicine (Lingard et al. 2008; Pronovost et al. 2006), eight global pilot sites (one Canadian) participated in a study to evaluate the effect of a three-phase safety checklist, to be completed prior to the administration of anesthetic, prior to incision and before the patient leaves the operating room (Haynes et al. 2009). Using a pre-post design, a study following 8,000 surgical procedures found that the implementation of the SSC resulted in a 30% reduction in the rates of both surgical complications and deaths (Haynes et al. 2009). Furthermore, there was an observed increase in the delivery of six surgical best practices. The publication of this article was met with much media attention globally, along with some criticism. Headlines proclaimed that a simple paper checklist can save lives, leaving the public shocked that such a practice was not already in place. The study design was criticized for its non-controlled nature and failure to describe which elements of the checklist were responsible for the observed changes. Nevertheless, there was immediate worldwide interest in embedding this “simple tool” into peri-operative practice. The UK National Health Service (NHS) declared the completion of the checklist mandatory less than one month following the article’s publication (personal observation), and in Canada public reporting of checklist completion was made mandatory in July 2010 (Ministry of Health and Long-Term Care [MOHLTC] 2009) and became an Accreditation Canada required organizational practice in January 2011 (Accreditation Canada n.d.).

Introducing the SCC in Canada

Recognizing the impact that the SSC could have on patient safety, the Canadian Patient Safety Institute (CPSI) formed and supported the National Safe Surgery Saves Lives Working Group in August 2008, with a membership representing nursing, surgery, anesthesia and national professional and accreditation organizations, as well as aviation, human factors and cognitive psychology. Instrumental to the group was the recruitment of Dr. Bryce Taylor, former surgeon-in-chief at Toronto’s University Health Network, as special advisor given his expertise with the implementation of the SSC. The overall mandate of the Working Group was to lead further development, adaptation (see Figure 1), implementation and support for the SSSL Campaign within the Canadian context. The Working Group coordinated national workshops, keynote presentations at national conferences, rounds at local hospitals, virtual grand rounds, a virtual collaborative and a mentor/support network. Within the first year, 5,000 checklist implementation kits were downloaded (CPSI 2010) and 67% of hospitals reported using the three-part checklist (Flintoft July 2011, personal communication). As of June 2011, Ontario hospitals were reporting the completion of the SSC in 99% of surgeries (MOHLTC 2011).

During the Canadian SSSL Campaign rollout, much feedback was obtained from participating organizations. Hospitals reported the enthusiastic adoption of the SSC by their surgical teams and the emergence of checklist champions within anesthesia, nursing and surgery. Anecdotal reports surfaced of improved teamwork dynamics in the operating room, a sense of improved patient safety and examples of patient harm being averted through the identification of safety issues during checklist completion. This response is in keeping with the findings of others. Participants in the WHO checklist study reported a perceived increase in teamwork and safety climate following the implementation of the SSC (Haynes et al. 2011). Taylor et al. (2010) surveyed operating room staff and found a perceived improvement in communication, teamwork, respect and patient safety related to the implementation of the SSC, a phenomenon that was also detected later through the responses of operating room staff on a hospital-wide employee opinion survey. Improved patient outcomes following implementation of surgical safety checklists has been clearly demonstrated within the Veterans Affairs (Nelly et al. 2010) as well as in the Netherlands (de Vries et al. 2010) and Iran (Askarian et al. 2011).

Despite the positive feedback during the Canadian SSSL Campaign, there was greater feedback about the challenges that hospitals and surgical teams faced in implementing the SSC. Concerns were voiced about gaining buy-in, about whose role...
it was to complete the checklist and that the checklist would cause surgical delays and possible cancellations (although there is evidence showing the contrary [Ali et al. 2011; Nundy et al. 2008]). Also there were challenges in having all the team members present during the three phases of the checklist; teams adopted a “tick-and-flick” attitude and did not really discuss the checklist elements; there was also a sense of pressure to complying with provincial and accreditation requirements. Similar challenges were experienced during the rollout of the SSC in the United Kingdom (Vats et al. 2010). Hierarchy, timing logistics, the perception of work duplication and the relevance of the checklist were factors that either inhibited its adoption or resulted in the checklist process being incomplete and hurried and the participants being dismissive or absent (Vats et al. 2010).

**Overcoming Barriers to Implementation**

With growing evidence demonstrating the effectiveness of the SSC in improving patient safety and outcomes and the knowledge of the challenges to its implementation, the question that arose was, what strategies can be used to increase the likelihood of successful and sustainable adoption of the checklist into peri-operative practice and surgical culture? Fortunately, lessons from those organizations that have embedded the checklist as a standard operating procedure can be used as guides for others. In anecdotes from the Canadian SSSL Campaign and strategies reported in the literature, there are common elements that are associated with the successful implementation of the SSC (by CPSI and WHO) that have been adapted from other change management strategies (Kotter 1996; Reinertsen et al. 2007).

**Leadership Support**

As with all quality improvement plans, leadership support for the implementation of the SSC has been paramount. Leadership support was deemed the strongest independent predictor of successful checklist implementation among 64 Veterans Health Administration facilities (Paull et al. 2009). In studying the implementation efforts of five hospitals, Conley et al. (2011) found that the engagement of leadership was seen as a key factor in the success of the checklist adoption. Having the department chiefs as members of the implementation team and actively promoting the SSC was deemed most successful, whereas having clinical leadership merely support the idea but not show active involvement was seen as less effective (Conley et al. 2011).

**Timing of Mandatory Participation**

The messaging from leadership is also important. Strategies that involved an upfront or early mandatory approach to SSC checklist adoption have induced resistance. At the European launch of the SSSL Campaign, following presentations from the keynote speakers, NHS informed all delegates that the checklist would immediately be mandatory, require provider signatures and be audited (personal observation). This quickly turned the atmosphere from one of eager participation to vocal opposition. Others have commented on the tactic of a mandated checklist (Schlack and Boermeester 2010; Taylor et al. 2010; WHO 2009), supporting the strategy of upfront willing engagement from providers with enforcement as a later-stage approach. This has been felt to maintain the integrity of the checklist process and avoid the tick-and-flick approach (Taylor et al. 2010).

**Implementation Team and Approach**

Other pivotal factors guiding the success of SSC adoption are the formation of an implementation team and the approach that they use (Safer Healthcare Now! n.d., WHO 2009). Given the interdisciplinary nature of the SSC, having all disciplines, particularly anesthesia and surgery, actively involved is important as they are likely to successfully influence their peers (Hayes et al. 2010; Paull et al. 2009; Reinertsen et al. 2007). This is especially true if physician champions are recruited as team members. Such champions act as vocal supporters and demonstrate the model process for checklist completion. A key tenet of quality improvement, supported by feedback from Canadian hospitals reporting successful checklist adoption (Flintoft, July 2011, personal communication), is to start the implementation process on a small scale – on one surgical team or in one division. This is important for several reasons: it allows for more in-depth training – to demonstrate and master the “correct” way of completing the checklist (Taylor et al. 2010); permits feedback from the front line in modifying the checklist content and process to the local environment; provides the opportunity to openly discuss barriers; and is more likely to gain team buy-in and to foster champions (Langley et al. 2009). Subsequent scale up is then often easier as word of the successful implementation spreads to other teams.

**Burning Platform**

Another tenet of quality improvement and change management is the use of data to create a “burning platform” (Kotter 1996; Langley et al. 2009). Although published outcome data on the effectiveness of the SSC may help set the stage and define its purpose, it is often local data that drive practice change (Hysong 2009; Safer Healthcare Now! n.d.). Sources of local data that can be used to support the implementation process include the following: (1) prospective audit feedback of surgical cases to identify opportunities in which the use of the checklist could have prevented error or harm, (2) a retrospective review of surgical cases in which the consequences could have been altered by checklist use and (3) a prospective collection of “good catches” during the initial rollout stage as proof of the checklist’s utility. Sharing of these data and stories helps build the case for checklist adoption. Another important use of data is in sustaining checklist use. Ongoing observation and audit of the checklist process can continue to identify good catches and ensure correct check-
list performance. As described above, several studies have used pre-post survey techniques to assess the attitudinal and culture shift associated with surgical safety checklist use (Haynes et al. 2011; Taylor et al. 2010), a strategy that can be employed locally for the purpose of providing feedback and securing sustainability.

### Team Training

Notwithstanding the impact that the SSC has had and will have on patient safety outcomes, it is merely a communication tool to remind teams to address key safety issues prior to and during surgery. In the majority of reported studies that evaluated surgical safety checklists, team training was included in the intervention (de Vries et al. 2010; Haynes et al. 2009; Neily et al. 2010; Taylor et al. 2010). Furthermore, safety culture and team perceptions were usually addressed, with demonstrable improvement realized post-implementation of the checklist (Haynes et al. 2009; Neily et al. 2010).

So, is the SSC a mechanism for introducing team training and safety culture awareness into surgical care? Similar to aviation, it was the use of checklists coupled with widespread team training that transformed the industry to its ultra-safe status (Helmreich 2000). For example, the primary focus of the program at the Veterans Health Administration was to implement an inter-professional medical team training program into hospitals providing surgical services; a safety checklist was introduced after program completion (Neily et al. 2010). The program involved a two-month preparatory session with each site’s implementation team, followed by a day-long onsite learning session. Using CRM-based theory, the inter-professional participants were trained to work as teams, challenge each other when safety risks were identified, perform situational awareness checks and learn rules of conduct for communication. To allow staff to attend as full teams, the operating rooms were closed for the day (a clear demonstration of leadership commitment to the program). The
program resulted in overall increased perceptions of teamwork and communication, an increased use of surgical safety checklists and an 18% reduction in mortality (Neily et al. 2010). The authors proposed that the team training facilitated more open communication in the operating rooms and that the checklist guided the discussion toward improved safety outcomes (Neily et al. 2010). Another widely used and evidence-based program for team training is the TeamSTEPPS program developed by the US Department of Defense in collaboration with the Agency for Healthcare Research and Quality (King et al. 2008). Similar to the training in the Veterans Health Administration program, TeamSTEPPS trains inter-professional teams in the importance of leadership, situational awareness, mutual support and effective communication (King et al. 2008). The implementation of this program into surgical programs has also resulted in improved team performance and outcomes (Armour Forse et al. 2011; Capella et al. n.d.).

Despite the impressive literature on communication issues in Canadian operating rooms (for example, Lingard et al. 2004), there are no published data of the effective implementation of inter-professional surgical team training in Canada. However, there is good reason to believe that programs similar to that of the Veterans Health Administration and TeamSTEPPS could be developed and implemented in Canadian hospitals and residency programs, given the similarities in sites included in those studies as well as in surgical team structures and processes. Following this logic, there is also good reason to implement inter-professional team training into health professional training programs. This would enable surgical team members to apply the required knowledge, skills and attitudes during their training rather than learning how to work in teams after the fact. Such inclusion would meet the competency-based requirements and recommendations of the American Council of Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada and the CPSI Patient Safety Competencies (Accreditation Council for Graduate Medical Education n.d.; Frank and Brien 2008; Royal College of Physicians and Surgeons of Canada 2011).

**Conclusion**

Equipping healthcare providers with the training to function as high-performing teams and providing them with tools to improve communication and patient safety may be the recipe for reliable improvements in safety culture and patient outcomes in surgery (and likely many other medical domains). Although more conclusive proof on the benefits of widespread inter-professional team training may be warranted, there is significant evidence to warrant its inclusion into surgical, anaesthesia and operating room nursing training programs and practice settings.

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**References**


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Ranjit Kaur is an 83-year-old woman who is brought to the hospital by her son because of worsening shortness of breath over the previous week. The emergency room physician correctly diagnoses a heart failure exacerbation (Wang et al. 2005), initiates appropriate treatment (Felker et al. 2011) and consults the hospitalist physician for admission and ongoing care (Wächter 2004). The hospitalist learns that the patient has been prescribed the various medications recommended by clinical practice guidelines and that her adherence to this medication regimen is excellent. No specific trigger for the heart failure exacerbation is found, and the hospitalist concludes that the most likely explanation is a gradual decline in cardiovascular function, perhaps combined with excessive sodium intake. The day after admission, a dietitian meets with the patient and her daughter-in-law to discuss how her diet could be modified to reduce her sodium intake. Three days after admission, Ms. Kaur is “back to baseline” and ready for discharge. The hospitalist discharges her on a slightly higher dose of her diuretic and instructs Ms. Kaur to see her family physician within a week of discharge. She is sent home with a discharge summary in hand that clearly explains the care provided in hospital and the follow-up plan. In other words, the emergency department and in-patient care are “textbook.” The admission is brief and efficient, there are no complications and Ms. Kaur’s symptoms are substantially improved. Nevertheless, three weeks after discharge, Ms. Kaur is brought back to the emergency department because of confusion. Her blood work in the emergency department shows a dangerously low sodium level. This adverse event may occur after a change in diuretic dose, and can be prevented or managed with careful follow-up after discharge.

This all-too-common patient vignette raises three important questions. Why are patients especially vulnerable to adverse events during transitions in care? Are these adverse events preventable? And, if so, how can we prevent them?

Vulnerability to Adverse Events during Transitions in Care

In countries such as Canada that have largely completed the epidemiological transition (Omran 2005), most deaths and hospitalizations now occur in individuals who suffer from one or more chronic diseases. During the past 50 years, we have also witnessed a profound shift in the way healthcare is provided. The rise of the hospitalist physician has been widely discussed in the United States (Wächter 2004), but in Canada too, most family physicians no longer care for hospital in-patients (Chan 2002). Finally, the changing nature of our society has resulted in smaller families with fewer individuals available to support an aging relative. Together, these changes have combined to produce a situation that leaves patients vulnerable to adverse events that occur soon after a care transition (Coleman and Berenson 2004).

Many post-discharge adverse events result in an unplanned readmission to hospital. Depending on the patient population, readmissions occur after 10–30% of medical admissions
The variability in risk-adjusted readmission rates between institutions and regions strongly suggests that some readmissions are preventable.

Patient Characteristics Associated with Adverse Events after Care Transitions

The risk of readmission or death after hospital discharge can be predicted with reasonable but not excellent accuracy (van Walraven et al. 2010a). Many physicians tend to consider medical co-morbidities, such as heart failure and chronic obstructive pulmonary disease, that increase the risk of post-discharge complications. However, “non-medical” patient-related characteristics, such as a substance use disorder, low educational attainment, health illiteracy, poverty, limited fluency in the language in which healthcare is being provided and the lack of a robust social support network may be more important. These characteristics, however, are less easily ascertained than health service utilization measures and comorbidity scores.

That poorly defined and difficult-to-measure patient characteristics are risk factors for post-discharge adverse events is neatly – if inadvertently – demonstrated in a recent study (Voss et al. 2011). In this study, 1,888 patients were offered an evidence-based post-discharge intervention. Only slightly more than half the patients accepted. Of these patients, only one quarter permitted a home visit. Therefore, only 13.6% of the eligible population received the intervention. Perhaps unsurprisingly, patients who declined the intervention or did not follow up were nearly 50% more likely to be readmitted to hospital within 30 days of discharge, even after adjusting for differences in measurable baseline characteristics. Although it is possible that the intervention was the reason for the lower rate of readmission, it is more likely that patients who decided not to participate were at higher risk of readmission to begin with.

Healthcare System Characteristics Associated with Adverse Events after Care Transitions

Although all Canadians benefit from publicly funded physician care and hospital services and many also from publicly funded prescription drugs and home care, healthcare delivery in Canada is the responsibility of a myriad of quasi-independent institutions and individuals. This situation has led to both horizontal and vertical fragmentation. The lack of system integration largely explains the lack of care integration as experienced by individual patients. For example, in a large observational study of Ontarians discharged to the community after an emergent or elective hospitalization, van Walraven and colleagues (2010b) found that both provider continuity and information continuity were poor. Information from the previous visit was available to physicians only 22% of the time (van Walraven et al. 2008). Patients who saw one of their regular physicians after being discharged were considerably less likely to be readmitted to hospital (van Walraven et al. 2010c).

Another healthcare system factor that may be related to the incidence of post-discharge adverse events is the decline of physician house calls in North America (Meyer and Gibbons 1997). This shift has resulted in a situation where many individuals who are at high risk of readmission receive their care at home, mostly from personal support workers, sometimes from nurses and only rarely from physicians. Paradoxically, healthy young adults are able to see family physicians even though lower-cost care providers with less training might be able to provide care of equivalent quality (Laurant et al. 2005).

Preventability of Readmissions and Other Post-Discharge Adverse Events

The proportion of readmissions that is preventable is a subject of considerable controversy. In part because there is no “gold standard” for post-discharge care, the proportion of readmissions judged to be preventable in peer-reviewed studies varies from as low as 9% to as high as 55% (Benbassat and Taragin 2000). Some research suggests that only a small proportion of readmissions are preventable. For example, van Walraven and colleagues (2011) recently conducted a study in which physicians were asked to review standardized case summaries of patients who had experienced an urgent readmission. The physician reviewers were asked to determine whether a readmission was the result of an adverse event and, if so, whether that adverse event was avoidable. The authors concluded that only 16% of readmissions were likely to be avoidable. On the other hand, the Medicare Payment Advisory Commission, an influential governmental agency in the United States, has estimated that up to 76% of readmissions within 30 days of discharge can be prevented (Medicare Payment Advisory Commission 2007). While this number is generally viewed as unrealistic by those who care for in-patients, physicians questioned in the 1960s...
may also have been skeptical if told that coronary heart disease mortality after myocardial infarction would decrease by 50% in the next two decades (Guidry et al. 1999).

At least three definitive conclusions can be made about the preventability of readmissions. First, physicians are not very good at predicting which patients will be readmitted (Allaudeen et al. 2011). Although risk prediction models appear to be superior to clinical judgment, more research is needed to better identify those patients who are at especially high risk of a post-discharge event (Kansagara et al. 2011).

Second, when reviewing an individual readmission, there is poor agreement among physicians as to whether the readmis-

sion was preventable or not. In one study, the sensitivity of reviewers for identifying avoidable readmissions (with the “gold standard” being assigned by a statistical model incorporating input from multiple reviewers) ranged from 4.5 to 90.5% (van Walraven et al. 2011).

Third, at least some readmissions are preventable. Two lines of evidence support this argument. First, although the research on post-discharge interventions to reduce readmissions remains underdeveloped (Hansen et al. 2011), at least three post-discharge interventions have been shown to be effective in clinical trial settings, with absolute reductions in readmissions or post-discharge emergency department use in the 5–10% range (Coleman et al. 2006; Jack et al. 2009; Naylor et al. 1999). Second, the variability in risk-adjusted readmission rates between institutions and regions strongly suggests that some readmissions are preventable (Goldfield 2011, Epstein et al. 2011).

**The Toronto Virtual Ward**

We have been involved in the development and ongoing evaluation of a post-discharge intervention called the Toronto Virtual Ward. Virtual wards use a team-based approach to care for complex patients in their homes. They are considered “wards” because of their hospital-like elements (e.g., an interdisciplinary team, a shared chart and a single point of contact for the patient) but are “virtual” because the patient is at home.

The Toronto Virtual Ward was developed as a multi-organizational collaboration, with the agency responsible for home care – the Toronto Central Community Care Access Centre – as a key partner. The virtual ward team, which includes a physician, two care coordinators, a part-time pharmacist and nursing and clerical support, provides support to patients and their family doctors for a few weeks after hospital discharge. A randomized controlled trial comparing the virtual ward with usual care is under way, with results expected in 2013.

**How Should We Prevent Post-Discharge Adverse Events and Improve the Quality of Care during Transitions?**

A useful way to consider how the quality of care during transitions can be improved is to think about pre-discharge interventions, post-discharge interventions and interventions that cross the transition (Hansen et al. 2011). Pre-discharge interventions include discharge planning, medication reconciliation at the time of discharge, patient education during the in-patient stay, preparation of a standardized discharge summary for the patient, communication with the primary care physician and the scheduling of post-discharge appointments. Post-discharge interventions include additional communication with the primary care physician and home care providers, follow-up telephone calls, home visits and the provision of e-mail or telephone access to the in-patient team for the patient and his or her care providers. Interventions that bridge the transition include those that improve provider continuity (e.g., if the same healthcare provider cares for the patient during and after the hospitalization) and information continuity (van Walraven et al. 2010c).

A single-component intervention is unlikely to have a substantial effect on improving the patient experience or reducing post-discharge adverse events (Hansen et al. 2011). Multi-component interventions are more promising and have been proven to work in randomized trial settings (Coleman et al. 2006; Jack et al. 2009; Naylor et al. 1999). One such intervention, the Care Transitions Intervention, reduced 90-day readmission from 22.5 to 16.7% in a well-conducted randomized controlled trial (Coleman et al. 2006). This intervention was delivered primarily by a “transition coach” and facilitated by the development of a personal health record that was maintained by the patient. The coach – an advanced practice nurse – met with each patient in hospital and then again at home. The coach helped to teach each patient how to communicate his or her needs more effectively, to identify a list of “red flags” that would warrant an intervention and to ensure that the patient’s needs were being met. The coach typically also phoned three times in the month following discharge. Although multi-component interventions such as the Care Transitions Intervention have been shown to be effective in randomized controlled trials, their effectiveness in real-world settings has not yet been conclusively demonstrated.

**Potential System Responses to the Care Transitions Challenge**

One possible response to the care transitions challenge is to develop a plethora of disease-focused models of care. We believe this would be a mistake, primarily for two reasons. First, just as there are insufficient resources to admit all hospitalized patients to disease-specific wards, it is unlikely that there will ever be sufficient resources available to implement different...
post-discharge models of care for each disease associated with a high risk of readmission. Even more importantly, most patients who are at high risk of readmission suffer from multiple chronic diseases and have non-medical characteristics that increase their risk of readmission. Therefore, family physicians or teams that can provide holistic care are likely to be more effective than specialty clinics working independently of one another.

Another possible response to the care transitions challenge is to use financial incentives to reduce readmissions. We believe that this would be premature, not only because the evidence base is immature but also because in a fragmented healthcare system it would be unfair to hold individual physicians or organizations responsible. Rather than penalizing or rewarding hospitals or primary care providers, healthcare payers could provide support for rigorous quality improvement and research. Relatively inexpensive interventions, such as same-day discharge summaries, post-discharge telephone calls and booking an appointment with the family doctor prior to discharge may be suitable targets for quality improvement initiatives and could be evaluated within individual institutions using relatively inexpensive non-randomized study designs (Fan et al. 2010). More expensive interventions should be evaluated using traditional methods such as randomized controlled trials that are less prone to bias. High-quality evaluations will help ensure that resources are deployed in a cost-effective manner.

There is also value in carefully studying high-performing healthcare systems (Baker et al. 2008) and adopting those characteristics that are most likely to improve care for patients with complex problems. Some of these characteristics are likely to be structural (e.g., better integration of acute, community and primary care). As Don Berwick has noted, real improvement often comes from change “within a system” rather than change “of a system” (Berwick 1996).

Real improvement often comes from change “of a system” rather than change “within a system.”

Conclusion

Transitions in care are increasingly being recognized as a time when patients are especially prone to adverse events. These adverse events can be serious, and at least some of them are preventable. Adverse events associated with transitions may be less common in integrated health systems that use shared records and where healthcare providers can easily communicate with each other. In fragmented systems, such as those that prevail in most of Canada, superimposed interventions are worth evaluating as a way to improve health outcomes and potentially reduce costs. A better understanding of the characteristics of high-performing healthcare systems would also inform a strategy to improve care transitions.

References


Irfan A. Dhalla et al. Toward Safer Transitions: How Can We Reduce Post-Discharge Adverse Events?


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Rethinking Healthcare Safety for Home Care
Canada’s aging population and rising healthcare costs have resulted in an increased number of chronically ill people and heightened demand for acute care. As a result, a growing group of clients is being cared for at home by family and friends, and there has been a 51% increase in home care clients since 1997 (Canadian Home Care Association 2008). Many, if not most, of these home care clients are elderly individuals with chronic health problems or people who require end-of-life care (Canadian Institute for Health Information 2006).

The complexity of the cases now handled at home increases the already-heavy pressure on family, caregivers and paid providers, a situation that can create and amplify serious safety issues (Macdonald et al. 2010; Stevenson et al. 2008). These safety threats are not limited to clients. Findings from various qualitative research studies focusing on the experiences and perspectives of those providing care in the home have confirmed that families, caregivers and paid providers can all face significant risks in a home care environment (Lang et al. 2006, 2008, 2009b; Macdonald et al. 2011).

However, because home care is so fundamentally different from the regulated and controlled environment of acute care (Lang et al. 2006), improving safety in home care requires a fundamentally different philosophy and approach. The challenge is to rethink our ideas of healthcare safety in the context of home care, and then follow through by developing and applying safety practices for the home. These practices must be client- and family-centred, include safety for providers and, above all, be flexible enough to adapt to an immense range of circumstances. Future qualitative and quantitative research will provide further insight into the impact of the home environment on care for specific populations and will guide the development of strategies to mitigate risks associated with care in the home.

Different Setting, Different Risks
Research funded by the Canadian Patient Safety Institute, Canadian Institutes of Health Research and others has led to significant headway in understanding factors in home care that contribute to its unique risks and safety challenges. Examples of these projects are listed in the sidebar.

According to the World Health Organization (WHO 2009), contributing factors are circumstances, actions or influences that may trigger a safety incident or increase the risk of an incident. Identifying those factors is an essential part of assessing threats and reducing risks. While our team is unaware of research outlining the quantification of the scale of harm to both unpaid and paid caregivers, we have learned the importance of considering the context of the home and the way many factors intertwine to influence safety there.

Unpaid family members, friends and neighbours provide more than 80% of care in home settings, contributing annual hidden savings of $5 billion to the Canadian healthcare system.
and since they are not controlled and are designed for living, not healthcare; life (Lang et al. 2009a). But homes and feel more in control of their surroundings than easing, the demand for healthcare because they are in familiar surroundings (Macdonald et al. 2010). Family caregivers are often unprepared for the extent of the care they have to give when paid care providers are not there (Lang et al. 2009b; Macdonald et al. 2011). Family caregivers find themselves responsible for complex, around-the-clock care, such as helping with mobility, toileting and pain control and possibly dealing with confusion and wandering. Caregivers’ sleep is further disrupted by technology, such as alarms and monitors, leading to fatigue.

Fatigue is a potential safety risk to home care clients because it may affect decisions (about medication or care) or lead to actions that can create a dangerous situation (Lang et al. 2009a). Further, fatigue and the psychological and physical impacts of stress on caregivers can lead to depression or substance abuse (Lang et al. 2008), endangering both caregiver and client, with their potential to lead to physical and psychological abuse (Macdonald et al. 2011). All these factors add up to a significant risk that caregivers will become patients themselves, ultimately increasing, rather than easing, the demand for healthcare (Macdonald et al. 2010).

Clients tend to like home care because they are in familiar surroundings and feel more in control of their life (Lang et al. 2009a). But homes are designed for living, not healthcare; and since they are not controlled and

Projects Furthering the Understanding of Home Care Safety Factors

- Doran, D., R. Baker and C. Szabo. 2012. The Identification of Serious Reportable Events in Home Care. (in progress)
regulated like institutional settings, they are often not particularly suitable locations for healthcare. Homes may be dirty, which affects the ability of care providers to deliver safe and quality care and increases the risk of infection for clients. Hazards, such as trailing electrical cords, scatter rugs and clutter, increase the risk of falls for the client and the risk of musculoskeletal injuries for caregivers and providers. While care providers can make recommendations to reduce these risks and improve safety in the home, clients and family members decide to follow or not follow these recommendations (Lang et al. 2009a).

All of these factors show how the safety of care providers, caregivers and clients is intertwined, and why threats to the safety of family, unpaid caregivers and paid providers must not be severed from client safety. By the same token, implementing strategies to improve safety for providers also benefits clients and families (Lang et al. 2009a; Stevenson et al. 2008), whereas not dealing with safety issues leaves everyone involved vulnerable to harm (Lang et al. 2009a; Stevenson et al. 2008; WHO 2009).

Safety in home care is viewed differently by different people. (Different language is also used in home care, with patients and family talking about concerns and challenges, rather than safety.) Paid providers tend to consider only the client, whereas clients also worry about their caregivers (Lang et al. 2009a). Providers focus on physical safety (such as falls), medication errors and safe syringe disposal – all reflecting institutional priorities and philosophical assumptions (Lang et al. 2009a). But there are also ethical concerns for paid providers, faced with the challenge of providing care in the presence of known risks – infestation, weapons in the home and unsanitary conditions. These risks affect providers’ safety and can therefore affect patients’ access to services – if they do not provide care, who will? (Stevenson et al. 2008).

Looking after someone in an environment designed for living, not healthcare, is already a challenge; but paid and unpaid carers repeatedly report problems with discharge information that lead to inadequate preparation for home care and no appropriate risk assessment before clients are sent home (Stevenson et al. 2008). Hospital discharge planners frequently underestimate the level of patient care that will be needed at home, resulting in a lack of equipment and other supports. This can put caregivers, providers and clients at risk (Macdonald et al. 2011). However, despite these concerns, paid providers, caregivers and clients are willing to accept a high level of risk when giving or receiving care at home.

### Threats to the safety of family, unpaid caregivers and paid providers must not be severed from client safety.

Our research with experts in home care delivery on threats to safe care shows that these threats can be grouped into four themes – the fragmentation of services, vulnerability of patients and providers, erosion of home as a haven and incongruence of what is expected and what is available in home care (Macdonald et al. 2011). Fragmentation includes the disconnect between how care is provided in acute care and home care and the impact of having multiple providers and multiple agencies providing care in one home.

Vulnerability covers the potential threats to the emotional, physical, social and functional health of recipients and providers. People can be vulnerable because of isolation, exposure to infection, medication mismanagement and the potential for abuse.

Home means something unique to each client, caregiver and family (Lang et al. 2009a), but most people consider it their haven. That sense of safety is eroded when the home is “medicalized,” that is, changed to accommodate care. Bringing in technology designed for acute care makes the home start to resemble a hospital room. The sense of the haven is further eroded because the support and resources are not immediately at hand, as in a hospital; instead, they are delivered by an army of strangers who seem to come in an endless stream through a revolving door.

Incongruence in home care arises from (1) unregulated healthcare workers’ responsibilities versus their knowledge and skills, (2) healthcare professionals not having access to current knowledge and in-time information and (3) the expectations of families about what resources and support are available for home care versus the reality of what is provided.

But the goal of home care isn’t to create a hospital at home, with a transformed environment and standardized care (Lang et al. 2009b ). In home care, the provider is a guest who has to collaborate with clients, caregivers and families (Hartrick Doane and Varcoe 2005) to determine what might improve safety. Providers should negotiate with clients and families to define care needs and safety goals in order to achieve the best outcomes possible, including keeping the client out of hospital and preventing caregivers from becoming patients themselves (Lang et al. 2009a).

### Our Research in Progress

WHO’s patient safety research motto is “better knowledge for safer care” (WHO 2011). This also sums up our current work on safety in home care and our ultimate goal of helping to develop guidelines that will enhance home care safety and bring about better individual, family, community and organizational outcomes.

Several nationally funded studies are under way. The first is looking into the different perspectives on home care safety of clients, families, caregivers and providers within a palliative care context in Quebec. A second, four-province study (Alberta, Ontario, Quebec and Nova Scotia) focuses on medication management safety in the households of chronically ill seniors.
The third study, intended to lead to the development of tools and strategies to reduce adverse events, is composed of five subprojects looking at the nature and scope of adverse events in home care, along with client and provider views on safety. One of the subprojects (in British Columbia, Manitoba and New Brunswick) is on safety at home for seniors living with chronic obstructive pulmonary disease and congestive heart failure. In conjunction, researchers are conducting a scoping review looking for safety markers in home care for these two populations. As well, part of the team is researching the “human factors” in home care. Human factors is a discipline that identifies and addresses mismatches between people, tools and environments – in home care, these are the kind of situations that arise when people try to deliver care with tools and in places not well suited to the task. The knowledge gained from these interrelated pan-Canadian studies will help develop health policies, education strategies and client-, family-, caregiver- and provider-centred clinical practice guidelines.

**Moving Forward**

*Approach*

Given the fundamental differences between institutional and home care, it stands to reason that how we conduct research, make decisions and provide care to promote safety are also different. The intricate and unique context of home care requires us to look through a different pair of glasses when developing knowledge, recommendations and best practices – different, to ensure that the results are measured and evaluated in terms of home, not institutional, care. These different lenses will yield better insight into how to align the inseparable needs of clients, unpaid caregivers, families and paid providers to mitigate hazards (Lang et al. 2006; Stevenson et al. 2008). Researchers, policy and decision-makers and practice leaders must continue to collaborate to advance knowledge on home care safety.

**Developing Knowledge**

The research agenda for home care safety should be developed with input from both providers and recipients of home care, as well as policy and decision-makers, and be informed by documents such as *A Framework for a Canadian Caregiver Strategy* (Canadian Caregiver Coalition 2008). Both quantitative and qualitative methodologies must be used to capture all the varying perspectives, experiences and features of home care.

The Canadian Caregiver Coalition (2008) developed a framework for a caregiver strategy because (1) it realized that individuals are living longer, increasing the likelihood of developing a chronic illness; (2) families are smaller today, with many women delaying child-bearing and in the workforce, limiting the number of available caregivers; and (3) to safeguard against the shifting of public responsibility for home care to unpaid caregivers. The framework principles are respect, choice and self-determination, and the framework strategies mirror much of the safety in home care evidence generated to date.

In future, home care research should focus on the development of a model that supports client- and family-centred care and creates an environment where risks are not necessarily eliminated but are at least mitigated to a level the clients and caregivers are prepared to accept for themselves and their situation.

**Recommendations for Policy and Practice**

Based on existing evidence, recommendations related to policy and practice are in order. As a prelude to this work, discussions of how the system will collaboratively address, implement and sustain safety recommendations unique to home care need to take place. Policy and decision-makers should prepare to:

- implement learning strategies to build staff understanding of and competency for providing care in the home environment;
- develop policies to ensure consistency in compensation, respite, training and ongoing support for unpaid caregivers across Canada;
- designate funds for home care–specific research; and
- implement technologies to support information flow across the care continuum.

Sustainable practice changes will have to reflect the experience of home care clients, their families and caregivers as well as paid providers in dealing with safety challenges. Evidence-informed guidelines should be flexible, client- and family-centred and adaptable to the nature of the home.

Transitions in care (from acute to home care, or as acuity increases) are some of the most dangerous and unsafe times for home care clients, and guidelines should cover improvement in handing off care. We strongly recommended establishing clear and consistent processes for:

- identifying and assessing home care risks – a “short, provider-centred tool” could increase uptake and provide a mechanism for communication between management and care providers (Stevenson et al. 2008);
- involving the client, families and caregivers in care planning prior to and after discharge; and
- communicating with clients, families and caregivers about home care risks before transfer to home care.

**Conclusion**

Choosing home care – as an individual in need of treatment and support, or as a society by shifting policy and resources – is a move away from highly structured and standardized care. It is a choice many are glad to make. Some slip into it, adapting day by day to changing health; some have little choice. Until now, safety has largely been defined by institutional norms and standards;
but as we shift to providing more care in home environments, we can no longer afford to leave the issue unexplored. Clients prefer to be at home, expectations are high of family caregivers, demand for home care is rising and transitions from hospital to home are not all smooth and orderly. The combination of these factors can lead to safety risks in home care for all involved. Given that care needs are increasingly complex and that the safety of clients, caregivers and providers are intertwined, collaboration to address risks is essential. Patients, families, paid providers and caregivers deserve to be educated on the risks of home care and the options for managing them, and then allowed the dignity to choose what risks they can accept. 

The goal of home care isn’t to create a hospital at home.

References


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“Ignore at your own peril.”
The surgical safety checklist. See page 60.
The Canadian Patient Safety Institute is partnering with Northwestern University, Chicago, USA to adapt a patient safety curriculum for practicing, frontline healthcare professionals in Canada.

The PSEP program is built on a Master Facilitator, train the trainer team model which provides a peer to peer framework to guide patient safety education for all healthcare professionals.

Teams who attend the program will have the opportunity to practice teaching skills and actively plan next steps for patient safety education in their home organization. PSEP is built with an interprofessional approach in mind. Participating teams will be comprised of at least three members, including a doctor, nurse, clinical professional and a senior executive from the organization.

CPSI is also currently opening a call for applicants to join our Pan-Canadian, multidisciplinary team of Master Facilitators. Our Master Facilitator team will be comprised of professionals who are passionate about patient safety work, and have the skills and ability to inspire change.

As a Master Facilitator you would join us in bringing this program to healthcare professionals across the country. If you are interested in this type of engaging work please watch for upcoming details on our application process on the CPSI website.

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